
# IMPLEMENTING TIME-BASED MANUFACTURING PRACTICES IN PHARMACEUTICAL PREPARATION MANUFACTURERS

## Improving Time-Based Manufacturing Practices and Enhancing Manufacturing Performance through Action Research

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# ABSTRACT

## IMPLEMENTING TIME-BASED MANUFACTURING PRACTICES IN PHARMACEUTICAL PREPARATION MANUFACTURERS

**Keywords**

Insider Action Research, Comparative Case Study, Time-Based Manufacturing Practices, Pharmaceutical Industry.

A double case study applying action research methodology was conducted in two pharmaceutical preparation manufacturers in the Netherlands to improve their manufacturing systems by implementing time-based manufacturing (TBM) practices.

Following the diagnosis phase, the situation of each Company was analysed and suitable improvement interventions were selected for implementation in the Case Companies. At the end of the action research project, semi-structured interviews were taken in each Company a year later, and the achieved results of the improvement programmes were collected and analysed. This research extends the existing theory of time-based competition and demonstrates that TBM practices apply also in the pharmaceutical preparation manufacturing industry. Furthermore, this study shows how to improve TBM practices and reduce the throughput time by providing the route for improvement and implementation. Although the first Case Company did not improve the core TBM practices and manufacturing performance, its infrastructure improved through the implementation of an ERP system and further enhancement of its quality management system, illustrating that the design of the infrastructure is a key factor to become a time-based competitor. The second Case Company succeeded to improve the

TBM practices and throughput processes resulting in the reduction of the order cycle time and increase of the delivery dependability. Based on the data of the two Case Companies, this study demonstrated the relationship between these two manufacturing performance parameters, which indicates that manufacturers may strive for both delivery speed and delivery reliability using the same improvement plan. Adopting TBM is a long journey of many years and needs a continuous improvement infrastructure.

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**LIST OF ABBREVIATIONS**

| | |
|---|---|
| AM | Agile Manufacturing |
| AR | Action Research |
| BOM | Bill of Materials |
| BPR | Business Process Reengineering |
| CM | Cellular Manufacturing |
| DMAIC | Define, Measure, Analyse, Improve and Control |
| EDI | Electronic Data Interchange |
| ERP | Enterprise Resource Planning |
| EU | European Union |
| GMP | Good Manufacturing Practices |
| GT | Group Technology |
| HACCP | Hazardous Analysis of Critical Control Points |
| HR | Human Resources |
| HTML | Hypertext Mark-Up Language |
| IT | Information Technology |
| IRR | Inter-Ratter Reliability |
| IS | Information Systems |
| JIT | Just-In-Time |
| KPI | Key Performance Indicator |
| LIMS | Laboratory Information Management System |
| LM | Lean Manufacturing |
| MC | Mass Customisation |
| MRP | Material Requirements Planning |
| MS | Manufacturing Strategy |
| NAICS | North American Industrial Classification System |
| OD | Organisational Development |
| OEE | Overall Equipment Effectiveness |
| PM | Preventive Maintenance |
| QA | Quality Assurance |

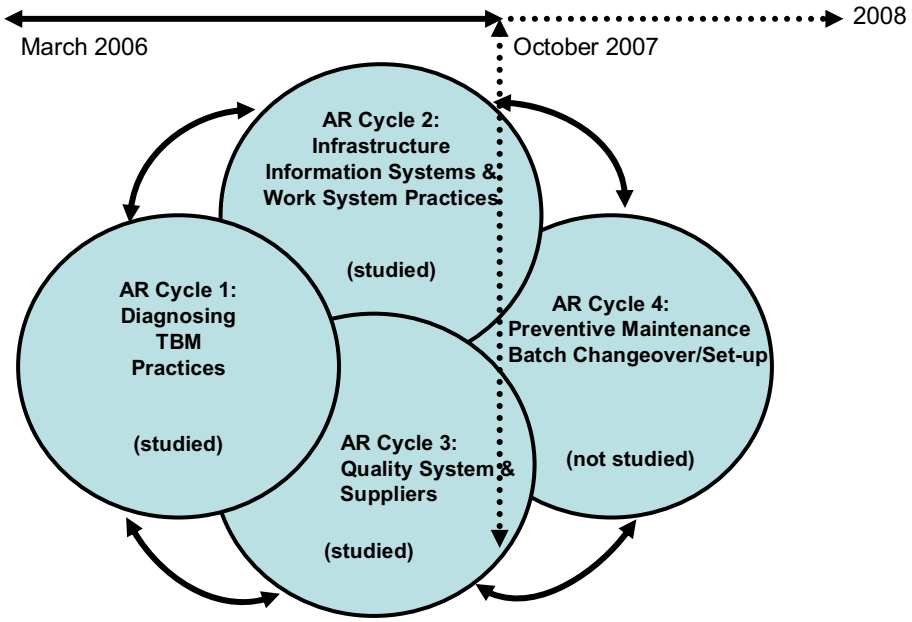
| | |
|---|---|
| QC | Quality Control |
| RLJ | Reflective Learning Journal |
| ROA | Return on Assets |
| ROE | Return on Equity |
| ROI | Return on Investment |
| SIC | Standard Industrial Classification |
| SOP | Standard Operating Procedures |
| SM | Strategic Manufacturing |
| SMED | Single-Minute Exchange of Dies |
| TBC | Time-Based Competition |
| TBM | Time-Based Manufacturing |
| TPM | Total Productive Maintenance |
| TQM | Total Quality Management |
| UK | United Kingdom |
| US | United States of America |
| WCM | World Class Manufacturing |
| WLD | Workgroup Logistics and Document Control |
| WLQ | Workgroup Logistics and Quality |
| WPE | Workgroup Production and Engineering |
| WPQ | Workgroup Production and Quality |

# 1 INTRODUCTION TO THE RESEARCH

Time-based competition (TBC) is a strategic paradigm, which has not been applied specifically to the pharmaceutical industry. Compared with other industries such as the automotive and discrete parts manufacturing industries, the pharmaceutical industry has been slow to adopt modern manufacturing practices and ignored the need to strive for operational excellence. This situation, however, is changing. Faced with increased competition, cost pressures, weakening new product pipelines and increasing regulatory standards, the pharmaceutical industry is looking for ways to improve the performance of their manufacturing operations to mitigate these challenges. Many companies in other industries have learned that compressing time in the product development and product delivery cycles leads to increased sales and market share and therefore increasing their business performance. TBC is a strategy of seeking competitive advantage by speeding up the critical organisational processes such as product development, order-entry, production, distribution and after-sale service. A company becomes time-based by developing superior insights into what customers value and building the company to deliver it quickly (Stalk and Hout, 1990). Time-based manufacturing (TBM) is one weapon for time-based competitors to reduce response time of the value-delivery system. This research has been focused on TBM as one part of the whole TBC concept, since the Case Companies are manufacturing organisations. TBM is an externally focused manufacturing system that emphasises fast response to changing customer needs with the primary purpose to reduce throughput time in the manufacturing system (Blackburn, 1991; Koufteros et al., 1998; Stalk and Hout, 1990).

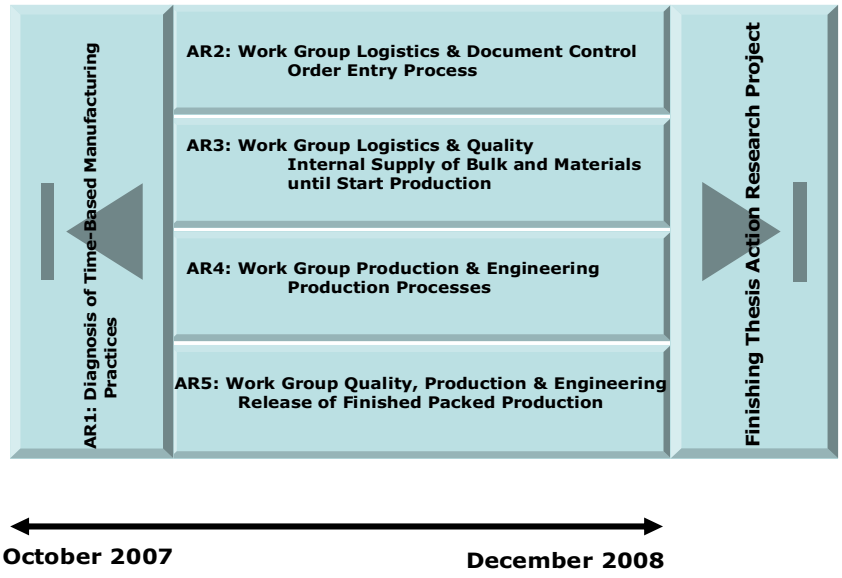
The research project has been conducted as an action research (AR) double case study in organisations, where I was employed. AR was justified, since changes of the Case Companies were needed and it contributed to both practical and theoretical understanding. The two Case Companies of this research are Dutch manufacturing companies, operating in the pharmaceutical preparation manufacturing industry. The research project started in March 2006 at the first Case Company after receiving the approval of the research proposal from my supervisor and agreement from the Company to conduct the research in the organisation; the research proceeded in October 2007 at the second Case Company and finished in December 2008, after sufficient data have been collected to answer the research questions. The research project at Case Company 1 had four AR cycles; see Figure 1.1. AR cycle 1 was the diagnosis phase and the remaining AR cycles were the result of discussions to plan the targeted improvements with the participants in a meeting, based on the diagnosis in the interim action research report. The outcome of this meeting was that the infrastructure, namely the Company's information system and quality management system needed to be improved first, because the infrastructure was weakly developed hindering further implementation of TBM practices. As result improving the information systems and work system practices of the Case Company was subject of AR cycle 2. Improving the quality management system, including a supplier selection program to enhance the supplier dependability was the next AR cycle 3. The last AR cycle 4 contained the improvement of preventive maintenance and the batch changeover/set-up, but this AR cycle was not conducted, since I left the company in October 2007.

Figure 1.1 Research Project - Time-Frame Case Company 1




The research project at Case Company 2 had five AR cycles; see Figure 1.2. AR cycle 1 was the diagnosis phase including the installation of the project organisation for studying the subsequent four AR cycles. These four AR cycles represent the main problem areas of the Company's throughput process and improvements of these problem areas were suggested in the interim action research report, discussed and agreed with the participants in management meeting. Participant observation, group feedback during Key Performance Indicator (KPI) meetings and semi-structured interviews were performed to assess whether the AR cycle has been successfully implemented. The four AR cycles represent the total throughput process, dividing in the order entry process (AR2), the internal material flow (AR3), the shop-floor production processes (AR4) and the release and delivery of the product to customers (AR5). Figure 1.2 illustrates the time-frame of the research project of Case Company 2.

Figure 1.2 : Research Project – Time-Frame Case Company 2




## 1.1 PURPOSE AND RATIONALE OF THE RESEARCH

The aim of the research is to develop and extend a model of time-based manufacturing (TBM) and to improve the manufacturing practices and manufacturing performance of two Case Companies. Changes in both companies were required in order to keep in pace with the company's rapid growth. The two manufacturing companies had similar problems at the start of the research and implementing TBM practices was considered to relieve the problems of the companies.

**Objective of the research**

*The objective of the research is to implement TBM practices in two pharmaceutical preparation manufacturers in order to improve the manufacturing performance and to develop a theoretical model describing these practices.*

Strategic manufacturing (Brown, 1996; Hill, 2000) relates to the flexibility to produce many different products with different volumes at low cost through flexible manufacturing systems. Several strategic manufacturing practices may be used to improve the manufacturing performance. Lean, Agile Manufacturing, Mass Customisation and TBM are manufacturing paradigms of strategic manufacturing. There are some differences among these paradigms, as expressed by Kumar and Motwani (1995).

"*The term, agility, refers to the firm's ability to accelerate the activities on the critical path and therefore it is a direct indicator of a firm's time-based competitiveness. There is a difference between time and agility; time refers to the time taken in completing all activities on critical path, whereas agility refers to how fast activities are performed. Thus, time has no competitive propensity per se whereas agility represents the degree of competitive time-advantage that a firm enjoys over its competitors.*" cited in Kumar and Motwani (1995), page 36.

A company can have a manufacturing strategy without being agile, but it cannot become agile and pursue mass customisation without having a manufacturing strategy in place. Lean, agile and TBM are not alternatives, but are mutually supporting concepts. Lean manufacturing emphasises cost reduction, since elimination of waste is the key

element. Although lean manufacturing will help to improve the performance, the weakness of lean manufacturing is its inability to accommodate the variations or reductions in demand for finished products, due to the relative high fixed costs. The problem of becoming lean could also be that the firm's ability to achieve long-term flexibility and innovative activities is narrowing and becoming lean does not always result in improving financial performance (Lewis, 2000; Fullerton and Wempe, 2009). The lean manufacturing system is in fact a fragile system, in which a slight disturbance of internal or external resources can seriously affect the performance, because of the considerable reduction of resources.

Although, the two Case Companies need to be flexible to meet the customer requirements of unforeseen demand and the high variety of customer products, the manufacturing processes and therefore also the products are standard and constant over time. Implementation of TBM practices was therefore considered to be the best option at the start of the AR project for both companies improving the manufacturing capabilities.

Koufteros et al. (1998) have constructed a model of time-based manufacturing (TBM), showing that shop-floor employee involvement is the antecedent for improved manufacturing practices (engineering set-ups, cellular manufacturing, quality improvement efforts, preventive maintenance and dependable suppliers), which in turn, leads to pull production. Other studies demonstrated the positive relationship between TBM practices and business performance (Davis et al., 2002; Fullerton and Wempe, 2009; Jayaram et al., 1999; Nahm et al., 2003; Nahm et al. 2004). The framework of Koufteros et al. (1998) provide a foundation for research in time-based *manufacturing*

and is a part of the total concept of time-based *competition*. Additional time-competitive practices are in the area of other business functions, namely product development, marketing and distribution, but these aspects were not studied in my research. The empirical study of Koufteros and other subsequent studies with extensions to the framework (Koufteros, 1999; Rondeau et al., 2000; Tu et al., 2001; Nahm et al., 2003; Rondeau et al., 2003; Nahm et al., 2004; Tu et al., 2006) have all been performed in the US discrete manufacturing industry. TBC concepts have also been empirically researched in the automotive industry (Jayaram et al., 1999) and examples of TBC in telecom, book distribution, apparel and services industries are provided in case studies (Blackburn, 1991; Hum and Sim, 1996; Stalk and Hout, 1990). However, TBC concepts have not been researched in the pharmaceutical industry previously prior to this study.

The constructs of the framework of Koufteros et al. (1998) changed in this research since:

1) The constructs were made specific to the pharmaceutical preparation manufacturing industry, because only organisations in the US discrete manufacturing industries have been used in above mentioned studies;
2) The production planning and control systems compared in discrete parts manufacturing (i.e. pull production planning) is different compared to batch manufacturing and in particular pharmaceutical manufacturing. Kanban and single-minute exchange of dies (SMED) are practices underpinning pull production, but the use of kanban is not adopted in the pharmaceutical manufacturing industry. Cellular manufacturing is another concept not fully adopted in these industries, however, identifying and grouping of families of products may be controlled by the use of MRP/ERP systems, which are used in

the Case Companies. Therefore, the "cellular manufacturing" construct has been named as "standardised manufacturing" in this research;

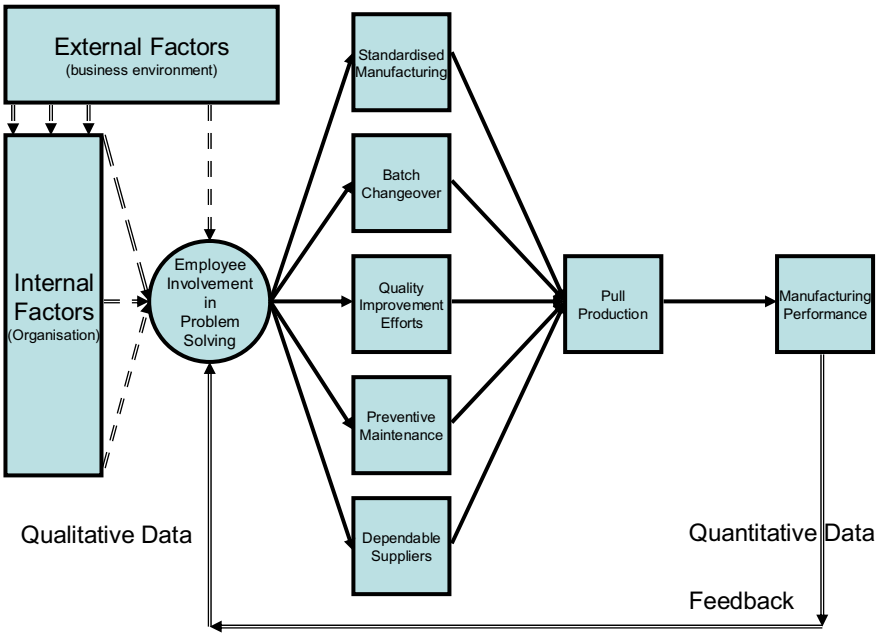
3) This research has been conducted in only two companies. The framework of Koufteros is developed and researched by cross-sectional quantitative surveys. However, AR is a case study methodology, which is based on multiple research methods and data sources, mostly qualitative research, although quantitative methods are also used. AR has also a longitudinal approach due to the cyclical research process. The framework of Koufteros has been used not only for diagnosis of the current state of the companies and to plan for further action, but also to critique and extend the framework in order contribute to theory development;

4) The framework of Koufteros has been extended by the adoption of Information Systems and Work System Practices, which can be considered as internal factors of the framework in Figure 1.3. The manufacturing performance measurements and external factors are also extensions of the framework of Koufteros;

5) This research has been conducted in the Netherlands and although Western Europe and North America have great cultural similarities, this may cause differences in the several manufacturing practices studied (Whybark, 1997).

Figure 1.3 presents the framework developed from the original TBM model of Koufteros et al. (1998) with possible extension areas (e.g. manufacturing performance, internal and external factors), as applied to the pharmaceutical industry in my research.

Figure 1.3: Initial Research Model of Time-Based Manufacturing Practices



## 1.2 RESEARCH QUESTIONS

The research questions of the research are:

- 1a) *What are the TBM practices of the Case Companies?*
- 1b) *What other practices can be applied to become a time-based competitor?*
- 1c) *How can TBM and other practices be improved to reduce the throughput time?*
- 2) *What are the internal and external factors that influence the implementation of TBM practices of the Case Companies?*
- 3) *What is the relationship between TBM practices and manufacturing performance of the Case Companies?*

The objective of the first AR cycle was to diagnose the TBM practices of the Case Companies according to the seven constructs of the framework of Koufteros. The findings of the first AR cycle are subject of the answer the first research question "*What are the TBM practices in the Case Companies?*"

The research sub-questions "*How can these practices be improved?*" and "*What other practices can be applied to become a time-based competitor?*" were answered with data collected during the implementation phase of the AR study, in which the planned interventions were based on the diagnosis of the TBM practices. The interim action research report and the feedback from the participants of the Case Companies on this report was the start of the implementation of the TBM practices.

The second question "*What are the internal and external factors that influence the implementation of TBM practices of the Case Companies?*" was answered with data collected during the diagnosis and implementation phases of the study. Internal factors contained in this study the infrastructure (Hayes et al., 1988; Hill, 2000; Nahm et al., 2003; Rondeau et al., 2000; 2003) and organisational culture (Nahm et al., 2004), that may affect the implementation of TBM practices. The external factors observed in this study are business environment, competition, customers and regulation (Bourgeois, 1980; Dess and Beard, 1984; Swamidass and Newell, 1987; Ward et al., 1995). Regulation is especially important, since the Case Companies operate in the high regulated pharmaceutical industry, and these regulations may deter the implementation of TBM practices.

The third and last research question "*What is the relationship between TBM practices and manufacturing performance of the Case Companies?*" was answered by performing time-series analysis during the whole research project. Cycle time (time between receipt of customer order and delivery) and delivery dependability have been measured as manufacturing performance data.

These two performance criteria were chosen, because cycle time is the basic metric in the TBM and TBC concepts and the low delivery dependability of the two Case Companies were considered as major problems to be solved, as described in the next paragraph 1.3 "Context". Through the possible relationship between cycle time and delivery dependability, implementing TBM practices may simultaneously lead to cycle time reduction and increase of the delivery dependability, and thus relieving the problems of the two companies.

## 1.3 CONTEXT

### 1.3.1 CONTEXT: CASE COMPANY 1

The first Case Company is a make-to-order manufacturer, operating mainly in the nutraceutical industry, which is highly related to the pharmaceutical industry. The Company with approximately 70 employees founded in 2000 is a young Dutch manufacturing company with a rapid growth of 40% in turnover in 2006. The Company is a secondary manufacturing company (e.g. it buys raw materials and processes into finished packed products) produces mixed powders, tablets (coated and uncoated) and capsules and packed them in blister packages, bottles and sachets.

Nutraceuticals, commonly known as dietary supplements are natural, bioactive chemical compounds isolated or purified from foods comprising herbs, vitamins, or other nutricients that provide medical, health benefits, including the prevention and treatment of disease and these compounds generally come in pharmaceutical forms, such as tablet, capsule, powder, or liquid form (De Felice, 1995; Hunt, 1994; Zeisel, 1999).

The application for the manufacturing license to the health authorities was submitted during the AR project to produce pharmaceutical products in order to diversify the existing business by entering the pharmaceutical manufacturing industry. The manufacturing processes of nutraceutical and pharmaceutical preparations are identical, only the regulations of pharmaceuticals are more stringent.

The reasons for the diversification are:

1) The market of the pharmaceutical industry is about 10 times bigger than the nutraceutical market;

2) The regulations of nutraceutical products are increasing and the regulatory status of some of these products (approximately 50% of the turnover) may change into medicines. In order to remain the production of these products, a manufacturing license for pharmaceutical products will provide security for a major part of the business;

3) Obtaining a manufacturing license will increase the status of the company towards the customers. The main competitor in the Netherlands is also a hybrid company, producing both pharmaceuticals and nutraceuticals;

4) The pharmaceutical manufacturers are facing up to the inefficiency of their manufacturing operations, which could lead to opportunities for contract manufacturers (Miller, 1999). The contract services industry is growing strongly in pace of the growth of the pharmaceutical industry (Miller, 2005).

Besides the less stringent regulations, there are other important differences. The Company has a simpler manufacturing process and lower batch volumes compared to the pharmaceutical industry. The following five competitive manufacturing capabilities were discussed and judged during the kick-off meeting of the AR project:

1) Quality is not sufficient and must be improved;
2) Delivery dependability is not sufficient and must be improved;
3) The throughput time of customers orders is low and is a strong advantage;
4) There is a low cost structure, however, the productivity can be improved;
5) High flexibility, which is probably the strongest asset.

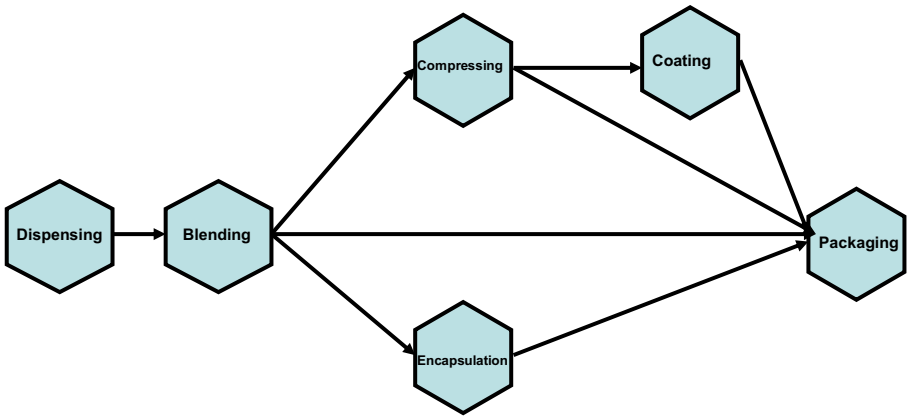
Although the Company has a good financial performance, the management team is convinced that some manufacturing capabilities must be improved. At the start of the AR project, the Company had planned to run several projects to improve the manufacturing system, such as expansion of the production and storage facilities, an IT project for implementing an ERP system and a quality improvement project for meeting the pharmaceutical requirements. These projects were integrated in the overall AR project. These changes were required in order to improve the business processes for meeting the rapid growth. Although, the manufacturing operations comply with the HACCP standards for producing nutraceuticals, the Company improved the quality management system in order to obtain a manufacturing license for pharmaceutical products from the health authorities.

**Problem statement:**

*The manufacturing performance (especially delivery performance and quality) is under pressure due to the rapid growth of the Company and must be improved to keep in pace with the growth of its industry and to enter the pharmaceutical market successfully*.

Keeping up escalating demand in the two different markets requires both different manufacturing capabilities (the nutraceutical industry needs high flexibility and high delivery reliability, whereas the pharmaceutical industry requires high quality, low prices and high delivery reliability). Since these industries, including the Company at the start of the AR project remains behind other industries in terms of manufacturing efficiency, building a modern manufacturing system may help the Company to meet the required competitive requirements. Production is divided into two major groups of activities – processing and packaging; see Figure 1.4.

Figure 1.4: Flowsheet for Secondary Manufacturing at Case Company 1




The processing activities concern the conversion of powdered ingredients into bulk tablets or capsules. Equipment is dedicated to a single operation such as blending, granulation, tablet compressing, coating and filling capsules. These products are manufactured in bulk usually in quantities dictated by the capacity of the particular piece of equipment. Filling bulk tablets, capsules or blended powder produced in the processing phase of manufacturing takes place in packaging. Tablets and capsules are packed either in blister packs or bottles according to a range of sizes.

**Expansion of capacity**

The manufacturing premises were built in 1951. The production facilities did not meet the Good Manufacturing Practices and modern manufacturing requirements at the start of the AR project. The warehouse and the packaging department especially were too small. In order to meet these requirements, the Company invested heavily in the reconstruction of the premises and new machines and equipment. Table 1.1 gives an overview of the realised investments in 2006 and 2007. The reconstruction and expansion of the facilities started early 2006 and finished end of 2007.

Table 1.1: Case Company 1 - Investments in 2006 and 2007

| **Investment** |
|---|
| Purchase of premises |
| Reconstruction of production area and warehouse |
| Reconstruction of the front face of the production building |
| GMP adjustments in premises (air-handling system, floors and walls) |
| High speed tablet compressing machine |
| Tablet compressing machine |
| Encapsulating machine |
| High speed bottle filling line |
| Bottle filling line |
| Packaging line (blister and packaging machines) |
| Packaging machine |
| High capacity coating unit |
| Laboratory equipment |

Source: unpublished business plan 2006 – 2010.

**Systems and procedures**

The infrastructure (IT systems, work system practices and quality management system) was not well developed at the start of the AR project. A project was started to automate and integrate all business processes, including the warehouse and production activities. It was very difficult to extract reliable data from the database and to use them as management information, such as financial performance or delivery performance data at the start of the AR project due to the weak performance of the Company's information systems. Therefore, the ERP implementation had the first priority for improvement, since it improved the production planning and material control system, enabling the Company to measure the order cycle time and delivery dependability more precisely and these performance parameters are the basic metrics in this study. ERP was also helpful to eliminate unnecessary double activities in the value-stream, which may lead to throughput time reduction. The Company needed also a good operating ERP system to improve its quality management system in order to obtain the manufacturing licence for medicines. Although the Company was meeting the Hazardous Analysis of Critical Control Points (HACCP) quality standards for nutraceuticals, the quality management system was not sufficiently developed and integrated in the business processes at the

start of the research. Implementing ERP was subject of the second AR cycle of the research project. Improving the quality management system and dependable suppliers were subjects of the third AR cycle. Improving the situation of the dependable suppliers and the quality management system was combined, because many quality problems related to the raw materials.

### 1.3.2 CONTEXT: CASE COMPANY 2

Case Company 2 with approximately 230 employees is a well established Dutch generics company belonging to a multinational organisation. The Company focuses on the sale of generics for the Dutch prescription market and off-patent brand products mainly for the OTC market. The Company is engaged primarily in packaging activities, not only for the local Dutch market, but mainly for other subsidiaries of the international organisation. Tablets and capsules are packed either in blister packs or bottles according to a range of sizes. The share of pharmaceutical production for which the international organisation utilises contract manufacturers amounted to approximately 60% in 2006. The international organisation is aiming to reduce the outsourced production by contract manufacturers through both the increase of the utilisation of its own production capacities and the acquisition of new production plants. The number of production facilities increased by six additional facilities in various East-European countries, due to acquisitions in 2006. The international organisation currently operates its own production facilities in: West Europe (Germany, Ireland and The Netherlands), East Europe (Russia and former Yugoslavia), and Asia (China and Vietnam).

Due to growth of the production volumes since recent years the international organisation will increase in-house production. Through the expansion of in-house

production during the forthcoming years, it is expected that the rapid growth of the production volume will also last at the plant of the Case Company during the forthcoming years. This year the Company will pack more than 1,000 million tablets, compared to the 800 million tablets in 2008 and 650 million tablets packed in 2007. Management is convinced that the manufacturing capabilities must be improved.
An improvement project was already running from January till October 2007 to improve the delivery performance to the customers, since this was very low (35 to 40% on-time delivery). The Company succeeded to improve the delivery dependability to a level of nearly 80%, but it did not succeed to improve other manufacturing capabilities, such as low throughput time. The most important actions leading to this improvement were:

1) Increase of inventory;
2) Introduction of a Master Production Plan;
3) Integration of the shop-floor planning and planning at the back office by the logistics department;
4) Instalment of a KPI measurement system.

Further improvements of the delivery performance and improvements of the business processes are needed in order to meet the rapid growth in volume of the Company.

**Expansion of capacity**

The Company has modern manufacturing facilities. The current production facilities meet the Good Manufacturing Practices for the pharmaceutical industry (European Commission – Eudralex, 2008; FDA, 2004). The Company continuously invests in the reconstruction of the premises, new machines and equipment. The high speed packaging lines are rather new machines and a new blistering machine and packing machine were acquired in 2006. The manufacturing capacity is also expanded through the introduction

of a 3 shift system, which will be rolled out over more packaging lines due to the expected increase of production volume during the forthcoming years. Additional technical skilled production employees will be recruited to enhance the capacity. An extensive training programme for the production shop-floor employees was also planned in 2008 and this training is important to increase the efficiency and quality of the packaging processes. The development of the training programme was subject to this study.

**Systems and procedures**

The infrastructure (IT systems, work system practices and quality management system) has to be improved. The Company uses standard ERP software to run its business processes, but this system runs on an old fashion IS environment. Not all business processes are properly controlled and integrated by the ERP system. For example, the order entry process is due to the ineffective ERP system very complex. A project to implement a new ERP is planned to start end of 2009 in order to improve the IS infrastructure and integrate the business processes within the Company and with affiliates of the international organisation. Although the current ERP system will be replaced, it is not difficult to extract reliable data from the database and to use them as management information, such as financial performance or delivery performance data for feedback information. Before the start of this study, the Company installed in 2007 a KPI measurement system and tried to install a system for continuous improvement, measuring the delivery dependability and throughput times of the operational processes. Although, the delivery dependability improved enormously from less than 40% to nearly 80%, the continuous improvement mechanism was not widely adopted throughout the organisation.

The Company meets the pharmaceutical GMP requirements, but the quality management system drifted the organisation towards inefficient complex business processes, resulting in many daily conflicts between operational and quality departments. The current stage of the quality management system is at the development stage of a "Quality Control" system, instead of a system that is company wide driven. Traditional improvements in the pharmaceutical GMP environment come out of reaction to quality deviations rather than from the need of variation reduction and this hinders the development of a company wide driven quality system. The fear of change and the current systems to control it, together make continuous improvement difficult. In modern manufacturing systems, such as lean manufacturing and TBM, the continuous improvement mechanism is the driven force to total quality. The challenge of the Company is to design new operational procedures in moving towards total quality following the development towards strategic manufacturing (i.e. TBM) that comply with all external regulatory requirements, supporting continuous improvement at the same time. This new direction is a major change and challenge for the Company. Manufacturing isn't considered in general as a core competence in the pharmaceutical industry, resulting that this industry is lagging behind other manufacturing industries (Benson, 2005; Friedli et al., 2006; Vervaet and Remon, 2005) and this applies also for this Company.

### 1.3.3 CONTEXT: EXTERNAL ENVIRONMENT

This research is focussed on the manufacturing area in the pharmaceutical industry. Figure 1.5 shows the NAICS North American Industrial Classification System (NAICS) and Standard Industrial Classification (SIC) codes for the different pharmaceutical manufacturing segments. The manufacturing of the two Case Companies corresponds to

SIC code 2834 for pharmaceutical preparations. The main business of the first Case Company is the nutraceutical preparation manufacturing, but it also started to diversify into the pharmaceutical manufacturing industry. There are no SIC codes listed for the nutraceutical manufacturing industry, however, this industry is highly related to the pharmaceutical preparation manufacturing industry. The nutraceutical preparation manufacturing corresponds mostly to SIC code 2834 for pharmaceutical preparations.

Figure 1.5: NAICS and SIC codes for the Pharmaceutical Manufacturing Industry

| NAICS | SIC | Description |
|---|---|---|
| **3254** | | **Pharmaceutical & medicine manufacturing** |
| **32541** | | **Pharmaceutical & medicine manufacturing** |
| **325411** | | Medicinal & botanical manufacturing |
| | 2833 | Medicinals & botanicals |
| **325412** | | Pharmaceutical preparation manufacturing |
| | 2834 | Pharmaceutical preparations |
| | 2835 | Diagnostic substances |
| **325413** | | In-vitro diagnostic substance manufacturing |
| | 2835 | Diagnostic substances |
| **325414** | | Biological product (except diagnostic) manufacturing |
| | 2836 | Biological products, except diagnostic |

(source: http://www.census.gov/eos/www/naics/)

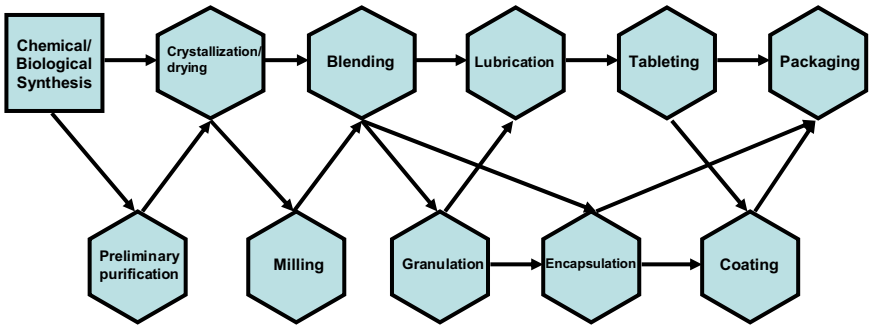
Most pharmaceutical products involve primary active ingredient bulk manufacturing and secondary (preparation) manufacturing (Shah, 2004). Pharmaceutical bulk manufacturing in general consists of batch chemical processing equipment and other pharmaceutical processing technologies (milling, blending, granulation, coating, filling, packaging) have been borrowed (and improved) from other batch industries, such as food, cosmetic or electronic industries (Fung and Ng, 2003; Muzzio et al., 2002). The nutraceutical industry has its roots in both the food and pharmaceutical industries. The influence of the pharmaceutical industry has largely been due to its considerable expertise in producing products in dosage forms. As nutraceuticals are designed to

supply nutrients in dosage forms, the greater proportion of products are manufactured using pharmaceutical skills and equipment. As a consequence, many factories producing both nutraceuticals and pharmaceuticals have to comply with stringent pharmaceutical regulations, as the first Case Company (Crowley and Fitzgerald, 2006; Gale, 2006). Pharmaceutical manufacturing is controlled by Good Manufacturing Practice (GMP) and the industry is intensively regulated. The manufacturing process is slow due the need for quality control activities at several points in the process and the requirement that pharmaceutical production is subject to extensive periods of cleaning between batches in order to avoid cross-contamination of products resulting in long downtimes between production batches (Shah, 2004). But also, the technology used to manufacture these products can at best be described as primitive. Plant design tends to be very traditional, with no real change in manufacturing technology for many years (Muzzio et al. 2002). The level of human capital employed in the industry is high, but the traditional pharmaceutical industry devotes more resources to marketing and less toward basic engineering and manufacturing process development. The existing pharmaceutical development and manufacturing philosophy, typically based on batch-campaign manufacture represents enormous waste and is the very opposite of Lean Thinking (Greene and O'Rourke, 2006; Geller, 2007). The production of solid dosage forms, such as tablets and capsules represents roughly 80% of all pharmaceutical products (Muzzio et al, 2002; Wibowo and Ng, 2001). Other types of pharmaceutical products, include aerosols, injectable products, suspensions, and topical products (creams, ointments, eye-drops). The production of tablets is a four-stage process involving dispensing, granulation, compression and packaging; see Figure 1.6 on next page.

The plants of generic drugs, nutraceutical and contract manufacturers must be flexible to be able to produce a wide range of different products. Primary manufacturing tends to

operate in campaigns whereas secondary manufacturing batch-sizes are typically 1 – 4 million tablets for branded pharmaceuticals and usually less than 1 million tablets for generics pharmaceuticals and nutraceuticals.

Figure 1.6 : Flowsheet for Tablet and Capsule Manufacturing




Source: adapted from Muzzio et al., 2002, page 2.

The current practice of relying on traditional manufacturing technology means that processes are designed to be operated in potentially ineffective ways, resulting in inefficient and costly operations and unable to ensure responsiveness (Schonberger, 1999). The relatively low production volumes result in multipurpose plants. There are more secondary manufacturing sites, serving local or regional markets than primary manufacturing, which have long cycle times making it difficult to ensure end-to-end responsiveness. It is not unusual for the overall supply chain cycle time to be 300 days (Shah, 2004). Holding sufficient stock is necessary to meet customers' demands that have short lead times (Shah, 2004). The relatively high levels of stock are required to buffer the slow supply chain against market dynamics.

Generic and traditional pharmaceutical companies, while of equal standard and manufacturing regulations, may have somewhat distinct manufacturing requirements. Many generic companies manufacturing a wide range of pharmaceuticals are used to manufacture different products using the same production lines and as consequence manufacturing must devote time to cleaning and preparing a line for the next product, which is a costly and time consuming process. Traditional pharmaceutical companies producing brand products with their large production volume for a single product are often able to run one product constantly on the same production line, resulting in lower manufacturing costs. However, generic competition may drive the industry to streamline the manufacturing process. The generic model of multiple products in one plant would seem to fit the requirements of lean manufacturing, requiring low volumes.

### 1.3.4 MANUFACTURING IMPROVEMENT INITIATIVES

The pharmaceutical industry does not have a strong legacy of leadership in manufacturing innovation and engineering supremacy when comparing to other technology driven industries (Benson, 2005; Friedli et al., 2006; Vervaet and Remon, 2005). There is a wide-spread under-appreciation for how other industries maintain modern manufacturing techniques (such as TQM, WCM) and introduce new processes. This may be the result of severe (traditional) product quality regulation with strict mandates for documentation and validation, which presents obstacles (cost and schedule) for innovation and productivity improvement. The OEE (overall equipment effectiveness) measure within the pharmaceutical industry is typically is only 30%, while a world-class manufacturing plant in other industries obtain a triple result (Benson, 2005; Vervaet and Remon, 2005; Jenkins and Orth, 2003). This suggests that the pharmaceutical industry has a potential to increase the output of the present assets and human capital with minimal investments. In the pharmaceutical industry “quality”

refers to product quality, however as in some other industries "quality" should be incorporated in the processes and the entire organisation.

With thinning pipelines, and demands for price control, the pharmaceutical industry must look for process improvements to stay competitive. Manufacturing can also contribute with safer, confident manufacturing and lower cost, faster response times and higher customer satisfaction. The pharmaceutical sector is now ready for manufacturing improvement, since efficient capacity utilisation will be important as regulatory pressures increase and margins erode (Shah, 2004). There is a trend that the pharmaceutical industry is starting to reconfigure their processes and develop strategies toward "operational excellence" (Hermel and Bartoli, 2001). Although many pharmaceutical companies have started with manufacturing improvement programmes to help them become more competitive, they are at the early stage.

Other industries have already adopted these lessons and these improvement programmes are also applicable for the pharmaceutical industry. There are nowadays many conferences and discussions in the field among pharmaceutical professionals to learn from these improvement programmes. The following improvement programmes can be found in pharmaceutical manufacturing conferences and literature:

1) Lean Manufacturing (Greene and O'Rourke, 2006; Geller, 2007; Basu, 2009);
2) SMED (Single-minute-exchange-of-dies) (Gilmore and Smith, 1996; Jindia and Lerman, 1995);
3) Six Sigma (McGurk and Snee, 2005; Anonymous, 2005; Chatterjee et al., 2005; Friedli et al., 2006; Basu, 2009);
4) World Class Manufacturing (Benson, 2005).

Pharmaceutical companies have started to employ Six Sigma in order to detect obstacles, and delays for improving the operational costs and customer service. Six Sigma can be combined with lean manufacturing. Another manufacturing improvement tool described in the pharmaceutical industry is SMED, a technique earlier applied in the automobile industry. For example, Gilmore and Smith (1996) described how a pharmaceutical manufacturer responded to an increased requirement for manufacturing flexibility through the introduction of SMED, namely machine set-up time reduction. A lot of the time is spent on clean-up and sanitation activities dictated by pharmaceutical regulations to ensure that products are free of contaminants. Achieving these quality standards has traditionally made manufacture a significant cost burden, since the time between producing the last product of a new series that meets all quality requirements has always been considered as waste or as 'added cost'. Numerous benefits can be realised from implementing quick changeover which decreases the cycle time. These include:

- An increased capacity since the line can produce for more hours instead of being down for changeover;
- Additional production flexibility – reduced changeover cycles permit production departments to package smaller lots in accordance with customer demands.

As earlier discussed adopting modern manufacturing techniques has the potential to triple the output of pharmaceutical production from existing assets. The application of lean or TBM with Six Sigma with continuous improvement techniques will have a major impact to the pharmaceutical industry. Companies who are not in the position or otherwise fail to adopt the necessary improvement programmes will find it increasingly difficult to maintain the competitive position of their products once the patent protection period has run out.

# 2 LITERATURE REVIEW: TIME-BASED COMPETITION IN CONTEXT WITH STRATEGIC MANUFACTURING

The literature review gives the reasons of conducting the research and outlines the background against which the research has been undertaken. Furthermore, the review identifies the conceptual frameworks using to locate the research and referring to the issues in the associated literature. First the mainstream and manufacturing strategies, followed with a description of a group of manufacturing systems called strategic manufacturing (SM) are discussed, starting with lean manufacturing (LM) as the precursor of SM. Agile manufacturing (AM), mass customisation (MC) and time-based manufacturing (TBM) belong to this group of SM paradigms. The last part of the literature review explores the literature behind the theoretical framework used as basis for the Action Research Project.

## 2.1 MAINSTREAM STRATEGY

There are many definitions of strategy. One of the definitions defined by Johnson and Scholes (1997: 10) is:

"*Strategy is the direction and scope of an organisation over the long term: which achieves advantage for an organisation through its configuration of resources within changing environment, to meet the needs of markets and to fulfil stakeholder expectations.*"

The strategy of an organisation is concerned with the following aspects (Johnson and Scholes, 1997):

1) Strategy is associated with long-term direction (Das, 1991) and scope of an organisation (Drucker, 1973; Abell, 1980; Hamel and Prahalad, 1989; Campbell and Yeung, 1991);
2) Strategy gives direction to achieve advantages for the organisation (Porter, 1985; Kay, 1993; Hamel and Prahalad, 1994);
3) Strategy can be seen as matching the organisation to its external environment, or vice versa. This refers to the search for strategic fit (Porter, 1980) or stretch of organisation's resources and competences (Hamel and Prahalad, 1993);
4) Strategy requires often major resource changes for an organisation and are therefore likely to affect operational decisions (Mintzberg, 1979; Kay, 1993; Hamel and Prahalad, 1994);
5) Strategy is also influenced by the values and expectations of the stakeholders of the organisation (Mintzberg, 1983; Kay, 1993).

Strategies can be made for different units within the organisation, while the highest level is the strategy at corporate level. Corporate level strategy is concerned with answering the question: in what set of businesses should we be in? (Ginsberg and Venkatraman, 1985). This level involves the selection of product markets or industries and the allocation of resources among them. Strategy at the business level requires the input of all functional departments for a distinct set of products or services that are intended for a specific market.

In literature there are two fundamentally different approaches to strategy content – the contingency approach and the resource-based approach.

The contingency or positioning approach of Porter places most emphasis on adapting the organisation to its environment (e.g. strategic fit). This approach is based on product-market characteristics, focusing on product-market positions in terms of cost and differentiation. Competitive advantage in this external based view is achieved by moving into feasible product-market positions and is mainly based on the deployment of static organisational capabilities to offer the products more effectively than competitors. This static assumption reduces the flexibility of the organisation. Several researchers have criticised Porter's generic strategies for their limitations (Kotha and Vadlamani, 1995). The simple generic strategies of low cost and differentiation are unable to describe the current environment of hypercompetition (D'Aveni, 1994) and as consequence the strategic management and operations strategy discipline has gradually moved from a market-based view to a resource-based view (Mahoney and Pandian, 1992; Gagnon, 1999; Dangayach and Deshmukh, 2001). Differentiation can also be a means for companies to achieve an overall low-cost position and in stead of Porter's stuck of the middle position a combination of low cost and differentiation could lead to sustainable competitive advantage (Hill, 1988). In a more dynamic environment, it may be better to follow the resource-based approach, which places most emphasis on adapting the environment to the organisation (Gagnon, 1999). A resource-based strategic view means that companies with dynamic capabilities show timely responsiveness, rapid and flexible product innovation and have the ability to adapt, integrate and transform internal and external organisational skills, resources and functional competences toward changing environment (Teece and Pisano, 1994). According to Hayes (1985), it is better to develop first the competitive capabilities for seeking continuous improvement, based on the obtained capabilities following the development of the plans. Thus strategy can also be seen as "stretching" the resources and competences of an organisation to create competitive advantages, by analysing the

environment, internal analysis of the company's resources, competences, choosing a possible strategy plan, and implementing a strategy plan. Strategic intent implies a sizable stretch for an organisation (Hamel and Prahalad, 1994). Its basic assumption is that a company can use superior organisational resources and capabilities to modify the industry structure and/or changing the rules of the industry. Resources are both tangible and intangible assets which are tied semi-permanently to the firm and the developing and exploitation of a set of unique resources can cause sustained profitability (Wernerfelt, 1984). Resources are often not enough to gain sustainable competitive advantage.

A strategic capability would be to develop core competences which are difficult to imitate, otherwise they will not provide long-term advantage and should meet three criteria (Prahalad and Hamel, 1990):

1) *Potential access to a wide variety of markets,*
2) *Significant contribution to the perceived customer benefits of the end product,*
3) *Difficult for competitors to imitate.*

When the market turbulence is expected to increase in the future and the competitive rivalry will also become more intense, building core competences is according to Hamel & Prahalad (1994) for the long run the best strategy. But organisations, including manufacturers may not have any core competences. The manufacturing capability of a company can be developed as a core competence (Banerjee, 2000) to become a strategic manufacturer. The implementation of manufacturing strategy will change the internal culture of the company (Bates et al., 1995), which is difficult to imitate (Itami, 1987) and provide better internal and external relationships, i.e. higher employee and customer

satisfaction and these aspects fit well with the strategy of Prahalad and Hamel. However, core competences are not necessary linked to manufacturing strategy (MS). A more recently dynamic concept called "strategic resonance" lying between the contingency and resource-driven approaches has been introduced (Brown, 2000; Brown and Blackmon, 2004) to provide this link better.

"*Strategic resonance will be achieved when firms align manufacturing strategy with business-level strategy to strategic flexibility through integrated market-led and resource-driven approaches.*" cited in Brown and Blackmon (2004), page 800.

## 2.2 MANUFACTURING STRATEGY (MS)

Strategy at the functional level refers to issues regarding specific functional aspects of a company. Functional-level strategy focuses on maximisation of resource productivity within each function (Ginsberg and Venkatraman, 1985). Marketing and manufacturing and other organisational activities of the value chain form a cluster of functional strategies, which complement higher level business unit and corporate strategies. The originator of the MS concept, Skinner (1969) defined MS as the exploitation of certain properties of the manufacturing function as a competitive weapon. Swamidass and Newell (1987: 509) defined MS as "the effective use of manufacturing strengths as a competitive weapon for the achievement of business and corporate goals", and MS contributes to the overall corporate success and complements other functional strategies (Wheelwright, 1984). The competitive capabilities and the MS choices should link to the overall business strategy (Hayes and Wheelwright, 1984). MS deals with both the content and the process. MS content refers to the competitive capabilities of the manufacturing function (Swamidass and Newell, 1987; De Meyer et al., 1989; Miller

and Roth, 1994). Some empirical studies demonstrated that the alignment between manufacturing and business strategies have a positive effect on business performance (Williams et al., 1995; Ward and Duray, 2000; Sun and Hong, 2002; Demeter, 2003). A strategic architecture and the necessary supporting elements such as information, communications links and organisational systems are needed to integrate the core competences through the whole organisation (Banerjee, 2000).

**Content**

The primary function of MS is to provide the business in putting together the manufacturing capabilities enabling the organisation to execute the chosen competitive strategy in an effective way over the long term (Hayes and Wheelwright, 1984). This means that MS should (Mills et al., 1995):

- Support the company's competitive success factors;
- Be consistent with business and other functional strategies;
- Show internal consistency between manufacturing decision areas.

MS is based on the assumption that the company should compete through its operational capabilities and align these with the key success factors and its corporate and marketing strategies. Hill (1993, 2000) defined the criteria of order winners and qualifiers as competitive dimensions of manufacturing. The competitive priorities define what the manufacturing system must achieve regarding cost, quality (product & process), flexibility (range, volume and mix of outputs) and delivery (speed & reliability) in order to support the business strategy (Skinner, 1969, 1974; Ferdows et al., 1986; New, 1992; Miller and Roth, 1994 and Hill, 1993, 2000). Manufacturing flexibility is an important attribute of a company's MS (Gerwin, 1993; Boyer and Leong, 1996; Narasimhan et al.,

2004). It provides the capability to respond fast to changes in the market requirements and can be used to relieve problems caused by an uncertain and dynamic environment (Hayes and Pisano, 1994; D'Souza and Williams, 2000; Anand and Ward, 2004; Pagell and Krause, 2004). Manufacturing flexibility leads to customer satisfaction (Zhang et al., 2003). According to Hayes and Wheelwright (1984), MS must help an organisation to achieve a desired manufacturing structure, infrastructure and set of specific capabilities.

**Process**

MS process refers to the formation and implementation of MS.

The traditional approach of strategy formation emphasises that first the corporate strategy is defined, followed by the business level and further the marketing and manufacturing strategies. According to Hill (1993), it starts with corporate objectives, such as growth, survival, profit, ROI or other financial measures. The next step is defining the marketing strategy. Herein, both operations and marketing should understand the critical competence factors in order to effectively formulate and link the MS to the needs of the market place (Jaworski and Kohli, 1993; Menda and Dilts, 1997). Working together on the marketing and manufacturing functions has a significant impact on the business performance (Hausman et al., 2002). MS can also be pro-active, based on the core competences of the manufacturing function, which offers a source of competitive advantage (Wernerfelt, 1984; Hayes, 1985; Stalk et al., 1992; Vickery et al., 1993; Brown, 1998). Furthermore, strategy decisions of the several levels of the overall business are made by linking these areas together and therefore the three levels (i.e. corporate, marketing and manufacturing) are not mutually exclusive (Mills et al., 1995; Brown, 1997; Sun and Hong, 2002). Hill (1993, 2000) stated that the formation of a

MS, linked to the market place should take place at top management level. Others, like Hayes and Wheelwright (1984) have a more adaptive view, based on the importance on learning and discuss the infrastructure aspects of manufacturing, including management policies, systems and practices (Hayes et al., 1988).

Some manufacturing objectives are more related with cost (i.e. materials-, unit-, and overhead cost) and others are more concerned with time (i.e. cycle-, machinery set-up-, and new product development time) or quality (defect rates and supplier quality). The manufacturing objectives must be achieved by selecting, which improvement programme must be implemented in the future. However, the impact of an improvement programme depends on the constraints of the options of the firm's overall strategy, like timing, capabilities, allocation of the resources and expectations of stakeholders. The right strategy formation has no end, only continuous improvement is needed.

Some researchers have developed a framework for MS. Hill (2000) presented a framework with a step by step procedure of developing MS. Mills et al. (1995) described the MS design in three steps, which are audit, formulation and implementation. Kim and Arnold (1996) have developed a framework for implementing the MS into the choice of action plans. Their model includes three constructs representing the different stages of developing MS – competitive priorities, manufacturing objectives and action plans.

How should the manufacturing competitive priorities be translated into decisions regarding action plans or manufacturing improvement programmes? This AR project with the several action plans may be considered as a MS process where the first AR cycle is the audit and the subsequent AR cycles are the improvement programmes.

Furthermore, the role of manufacturing managers is important in the MS process. Several studies demonstrated their importance in the role of the company's strategic decision making process (Swamidass and Newell, 1987; Brown, 1998; Tracey et al., 1999; Brown and Blackmon, 2004). Both involvement and influence of the manufacturing manager in strategic decision making process are important antecedents of the alignment between organisational and manufacturing strategies affecting the business performance (Papke-Shields and Malhotra, 2001; Brown et al., 2007).

## 2.3 STRATEGIC MANUFACTURING AND ITS PARADIGMS

Strategic manufacturing (SM) is becoming increasingly important due to globalisation, fast technology development, intense competition and fragmentation of markets (Hitt et al., 1998; Krause et al., 1998; Zhang et al., 2003). Low cost and quality are no longer necessarily the principal order winners. Manufacturers are therefore seeking to differentiate their products and services, which requires a strategy of creating flexibility by achieving reduced design cycle time, reduced time to market for new products and reduced order cycle time to customers. SM means that the company will see its manufacturing capability as a core competence able to produce many different products with different volumes at low cost through flexible manufacturing systems (Brown, 1996; Hill, 2000). The implementation of SM requires a long-term vision and incremental steps are needed to integrate and build manufacturing systems with other functional resources, including human resources and technology.

Traditional manufacturing accepts long cycle times as the "price" of "efficiency" (Schlie and Goldhar, 1995) and the strategic objective of this approach is to become the low cost producer. There are many new manufacturing systems evolved, since mass

manufacturing was not anymore useful for various industries. Mass production may still be a viable strategy in a particular stable market (Kotha, 1995), where little flexibility is needed, however, the inability of the traditional manufacturers to respond to the external environment (e.g. market changes and new technology) is the cause that the mass manufacturing concept is inappropriate for obtaining satisfactory competitive performance in most industries (Skinner 1978, 1985). The new manufacturing practices can be roughly grouped into two key areas of manufacturing systems (Clark 1996). The first group is bases on integration of engineering and technology with manufacturing, such as Computer Integrated Manufacturing to achieve flexibility. The second group of manufacturing practices is based on 'world class' concepts, such as Total Quality Management (TQM), Just-In-Time (JIT), World Class Manufacturing (WCM), Lean Manufacturing (LM) and the Strategic Manufacturing (SM) concepts.

Much of the best practice concept of manufacturing has been brought by the WCM paradigm of Hayes and Wheelwright (1984), but also the outstanding performance of Japanese manufacturers, TQM, continuous improvement and the concept of benchmarking (Voss, 1995).

The underlying assumption is that best practice [e.g. "World-Class – stage companies lead to grow faster and be more profitable than their competitors" cited in Hayes et al. (1988), page 23] will lead to superior performance.

However, adopting new practices in the organisation does not always have a competitive value. Best practice will by itself not guarantee improved performance and there is a substantial failure rate in the implementation (Voss, 1995; Gagnon, 1999). Since the company has limited resources, there is a need to determine which activity to

use to improve specific areas of performance (Davies and Kochlar, 2002). Ketokivi and Schroeder (2004) concluded in their empirical study that new manufacturing practices, TQM and JIT are still implemented with little consideration given to strategic goals and fit. Organisations feel often the need to do something about adopting best practices, but it stops people from thinking (Senge, 1992). This is mentioned by Hayes and Pisano (1994; 78) that "Being 'world-class' is not enough; a company also must have the capability to switch gears – from, for example, rapid product development to low cost". The objective of MS in a turbulent environment is *strategic flexibility* and manufacturing has to provide that capability (Kotha, 1995). The flexibility following quality evolution is consistent with the suggestions of Ferdows and De Meyer (1990), to start with enhancing quality, then improving the dependability of the production system, followed by enhancing the flexibility of the production system.

Three SM practices can be considered as a group consisting of agile manufacturing (AM), mass customisation (MC) and time-based manufacturing (TBM), the latter as part of the overall time-based competition concept. Lean Manufacturing (LM) is considered as a precursor of SM (Brown, 1996). LM is not considered as strategic due to its fragile system putting emphasis on costs and without emphasis on strategy. The new SM concepts have been emerged in the 1980s and may be considered as a logical follow up to processes that have become increasingly flexible and improved regarding quality and costs (De Meyer, 1998; De Meyer et al., 1999). In addition, SM can be viewed as a means to differentiate in a highly competitive and segmented market. There are some differences among these paradigms. Lean, AM, TBM and MC are not alternatives, but are mutually supporting concepts. The time-based competition paradigm has a broader context and includes all functions, for example, also non manufacturing related marketing and finance, whereas the concept "agile organisation"

refers only to operational activities from product development and design to delivery (Goldman and Nagel, 1993; Kumar and Motwani, 1995; Vokurka and Fliedner, 1998; Gunaresekaran, 1999; Zhang and Sharifi, 2000). Furthermore, there are some differences in the emphasis of the different manufacturing capabilities, as illustrated in table 2.1.

Table 2.1: The Strategic Manufacturing Concepts and their First Manufacturing Capability Priorities

| **Manufacturing concept** | **Manufacturing capability priority** |
|---|---|
| Lean Manufacturing | Cost |
| All | Quality |
| All | Delivery Dependability |
| Agile Manufacturing and Mass Customisation | Flexibility |
| Time-Based Manufacturing | Speed |
| Agile Manufacturing and Mass Customisation<br>Time-Based Manufacturing | Innovation: flexibility to bring new products to market<br>Innovation: time to market of new products |

The Japanese manufacturers have adopted the following sequence in strategic planning (Ferdows et al., 1986), which combines low cost manufacture with flexibility:

(1) First high quality which leads to “best practice”;

(2) Then delivery reliability must be achieved which leads to “best practice” (e.g. process quality);

(3) Then production costs must be lowered, which leads to “lean”;

(4) Finally manufacturing flexibility must increase which leads to “strategic”.

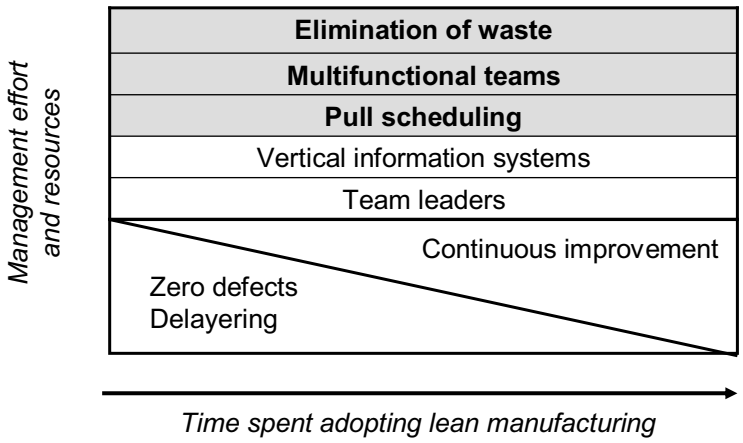
### 2.3.1 LEAN MANUFACTURING (LM)

Since the work of Womack et al. (1990), many manufacturers adopted LM as a strategy to increase their competitiveness. A key element is that fewer resource inputs are required by the lean manufacturing system and to put pressure for obtaining higher productivity, improved quality, shorter lead times and reduced operational costs (Karlsson and Ahlström, 1996; Katayama and Bennett, 1996).

According to a recent empirical study of Shah and Ward (2007), LM consists of ten practices in an integrated manufacturing system, consisting of supplier feedback, JIT delivery by suppliers, supplier development, pull, continuous flow, set-up time reduction, total productive/preventive maintenance, statistical process control, and employee involvement; and lean practices have together a synergistically effect on the operational performance (Shah and Ward, 2003). The individual lean practices can be grouped in JIT for production flow practices, TQM for continuous improvement practices, Total Productive Maintenance (TPM) for practices concerning planned and preventive maintenance and the human resources practices, such as training and employee involvement (Shah and Ward, 2003; Li et al., 2005; Shah and Ward, 2007). Inventory, especially work-in-progress is wasteful, hides operational problems that has to be solved and the elimination of waste is the key element of LM. The decline of down time of production lines is another example, which can be accomplished through preventive maintenance (Karlsson and Ahlström, 1996). The application of manufacturing cells where families of products are produced is one of the means to reduce waste. But first it is necessary to change employees' attitudes to quality, in order to remove the activities that do not add value to the product. In a LM system, materials are scheduled through a pull system. Reduce batch sizes and non-defective materials are necessary requirements for a pull system. Batch size reduction requires reduced set-up

times, which is also an elimination of waste. Figure 2.1 shows how management should start the continuous improvement of LM on the fundament of adopting zero defects and de-layering by using multifunctional teams to solve day-to-day problems (Ahlström, 1998).

Figure 2.1: Sequences in the Implementation of Lean Manufacturing
(source: adapted from Ahlström, 1998)




Adopting LM starts with improving quality for obtaining zero defects, where quality control is delegated to the shop-floor employees, operating in multifunctional teams. The quality objective is to achieve a high degree of process capability and control, which improves also the productivity. Thus, instead of performing quality checks on the products produced, the process is kept under control (Karlsson and Ahlström, 1996). Other tasks, such as maintenance, procurement and material handling are also made responsible to the team. Training efforts and increasing the number of functional tasks of the employees are therefore needed for achieving multifunctional work-teams (Karlsson and Ahlström, 1996). Flatter organisation structures improve also communication and co-ordination from the shop-floor and since LM with low inventories lies close to customer demand and supplier deliveries (James-Moore and

Gibbons, 1997; Robertson and Jones, 2001), changes in demand will adapt the production schedule rapidly. Vertical information systems are relying on direct information flows to the decision makers on the shop-floor for rapid feedback and control. The team leaders have herein high responsibilities and play an important role. As a result, the LM system will reduce the number of hierarchical levels in the organisation, where the multifunctional teams are also performing supervisory tasks through rotating team leadership (Karlsson and Ahlström, 1996). However, large plants are more likely to implement the lean practices extensively compared to small plants (Shah and Ward, 2003). Continuous improvement involves shop-floor employees in problem solving to improve the manufacturing processes.

An important note to mention is that LM must be seen as a direction, rather than as a state which can be accomplished after a certain period. Katayama and Bennett (1996) argue that a weakness of LM is its inability to accommodate the variations or reductions in demand for finished products, due to the relative high fixed costs. The problem of becoming lean could also be that the firm's ability to achieve long-term flexibility and innovative activities is narrowing and becoming lean does not always result in improving financial performance (Lewis, 2000; Fullerton and Wempe, 2009). The LM system is in fact a fragile system, in which a slight disturbance of internal or external resources can seriously affect the performance, because of the considerable reduction of resources (Biazzo and Pannizzolo, 2000). Setting up a LM system requires therefore the adoption of best practices, not only in manufacturing but also in other functions of the company (Warnecke and Hüser, 1995) and its suppliers (Panizzolo, 1998; Bruun and Mefford, 2004).

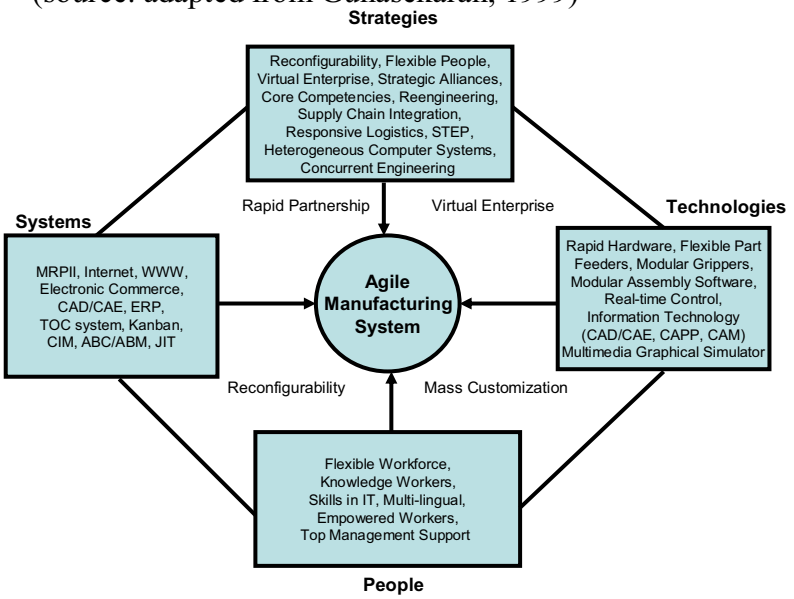
### 2.3.2 AGILE MANUFACTURING (AM)

The concept of agility is an enhancement to LM (Willis, 1998; van Asten, 2000). Agility means being able to rapidly adapt operations, processes and business relationships efficiently in an environment of change (Hormozi, 2001; Narasimhan et al., 2006; Bernandes and Hanna, 2009). It is a set of operational capabilities for meeting widely varied customer requirements in terms of price equal to mass production and fast delivery of products meeting unique customer specifications (Willis, 1998; Katayama and Bennett, 1999). Agile organisations are flexible and quick to respond to fast moving conditions as well as being pro-active in developing future market opportunities (Brown and Bessant, 2003). Companies adopting agile manufacturing require the creation of strategic alliances and virtual organisations and they must be willing to rethink the way of conducting business. They must become more flexible, more creative, and better able to design products which can be upgraded in the aftermarket. AM strives for economies of scope rather than economies of scale, because it is a system that allows for customisation without the associated higher costs, through efficient use of flexible workforce in a decentralised organisational structure and the use of flexible manufacturing systems (Van Assen, 2000). Agility is often equated with MC, because these two concepts aim to produce exactly what customers want. MC can be considered as an example of a manufacturer's ability to be agile (Brown and Bessant, 2003).

Bessant et al. (2001: 33) described agility as: "*a dynamic capability, which involves the continuing and conscious search of the environment to detect and choose which puzzles to work on, and the active search for innovative solutions to those problems through developing both core competences and organizational capability*".

Companies that implement AM already have invested in quality and technological based individual competences, for example, with TQM or TPM programmes. These organisations are largely dependent on the capabilities of its employees in order to produce high quality and defect free products, reduce throughput times and deliver high customer service in a market with constant and unpredictable change (Van Assen, 2000; Hormozi, 2001). Firms adopting AM require the creation of strategic alliances and virtual organisations and they must be willing to rethink the way of conducting business. They must become more flexible, more creative, and better able to design products which can be upgraded in the aftermarket. Agility in supply chain can be achieved by integrating organisations, people, and technology into a meaningful unit by deploying advanced information technologies and flexible organisation structures to support highly skilled, knowledgeable, and motivated people (Gunasekaran, 1999). Kumar and Motwani (1995) have identified 23 factors influencing the company's agility in relation to the time-based competitiveness of a firm, which can be used as framework for re-evaluation the agility of business processes. The majority of literature regarding AM is either conceptual or exploratory and most of these studies lack theoretical foundation and empirical evidence. Gunasekaran (1999) presented a framework for designing AM through information systems and technologies; see Figure 2.2. Others (Bessant et al., 2001) presented also a framework of the development of AM practices, which include agile strategy, agile processes, agile people and agile linkages as AM practices, but these frameworks have not been empirical tested so far and only a few examples of IT supporting AM can be found, despite there has been a large number of works that have explored the relationship between IT and manufacturing in general. There are only a few empirical studies conducted testing an AM framework showing that AM practices have a positive influence on business performance (Cao and Dowlatshahi, 2005; Vazquez-Bustello et al., 2007).

Figure 2.2: Development of an Agile Manufacturing System
(source: adapted from Gunasekaran, 1999)




### 2.3.3 MASS CUSTOMISATION (MC)

Mass customisation (MC) can be considered as a successor to mass production (Pine et al., 1993; Willis, 1998) and appears to go beyond "flexibility" and "quick responsiveness" to the supply of customised products and services for the mass market (Kotha, 1995; Ahlström and Westbrook, 1999; Da Silveira et al., 2001). In contrast to traditional systems based on economies of scale, MC is based on economies of scope. A MC-producer has the abilities to both produce and distribute customised goods and services within a high volume or mass market at close to mass-prices (Tu et al., 2001) and these abilities can have profound strategic opportunities for companies, which are based on resource-based strategies (Brown and Bessant, 2003). MC uses IT, flexible processes (e.g. JIT, setup and changeover reduction), and organisational structures to provide a wide range of products or services that meet specific needs of individual customers, at reasonable low costs. The most important aspect to achieve MC is to make

advanced in the manufacturing system, enabling to produce a high variety of products (i.e. flexibility) in a connected flow environment (i.e. mass production) and, more importantly without accompanying cost penalty (i.e. efficiency). The success of MC systems depends on both market related and organisation-based factors (Da Silveira et al., 2001). The customer demand for variety and customisation must exist and the market conditions must be appropriate. Other success factors are organisation-based which can be enabled as demonstrated in Table 2.2.

Table 2.2: MC Enablers and Related Success Factors

| Related success factors (organisation-based) | Enablers |
|---|---|
| | *Processes and methodologies* |
| Knowledge must be shared<br>Value chain should be ready<br>Products should be customisable<br>Value chain should be ready | Agile manufacturing<br>Supply chain management<br>Customer-driven design and manufacturing<br>Lean manufacturing |
| | *Enabling technologies* |
| Technology must be available;<br>Products should be customisable | Advanced manufacturing technologies |
| Technology must be available;<br>Knowledge must be shared | Communication and networks |

Adapted from Da Silveira et al. (2001)

When developing the MC system, the manufacturer must consider several aspects, including logistics, operations, distribution and a close link between marketing and manufacturing must exist to obtain a good balance of internal and external flexibility, since this needs a change in the view on product variety and manufacturing flexibility. To become a successful mass customiser, companies must first achieve high levels of quality and skills and low cost. For this reason continuous improvement should be the first step to become a mass customiser (Pine et al., 1993). Companies must change at the end long-lasting, cross functional teams into an efficient linkage system.

Organisations, adopting only continuous-improvement look at defects as process failures and provide the knowledge to solve problems and ensure that failure never recurs. In the dynamic networks of MC, defects are considered as capability failures, unable to satisfy the needs of specific customer or market.

### 2.3.4 TIME-BASED MANUFACTURING (TBM)

Time-based competition (TBC) is a collection of concept, tools, techniques and a management practice that gives a company quick response capability in designing, producing, delivering products and services to customers. In order to become a time-based competitor, companies must start improving their manufacturing practices, followed by other functions of the value chain.

"*Companies generally become time-based competitors by first correcting their manufacturing techniques, then fixing sales and distribution, and finally adjusting their approach to innovation. Ultimately, it becomes the basis for a company's overall strategy*" (Stalk, 1988: 46).

TBM is based on the extension of the principles from JIT and TQM to the entire manufacturing system, including new product development, logistics and customer order management (Blackburn, 1991) and extends beyond the factory by linking suppliers and customers to the distribution and manufacturing system (Handfield and Pannesi, 1995). TBM is external oriented, focussing on fast response to changing customer needs, whereas JIT is an internal system, responding on demand (Koufteros et al., 1998). JIT's primary goal is cost reduction. Carter et al. (1995) have identified the following strategies for implementing TBC:

1) Less Of / System Simplification
2) As One / System Integration
3) Same As / Standardisation
4) At Once / Parallel Activities
5) Watch It / Variance Control
6) Better Than / Automation
7) More of / Excess Resources

The benefits of adopting time-based strategies are increased productivity, market share gain, obtain price premium, customer loyalty and shut out competition due the fast introduction of new products, causing that products become obsolete (Stalk and Hout, 1990). Empirical studies have confirmed that the business performance and profitability will rise, if manufacturers adopt time-based practices, which also leads to reduced cycle time (Davis et al., 2002; Jayaram et al., 1999; Nahm et al., 2003; Nahm et al. 2004).

Time-based companies compete in two different forms: fast-to product and fast-to market (Carter et al., 1995; Zairi, 1996), both leading to reduction in manufacturing cost and increasing market share (Sim and Curatola, 1999) and these companies work close with their suppliers. Fast-to market emphasises a reduction in design lead time, i.e. from concept to production and the ability to introduce more new products faster than its competitors. Fast-to product emphasises speed of responding to customer needs for existing products. Time performance can be viewed as internal into a cost strategy, e.g. measurable by the company or external into an innovative strategy, e.g. visible to the customers (De Toni and Meneghetti 2000). Standardisation of designs has a strong impact on delivery speed (Handfield and Pannesi, 1992; Jayaram et al., 1999). The factors for choosing the strategic orientation of either time-based or cost-based

depend on the sensitivity of customers to external time performances. The reduction of lead time, either obtained by introducing new products or by producing existing products faster mostly leads to improved business performance as a result of higher revenues and lower operational costs.

Figure 2.3: Internal and External Time Performance, adapted from De Toni and Meneghetti (2000)

| Time Performance / Phase | Internal | External |
|---|---|---|
| Product Development | TTM (Time-To-Market) | FI (Frequency of Introduction)<br>- new products<br>- existing product improvements |
| Procurement<br>Production<br>Distribution | LT (Lead Time)<br>- procurement<br>- production<br>- distribution | DT (Delivery Time)<br>- speed<br>- punctuality |

Competition is not anymore mono-dimensional and time-based strategy will focus on more than one measure to obtain competitive advantage (Wagner and Digman, 1997). The six time-based measures (Jayaram et al., 1999), involving the whole value chain are:

1) New product development time

2) New product introduction time

3) Manufacturing lead time

4) Delivery reliability/dependability

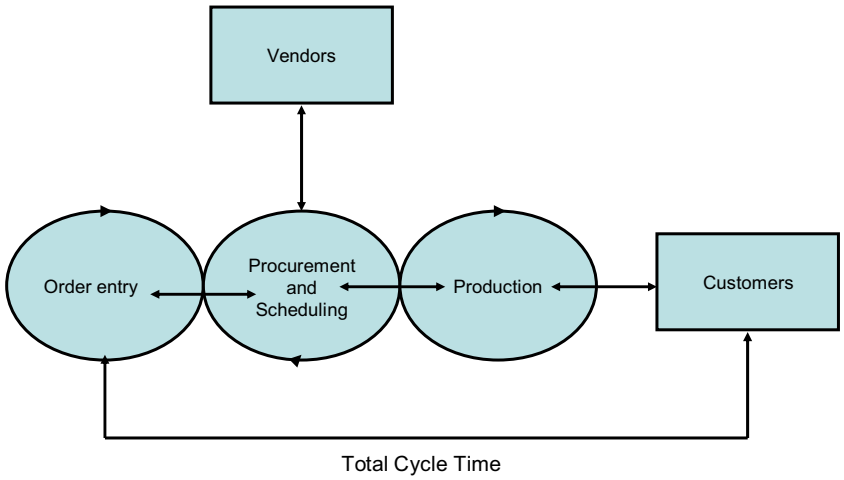
5) Delivery speed

6) Customer responsiveness

Tactics on rationalisation resemble those used in a JIT manufacturing environment, and include elimination unnecessary steps, reducing bottlenecks and streamlining the flow of work so that information as well as products can be processed in small batches. TBM can also be used by building capabilities to improve the flexibility and responsiveness of business processes to changing customer requirements with enhanced new product development (Bozarth and Chapman, 1996). This can be achieved through redesigning the organisation's structure to directly support time-compressed flows and business processes. As shown in Figure 2.3, it is essential to reorganise the entire supply chain to attain a strategic advantage (Handfield and Pannesi, 1995), so that a customer-order-driven production will be achieved where it is not necessary to trigger the processes by unreliable forecasts of demand (Zäpfel, 1998). The requirements for an economical customer-order-driven production are the actions to be taken to eliminate all obstructions preventing short throughput times and full utilisation of existing capacities. A manufacturing organisation must be able to identify and solve problems rapidly to guarantee a low work-in-process, short cycle, high quality production system. Therefore, all manufacturing employees must be able to diagnose problems as they occur and solve them fast (Koufteros et al., 1998). Shop-floor employee involvement in problem solving is the antecedent for other TBM practices, reengineering set-ups, cellular manufacturing, quality improvement efforts, preventive maintenance, dependable suppliers and pull production. TBM practices lead to high levels of standardisation, formalisation and integration to form cross-functional teams (Rondeau et al., 2000). The speed of information being shared between all organisational resources is critical for time compression, in which the workforce within a turbulent and uncertain manufacturing environment must be able to inquire and relay information fast. The organisational structure can help or hinder the information and communication process. The nature of formalisation, the number of hierarchical layers and level of

horizontal integration have direct positive effects on the shop-floor employee involvement in solving problems and level of communication, followed by increasing TBM practices (Nahm et al., 2003), and leading to enhanced IT systems capabilities (Rondeau et al., 2003). Short manufacturing throughput time is not enough to satisfy customers, if other parts of the value chain are slow. The whole "value-delivery" chain from order entry to delivery is important. In order to become a time-based competitor, the organisation must also diminish the non-value added activities, such as administration, inspections, waiting, inventories and rework (Blackburn, 1992).

Figure 2.4: Conceptual View of the Organisation in a Time-Based Manufacturer (adopted from Bozarth and Chapman, 1996)



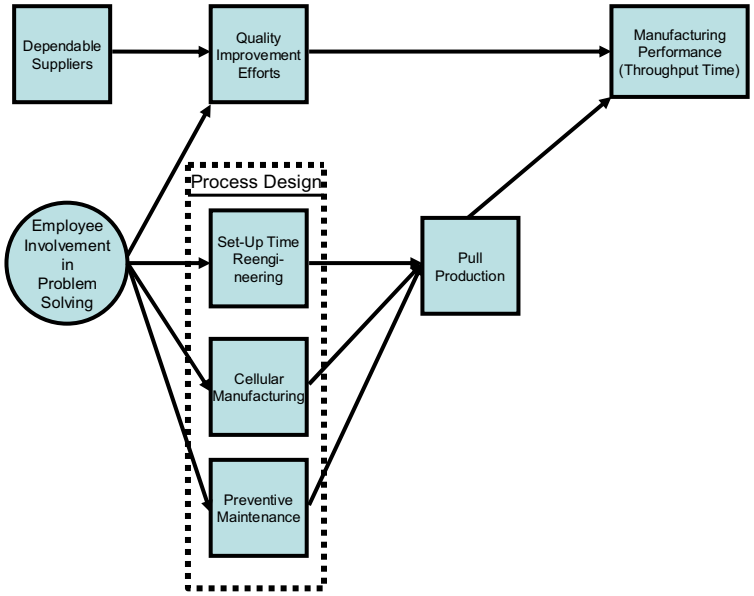
## 2.4 THE TIME-BASED MANUFACTURING RESEARCH FRAMEWORK

Several surveys have been conducted to study TBM in the US discrete manufacturing industry by using the research instrument of the seven TBM practices of the original study of Koufteros, et al. 1998. These studies (Koufteros, 1999; Rondeau et al., 2000; Tu et al., 2001; Nahm et al., 2003; Rondeau et al., 2003; Nahm et al., 2004; Tu et al., 2006) have been conducted to extend the framework and some of the extensions may be seen as the "internal factors" in Figure 1.3, page 23. However, the framework of Koufteros has not been studied in the nutraceutical and pharmaceutical industries so far and in particular in manufacturing companies in AR studies. The internal factors researched earlier in surveys in relation to TBM are: organisational structure (Nahm et al., 2003), organisational culture (Nahm et al., 2004), information systems (Rondeau et al., 2003), and work system practices (Rondeau et al., 2000). Other internal factors not studied earlier in relation to TBM are in this study the quality management systems and production planning & material control systems of the Case Companies. The external factors as extensions of the framework in this study are the business environment, competition, customers and regulation (Bourgeois, 1980; Dess and Beard, 1984; Swamidass and Newell, 1987; Ward et al., 1995).

The objective of the research is to implement TBM practices in two pharmaceutical preparation manufacturers in order to improve the manufacturing performance and to develop a theoretical model describing these practices. Coghan and Brannick (2001) bring the use of theoretical framework in relation to AR in order to examine an organisation's current situation and predict outcomes. The initial framework of figure 1.3 was used as diagnostic tool for planning further action and the framework may be extended in order to contribute to theory development.

The instruments used in the survey of Kouferos may be re-designed according to the characteristics of the Case Companies in context to the pharmaceutical preparation manufacturing industry. In fact, the researchers have already reconfigured the TBM model, in a subsequent article as presented in Figure 2.5 (Koufteros et al., 1999). The researchers stated that the relationship between employee involvement in problem solving and dependable suppliers is weak and as consequence the following framework is proposed, indicating that employee involvement is not an important factor to develop relationships with dependable suppliers.

Figure 2.5: Revised Research Model of Time-Based Manufacturing Practices
(source: adapted from Koufteros et al., 1999)




### 2.4.1 SHOP-FLOOR EMPLOYEE INVOLVEMENT IN PROBLEM SOLVING

The heart of the TBM concept is that TBM involves practices require shop-floor employee involvement in problem solving which is supported by many human resources literature (Dean and Snell, 1991; Doll and Vonderembse, 1991; Arthur, 1994; Banker et al., 1996; Youndt et al., 1996; Murray and Gerhart, 1998; Biazzo and Pannizollo, 2000; Snell et al., 2000). These studies indicate that investments in training, increasing multi-skills and perform based rewards ensuring that the workforce is highly

motivated and committed, are needed to involve employees in problem solving followed by improved manufacturing performance. Enhanced employee problem solving facilitates other TBM practices including pull production leading to high manufacturing performance.

### 2.4.2 PROCESS DESIGN

According to the revised framework, pull production may be enabled by specific process design capabilities consisting of reengineer setups, cellular manufacturing (CM) and preventive maintenance (PM) in the discrete parts manufacturing industry. Kanban, CM and single-minute exchange of dies (SMED) are practices underpinning pull production, but the use of Kanban and CM are not fully adopted in the pharmaceutical manufacturing industry. However, the identifying and grouping of families of products may be controlled by the use of MRP/ERP systems, which are often used in the pharmaceutical industry. Van Donk and Fransoo (2006) stated that the production planning and control models within operations management lack specific knowledge of the process industry. This means that all measures, especially those for the CM and pull production constructs of the TBM framework may be re-designed, verified and made specific for the pharmaceutical manufacturing industry. The construct of CM is mentioned in this study as standardised manufacturing.

**Batch Changeover**

Changeover time is defined as the time from the last product of one batch leaving the machine to the first good product coming out of the next batch. Fast and reliable set up is determined by three key elements 1) technical aspects of equipment and tools, 2) the organisation of work, and 3) the methods used. All three key elements have to be

optimised for having fast and reliable set-ups. The ideal situation is that production operators usually perform the changeover and in exceptional cases machine setters from the technical/maintenance department. According to the 'single minute of exchange of die' method (SMED), originally developed by Shingo (1985) all activities related to a set-up can be divided into two categories:

1) Internal or on-line activities which are performed while the machine is down and thus the production process is stopped;
2) External or off-line activities which take place while the machine is running. These can be performed either before or after the actual downtime of the machine.

The main reasons for changeover reduction is for flexibility to respond to changing customer orders and reduced batch sizes, leading to lower throughput times, lower costs and reduced inventory. Improved changeover also leads to improved quality through consistent repetition. Set-up is an important element of the throughput time and indicator of shop-floor responsiveness and low set-up time is an important factor of pull production allowing manufacturers to respond quickly to changing customer orders (Monden 1981, 1983).

**Standardised Manufacturing**

Pharmaceutical batch manufacturing involves often the movement of large lots of goods between functionally specialised departments of work centres. Each department or work centre is composed of a group of employees who perform similar tasks using similar machinery or equipment. Theoretically, each batch may take a slightly different route through a system, and each will have different processing requirements in each work

centre. Additionally because this system is designed to accommodate a variety of large-lot jobs, several of such jobs may be queued up in each of several departments. In fact, in a typical batch system, components spend most of their time queued up at work stations. Batch systems may be subject to excess work-in-process, long lead times, scheduling problems and large rework quantities.

In the discrete parts manufacturing Cellular Manufacturing (CM) is an application of group technology (GT), consisting of production cells of machines, each dedicated to the processing of similar parts having similar processing requirements and geometrical shapes, that are grouped into families (Wemmerlov and Hyer, 1987). Identifying families of products enables dissimilar machines with different processing capabilities to be grouped together to form a production cell. GT cell formation produces in an optimal case perfectly with independent production cells. However, this is rare in practice and very often some of the parts in a family have to move across machine cells. The production cells are self-contained, because they have all the equipment necessary to make a part and the operators in production cells as a team to execute the several sequential processes work rather than for their own process department. The benefit of CM is that there is a mutual shaping between the technical and social aspects, due to the self-containment with integrated quality, maintenance, and schedule responsibility. Because each production cell manufactures products that have similar characteristics, product changeovers are relatively easy to accomplish, and small lot sizes may be justified economically. By producing parts with similar size, shape and processing requirements and therefore the reduction in material handling time, CM cuts both throughput and changeover time, enhances quality, and increases flexibility (Hyer and Wemmerlov, 1984).

A production cell differs from a traditional batch production line that workers may be cross-trained in all of the functions within the cell, allowing adaptation to the processing requirements of the various products within a family (Angra el al., 2008; Brown and Mitchell, 1991). Changes from batch to cellular layouts have been associated with numerous benefits, including improvement in inventory levels, throughput and set-up times, quality, and flexibility (Brown and Mitchell, 1991; Fry et al., 1987; Huber and Hyer, 1986; Hyer and Wemmerlov, 1984). In batch manufacturing, a production lot completed by one department goes to the next department regardless of whether or not that department is ready to receive it. Bottlenecks and excess work-in-process often result from this push approach to scheduling. The pull approach prohibits any movement of goods or work on subsequent units until the next station signals that is ready to receive them. In support of the pull system, parts and materials are purchased and delivered only as needed. The intended results include reduction in work-in-process, a cleaner work environment, and shorter throughput time (Brown and Mitchell, 1991). This involves processing groups of similar components in a dedicated cluster of dissimilar machines.

The most important and primary step in CM is to group parts with similar design characteristics or processing requirements into families and form associated machines into production cells (Angra et al., 1998). The equipment requirements for each part family are determined subsequently or simultaneously to the identification of part families. Although adoption of CM is not fully usable in pharmaceutical preparation manufacturing, some aspects of GT may be applied. Identifying and grouping of similar products having similar processing requirements and geometrical shapes controlled by the use of MRP/ERP systems, cross training of shop-floor employees, small batch sizes, no storage of intermediate, and scheduling of production lines by shop-floor employees

are usable examples of GT (Ahlström, 1998; Hyer and Wemmerlov, 1984). The adoption of these GT practices in the batch manufacturing of pharmaceuticals is in this research project referred as “Standardised Manufacturing”.

**Preventive Maintenance (PM)**

Effective maintenance is important to many operations. It extends equipment life, improves equipment availability and retains equipment in proper condition. Poorly maintained machines may lead to delayed production schedules, poor utilisation of equipment and more frequent equipment failures, resulting in scrap or reduced product quality and more frequent equipment replacement because of shorter life. Reactive maintenance may be described as a troubleshooting approach allowing machines to run until failure and minimises the amount of maintenance manpower to keep machines running. However, the disadvantages of this approach include unplanned downtime long waiting time and increased inventory in order to compensate for poor reliability. PM is a scheduled downtime, usually periodical, in which a well-defined set of tasks (e.g., inspection, repair, replacement, cleaning, lubrication, adjustment and alignment) is performed. The benefits of PM are reduced probability of equipment breakdowns and extension of equipment life (Swanson, 2001). Manufacturers with successful PM programmes involve employees in designing and performing maintenance activities and these firms reduce unplanned downtime and achieve pull production (Schonberger, 1986). However, it is important to mention that PM is justified only when it is cost effective, reduces the occurrences of unscheduled breakdowns, and extends the useful life of equipment (Das et al., 2007). This is because PM incurs a large cost for the user in maintaining the required level of reliability, since many items are replaced prematurely despite still having useful lives remaining.

Total Productive Maintenance (TPM) is considered an evolution in PM (Rodrigues and Hatakeyama, 2006). The objective of TPM is to obtain maximal equipment effectiveness, by establishing a comprehensive maintenance system. The TPM concept goes beyond prevention to include improvement in productivity and has much in common with total quality. TPM has a positive relationship with low cost, high levels of quality and strong delivery performance (McKone et al., 2001).

The concept of TPM includes the following three elements (Nikajima, 1988):

- TPM aims to maximise machine effectiveness (overall efficiency) and availability (*Total effectiveness*);
- TPM establishes a thorough system of PM for the entire life span of the machine and establishes a schedule of clean-up and good housekeeping (*Total maintenance system*);
- TPM is implemented by various departments in a company, involving all employees, from top management to workers on the shop floor and includes autonomous maintenance by operators through small group activities, in which the operator is responsible for the care of the machine (*Total participation*).

TPM is thus aimed to improve the production efficiency improvement to its maximum extent in an overall manner in which the operators must preserve their own machines, whereas the approach of traditional PM is centred on equipment specialists. Due to its employee involvement, TPM can also be seen as integral to TBM involving JIT, TQM elements. Manufacturers with higher implementation of JIT, TQM and employee involvement also have higher implementation levels of TPM. Manufacturing improvement programs, such as TPM, TQM and JIT should not be evaluated in

isolation, because their practices are closely related and mutually supportive (Cua et al., 2001) and also in combination with HR management (Shah and Ward, 2003). The use of TPM to improve equipment performance and the increase of the skills of workers are additional positive outcomes of manufacturing practices. Top management should therefore demonstrate their commitment to TPM by spending sufficient time and allocating enough resources to create the necessary cultural changes and provide training for employees to achieve autonomous maintenance.

### 2.4.3 QUALITY IMPROVEMENT EFFORTS AND DEPENDABLE SUPPLIERS

Quality improvement efforts are the methods developed and used to reduce defects and enhance quality. But the impatience of top managers who remain keeping attention on short-term financial objectives and cost-cutting myopia has caused the problem of "quality" of viewing as reduction of defects by inspection, rather than a holistic approach of quality (Brown, 1997). Therefore, quality improvement efforts and programs should be brought a strategy with the aim not to reduce costs but obtaining higher performance by linking manufacturing capability with market requirements, where cost reduction is seen as a result (Brown, 1998). Six Sigma is an example of a quality improvement programme developed by Motorola and has been used successfully to reduce defects, redundancy, and waste in operational processes (Antony et al., 2007; Barnley, 2002; Breyfogte, 2003; Eckes, 2001; Folaron, 2003; Linderman et al., 2003; Tennant, 2001). As a result of implementing a Six Sigma process, companies may realise improvements in quality, customer satisfaction, and operational and financial performance (Goh et al., 2003; Lee and Choi, 2006). Six Sigma is pragmatic and it is based around process and variation, uses well-established statistical concepts, has a clear structured methodology and a recognised practitioner route through "black belt"

training (Linderman et al., 2003; Pyzdek, 2003; Schroeder et al., 2008). The life cycle of a Six Sigma program comprises five major phases, which are: 1) define; 2) measure; 3) analyse; 4) improve; and 5) control.

At a higher level, Total Quality Management (TQM) involves meeting (internal and external) customers needs as focal point of operations, external focus, i.e. partnerships with suppliers and customers and benchmarking against competitors for continuous improvement, supported by top management involvement and commitment (Flynn et al., 1994; Kaynak, 2003; Wilson and Collier, 2000). Since TQM is an organisational philosophy, each company may define it differently. TQM involves all functions within the company and aims continuously improvement of process performance in order to satisfy customer requirements. However, the following major components can be readily identified (Vonderembse and White, 1996):

- *Focus on the customer*
- *Everyone is responsible for quality*
- *Team problem solving*
- *Employee training*
- *Fact-based management*
- *A philosophy of continuous improvement*

Flynn et al. (1994) has designed in a empirical study a validated measurement instrument for quality management, containing seven dimensions, namely 1) Top management support, 2) Quality information, 3) Process management, 4) Product design, 5) Workforce management, 6) Supplier involvement and 7) Customer involvement. This measurement instrument has much in common with the Malcolm Baldrige Award criteria (Criteria for Performance Excellence, 2005), and these quality

management practices have been extensively documented in other quality research and literature (Ahire et al., 1996; Black and Porter, 1996; Crosby, 1984; Deming, 1986 and 1993; Feigenbaum, 1982; Juran, 1986; Kaynak, 1983; Kaynak and Hartley, 2008; Nair, 2006; Powell, 1995; Saraph et al., 1989; Wilson and Collier, 2000), so it can be applied as TQM assessment tool in studying organisations. The construct of quality improvement efforts of Koufteros et al. (1998) has been extended with the quality measurement instrument of Flynn et al. (1994). The reason to extend this quality construct is to obtain more information of the quality management system beyond the quality improvement efforts, covered by the instrument of Koufteros, containing only a few questions related to quality. Top management support, employee training and involvement and feedback are additional quality topics, used in this study.

Developing manufacturing systems that can provide high quality products on-time depends on suppliers who deliver the same. It is also important to build a dependable supplier network and following the JIT philosophy to strive to single suppliers. Suppliers are merely an extension of a firm's manufacturing system. Dependable suppliers cut throughput time, reduce costs and improve competitive capabilities (Carr et al., 2008; Kaynak, 2003; Kaynak and Hartley, 2008; Yeung, 2008), and on-time deliveries allow the organisation to keep inventory low and shorten response time to its customers. High supplier performance can help to reduce downtime and the shortages associated with delivery delays. If a supplier's product does not comply with the quality specification, production is delayed until it has been replaced by a new product.

### 2.4.4 PULL PRODUCTION

Pull production is originally developed as component of JIT manufacturing to eliminate inefficiencies in the production system. The trigger of the pull system is the Kanban, the Japanese word for card to start the upstream production line and replenishment of materials. In practice, Kanban is a signal that can take many forms, for example, cards, magnetic strips, empty box, or barcode to react to the demand of the customer. The planning for delivery of product to customers is less troublesome, and demand becomes more stable if customers have confidence in knowing that they can get what they want when they want it. The opposite are push systems of traditional manufacturing, making centralised computer control necessary because factors of space, time, and inventory create insurmountable obstacles to local communication between stations, (Blackburn, 1991).

Stalk and Hout (1990: 20) describe this as follows:

"*Scheduling. The scheduling of traditional factories is complicated by the process centre organization as well. Traditional factories are often centrally scheduled, requiring sophisticated MRP (material resource planning) and shop floor control systems. These systems direct much of the activity on the floor and feedback to management the results of their decisions. As sophisticated as these systems can be, they still consume time. In addition, the floor direction modules may only be exercised monthly or weekly. Between exercises parts wait. Flexible factories use more local scheduling. More production control decisions are made on the floor without a loop back to management for approval. Local scheduling does not require more capable employees. Quite the opposite is true. The product-oriented layout of the flexible factory means that when a part is started, many of the movements between manufacturing steps are obvious and do not need intermediate scheduling*."

There is an association between implemented pull systems and type of manufacturing system (White and Prybutok, 2001). For instance, manufacturers in discrete industries are more likely to implement JIT than those in the process industry (Shah and Ward, 2003), although JIT manufacturing is applicable in any manufacturing system. There is also a distinction between make-to-stock and make-to-order system in which the pull mechanism is easier to implement in a make-to-order manufacturer. Those able to produce to the pull of customers do not need to manufacture goods that traditional batch-and-queue manufacturers must rely on. Although the Kanban system is not fully usable in pharmaceutical preparation manufacturing, some elements of pull systems may be applied, for example local scheduling at the shop-floor.

### 2.4.5 FEEDBACK

The concept of feedback can, once again, be seen as part of the philosophy of continuous improvement. The Plan-Do-Check-Act Cycle, also referred as the Deming Wheel embodies the philosophy of continuous improvement. The "Check" element of the wheel analyse the revised process to see if goals have been achieved, if not determine why not and "Act" accordingly. Measurement is an important requirement of continuous improvement processes. It is necessary to establish appropriate metrics for measurement purposes. Time is perhaps the single most important measure in lean and supply chain. This is because it directly influences customer satisfaction and indirectly other measures, for example costs, quality, inventory turnover and other financial ratios. So give time achievement and reduction a prime place in measurement systems. Combination measures such as OEE (availability x performance x quality), delivery (on-time x quantity x quality), total satisfaction (right product x when needed x right

quantity) are useful measures to get for improvement and employee involvement. Employee involvement in problem solving is then triggered by the feedback loop, as illustrated in Figure 1.3 of page 23.

### 2.4.6 INTERNAL FACTORS

Internal factors of the research framework influencing the TBM practices refer to the infrastructure and organisational culture. Infrastructure is subject to the management policies, systems, procedures, controls and organisational issues that determine how the manufacturing system is managed and includes (Hayes et al., 1988; Hill, 2000):

1) Human resource policies and practices, including management selection and training policies;
2) Quality assurance and control systems;
3) Production planning and inventory control systems;
4) New product development processes;
5) Work system practices, including standard operating procedures;
6) Performance measurement and reward systems, including capital allocation systems;
7) Organisational structure and design;
8) Information systems environment.

The internal factors studied in this research are the organisational structure and culture, information systems, work system practices, quality management systems, and production planning & material control systems. The study of the internal factors on

these Case Companies is a part of the research project and corresponds to the following questions:

1) *What other practices can be applied to become a time-based competitor*?
2) *What are the internal (and external) factors that influence the implementation of TBM practices of the Case Companies*?

To become a time-based manufacturer, it may be necessary to improve the infrastructure of the organisation, before implementing one of the seven TBM practices. For example, IT has a positive relationship with the reduction of the throughput time, resulting in increased business performance (Davis et al., 2002). After the diagnosis of the first Case Company, it was decided to improve the IS before the implementation of the TBM practices. The speed of information being shared between cross-functional teams is critical for time compression, within a turbulent and uncertain manufacturing environment where these teams must be able to inquire and relay information fast. Information feedback provides a workforce with process and performance information to assist a decentralised management of production process and variance minimisation.

Marchand and Raymond (2008) introduced the term performance management information system (PMIS) and described the importance of IS to enhance the efficiency and effectiveness of performance measurement systems. IS enables the closed loop deployment and feedback and thus enabling continuous improvement, in which PMIS (mentioned in this study as KPI measurement system) should integrate all relevant information from relevant systems. Time is in this study the main performance metric of the throughput process, which can be traced by a KPI measuring system when connected to an ERP system through its access in an integrated, real-time and

synchronous dataset storing the firm's transactions and operational activities. This enables time-based manufacturers to measure the cycle times of the throughput process and perform time-series analysis of the delivery performance.

In this environment, IS of time-based manufacturers is likely to play an important role. However, there are only a few studies performed linking TBM to IS. One empirical study demonstrated that adopting time-based practices in manufacturing and new product development will enhance IS capabilities (Rondeau et al., 2003). An explanation for this may be that the high degree of cross-functional involvement inherent in TBM creates a good work system environment.

Five dimensions of the information systems environment of time-based manufacturers were studied according to the research of Rondeau et al. (2003).

1) IS strategic planning effectiveness,
2) Cross-functional involvement in IS related activities,
3) IS responsiveness to organisational computing demands,
4) End-user computing,
5) End-used effectiveness.

Besides IS, work system practices were also studied in the two Case Companies.
Work system practices include standardisation, formalisation, routinization (routine use) and integration (Rondeau et al., 2000). Manufacturers employing TBM practices need to have high levels of work system practices. Dealing with varying customer demands, standardisation is important for time-based manufacturers. Standardisation include the operating procedures and methods used to make products (work processes) and assess

performance (output measures). Formalisation copes with the written documentation of work instructions and job descriptions, accessible to employees that can be shared between departments and across the organisation. Routine use refers to the work to be done on a daily basis characterised a routine production environment. Integration is mixing the activities and functions of the whole organisation to form an integral unit. TBM practices lead to integration because groups of employees from different functions need to co-operate to solve complex problems.

## 2.5 FURTHER CONSIDERATIONS OF THE LITERATURE REVIEW

This AR project is research driven, as explained further in the Methodology Chapter, on page 93. The preliminary literature survey of this chapter focuses only on the research framework defined a priory and deals with the "What" research questions; see page 24. The "How" research question is the implementation part of the research, which is covered with the development of the AR methodology, described in the next chapter. The findings of the study are compared and contrasted with the existing literature, which is discussed in the final chapter.

Other useful fields providing additional relevant information on the "How" question which have not been explored in the preliminary literature survey are mentioned briefly here.

*Organisational change management and implementation*

Change management is defined as "the process of continually renewing an organization's direction, structure and capabilities to serve the ever-changing needs of external and internal customers" (Moran and Brightman, 2001: 111).

Relevant literature on organisational change management and implementation can be found in Burnes (2004), Kanter et al., (1992), Kotter (1996) and Luecke (2003).

Other areas of organisational change are organisational development and learning, TQM and business process re-engineering, innovation management and project management.

*Organisational development and learning*

The field of organisational development and learning is briefly discussed in the last chapter; see pages 243 – 245. Important literature in this field can be found in Argyris (1999), Argyris and Schön (1978), French and Bell (1998), Kolb (1984), Schön (1987) and Senge (1990).

*Business process re-engineering and TQM*

Business process re-engineering (BPR) was first introduced by Hammer (1990) and Davenport and Short (1990). BPR is a process of analysing, fundamental rethinking and radical redesign of the key processes of the company to achieve dramatic improvements (Ascari et al., 1995; Hamer and Champy (1993). The concept of TQM is discussed earlier in this chapter; see section 2.4.3, page 73. BPR and TQM co-exist in organisations and both approaches share certain principles, adopt a process perspective and can be used in the same organisation, but at different times. The choice depends on whether to adopt a more radical re-engineering approach or a more gradual continuous improvement approach based on TQM, its feasibility and the resources required. The often cited literature in the BPR field are Carr and Johansson (1995), Davenport and Short (1990), Hamer (1990), Hamer and Champy (1993), Johanssen et al. (1993) and Lowenthal (1994).

*Innovation management*

Innovation management is the discipline of managing processes in innovation and can be used to develop both product and organisational innovation (Troth, 2008). Innovation management involves both incremental change through and incremental innovation, based on continuous improvement and discontinuous innovation, which requires radical change. Implementing TBM practices, like implementing lean manufacturing practices is a long lasting continuous improvement effort and needs an incremental innovation approach. A number of relevant texts to innovation management can be found in Drucker (1985), Ettlie (1999), Tidd and Bessant (2009), Trott (2008) and Utterback (1994).

*Project management*

Project management is the discipline of planning, organising, and managing resources to bring about the successful completion of specific project goals and objectives and refers to change management as way to organise change (Pellegrinelli, 1997). A project has a defined beginning and end to meet specific goals and objectives, and can benefit from the application of project management skills (Partington, 1996). How projects can be managed is described in many books and can be found for example in Cleland and Gareis (2006), Ireland, (2006), Look (2007), Stevens (2002) and Turner (2009).

# 3 METHODOLOGY

This section presents the double case study design, using action research (AR) methodology. It gives a rationale for the approach to research used in the study, based on the philosophical assumptions and describes in detail how the data collection and analysis methods were used in a rigorous and ethical manner to the research of implementing time-based manufacturing (TBM) practices at the two Case Companies.

## 3.1 OBJECTIVE OF THE RESEARCH

The objective of the research is to implement TBM practices in two pharmaceutical preparation manufacturers in order to improve the manufacturing performance and to develop a theoretical model describing these practices.

The two manufacturing companies had similar problem statements at the start of the research and implementing TBM practices has been considered to relieve the problems of the Companies. Since I was employed at both Companies during the project research and interventions were necessary to improve the manufacturing practices, a combination of AR and case study approaches was chosen to achieve this and as consequence the research has been designed specifically such that interventions could be determined, implemented and assessed. I had the dual role of participant and observer in the two Companies, combining action and reflection, characteristic of AR.

Improving the situation and involving the participants are two essential aims of AR (Greenwood and Levin, 2007; Herr and Anderson, 2005; Kemmis and McTaggart, 2005). AR aims at improvement of three areas: firstly the improvement of the practice; secondly, the improvement of the understanding of the practice by the practitioners; and thirdly, the improvement of the situation in which the practice takes place (Carr and

Kemmis, 1986: 165). AR is a participative form of research (Coghlan and Brannick, 2001; Greenwood and Levin, 2007) and my participation and the involvement of other persons as participants of this study were clear. My role as researcher was mainly to act as co-ordinator of collaboration, a distributor of responsibility and an agent of change.

## 3.2 METHODOLOGICAL ASSUMPTIONS: PHILOSPHICAL RATIONALE

There are two main research philosophies, positivism (or 'etic' or nomothetic), and phenomenology (or 'emic' or idiographic). This research is qualified according to its position upon a continuum linking these philosophies (Smith, 1998).

This research does not have a positivist structure, since it does not make comparisons across a large sample. Empiricism means that the world can only be known through experience. Empiricists contend that the social and natural sciences can be investigated by the same scientific methodology (Frankfort-Nachmias and Nachmias 1996: 13). Positivism holds that empirical data must be observed and measured so that the various objects can be compared for relative frequency. The observation of a particular set of objects and the examination of regularities is the basis for developing scientific law. Empirical regularities consist of two or more variables which occur together in the same place and time and have the status of scientific law. Empiricists aim to obtain objective data, without bias or prejudice and presume that facts and values should be separate from each other. Further, objectivity has been associated with claims to universally and detachment of the object and the researcher. The aim is to obtain empirical regularities on the basis of quantitative evidence, which may then be generalised to other situations by examining a large number of objects and to making comparisons and generalisations. Therefore the objects of analysis are studied less critically in empirical research by

restricting the number of properties used to define them, compared with phenomenological studies.

Research with people rather than on people means, that the nomothetic separation of subject and object is no longer tenable. This study leans towards the phenomenological paradigm, because it focuses on meaning rather than measurement in which knowledge construction exists through the relations of the actors involved as the product of meaningful communication. Understanding action is like understanding a language, where it depends on the meanings and shared practices of the actors involved and it is a matter of knowing rather than feelings (Argyris et al., 1995).

AR is 1) phenomenological, focussing on people's actual lived experience and reality, 2) interpretative, focussing on their interpretations of acts and activities, and 3) hermeneutics, incorporating the meaning people make of events in their lives (Stringer, 2007). Interpretative studies, like positivist research have both the difficulty of relating retrospective explanation or understanding to prospective action. Positivist research relies on a notion of prediction based on scientific laws established in past situations and expressed as controlled interventions, as its basis for informing future action. Interpretative research relies on a notion of practical judgment based on understanding of the practitioner derived from the observations of previous situations. AR requires therefore a different epistemology than pure phenomenology. Table 3.1 shows the contrasts of AR with positivist, and interpretative hermeneutics sciences.

Table 3.1: Comparison of Action Research, Positivist and Interpretative Sciences

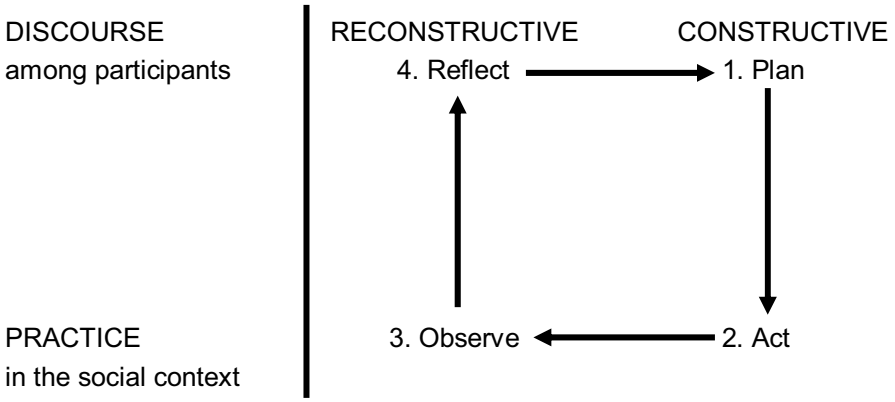
| Paradigm | Action Research | Positivist | Interpretative, Hermeneutics |
|---|---|---|---|
| Ontology | Reality is objectively given but subjectively represented | Reality is singular and objective | Reality is dual, subjectively given and represented. |
| Epistemology | Manager/practitioner and researcher can both contribute specific and general knowledge | Manager as subject of experiment/study. Researcher as detached expert. | Manager as subject, but the researcher can not be completely detached from its objects. |
| Cognitive interest | Critical, emancipatory | Technical | Practical, interpretative. |
| Aim of the study | Prediction, development of activity, change, empowerment | Cause-effect relations, prediction. | Understanding, interpretation. |
| Theory-practice relation | Interaction between theory and practice | From theory to practice, deductive. | From practice to theory, inductive. |
| Researcher's role | Active participant, shared responsibility, actor, change agent. | Outside expert, observer. | Outsider or participant does not try to influence. |
| Researcher-participant relationship | Responsibility, participants as subjects, "us". | Independence, "them" | Co-operation, "you" |
| Time perspective | Future oriented | Observations of the present and explanations of the past. | Observations of the present and explanations of the past. |
| Reflection | "What", "How" and "Why" | "What" | "What" and "How" |
| Validation | Occurrence of intended outcomes | Logical consistency, prediction | Comparison with previous cases and literature |

Source: adapted from Coughlan and Coghlan (2002); Daniel and Wilson (2004); Kyrö (2004).

AR involves both controlled interventions and practical judgment, but gives them both a limited place in the notion of the self-reflective spiral of AR which is arranged as a programme of controlled interventions and practical judgment performed by participants understanding not only their environment but also changing it. AR empowers actors through the process of constructing and using their own language. This is the meaning of consciousness raising or in Freire's praxis of "conscientization" which explains the dialectical relationship between retrospective understanding and prospective action (Reason, 1994). The underlying assumption is seemingly that it takes time for actors to acquire new knowledge, or more precisely to change their cognitive structures in such a way that their reality constructions change. The emphasis in AR on

what Argyris and Schön (1974) have termed "double-looped learning" exactly related to this point, i.e. the actor's cognitive structure or "world view" must be altered if the actor is going to initiate change for improvement (Ottoson, 2003). According to Carr and Kemmis (1986), the essential epistemological problem to be considered in relation to the self reflective spiral of AR is the problem of retrospective understanding to prospective action. The tension between retrospective understanding and prospective action is enacted in of the four "moments" of the AR process, as represented in Figure 3.1.

Figure 3.1: The 'Moments' of Action Research




Adopted from Carr and Kemmis (1986, page 1986)

Constructivism is near the phenomenological end of the continuum. It is an approach that suggests that we each construct our own view of the world through social mechanisms (happenings and interactions in our lives), where reality is the world but each person views it differently. Truth and action are interdependent and exist in a social matrix within meanings are constructed and actions can be given meaning (Carr and Kemmis, 1986). AR very much lends itself to this approach. The epistemology of

this study is constructivist, seeing knowledge as developing by a process of active construction and reconstruction.

## 3.3 RESEARCH DESIGN – DOUBLE-CASE ACTION RESEARCH

AR was specifically chosen to implement TBM practices to improve the business performance of the Case Companies, since these companies were in a transition stage and it was aimed to restructure and improve their manufacturing system. The cross-sectional design is obviously the most used design and is often used by other researchers in the area of TBM (Davis et al, 2002; Fullerton and Wempe, 2008; Jayaram et al., 1999; Koufteros, 1999; Koufteros et al., 1998, 1999; Nahm et al. 2003, 2004; Rondeau et al., 2000, 2003; Tu et al., 2001). However, AR has been promoted or used by some researchers in production and operations management (Bartunek, 2000; Coughlan, and Brady, 1995; Coughlan and Coghlan, 2002; Karlsson and Ahlström, 1996; Schroeder et al., 1990; Westbrook, 1994), since cross-sectional studies are only single time slices of the research problem and lack some in-depth internal validity (Frankfort-Nachmias and Nachmias, 1996: 148). Longitudinal studies, such as AR change over a longer period of time, but they are weaker to obtain external validity. Therefore, an intensive research design is justified since TBM practices have not been applied in the pharmaceutical preparation manufacturing industry, in which the Case Companies operate.

### 3.3.1 CHARACTERISTICS OF ACTION RESEARCH

This study is different to other kind of research. In traditional research on people, the roles of the researcher and the subject are mutually exclusive; the researcher only contributes the thinking that goes in the project, and the subject only contribute the action to be studied. The valuable differences of this study are that it is practitioner based, it focuses on problem solving and changing practices by the participants in collaborative learning, and thus it is firmly concerned with change. AR simultaneously intends to produce change ("action") and understanding ("research"), and AR brings together action and reflection and theory and practice in participation with others. There are numerous definitions of AR. One of the most cited is the definition of Reason and Bradbury (2001) who define:

"*a participatory, democratic process concerned with developing practical knowing in the pursuit of worthwhile human purposes, grounded in a participatory worldview…It seeks to bring together action and reflection, theory and practice, in participation with others, in the pursuit of practical solutions to issues of pressing concern to people, and more generally the flourishing of individual persons and their communities.*" (cited in Reason and Bradbury (2001: 1)

A primary purpose of AR is to produce practical knowledge that is useful to people in the everyday conduct of their lives (Stringer, 2007), and AR tries to find solutions to the concrete functional problems of organisations by questioning the existing status quo and by aiming to change the behaviour and thought structures of participants (Argyris et al., 1985). AR can be best applied in collaboration with other practitioners who have a stake in the problem under investigation, which result generally to the improvement of

organisational practices and the development of individual practitioners (Greenwood and Levin, 2007; Herr and Anderson, 2005; McNiff et al., 2003).

Several broad characteristics define:

- AR aims to contribute to the practical concerns of people in an immediate problematic situation by joint collaboration (Rapoport, 1970; Stringer, 2007);
- AR is a participatory democratic process (Coghlan and Brannick, 2001; Reason and Bradbury, 2001; Greenwood and Levin, 2007);
- AR is collaborative learning by changing practices (Argyris et al., 1985; Coghlan and Brannick, 2001; Kemmis and McTaggart, 2005; McNiff et al., 2003; Ottoson, 2003);
- AR is based on collecting data about an ongoing system (French and Bell, 1998; Susman and Evered, 1978);
- AR is research in action, rather than research about action (Altrichter et al. 2002; Ballantyne, 2004; Coghlan and Brannick, 2001; Grønhaug and Olson, 1999).

AR is a research approach that includes documenting, specific problems and actively working toward solving the problems. AR is a cyclical and spiral process in which the researcher alternates action with critical reflection. Critical reflection can be about the data and interpretations that the researcher is making from it. It can also critique and improve the methodology. Beyond that, it may be used as an opportunity to examine the assumptions about knowledge that inform the research design.

This study meets the criteria of AR according to Susman and Evered (1978):

1) This study is future oriented, since the Case Companies proceeded to implement TBM practices during the following period after the problem was identified;
2) This study is collaborative, since the participants were willing to improve implying a partnership between myself as the researcher and the stockholders (i.e. managing director and employees) of the Case Companies;
3) This study implies system development, since implementing TBM practices improved the manufacturing systems of the Case Companies;
4) This study generates theory grounded in action, since the TBM framework was changed and extended after many actions were taken to improve the manufacturing practices of the Case Companies as the research process developed further;
5) This study is agnostic, since the prescriptions for action and further developed theories are the result of previously taken action in which the objectives, the problem and research methods were generated from the process itself and that the consequences of the chosen actions were not fully known ahead of time;
6) This study is situational, since it was used in work situations as part of the researcher's normal activities, working as change agent of the Case Companies.

This study was used as a meta-methodology, which has been advocated by Yin (2003) as a method of contributing towards validity based on the assumption that triangulation of multiple data sources add up to a "chain of evidence". Participant observations, minutes of meetings or secondary data, such as company documents were used to compare the data collected with semi-structured questionnaires.

In order to argue for the generalisability of the results, the interpretations have been compared in the relevant literature, and comparative analysis of the two cases have been

conducted, in which the research questions and instruments for data collection, for example questionnaires of semi-structured interviews were already developed at the beginning of the research project of the second Case Company. But also in the second case both research content and research process have also been developed further during the study.

AR can be either theory driven or data driven (Avison et al., 2001; Dick, 2002). The former is case research driven situation, the latter case is problem driven situation. Although Dick (2002) favours data driven AR, this study is more theory driven and this is in accordance with Elden and Taylor (1983: 4), who stated that:

"*AR by definition must be theory-based and grounded in field testing over time of the theory in a real situation*".

This study is theory driven because it turns first to a body of extract literature and contributes to knowledge by assuming that literature as a given and extending or refining it, or challenging it, whereas data driven AR deals with the research situation and the people in they as they are, as far as possible putting aside your preconceptions so that the researcher is more open to fully experiencing the research situation.

Data driven AR will start by asking fuzzy questions using initially fuzzy methods, thereby gaining initially fuzzy answers. The initially fuzzy answers will be used to refine the methods as the research proceeds. AR lends to early action and it is enough to have a research situation, since AR does not require there is a research question, extensive preparatory reading, extensive early data collection or complete analysis

(Dick, 2002). To some extend this study is also data driven since research content and research process both have been developed further as the research proceeded.

### 3.3.2 ACTION RESEARCH METHOD

Traditional AR stems from the work of Kurt Lewin (1973). There are various other forms of AR, each with differences normally pertinent to the field they are applied, for example, in education, technology, behavioural or business science:

- Action science [developed by Argyris (1982)]
- Learning history [based on the framework presented by Kleiner and Roth (1997)]
- Participatory AR [associated with the work of Whyte (1991)]
- Soft systems methodology [developed by Checkland (1981)]

These AR forms allow theory generation, intervention and theory testing to co-exist, in an iterative loop. For this study, I have chosen to use the traditional form of AR described by Coghlan and Brannick (2001) with the following phases of the AR cycle:

*1) Context and purpose*

The first step is the pre-stage, which begins with the establishment of the context for the AR intervention and an understanding of the scope of the research, with particular reference to external and internal situation that suggest that change is necessary. In this step the problem statement of the company and research questions are defined.

*2) Diagnosing*

The diagnosing phase is concerned with the identification of the issues and therefore the focus for action. In keeping with the spirit of action, diagnosis must be a collaborative venture, so that the process commences with a shared understanding of the basis for subsequent action. Coghlan and Brannick (2001) bring the use of theoretical frameworks in relation to action research in order to examine an organisation's current situation and predict outcomes. Frameworks, which postulate essential organisational variables and relationships are important diagnostic tools and help organise data into useful categories and point out what areas need attention and the framework may be extended in order to contribute to theory development (Coghlan and Brannick, 2001). The TBM framework of Koufteros et al. (1998) has been used as a diagnosis instrument and for planning further action.

*3) Planning action*

The planning phase is the stage where the diagnosis is translated into a practical plan of the interventions; like diagnosis, planning should be collaborative. The planned actions are guided by the theoretical TBM framework, which indicates both some desired future state for the organisational, and the changes that would achieve such a state. The plan establishes the target for change and the approach for change.

*4) Taking action*

Taking action is the intervention stage during which plans are implemented and intervention enacted.

*5) Evaluating action*

Evaluating action is the phase where the intervention is recorded and the outcomes assessed. Outcomes are evaluated in terms of whether the desired outcome has been achieved, but also assess whether:

- The original diagnosis was correct.
- The action taken was correct and taken in an appropriate manner.

The next AR cycle starts after the following evaluating question "What feeds into the next cycle of diagnosis, planning and action?

Figure 3.2 shows the spiral of AR cycles, in which the first cycle comprising a pre-step, context/purpose and the subsequent cycles comprising four basic steps, diagnosing, planning action, taking action and evaluating action.

Figure 3.2: Spiral of Action Research Cycles in this Study

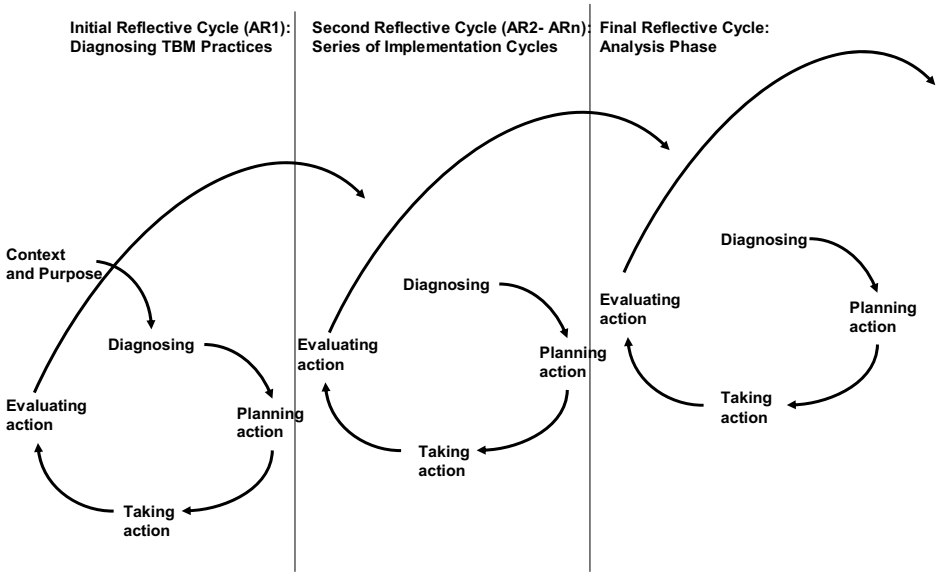


Table 3.2 represents this spiral of AR cycles in diagrammatic form with practical examples given from this study for each stage in the AR cycle. The essence of this study is a simple two stage process. First the diagnosis stage involves a collaborative analysis of the TBM practices by me as the researcher and the other participants of the Case Companies and includes the answering of the first question:

"*What are the TBM practices in the Case Companies*?"

The second stage involves the collaborative change by implementing TBM practices at the Case Companies. In this stage changes are introduced and the effects are studied to answer the remaining research questions; see Thesis Chapter 1. However, this study was in accordance of Kemmis and McTaggart (2005) not as neat as this spiral of self-contained cycles of planning, acting and observing and reflecting suggest, because the stages overlapped, and initial plans quickly became obsolete in the light of learning from experience. In reality, the process was more fluid, open, and responsive. The spiral of AR cycles also finds expression in Deming's TQM concept of continuous improvement, as plan, do, check and act (Ballantyne, 2004).

AR is a cyclical and spiral process in which the researcher alternates action with reflection. Reflection is the practice of periodically stepping back from experience to process what the experience means, providing a basis for planning future action (Coghlan and Brannick, 2001; Daudelin, 1996; Kolb, 1984; Realin, 2000). In AR, reflection is an essential practice, which integrates action and research, because it is the critical link between the concrete experience, the interpretation and taken new action (Coghlan and Brannick, 2001). Reflection was also done with other participants in project meetings in this study.

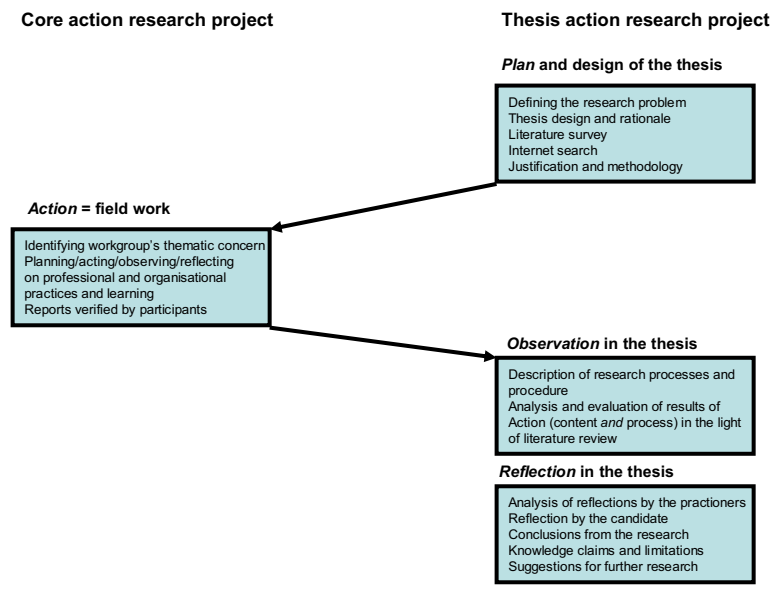
Table 3.2: Diagram of the Spiral of Action research Cycles in this Study
(see further Thesis Chapters 4 and 5)

| Context and Purpose | **Reflective Cycles Phases** | **Initial Reflective Cycle Diagnosing Phase:**<br>**AR1**<br>Diagnosing the Time-Based Manufacturing Practices of the Case Companies | **Second Reflective Cycle Implementation Phase:**<br>**AR2 – ARn (series of implementation cycles)**<br>Implementing the Time-Based Manufacturing Practices in the Case Companies | **Final Reflective Cycle Analysis Phase**<br>Comparative Analysis of Time-Based Manufacturing Practices between the Case Companies |
|---|---|---|---|---|
| | Diagnosing | • Open Interview with General Manager and agreement for conducting the research<br>• Work shop with management team members, discussing manufacturing strategy | • Interim Action Research Report<br>• Feedback on Interim Action Research Report from the participants | Process & use of measures:<br>• Suitability of methods<br>• Ethics/Publish ability<br>• My behaviour<br>• Overall results with respect to original requirements<br>• Critique methodology |
| | Planning Action | • Preparing questionnaires for semi-structured interviews<br>• Preparing Start List of Codes<br>• Making formats for memos, document summary forms and contact summary sheets | • Installation of the project organisation : improvement team<br>• Organising project meetings | • Written Thesis production<br>• Further implementation and improvement of Time-Based Manufacturing Practices<br>• Further research |
| | Taking Action | • Participant observation<br>• Keeping reflective journal and memos as data source<br>• Collecting secondary data (company documents)<br>• Semi-structured interviews with employees<br>• Feedback discussions on delivery performance data | • Implement action by implementation work groups<br>• Collecting/making minutes of meetings<br>• Participant observation<br>• Keeping reflective journal and memos as data source<br>• Semi-structured interviews at the end of the implementation | • Collate/tabulate all results into comparable forms |
| | Evaluating Action | • Analysing and reviewing delivery performance data<br>• Analysis of the collected data (coding, reflection)<br>• Interim Action Research Report<br>• Feedback on Interim Action Research Report from the participants | Results:<br>• How change is handled<br>• How things improve / don't<br>• My feelings about the behaviour of participants<br>• Triangulate interview data with participant observations and minutes of project meetings<br>• My behaviour<br>• Why things improve / don't<br>• Identify specific further areas for change<br>• Critique method | • Compare the Interim Action Research Reports of the Case Companies<br>• Compare the propositions of Time-Based Manufacturing Practices between the Case Companies<br>• Interpret the similarities and differences between the Case Companies<br>• Compare and interpret the results with existing literature |

Two critical elements of self-reflection are the ability to critique one's own thought processes in order to improve the methodology, and to attend to one's own feelings (Coghlan and Brannick, 2001). These were all considered in the analysis phases of this

study. There are two AR cycles occurring at once in this study. The first relates to the project and is the AR cycle of diagnosing, planning, taking action and evaluating, as described above. The second focuses on the AR method of the project and is the AR cycle about the first AR. This reflection generates learning about learning, described as meta-learning by Coghlan and Brannick (2001) and it embeds the learning process of the AR cycle. This process involves experiencing, reflecting, interpreting and taking action. The meta-learning process of this study can also be explained by the model designed by Zuber-Skerritt and Perry (2002). Figure 3.3 illustrates the linkages and differences between core and AR projects in preparing the thesis which shows the four steps of meta-learning, namely *action* =field work (= taking action), *plan* and design of the thesis (= interpreting), *observation* in the thesis (= experiencing) and *reflecting* in the thesis (= reflecting).

Figure 3.3: Relationships between Core and Thesis Action Research Projects




Source: Adapted from Zuber-Skerritt and Perry (2002), page 176.

## 3.4 DATA COLLECTION

Table 3.2 represents the initial reflective cycles as the diagnosis phase and the second reflective cycles as the implementation phase with the data collection mentioned. The data collection started after the problem statement was defined and discussed with the management team members of the Case Companies. The data collection methods mainly used in this study are presented in Table 3.3.

Table 3.3: Data Collection Methods Applied during the Diagnosis and Implementation Phases

| | Data Collection Method | Data collected during diagnosis and/or implementation phase |
|---|---|---|
| 1 | Convergent interviews with participants (semi-structured and unstructured) | diagnosis and implementation phase |
| 2 | Keeping reflective journal as data source for participant observation and document collection | diagnosis and implementation phase |
| 3 | Collecting delivery performance data (lead-times and delivery dependability), and financial data (inventory turnover) | diagnosis and implementation phase |
| 4 | Minutes of project meetings | implementation phase |
| 5 | Flowcharts of the value-stream mapping process | implementation phase |

Furthermore feedback from the participants set on interim case reports and achieved results of the improvement programmes at the end of the AR cycles were also collected.

### 3.4.1 START OF THE RESEARCH PROJECT AT THE CASE COMPANIES

**Case Company 1**

The research project started in March 2006 with a presentation of the research project plan to the management team members in a workshop meeting. A part of the presentation was a feedback discussion on the results of the survey, performed on the 6 management team members. The questionnaire was based on the structured questionnaire of Koufteros et al. (1998) (i.e. the TBM framework), but also some open questions were included in order to obtain information of the company problem, as seen by the participants; see appendix B for the questionnaire. This discussion has brought some insight in the strong and weak TBM practices of the Company, the current problem(s) of the Company and who are the best informants of the management team members on the certain TBM aspects. The objective of the workshop was also to obtain their support on the project (including the already planned organisational changes). Notes have been taken during the meeting. The problem statement (see Introduction Chapter) has been well recognised and agreed.

**Case Company 2**

The research project started during the first working day at my new company in October 2007. I discussed with the General Manager the company problem in order to define the problem statement. We concluded both that my research may help solving the problem of the Company and as consequence I received the agreement to conduct the research at the Company. The problem statement was further discussed with the management team members at the strategy meeting in November 2007. I was able to start immediately with the data collection, since the research instruments (such as semi-structured questionnaires and formats for the learning journal) were already developed during the study of the first Case Company.

### 3.4.2 SEMI-STRUCTURED INTERVIEWS WITH PARTICIPANTS

Semi-structured interviews have been conducted to assess the TBM practices and Information Systems (IS), according to the constructs of Koufteros et al. (1998) and Rondeau et al. (2003); see Appendix C and D for the semi-structured questionnaires. The informants have been selected based on their theoretical background and their position in the company. Depending on their position, only a fraction of the total questionnaire has been used during the interview and some of them (the managing director and the production manager) have been interviewed twice (for example, the supervisor packaging has been interviewed on the following topics: shop-floor employee involvement, batch changeover/set-up, standardised manufacturing, and preventive maintenance, whereas, for example, the purchase manager has only been interviewed on dependable suppliers). The average duration of the interview was 1½ hours. Notes were taken during the interviews and the interview reports were prepared within 2 days, after the interview, followed by sending the reports to the participants for feedback. Most of the reports remained unchanged and only a few changes on the reports have been made.

The construct of quality improvement programmes has been extended according to the quality measurement instrument of Flynn et al. (1994). The reason to extend this quality construct is to obtain more information, since the quality system of the first Case Company was a weak point (as outcome of the workshop). The extension of this quality construct was also very meaningful for the second Case Company to obtain more information, since the existing quality system, like many other pharmaceutical companies was one of the main reasons that this company had inflexible operations. The questions are related to the following topics of quality: 1) top management support, 2) process management, 3) product development, 4) suppliers, 5) employees, 6) customer

involvement and 7) feedback on quality. The questionnaire of Koufteros has only 7 questions related to quality, whereas the extended questionnaire has 28 questions. Top management support, employee training and involvement and feedback are additional quality topics, which are not included in the questionnaire of Koufteros.

The questionnaire of measuring the TBM practices used during the diagnosis phase has been re-used at the end of the implementation phase to assess the improvements. The questionnaire has been modified by using Likert scale questions (from 1 to 5) and an open question after each Likert scale question: *"Is this aspect improved during last year? Please comment"*. Although some descriptive statistics was performed, there was no broad intention to measure these 'scores' statistically because most respondents followed up with an explanation by answering the open question and these explanations provided much richer data than the pure 'score'. AR researches people and people's behaviour cannot be treated as a purely scientific phenomenon measurable on a Likert-scale.

In addition, the sample sizes in all cases were too small that even in an appropriate study, results would not have been statistically meaningful. The value of these Likert questions was for general comparison of answers. Using Likert-scale questions made it easier to discuss and assess during the interview the improvements made at the end of the implementation phase.

The questions regarding IS are related to: 1) strategic planning effectiveness, 2) responsiveness to organisational computing demand, 3) end-user training effectiveness, 4) end-user computing skill, 5) cross-functional involvement, 6) end-user involvement, 7) IS performance. The questionnaire contains Likert-scale questions and open questions; see appendix D.

### 3.4.3 REFLECTIVE LEARNING JOURNAL (RLJ)

Keeping a RLJ on a regular basis, following on an agreed format was used both as data collection source and reflection on the research method. My ongoing observations and notes were kept on the computer, using a special RLJ template that I devised from the format of Pedler et al. (1986). The RLJ was formatted with spaces for Data, Significant Experience, What Happened and My Responses (My feelings, My thoughts and ideas, My action-tendencies and My behaviour). I did all my work electronically so this posed no practical problems for me. Figure 3.4 is an example of a journal entry. In this example, I was making a note of a participant observation. These journal entries were also coded.

Figure 3.4: Example of an Inquiry in the Reflective Learning Journal

| | |
|---|---|
| THE LEARNING LOG, 024 date: 25/8/2006<br>SIGNIFICANT EXPERIENCE:<br>**(type of data collection or reflective memo)**:<br>PARTICIPANT OBSERVATION:<br>Discussion with the customer order planning employee concerning the collection of delivery performance data.<br>WHAT HAPPENED<br>I discussed with her about the quality of the order input data and delivery times. I want to analyse the data of the orders received starting from week 8 till 24. **(PI-CT)** We are now in week 34, but the customer order planner feels that more data will be filled in after the backlog of the invoicing has been solved. **(WS-RO)** Hence, these data are not ready for analysis and must be completed. I asked the customer order planner to put the Excel file in the company database, protected with passwords. | MY RESPONSES<br>*My feelings*<br>I have the feeling that I must take more efforts to secure these data.<br>*My thoughts and ideas*<br>I want to analyse as soon as possible, because this is a part of the diagnosis of the company and I want to use the outcome for feedback. There are no feedback data available (even no monthly financial data) in the Case Company. **(FB-QT)**<br>*My action-tendencies*<br>I will take immediate ACTIONS (ANALYSING SECONDARY DATA AND FEEDBACK INTERVIEW ON THESE DATA) and I will have the initiator role, since the issue relates to the CYCLE 1 of the AR project. I can use the feedback interview to learn about Pull Production mechanism of the case company.<br>*Hence*<br>*My behaviour*<br>First, I have to secure the data collection of these data, then starting with analysing the data, followed by feedback interviewing. |

I had easily access on the daily events relating my research project, due of my dual role as both researcher and participant of the Case Company even though they may arise unplanned and unstructured. These unplanned observations and collected documents, which I received as a participant from other participants were used as inquiry and stored in my learning journal. As I found data relevant to the research, it was immediately

referenced within the RLJ. Both informal documents (emails, notes) and formal documents (meeting minutes, company documents, delivery performance and financial data, etc.) were collected and stored in the computer. This made it easy to retrieve the data that I had pursued and to track the development by periodically reviewing the 'actions' to ensure that these were carried out, and if not, to determine why not. Summary contact sheets and document summary forms were occasionally used, if the collection of this information is more structurally planned.

### 3.4.4 COLLECTING PERFORMANCE DATA

The secondary quantitative data that have been collected during this study are presented in Table 3.4 and these performance data were used as feedback information.

Table 3.4: Performance Indicators for Manufacturing Capabilities of the Case Companies

| **Manufacturing Capabilities** | **Performance Indicator** |
|---|---|
| Delivery Dependability | • Deviation of Confirmed Delivery Date and Realised Delivery Date<br>• On-Time Deliveries (% of orders sent before or at the confirmed delivery date) |
| Delivery Speed | • Total Cycle Time (from order entry to delivery to the customer) |

There was at the beginning a problem at the first Case Company to obtain accurate data on the delivery performance (delivery speed, on-time deliveries and delivered quantities according to the received customer orders) due to the weak infrastructure (non-effective ERP system). Feedback interviews were necessary to assess the reliability of the data. Based on these interviews the collected performance data of the first two months of the research project have been rejected. The implementation of the ERP system made it

easier to perform the time-series analysis of the delivery performance started during the further progress of the research project.

The second Case Company is a mixed make-to-order and make-to-stock manufacturer. The consulting company and the internal business analyst of the second Case Company have already developed and installed a Key Performance Indicator (KPI) measurement system for measuring the lead times and delivery dependability (on-time delivery) of orders delivered to the customers before the start of this study. Delivery performance data of only make-to-order deliveries were measured. A system for collecting performance data for make-to-stock orders was developed during the research project and the data collection of delivery performance of make-to-stock orders has also been started from January 2008. The performance outcomes were used and discussed in the project (KPI circle) meetings for group feedback.

### 3.4.5 MINUTES OF PROJECT MEETINGS

Project meetings were regularly held at both Case Companies during the implementation phase of the study. Minutes of these meetings with the actions defined and group reflection on the actions and progress of the planned changes were used as data source.

**Implementation Phase – Case Company 1**

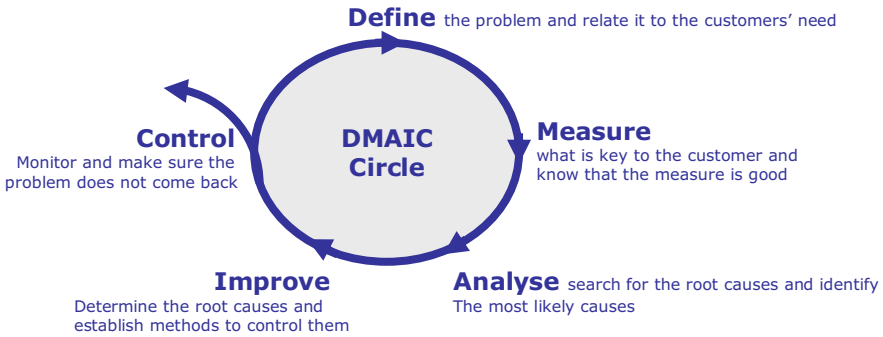
Two projects were running simultaneously during the study of the first Case Company. Implementing an ERP system was subject to the second AR cycle of the research project. Improving the quality system and dependable suppliers was subject to the third AR cycle. Improving the situation of the dependable suppliers and the quality system

was combined, because many quality problems were related to the raw materials from suppliers. I was the project leader of the IT project and a project member of the quality project.

**Implementation Phase – Case Company 2**

Before the implementation phase started, KPI circle meetings were already held twice a month until the end of the study. I was acting as a change agent leading the KPI circle meetings. The KPIs discussed during these meetings were the order cycle time (which is the basic metric of my research) and delivery dependability (measured as on-time deliveries). The KPI measurement system has a continuous improvement mechanism, as illustrated in Figure 3.5.

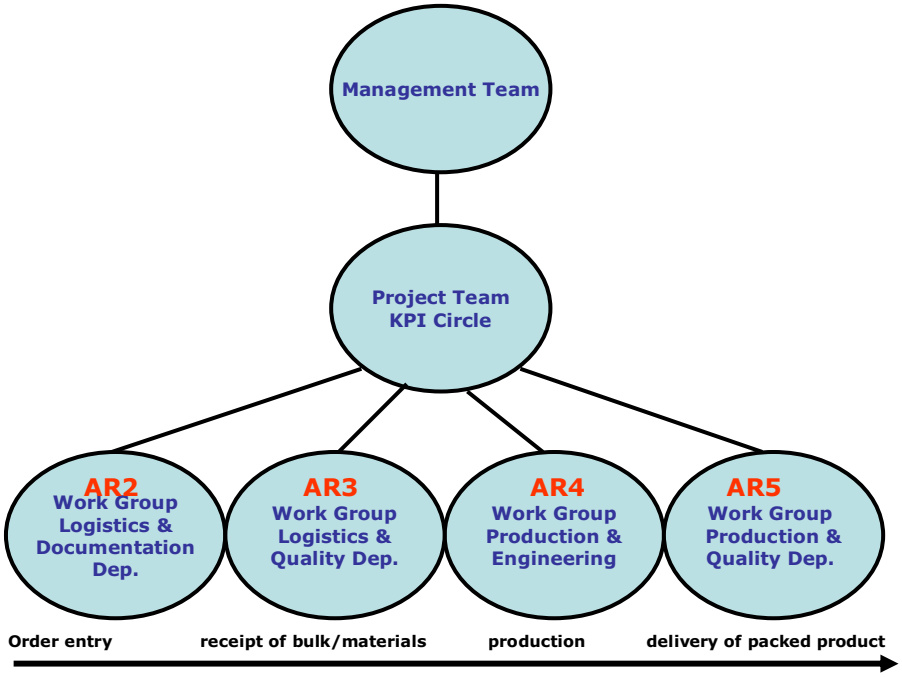
Figure 3.5: KPI Circle Meetings with DMAIC mechanism (6σ)




A project organisation has been further developed by installing 4 work groups in January 2008 to implement the actions and changes to solve problems identified in the KPI circle meetings on the shop-floor; see Figure 3.6. The four work groups (corresponding with AR2 – AR5) represent a part of the total throughput process, starting with the order entry process and ending by the delivery of the product to the

customer. An example of an improvement action is the development of a training programme by workgroup 3 in order to increase the shop-floor employee involvement in problem solving (which is the start of the TBM framework). I participated in all these work groups in order to follow the good progress of the project, discussed the collected data and decided for further action.

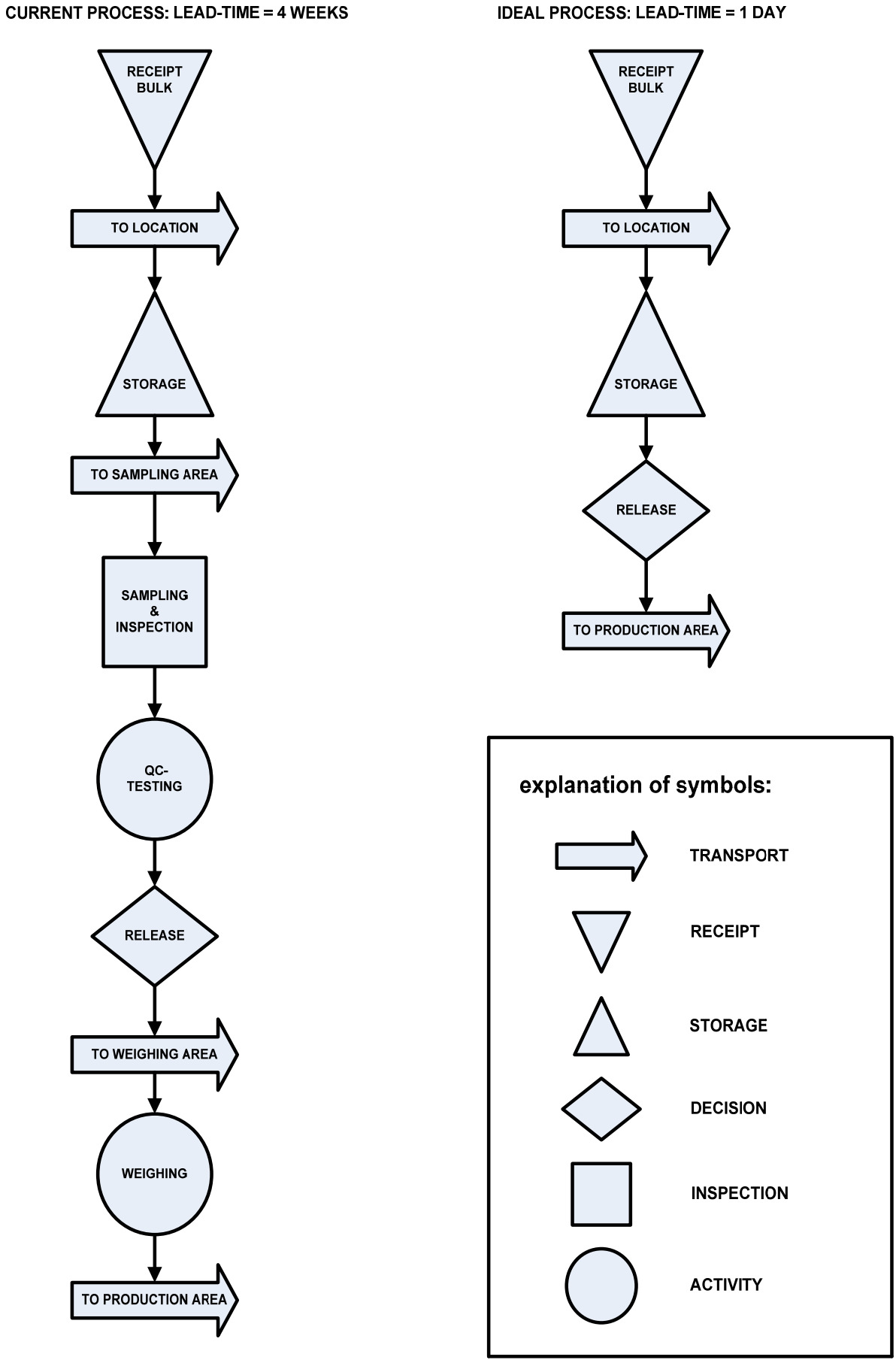
Figure 3.6: KPI Project Organisation for Continuous Improvement of the Cycle Time



### 3.4.6 PROCESS MAPPING

Process mapping is a technique that helps to visualise and identifies areas for streamlining the business processes. Process maps were made from the present state and ideal state of the processes concerned. Process mapping was used at both Case Companies during the implementation projects. Process maps was made at the first Case Company to support the IT project and at the second Case Company to streamline the total throughput processes, starting with order entry processes, until delivery of products to the customer. Figure 3.10 is an example of a process mapping of the present and desired state of a business process at the Second Case Company. This example shows that the lead-time of the process of the receipt and release of incoming bulk product can be reduced from 4 weeks to 1 day when the current process will be transformed to the ideal process by removing non-added value activities. The process maps were used as data source.

Figure 3.7: Process Mapping of the Receipt and Release of Incoming Bulk Product



## 3.5 DATA ANALYSIS

AR is a fairly close relatively of case research, and raises similar questions of methodology. As AR can be seen as a variant of case study research, the techniques applied in the analysis of case studies were used in this study. According to Yin (2003: 109):

"*Data analysis consists of examining, categorizing, tabulating, testing, or otherwise recombining both quantitative and qualitative evidence to address initial propositions to a study*".

The collected data, including interview reports were coded by using the start list of codes. The start list of codes has been developed further, because some new concepts and categories emerged during the research project; see Appendix A. The experiences (for example, an interview or observation) were put onto a qualitative category card. Figure 3.8 is an illustration of the category "shop-floor employee involvement in problem solving".

Figure 3.8: An Example of a Category Card

| **Card 1: Employee involvement in problem solving (EM-SF)** | |
|---|---|
| **Location in database** | **Brief reminder of incident/evidence** |
| **Survey and workshop** | **Workshop 23 March 2006** |
| **Interview 1, 1 October 2006** | **Managing Director** |
| **Interview 2, 15 June 2006** | **Production Manager** |
| **Interview 3, 18 August 2006** | **Technical Manager** |
| **Interview 4, 1 September 2006** | **Quality Manager** |
| **Interview 6, 16 June 2006** | **Supervisor Production** |
| **Interview 7, 7 July 2006** | **Supervisor Packaging** |
| **Interview 8, 18 June 2006** | **Production Operator – Dispensary** |
| **Interview 9, 12 July 2006** | **Production Operator – Coating** |
| **Interview 10, 12 June 2006** | **Technician** |
| **Learning Journal 21 July 2006, no. 007** | **Reflection on automation project** |
| **Learning Journal 29 August 2006, no. 028** | **Participant Observation: discussion with Managing Director and Quality Manager** |
| **Learning Journal 24 April 2006, no. 013** | **Participant Observation: Warehouse starts to book the receipt of materials with ERP system.** |
| **Learning Journal 23 February 2006, no. 002** | **Participant Observation: Discussion with Supervisor about the cleaning during set-up.** |
| **Learning Journal 7 March 2006, no. 008** | **Participant Observation: Discussion with Supervisor about production failure.** |
| **Learning Journal 21 March 2006, no. 024** | **Participant Observation: inspection on the shop-floor.** |
| **Links with: C-OC; C-CO; EF-RG; IF-CO; IF-FO; IF-WO; PI-AG; PM-CC; PM-PT; PP-DS; QI-DM; WS-FO; WS-RO.** | |

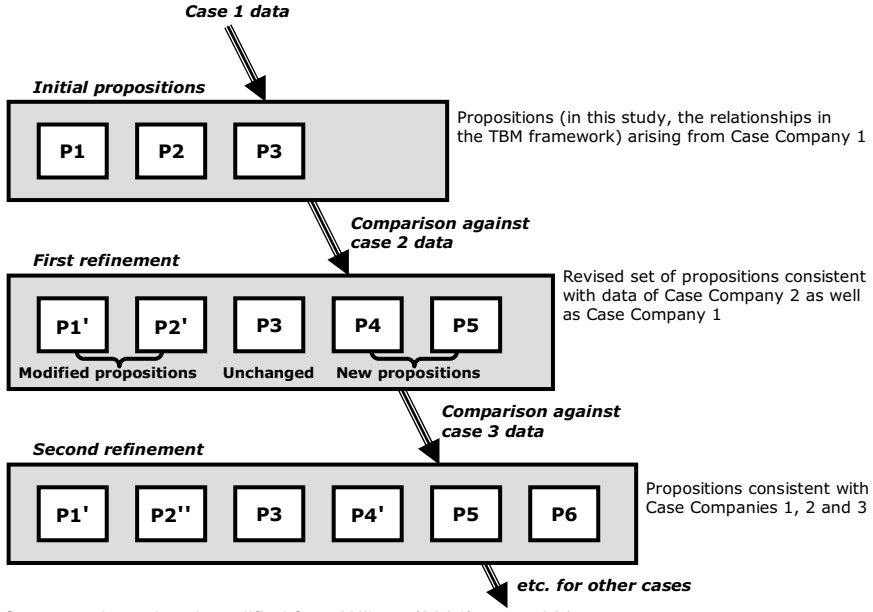
The purpose of the interviews and subsequent data analysis was to try to categorise and characterise the 'state' of the Case Companies such that interventions derived from the TBM framework and relating literature could be selectively applied to problem areas, fixing the worst areas first (for the first Case Company improvement of the IT systems was the first priority and for the second Case Company developing a training programme was considered as the first action to do). It was not intended for the responses and categories to be analysed statistically as the sample sizes were very small and many interventions were specific to a particular sub-group within each Case Company. Multiple data sources within each AR circle was used for triangulation. Dialectic comparison of two or more interview data (convergent interviewing) was used to focus on agreements and disagreements. Information which was unique, provided by only one participant, was then in most cases discarded. A conceptual framework (causal network) was formed by linking the relationships among the constructs. The relationships between categories were also recorded in the category cards. These relationships appeared much stronger in time after the diagnosis phase when the TBM practices were implemented during the following AR cycles and by comparative analysis of the two Case Companies. Therefore, the longitudinal approach and the comparative analysis of this study contributed to increase both the internal and external validity. Software (such as NUDIST or ATLAS) may be useful for coding, categorising large amounts of narrative text that have been collected from open-ended interviews or documents. The verbatim record and documentary records, stored by the use of these software tools are only a part of a case study and they may be used during the initial phase of this AR study, aiming to recover salient concepts or themes. However, this AR study is more theory driven, relying on theoretical propositions and as consequence semi-structured interviewing and participant observation by using prior start list of codes, both based on the theoretical construct (i.e. the TBM framework) are the main

qualitative data collection methods. Therefore, I have chosen not to use these software tools, although some data sources were collected unstructured without prior instrumentation.

Three specific techniques for analysing case studies were used in this study: pattern matching, use of logic models and time-series analysis. The grounded theory approach of Stauss and Corbin (1998), which is composed of three groups of coding procedures, called open, axial and selective coding was used to support these techniques. Open coding is the process of identifying naming and categorising the essential ideas found in the data. Axial coding develops a deeper understanding of the relationships in the phenomenon underlying data through the process of connecting various data categories that were determined during coding. Selective coding develops the theory best fits the phenomenon by identifying a story that reveals the central phenomenon under study. The core issue or "core" category is in this study namely the TBM practices. Although this study and other AR studies typically commence with a practical problem suggesting predefined categories and concept, it was helpful using the data driven analysis techniques of grounded theory and analytic induction in order to bring more rigour in this study. The AR cycles reach a final point when the categories reach saturation. This means that evaluating and learning phases produce little change to any of the categories, especially in case of the core category.

Comparative analysis of the two Case Companies was conducted by using cross-case displays from Miles and Huberman (1994) to assemble descriptive data from each of the two Case Companies in a standard format. The logic of analytic induction to develop multiple propositions between the two Case Companies as presented in Figure 4.12 was used to design the TBM framework from the data of the two Case Companies.

Figure 3.9: Analytic Induction – Developing Multiple Propositions across Multiple Cases




Source: adapted and modified from Wilson (2004), page 388

The process of analytic induction is as follows (Robson, 2002):

1) Formulate a rough definition of the phenomenon (TBM practices) to be studied;
2) Formulate an initial hypothetical formulation of the phenomenon;
3) Study the first Case Company to see if the hypothesis (in this study the TBM framework) fits the facts of the case;
4) If not, either reformulate the hypothesis (TBM framework) or re-define the phenomenon more precisely, so that the phenomenon is excluded;
5) Repeat with a second Case Company. Confidence in the hypothesis increases with the number of cases fitting the evidence, but a single negative case requires a re-formulation.

The method involves step-by-step consideration of cases, which may also be applied in AR by using AR iterations in the action and reflection cycle within one company.

Quantitative data analysis was performed on the performance data and on the Likert-scale results of the semi-structured interviews and surveys. The relationship between TBM practices and manufacturing performance was measured by time-series analysis during the whole research project. Quantitative performance data were analysed in time to assess the improvement made. Correlation analysis was performed to identify possible relationships between manufacturing performance data. MS-Excel was used for analysing the quantitative data (i.e. correlation analysis and time-series analysis). Student-t test was performed for comparative analysis to assess possible differences of TBM and other practices between the two Case Companies.

The interrater reliability (IRR) was measured for assessing the reliability of the Likert-scale item scores within a construct collected from a group of participants according to the method of James et al., (1984). This study considers that there is no agreement of the item scores within a construct when IRR scores are lower than 0,8 (Boyer and Verma, 2000).

## 3.6 RIGOUR: RELIABILITY AND VALIDITY

Methodological rigour in qualitative research is based on checks to ensure that the outcomes of the research are meeting the two main criteria of reliability and validity (Kirk and Miller, 1986).

### 3.6.1 RELIABILITY

Reliability is concerned with the consistency of the results obtained in the study. The objective is to be sure that another researcher will find the same findings and conclusions, if the same procedures have been followed and to minimise the errors and

biases in the study. The reliability of this study was increased by using a case study protocol prior data collection and creating a case study database during data collection, as suggested by Yin (2003). The case study protocol was presented as a research proposal and discussed with my supervisor before I started with the study at the first Case Company. The study protocol contains the purpose of the study, research questions, hypotheses, theoretical framework, data collection plan and the instruments (semi-structured questionnaires, start list of codes and templates of document summary forms and RLJ). The case study protocol enabled me to starting already with the data collection during the first working week of my new second Case Company without much preparation. The reliability of the study further increased by creating a database, where all raw materials, (scanned) documents, RLJ, project meeting minutes, interim action research reports and tabular material have been stored. The study database could be easily retrieved for the review of the data, if necessary.

### 3.6.2 VALIDITY

Validity is concerned with the integrity of the outcomes and conclusions obtained in the study. The main types of validity are distinguished by Yin (2003: 34):

- Construct validity
- Internal validity
- External validity

This study has obtained construct validity by using multiple data sources (triangulation) and key informants to assess the interim action research reports.

Internal validity has been achieved by pattern matching, time-series analysis and the use of the TBM framework as logic model. The formation of the TBM framework by using the coding techniques and through analytic induction as discussed earlier has increased the internal validity of the study.

External validity means establishing the domain to which a study's findings can be generalised (Yin, 2003). Surveys and experiments generalise on the basis of a sample to a population, whereas case studies rely on analytical generalisation in which a theory must be tested by replicating the findings in a second or more cases. Therefore this study can be only generalised to theory, not to a population. This study cannot produce a list of generalised outcomes, but the outcomes of the study will be pertinent to many other manufacturing firms. I may argue for the external validity of my results. These grounds can be developed by comparing the interpretations to those in the relevant literature, through logical analysis and through comparative analysis of the two Case Companies. TBM practices have originally been studied and developed in the discrete parts manufacturing industry and the results of this study demonstrate that TBM practices are also applicable to pharmaceutical preparation manufacturing firms. The two Case Companies are both located in the Netherlands manufacturing similar products relevant to their respective markets covering the Dutch home market and to a greater extend other European countries. Whilst there are many operational, organisational and cultural differences, the process design and manufacturing technologies are similar. By studying both Case Companies, external validity was developed by demonstrating where similarities exist, where they do not, and why. The external validity of this study was further obtained study through analytic induction.

### 3.6.3 RIGOUR IN ACTION RESEARCH

AR differs from regular case study research in that the researcher is directly involved in planned organisational change and consequently subjectivity is the main methodological weakness of AR. AR needs therefore additional features to obtain rigour. It is important to note that AR can be rigorous without surrendering action outcomes (Dick, 2002). Coghlan and Brannick (2001) state that rigour in relation to AR refers how data are generated gathered explored and evaluated, and how events are questioned and interpreted through multiple AR cycles.

The RLJ was used to bring rigour in the data collection process. Reflection is an essential practice in AR, which integrates action and research and brings rigour in the AR project. Reflection is important due to the close relationship between the researcher and his respondents. This addresses the importance of reflexivity, i.e. the awareness of the researcher that his social identity and background has an impact on the research process, which requires precision about analytical and data collection methods (Gilbert, 2001; Robson, 2002). The researcher's bias can be reduced when the researcher used reflection in his study for identifying areas of potential researcher bias, but also reflection is needed for dealing with ethical issues. For rigorous AR, it is necessary to show:

- That the researcher engaged in the steps of multiple and repetitious AR cycles (Couglan and Brannick, 2001: 23). As can be seen in the research framework in Table 3.2, the reflection phase is a repetitive one. By working through the thought processes listed in the framework, and recording them and subsequent reflective cycles, it was possible to go back and see how the conclusions had been drawn.

- That the researcher challenged and tested the assumptions and interpretations made of what was happening (Coghlan and Brannick, 2001: 23). This was addressed by using the participants not just for data gathering, but also by working together in the project groups through group feedback on the actions and results, assessing interim action research reports and by conducting interviews at the end of the implementation phase to assess the study outcomes.

- That the researcher accessed different views of what was happening, which probably produced both confirming and contradictory interpretations (Coghlan and Brannick, 2001: 23). By triangulating the interview data of multiple participants with the RLJ data, minutes of project groups meetings and company documents, the data obtained from the participants were examined from many angles. Where different points of view were held, these were described in relation to the participants with background information as to why.

- How the researcher's interpretations and diagnoses are grounded in scholarly theory (Coghlan and Brannick 2001: 23). Referring findings back to the findings of the literature review achieves this.

## 3.7 ETHICAL CONSIDERATIONS

The ethical implications in this study such as confidentially and anonymity are important in terms of gaining access to the companies and individuals, and these issues should also be considered during the report stage.

### 3.7.1 ETHICAL ISSUES

Ethical issues in this study include:

- Negotiating access with individuals, their managers and keeping good faith.
- Promising confidentiality of information and identity of data.
- Acknowledging and respecting the right not to participate in the research.
- Asking permission to access organisational databases and documents.
- Negotiating with those concerned about the representation and publication of their work and any other personal information or views.
- Maintaining the researcher's own intellectual property rights.
- Ensuring good professional and academic conduct.

Confidentiality and anonymity ware never an area of concern in this study. All participants were given the choice whether to take part and reassured that if they chose not to participate, or to withdraw their participation, they could not be penalised. When asked for personal information from the participants, it was stressed that they could choose whether to provide the information or not, and, second, that it would kept strictly confidential. Once promises about confidentiality and anonymity have been given, it was maintained throughout the study. Deletion of personal and company names from the data did not permit outsiders identifying the participants. This included protecting the anonymity of participants, not misleading or deceiving them, conducting research in a way not to embarrass the participants. Also, the right for privacy of the participants

was protected. Participant's anonymity is also important in this study. The participant's identity should be protected and should not be disclosed to anyone. Special care was taken to ensure that any record which contains a reference to the identity of an informant is securely and confidentially stored or destroyed.

An overly long questionnaire was avoided and the questionnaires were designed with non-confusing questions in order to obtain the required responses with good quality in an unbiased manner. Ethical issues can arise during the data analysis step. While checking, editing, coding, transcribing and cleaning of raw data, I was getting some idea about the quality of the data. The maintenance of the researcher's objectivity is vital during the analysis stage to make sure that data collected is not misrepresented or biased. This included not being selective about which data to report, or where appropriate, avoiding misrepresentation of its statistical accuracy. The selection of a data analysis strategy was based on the earlier steps of the research process.

Possible dilemmas could also exist when using secondary data (Robbin, 2001). It is important that the data were collected using procedures which are morally appropriate. Access to such data about, especially unpublished company data may have been obtained without consent. I am obliged to treat these data in strict confidence and not to abuse them anyway. The good treatment of secondary data collected during this study was obtained by high ethical standards.

### 3.7.2 DISSEMINATION

Prior to the start of the data collection at the two Case Companies, I mentioned to all participants that the interviews would form part of my doctoral thesis. I have avoided that detailed information of the companies was presented in order to preserve the anonymity of the companies and individuals involved in this study. Since these companies are middle-sized organisations and the participants are only mentioned by job title, it has been decided to issue this document without mentioning the names of the companies and the participants. Under these conditions it is allowed that the Thesis will be placed in the library. In the exceptional event, that I am willing to mention an organisation by name, I will request the organisation to give permission to use its name.

# 4 RESEARCH FINDINGS

This Chapter describes the outcomes of the diagnosis and implementation phases of the AR projects at the two Case Companies. Within the AR framework presented in Table 3.2; see page 93, the primary data were gathered through semi-structured interviews in each Company. Secondary supporting data (mainly participant observations and company documents stored in the RLJ) were also gathered and triangulated with the respect to the primary data. These data together with the manufacturing performance data were analysed and specific improvement areas were identified for change and finally interventions were planned with respect to the TBM framework and related literature. This completes the first reflective cycle, representing the diagnosis phase of the AR project. The second reflective cycle contains many mini-reflective cycles, and begins with implementing the planned action, then repeating the cycle (diagnosing, planning action, taking action, evaluating action) as the various outcomes were processed, amended (if necessary) and observed. Again, secondary supporting data (RLJ data and minutes of project meetings) were gathered and triangulated with respect to the primary data (semi-structured interviews). The whole data set was analysed, recommendations for further change were made until the data set was reviewed ready for the final analysis at the end of the AR project at each Case Company. Finally the third and final cycle contains the comparative analysis of the TBM practices between the Case Companies at the end of this Chapter, followed by the Discussion, Conclusions, and Recommendations in the final Chapter.

## 4.1 CASE COMPANY 1

Table 4.1 illustrates the time-frame of the research project. The objective of the first AR cycle is to diagnose the TBM practices.

Table 4.1: Research Project at Case Company 1 – Time-Trame

| Phase of the AR project | Data collection method | Period |
|---|---|---|
| Diagnosis Phase<br>Assessing TBM practices (AR1) | Workshop<br>Interviews<br>RLJ<br>Feedback on interim action research report | March 2006<br>June – October 2006<br>March 2006 – June 2007<br>February – March 2007 |
| Implementation Phase<br>IT Systems (AR2) | Process maps<br>Project meetings<br>Interviews<br>RLJ | October – December 2006<br>October – June 2007<br>June 2007<br>March 2006 –June 2007 |
| Implementation Phase<br>Quality Management System (AR3) | Project meeting<br>Interviews<br>RLJ | November – September 2007<br>September 2007<br>November - June 2007 |
| Implementation Phase<br>Work System Practices | RLJ<br>Survey | November – June 2007<br>May – June 2007 |
| Manufacturing Performance Data | ERP database and feedback | May 2006 – June 2007 |

The findings to answer research question 1a "What are the TBM practices of the Case Company?" are according to the data accounting sheet (see Table 4.2) complete. Table 4.2 shows also missing and incomplete data, since the participants have been interviewed by using only a part of the questionnaire, as explained earlier in section 3.4.2 on page 102. Some information has been gathered by unstructured data collection, such as unplanned participant observation and document collection. These data have been considered as useful information, but are incomplete for a full description of a construct.

Table 4.2: Data Accounting Sheet – Interview Data of Case Company 1

| Participants | Number of Interviews | EM | BS | ST | PM | DS | QI | PP | IS |
|---|---|---|---|---|---|---|---|---|---|
| Survey and Workshop | 1 | √ | √ | √ | √ | √ | √ | √ | X |
| Managing Director | 5 | X | X | X | X | √ | √ | √ | √ |
| Production Manager | 2 | √ | √ | √ | √ | √ | X | √ | - |
| Engineering Manager | 1 | √ | √ | √ | √ | - | X | - | - |
| Quality Manager | 2 | - | - | - | - | X | √ | - | - |
| Assistant Quality Manager | 1 | - | - | - | - | X | √ | - | - |
| Purchase Manager | 1 | - | - | - | - | √ | - | - | - |
| Supervisor Bulk Production | 1 | √ | √ | √ | √ | - | - | - | - |
| Supervisor Packaging | 1 | √ | √ | √ | √ | - | - | - | - |
| Production Operators | 2 | √ | √ | √ | √ | - | - | - | - |
| Engineer | 1 | √ | √ | √ | √ | - | - | - | - |
| Customer Order Planner | 1 | - | - | X | - | - | - | X | - |
| External Quality Consultant | 1 | - | - | - | - | X | √ | - | - |
| IT Specialist and Consultants | 3 | - | - | - | - | - | - | - | √ |
| Group Interview | 1 | - | X | X | - | - | - | - | - |
| TOTAL | 24 | √ | √ | √ | √ | √ | √ | √ | √ |

Legend:
√ = data complete
X = some information, but incomplete
- = missing data
EM = Shop-Floor Employee involvement in problem solving
BS = Batch changeover/set-up
ST = Standardised Manufacturing
PM = Preventive Maintenance
DS = Dependable Suppliers
QI = Quality Improvement Efforts
PP = Pull Production
IS = Information Systems

Further research during the subsequent action research cycles gives answers on research question 1b "how TBM practices can be improved" and the remaining research questions. The other practices that can be applied to become a time-based competitor are in this study related to the infrastructure (research question 1c).

There were two projects running during the study to improve the infrastructure with support of external consultants and these projects represent AR2 (ERP implementation project) and AR3 (quality project). Unstructured data collection, mainly participant observations and documents collected provides additional information on the internal and external factors influencing the implementation of TBM practices (research question 2). The change process of the remaining research project provides data concerning the relationship between TBM practices and delivery performance (research question 3).

Table 4.3: Data Accounting Sheet – Number of Open Codes Stored in RLJ of Case Company 1.

| Construct | Number of codes in RLJ |
|---|---|
| Shop-floor employee involvement in problem solving | 16 |
| Batch changeover/set-up | 6 |
| Standardised manufacturing | 9 |
| Preventive maintenance | 16 |
| Dependable suppliers | 42 |
| Quality improvement efforts | 76 |
| Pull production | 3 |
| Feedback to employees | 14 |
| Information systems | 131 |
| Work system practices | 74 |
| Quality management system | 29 |
| Internal factors | 82 |
| External factors | 52 |
| Change process | 160 |
| Total | 710 |

300 participant observations and documents were stored in the RLJ during the diagnosis and implementation phases. Table 4.3 shows the number of codes stored in the RLJ,

divided in the various constructs according to the start list of codes; see Appendix A. An observation or document may contain more codes.

### 4.1.1 DIAGNOSIS PHASE OF CASE COMPANY 1

*Assessing TBM Practices – Workshop*

Table 4.4 presents the results of the survey and the feedback during the workshop with six management team members; see Appendix B for the questionnaire. The survey scores were analysed together with the information and comments from the participants of the workshop.

Table 4.4: Results of the Survey and Feedback during the Workshop

| Construct | No. of items | Mean | Standard deviation | Interrater reliability (IRR) | Result of the feedback | View of management team |
|---|---|---|---|---|---|---|
| Shop-employee involvement in problem-solving | 5 | 3.10 | 0.59 | 0.88 | Moderate | Consensus |
| Batch changeover/ set-up | 8 | 2.43 | 0.53 | 0.92 | Moderate | Consensus |
| Standardised manufacturing | 8 | 2.65 | 0.54 | 0.86 | Moderate | Consensus |
| Preventive maintenance | 6 | 1.94 | 0.75 | 0.86 | Weak | Consensus |
| Quality improvement efforts | 7 | 2.75 | 0.98 | 0.67 | - | No consensus |
| Dependable suppliers | 6 | 3.47 | 0.50 | 0.92 | Strong | Consensus |
| Pull production | 4 | 3.76 | 0.73 | 0.30 | Very Strong | Consensus |
| Total score | 7 | 2.88 | 0.26 | NA | NA | NA |

NA = not applicable - = no outcome

As stated in the Methodology Chapter (3.4.2) with a few respondents, it was felt that numerical averages would not adequately represent the data, so both the numerical and verbal responses during the workshop were taken. If there was a consensus, a judgement was made on whether the participants felt the practices as (very) strongly, moderately or (very) weakly developed. The interrater reliability (IRR) was measured for assessing agreement among item scores made by the management team members.

Pull production and dependable suppliers are the strongest practices and preventive maintenance the weakest. Although the workshop demonstrated a fair representation of the current status of TBM capabilities of the company, it appeared to me that the standardised manufacturing and batch-changeover constructs may be too low assessed. The managing director argued that the batch set-up time is short compared to other pharmaceutical manufacturers. The batch-changeover includes time-consuming cleaning of equipment and that may be the cause of the moderate score. The Case Company produces many different products with complex compositions and that may be the reason of the low score in which the classification of products into families is not well recognised.

There was no agreement on the item scores of the “Quality Improvement Efforts” and “Pull Production” constructs. Although there was agreement during the workshop that the Case Company must improve the quality management system to obtain the manufacturing license from pharmaceuticals, there was no agreement whether the current quality management system was strongly of weakly developed and there was also no clear vision how to improve the situation. The low IRR score of the quality construct (0.67) may confirm this disagreement. The pull production capability of the Case Company was well recognised during the workshop feedback discussion, but the

IRR score of 0.30 may be the result that not all management team members were the right informants to assess this construct only by the survey. Preventive maintenance was well recognised as a weak practice within the group.

*Assessing TBM Practices – Interviews and RLJ*

The TBM practices were primary assessed by interviewing the key participants. The Tables 4.5 – 4.8 contain convergent interview data presenting the generalised perspectives by combining the responses common to all participants. If no common information on a question could be acquired, different perspectives of the participants are also presented. RLJ data are used as secondary data to triangulate the interview data and are also included in these tables.

Table 4.5 describes the results of the semi-structured interviews concerning the shop-floor employee involvement in problem solving and Table 4.6 provides the results concerning the batch changeover, standardised manufacturing and preventive maintenance as parts of the process design from the perspective of the participants; see Appendix C for the questionnaire. 7 participants from the production and engineering departments were used as key-informants to assess these constructs in one interview; see Table 4.2 for the functions of these participants.

Table 4.5: Results of the Semi-Structured Interviews on Shop-Floor Employee Involvement in Problem Solving of Case Company 1

| # | Question | Results - interviews and secondary data |
|---|---|---|
| 1 | Shop-floor employees involvement in solving problems | The motivation and spirit of the shop-floor employees are good and they are willing to help each other in case of problems. For example, the employees are trained to pull materials to the packaging lines and to solve simple breakdowns of the packaging machines. RLJ notes corroborate interview data. The motivation of shop-floor employees to solve problems is also good in the warehouse. The employees are insufficient trained to improve quality. |

| | | |
|---|---|---|
| 2 | Shop-floor employees involvement in group meetings | There are no regular group meetings organised with the involvement of shop-floor employees. Shop-floor employees are only involved by unplanned discussions on the shop-floor, or during coffee breakdowns. Group meetings are not organised by production management due to the high pressure on production to deliver the orders on-time to the customers. RLJ notes corroborate interview data. For example, quality complaints are discussed unplanned on the shop-floor instead of discussing quality problems in quality circle meetings with shop-floor employees. |
| 3 | Shop-floor employees involvement in making new products | Production operators are only partly involved in the development of new products. The dispensary operator is involved in case of trial production of new products and sometimes other operators. The QA manager is seldom involved in these trials. These trials are mainly managed by the production manager. The QA manager is only involved in the design of the composition of the bulk product, which in mainly a desk job. The packaging operators are not involved in the development of new products. Most compositions of new products contain raw materials, which are already used in other existing products. The production process of these incremental new products is already developed. Few customers are using compounds, which are new for production. RLJ notes corroborate interview data. |
| 4 | Role of production management in the involvement of shop-floor employees | Production management listens to the ideas and initiatives from the shop-floor and the employees are involved, although not all suggestions are accepted at first hand by the production manager. RLJ notes corroborate interview data. |

Table 4.6: Results of the Semi-Structured Interviews on Process Design of Case Company 1

| # | Question | Responses and secondary data |
|---|---|---|
| | *Batch Changeover/Set-up* | |
| 1 | The activities during batch changeover | 1) Re-movement of previous product and materials, including cleaning of machines, equipment and tools;<br>2) If necessary, conversion of the machine with other machine parts or moulding;<br>3) Control of cleanliness of the production cabin and machines, receipt of materials from the warehouse and production documents from production management;<br>4) Control whether the right materials have been picked from the warehouse. |
| 2 | Set-up time and activities when different punches or moulds are used during | The set-up activities by the production operators on the tablet compressing machines are performed by more than one person and the packaging operators will not switch to another packaging line, which means that more set-up |

| | | |
|---|---|---|
| | a set-up | activities such as cleaning, receiving materials and removing machinery parts are done simultaneously. |
| 3 | Set-up time and activities if the same punches or moulds are used with another product | Cleaning is the most important activity in time during the batch changeover, especially when active compounds are difficult to clean. |
| 4 | Set-up time and activities if the same punches or moulds are used with the same product | When similar products of the following batches are produced, the set-up times are much lower, compared to set-up times of different products between batches. The coating process is also standardised using in most cases standard coating solutions. This is important, since cleaning of coating equipment is very time-consuming. There are only two standard coating solutions used. Other colour coating of tablets is in few occasions required. Most tablets are coated and this has a positive effect on cleaning activities during the batch changeover of the packaging machines. Coated tablets stain less dust during packaging, resulting in less cleaning and lower batch changeover times. |
| 5 | Support from engineering department | The bulk production operators (e.g. tablet compressing, capsule filling and coating) don't need additional support from the engineering department during the set-up. The packaging operators are not completely self supportive and need technical support during the set-up of the blister machines, despite the high standardisation. Only the packaging supervisor is capable to convert all packaging machines and few operators are capable to convert one machine. When two set-ups are simultaneously needed, additional technical support is needed. Most blisters are manually packed into the final packaging. This has an advantage, since no technical support is needed for the batch changeover. RLJ notes corroborate interview data. |
| 6 | Motivation to improve set-up times | There is in the bulk production no motivation to shorten the batch changeover times, since the set-up times are already considered to be low and further improvement is rarely possible. Only new production operators will be trained to fasten set-ups. The packaging supervisor is more motivated to improve the batch changeover, since help is needed from engineers. There is a good co-operation between these two departments. RLJ notes corroborate interview data. |
| 7 | New set-up method of new machines and processes | A new set-up method for new machines is not usually developed. New machines will be investigated by the engineering department before usage in production. An explanation to the production operators will be given after this investigation. A new set-up method for new machines is not usually developed. New machines will be investigated by the engineering department before usage in production. An explanation to the production operators will be given after this investigation. |
| 8 | Location of tools | Cleaning materials are conveniently located. Set-up tools |

| | | |
|---|---|---|
| | | for compressing machines are not located in the production cabin. These tools and machinery parts needed for a batch changeover are centrally stored in the production area. The production supervisor checks daily if these tools are complete. The tools needed for the packing machines are located in the cabin, however, it may happen that the right tools are not available. The production manager admitted that some improvement is possible. |
| 9 | Adjustment of equipment to shorten set-up times | Machines are usually not reconfigured in bulk production. Two cases were mentioned in the packaging area, namely marking the level for adjustments on the blister machine and a small adjustment on the packaging machine for coding the carton boxes during the packaging process. |
| 10 | Special tools to shorten set-up times | Only the packaging supervisor uses special set of tools. |
| 11 | Jigs or fixtures used to shorten set-up time | The engineering department redesigns occasionally fixtures on machines to shorten set-up time, for example, replacing existing bolds that are easier to handle in compressing machines. |
| 12 | Training of shop-floor employees to shorten set-up times | Only new production operators of the bulk production are trained. |
| 13 | Role of production manager to shorten the set-up times | The production manager has herein a role by preparing the weekly production plan and organising the shop-floor papers. Standardised products are sequentially planned and produced to keep set-up times low. |
| 14 | Suggestions to shorten the set-up times | Some suggestions are given:<br>1) Increase the availability of all materials prior to production by improving the production planning system;<br>2) Use of dedicated tools for the set-up of machines;<br>3) Delegate the line-clearance of quality control to the production operators;<br>4) Training of packaging operators in the set-up and solving small disturbances of machines.<br>RLJ notes corroborate interview data regarding the line-clearance by QC employees and training of packaging operators. |
| | *Standardised Manufacturing* | |
| 1 | Grouping in families of products | Products forming families are grouped together when dispensing the raw materials in order to save batch changeover time. Some products contain more than 30 different raw materials. Weighing of these products is very time-consuming and may last in a worse case situation about 2 days, thus grouping into similar families is important. The same applies for the coating process where two different standard coating solutions are mainly used. RLJ notes corroborate interview data. |
| 2 | Grouping of products | The production processes are grouped by using 6 |

| | | |
|---|---|---|
| | on basis of the shape | different seizes of punches on the tablet compressing machines. The packaging machines use mainly one blister size for 80% of the products. RLJ notes corroborate interview data. |
| 3 | Coding classification | There is no coding classification used to group materials and products into families in bulk production. The moulding parts of the packaging machines are numbered and recorded in the batch packaging documents. |
| 4 | Location of machines and equipment to group families of products | The machines are not places together, but this will be improved when the reconstruction of the production facilities is finished. The machines and equipment of the individual sub-processes (e.g. tablet compressing, capsule filling, coating and packaging) will then be placed to form groups with similar routing requirements. RLJ notes corroborate interview data. Both the bulk production and packaging area must be improved. |
| | *Preventive Maintenance* | |
| 1 | Preventive maintenance on machines | Preventive maintenance is rarely performed by the engineering department. A reason of the lack of technical support is that engineers are involved in the reconstruction of the production facilities. The engineer will only inspect the machine when there is a breakdown. RLJ notes corroborate interview data. Validation of (new) machines is also not performed. Validation and cleanliness of machines are strict requirements according to pharmaceutical regulations. |
| 2 | Performing preventive maintenance performed by production employees | The production operators only lubricate the tablet compressing and capsule filling machines with oil once a week. |
| 3 | Preventive maintenance during non-productive time | Solving technical breakdowns and replacement of parts are often done after production time. RLJ notes corroborate interview data. |
| 4 | Emphasis on preventive maintenance | Preventive maintenance is considered to be important, however according to the production manager preventive maintenance has no influence on the loss of capacity. An operator mentioned that one tablet-compressing machine has 3 or 4 breakdowns a week and this machine runs at half speed. RLJ notes corroborate only partly interview data. The engineering manager does not believe that preventive maintenance is really necessary, because a machinery breakdown can be managed without loosing much time, compared with the time loss for preventive maintenance. |
| 5 | Records of routine maintenance | No records for maintenance are being kept. RLJ notes corroborate interview data. |
| 6 | Regular maintenance of equipment | Machines are not regularly maintained. RLJ notes corroborate interview data. |
| 7 | Occurrence of machinery breakdowns | The tablet compressing machines are not sensitive to disturbances. The production operators are skilled to |

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| | | solve small technical breakdowns. Packaging machines are more sensitive for disturbances. Many breakdowns of packaging machines occur with an average of 3 to 4 times a day. Many problems occur due to adjustments of machines during the set-up. A breakdown will have a stagnation of 1 to 1½ hours and in case of a big breakdown, the machine will be repaired after working times in the evening with a maximum loss of one week. RLJ notes corroborate interview data. |
| 8 | Role of production manager in preventive maintenance | The production manager has no role in the preventive maintenance policy. |

Table 4.7 below describes the results of the semi-structured interviews concerning Quality improvement efforts and dependable suppliers. Three participants, the managing director, production manager and purchase manager were interviewed; see Appendix C for the questionnaire.

Table 4.7: Results of the Semi-Structured Interviews on Quality Improvement Efforts and Dependable suppliers.

| # | Question | Responses and secondary data |
|---|---|---|
| | *Quality Management* | |
| 1 | Top management support for quality | Quality is not a strong aspect of the company. There is some support from top management for quality, but top management has no active role to improve quality. Production management is more output oriented then to support quality. Cleaning activities are not done properly and quality is affected under these circumstances. RLJ notes corroborate interview data. |
| 2 | Quality seen as central theme within the organisation | Production output is more important then to obtain quality. RLJ notes corroborate interview data. |
| 3 | Active role in quality improvements and communication by top management | The communication between the quality manager and the managing director is good, but the active role is lacking. The managing director inspects often the cleanliness of the production shop-floor and discusses observed problems with production employees. RLJ notes corroborate interview data. |
| 4 | Organisational culture on quality | The organisational culture is not focused on quality. The pressure is very high, since the Company is not able to deliver the products on time to the customers, caused by the rapid growth of the Company and weak infrastructure. RLJ notes corroborate interview data. |
| 5 | Rewards of quality results | Quality results are rewarded by top management by giving compliments to employees. |

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| 6 | Communication of quality results and feedback | The quality manager is not happy with the feedback from the shop-floor. He receives only some information of quality problems from QC employees and production supervisors. The managing director stated that quality complaints are always communicated with production management. RLJ notes corroborate interview data. |
| 7 | Key performance indicators for quality | The quality manager only reports the overview of complaints during management team meetings, but regular production meetings with shop-floor employees don't occur. Other quality performance indicators are not measured. |
| 8 | Implementation of processes to prevent possible defects caused by employees | The Company aims not to implement production processes which prevent as many as possible defects caused by employees, because the first in-process controls are not always measured before the start of production. The production process is therefore not safely controlled. The automatic weighing system is an example of a process aiming to prevent human errors. RLJ notes corroborate interview data and give some examples of problems. |
| 9 | Quality control charts | Quality control charts are used to control the production processes, but not all parameters, e.g. disintegration time and the friability of tablets are measured. |
| 10 | Validation of production machines | New machines are only tested before use. Validation according to the pharmaceutical regulations requires documenting the tests, but this is not done. RLJ notes corroborate interview data. |
| 11 | Authorisation to stop the production process | Production operators are authorised to stop the production process in case of quality defects. RLJ notes corroborate interview data. |
| 12 | Cleanliness of machines and the shop-floor | The cleanliness of the machines and the shop-floor is important for employees. The production shop-floor and machines are often not clean due to high pressure of production. The cleanliness will improve after the reconstruction of the production facilities is finished. |
| 13 | Slow speed production process in order to guarantee quality | No clear information was obtained. |
| 14 | Development of new products | The development of new products is a routine desk job, looking whether the composition of the product complies with the regulations. The proposed composition will be discussed with the customer. There is close contact with few customers in the development of new products. Only in a few occasions, a pilot batch will be produced. But often, the technical aspects, such as in-process control and product specifications will be determined during the manufacture of the first production batch. It takes sometimes additional production batches to further develop the composition and the production process. RLJ notes corroborate interview data. Examples of quality problems are given when no pilot batches are produced and some problems with customers occur. |

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| | | Some stability problems of products are also noticed several times. |
| 15 | Role of customers and suppliers in the development of new products | The Company receives in most cases raw ideas about a composition, that will be developed further in the quotation stage. There are also customers coming with their own suggestion for a new product. There are rarely contacts with suppliers about new product development. RLJ notes corroborate interview data. |
| 16 | New product development teams | The development of new products is organised without working in development teams. RLJ notes corroborate interview data. |
| 17 | Quality meetings with employees | There are no regular meetings to improve quality. RLJ notes corroborate interview data. |
| 18 | Recruitment and training of employees | Although the Company has a good recruitment, the new employees are not regularly trained. RLJ notes corroborate interview data. |
| 19 | Quality problem solving within small teams | The quality manager has often contacts with his quality team and the managing director and less contacts with production operators to solve quality problems. RLJ notes corroborate interview data. |
| 20 | Differences in treating employees | The managing director stated that there are some differences in the treatment of employees. |
| 21 | Employee flexibility in quality improvements | The employees are highly motivated and flexible, but due to the lack of training, there is also a lack of knowledge to perform quality improvements. RLJ notes corroborate interview data. |
| 22 | Customer requirements on quality | Requirements in quality vary per customer. There are close contacts with most customers to discuss the quality of design of new products. RLJ notes corroborate partly interview data. It varies per customer and there are problems with some customers where less care is taken. |
| 23 | Certification by customers | The nutraceutical industry is a new market. Customers do not certify their supplies to meet the quality requirements as done in the pharmaceutical industry. RLJ notes corroborate interview data. Only one customer has recently performed a quality audit. |
| 24 | Exchange of information regarding production processes to customers | The Company is not eager to exchange detailed documented information of the production processes to customers. Only brief information is given, since management is afraid that customers may switch to other contract manufacturers. RLJ notes corroborate interview data. |
| | *Dependable Suppliers and Quality* | |
| 25 | Communication of specifications with suppliers | Specifications are not always communicated with suppliers when materials are purchased. There are regular meetings with suppliers, but specifications are only in case of severe quality problems discussed. RLJ notes corroborate interview data. |
| 26 | Quality as important criterion for supplier selection | Quality is an important criterion, but low prices are more important. The manufacturability is also important, but most raw materials are meeting this criterion. RLJ notes |

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| | | corroborate interview data with examples. |
| 27 | Certification and policy to select a small number of suppliers | Suppliers are certified by sending a quality questionnaire, but most suppliers are still not certified. There is a selection program running to certify all suppliers. The Company does not select a small number of suppliers and many new materials from different sources are purchased, often initiated by management prior certification. The production manager mentioned that long-term relationships with single suppliers may provide a constant quality of raw materials causing less problems in production. RLJ notes corroborate interview data, only 30% of the suppliers are certified. |
| 28 | Policy for keeping long-term relationships with suppliers | Good relationships with suppliers are necessary to obtain good service and reliable deliveries. The purchase and production managers strive to long-term relationships, however the managing director adopts more a low cost policy and this may often lead to switching of suppliers. RLJ notes corroborate interview data by giving examples of internal conflicts. |
| | *Dependable Suppliers* | |
| 29 | Purchase of (bulk)materials from manufacturers and intermediate suppliers | Raw materials are purchased in the Benelux countries, Europe and China. Many raw materials are purchased from intermediates, since in most cases it is not possible to purchase directly from the manufacturer. RLJ notes corroborate interview data. |
| 30 | Number of different suppliers | There are 300 to 400 different raw materials regularly purchased from 30 different suppliers. The Company has in total 80 -100 suppliers for all materials needed in production, including packaging materials. |
| 31 | The company's requirements of suppliers | The requirements are quality (meeting the regulations), price, delivery performance and service. Price and quality are seen as the most important requirements. RLJ notes corroborate interview data. |
| 32 | Delivery times of (raw)materials | The delivery times of raw materials from suppliers in Europe are 1 to 3 weeks and 8 -12 weeks or 4 weeks by airfreight from suppliers in China. Most purchased materials are delivered on-time, but deliveries from China are less reliable. More suppliers are needed for one raw material, because suppliers don't have always stock. Therefore a second source is needed. |
| 33 | Differences in delivery times among suppliers | There are differences among different suppliers within Europe and China. |
| 34 | On time deliveries from suppliers | Materials are not always received on-time, but in most cases there are no delivery problems. The purchase and production managers estimate both that 80% of the orders are received on-time. RLJ notes corroborate interview data. Problems occur with too-late deliveries due to the ineffective planning system of company |
| 35 | Flexibility of suppliers in meeting company's requirements | The Company has flexible suppliers. RLJ notes corroborate interview data. |
| 36 | Flexibility of suppliers | Most suppliers are flexible enough to meet unexpected |

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| | flexible in meeting unexpected demand | demand. Suppliers from China are less flexible. |
| 37 | Delivery dependability on order quantities | Suppliers deliver always the exact ordered quantities, only in very exceptional cases deviated quantities were received. |
| 38 | The delivery of the right type of materials from suppliers | Suppliers deliver always the right type of raw materials, although some exceptions of wrongly delivered materials occurred. |
| 39 | High quality materials from suppliers | Quality specifications are not exactly known by the purchasing department when buying raw materials. There is not a constant quality of raw materials and this may cause problems in production. High quality can also not be guaranteed by the quality department, since most materials are only released according to the certificates of analysis of the suppliers without formal testing. When a material meets the specifications, it will not guarantee the good manufacturability of the material. It is therefore important to purchase the raw materials from the same source. The materials are often purchased from intermediate companies and this doesn't guarantee a constant source. RLJ notes corroborate interview data. |
| 40 | Supplier's ability to meeting specifications | Quality is sometimes a problem, especially materials from plant origin, such as herbs. These materials do not often meet the microbiological requirements causing delays of the customer order deliveries. It takes more efforts to find materials meeting the specific specifications of the Company due to the lack of international standards in the nutraceutical industry, whereas the specifications of raw materials are always clear in the pharmaceutical industry. RLJ notes corroborate interview data. |

Table 4.8 below describes the results of the semi-structured interviews concerning pull production; see Appendix C for the questionnaire. The production manager and the managing director were interviewed as they appeared to be the best informants in the workshop to assess the pull production construct.

Table 4.8: Results of the Semi-Structured Interviews on Pull Production

| # | Question | Responses |
|---|---|---|
| 1 | Explanation of the company's pull production system | The pull production system has been developed from the start of the Company. Production has direct contact with the customers and this may often happen with new small starting manufacturing companies. The pull system demands a lot of the people and this could only work with good motivated and flexible employees. Production is driven by the receipt of customer orders. |

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| | | Customer orders are given directly to the production manager for planning the shipment of products to customers, packaging and bulk production. The packaging supervisor pulls the bulk product from production and production pull the raw materials from the warehouse. RLJ notes corroborate interview data. Sometimes production operators enter the warehouse to collect the materials. |
| 2 | The capability of the production system to react on the continuously changing demand of the customers | The production system is well capable to react on the demand of the customers. The Company has very fast set-up times due to the high standardisation with dedicated machines for each tablet seize. The production throughput time varies between 1 to 2 weeks. The production manager has direct contact with customers. The capacity of tablet coating and the lack of an effective operating computer system for production planning and inventory control were mentioned as constraints. RLJ notes corroborate interview data that the production manager has direct contacts with customers regarding scheduled deliveries. |
| 3 | The weekly planning for production, packaging and deliveries of finished products | The customer order planner enters every week the customer orders in the computer system and provides the production manager the order list. The production manager checks every weeks the availability of materials. The production manager gives a sign to the purchase manager to replenish the raw materials from suppliers. Most orders are repeating orders of existing products and raw materials needed for the order are almost on stock. However, this system is not reliable and it is expected that an ERP system will improve the material requirement planning and procurement. The received customer orders will be confirmed after receiving the feedback from the production manager. As the product will be delivered immediately after packing to the customer, there is very little inventory of finished product and sometimes the order quantities are divided in smaller quantities in order to deliver the product on-time. The quality department is under constant pressure to release the product immediately after production. The ineffective ERP system brings the following problems: 1) item numbers are not used; 2) no pick-list is issued for collecting the materials in the warehouse; 3) insecure inventory data of raw materials. RLJ notes corroborate interview data. Examples of conflicts between production and quality departments are mentioned. |
| 4 | PULL and PUSH planning and control system | The informants stated clearly that the planning and control system of the Company resembles completely the pull system. There is no Kanban system, but there is good communication between the bulk production and packaging departments on the shop floor. An |

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| | | empty machine on the bulk production will trigger the production and this may be considered as a kind of sign. There is more machine capacity available then labour capacity at the packaging department. When packaging operators have temporary no product on the line, they are allowed to collect a bulk product from the bulk production department and the packaging materials from the warehouse. The sign that operators have no production activity is a trigger for the packaging supervisor to pull the order at the packaging line. The production manager gives a sign to the purchase manager to order the raw materials, based on the received orders and the current stock of materials. RLJ notes corroborate interview data. |
| 5 | PULL and PUSH material flows | The pull mechanism works since the batch size is less important due to the high standardisation grade. This is the result from the start of the Company. There were little financial means available to invest in different sizes of machinery parts, such as punches used for tablet compressing and therefore the machines are normally not converted into another tablet shape. No storage of materials (exception is uncoated bulk-product) is needed due of excess of capacity of tablet compressing and packaging due to investments in new machines. The average storage period between the bulk production and packaging is about 2 – 3 days. There is a shortage of coating and capsule filling capacities, but new machines are ordered to increase capacity. The bulk product must be approved by quality control quickly. The product is sent immediately to the customer after packing. The pull system is more difficult to realise when production must meet the pharmaceutical requirements. Cleaning is more severe and there are many different tablet dimensions used in pharmaceutical production. |

*Assessing TBM Practices – Feedback on Interim Action Research Report*

The interim action research report describes the diagnosed TBM practices, based on the interviews and RLJ and suggestions for improvements. Pull production and standardised manufacturing are the strongest developed TBM practices, whereas quality improvement efforts and preventive maintenance are the weakest TBM practices. The Case Company has the ability to obtain fast set-up times due to high standardisation and grouping production into families with similar sizes or colours. The interim action research report was discussed in a meeting with the management team members in

March 2007. Table 4.9 presents 15 suggestions for improving TBM practices mentioned in the report. The outcome of the feedback is that the majority of the management team agreed with the improvement suggestions. There was some disagreement with the necessity that all packaging operators must be trained to improve the batch changeover, only the training of a few operators is considered to be necessary. Preventive maintenance was not considered as a major hinder due to the excess of machine capacity and high standardisation of production processes. The weak quality management system is a major hinder leading to some conflicts between de production and quality departments. The Company's IS is also weakly developed. The management team decided to improve the infrastructure with the implementation of an ERP system and enhancement of the quality management system of the Company in order to meet the pharmaceutical requirements.

Table 4.9: Improvement Suggestions in Interim Action Research Report

| | Improvement suggestions |
|---|---|
| | *Shop-floor employees* |
| 1 | Regular training of all shop-floor employees. |
| 2 | Organising formal meetings with production, engineering and quality management must be performed for continuous improvement on the shop-floor. |
| 3 | Installing project meetings for new product development with sales, production and quality departments. |
| | *Batch changeover/set-up* |
| 4 | Training of packaging operators to shorten set-up times |
| 5 | Developing standardised work system practices for the set-up and batch changeover and set-up of machines. |
| 6 | Organising the storage of set-up tools in the near of machines. |
| | *Preventive maintenance* |
| 7 | Top management emphasis on preventive maintenance. |
| 8 | Keeping a log book for maintenance. |
| 9 | Organising regular inspections of machines on maintenance and cleanliness. |
| | *Quality improvement programmes* |
| 10 | Reconstruction of production and warehouse facilities. |
| 11 | Validation of machines, cleaning process and information systems. |
| 12 | Feedback of quality problems and customer complaints with the shop-floor. |
| 13 | Quality training of the shop-floor employees. |
| 14 | Finalising the supplier selection programme. |
| | *Pull Production* |
| 15 | Automation of issuing the batch production documents for the shop-floor. Using ERP system may not lead to a push planning control system. |

### 4.1.2 IMPLEMENTATION PHASE – INFORMATION SYSTEMS

The ERP implementation project, started in October 2006 and ended in July 2007 was part of the AR project in order to improve the Company's infrastructure. The objective of this project was to integrate the business processes of all departments, including the shop-floor. The integration of the ERP system with the shop-floor was an important part of the project by developing an interface to connect the automatic weighing system for raw materials with the ERP system. Table 4.10 shows the major stages of the IT project. I managed 26 project meetings and several workshops for process mapping involving 3 IT consultants and key persons of the financial, logistics and production departments.

Table 4.10: Realised IT Project Stages

| **No.** | **Project stage** |
|---|---|
| 1 | Process maps of business processes (blue-print) |
| 2 | Selection and definition of interfaces to connect ERP and weighing system |
| 3 | Design of documents to be issued by the new system |
| 4 | Recruiting additional employees for the logistics department |
| 5 | Purchase of computer hardware |
| 6 | Development of interface programmes |
| 7 | Clearing all master data |
| 8 | Clearing all variable data |
| 9 | Testing the system (step by step) |
| 10 | Description of detailed internal processes with flowcharts and work instructions in HTML environment for training |
| 11 | Developing standard operating procedures |
| 12 | Training of key and end-users |
| 13 | System/procedure validation |
| 14 | Go live of ERP system |

Process maps of the current an integrated business processes were developed and used for the blueprint of the new system. Table 4.11 describes the process maps and improvement gains through the implementation of the new IS.

Table 4.11: Mapped Processes and Achieved Improvement Gains

| # | **Process** | **Major improvement gains** |
|---|---|---|
| 1 | Developing BOM of bulk product and final packed product. | The BOM is only entered once in the ERP system instead of entering the BOM in three different stand alone systems. |
| 2 | Picking raw materials and packaging materials for production for bulk production and packaging. | Picking materials is more efficient by the automatic generation of the pick list with storage locations of each component listed. Used quantities are automatically written off by the system. |
| 3 | Generation of manufacturing and packaging orders. | The ordering process is more efficient and accurate by the automatic generation of shop-floor papers for bulk production and packaging, electronic weighing list and replenishment of materials. Customer order confirmations are also automatically generated. |

The managing director and three IT consultants were interviewed at the end of the project. Table 4.12 presents the results of the Likert-scale questions and Table 4.13 presents the results of the open questions with the information of the achieved improvements at the end of the project; see Appendix D for the questionnaire.

Table 4.12: Information Systems Variable Characteristics of Case Company 1

| Construct | No. of items | Mean Scores | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| I.S. strategic planning effectiveness | 4 | 3.00 | 0.27 | 0.88 |
| I.S. responsiveness to organisational computing demands | 4 | 3.72 | 0.16 | 0.98 |
| End-user training effectiveness | 2 | 2.25 | 0.65 | 0.83 |
| End-user computing skill | 3 | 3.17 | 0.64 | 0.90 |
| Cross-functional involvement (in I.S. related activities) | 5 | 2.90 | 0.54 | 0.75 |
| End-user involvement (in I.S. related activities) | 5 | 3.15 | 0.62 | 0.91 |
| I.S. performance | 5 | 3.95 | 0.09 | 0.95 |

Table 4.13 clearly demonstrates the improvement of the Company's IS. Table 4.12 shows that IS performance and IS responsiveness to organisational computer demand

are strong elements achieved at the end of the project. The end-user training effectiveness is a weak practice and this may be the result that the interviews were conducted at the start of the user training. The lack of training at this stage of the IT project may also be the reason of the low IRR of cross-functional involvement.

Table 4.13: Results of the Semi-Structured Interviews on Achieved Improvements at the End of the IT Project

| # | Question | Responses on improvements made |
|---|---|---|
| | *Strategic planning effectiveness* | |
| 1 | IS strategy and objectives. | All participants confirmed improvement. There are still discussions ongoing and the IS strategy and objectives are not yet documented. |
| 2 | Procedures and instructions defining the scope of IS functionalities. | All participants confirmed improvement. Written instructions are made. These instructions have to be developed further. |
| 3 | Improvement of business processes due to IT project. | All participants confirmed improvement, although it is mentioned that the project was not yet completely finished. Examples given are the automatic issue of shop-floor papers, the ordering processes and labelling of products by QC. |
| 4 | Policies and procedures defining the scope of IS responsibilities. | All participants confirmed improvement, but further improvements will further occur. For example, the financial department enters the sales prices in the system, which is the task of the sales department. |
| | *Responsiveness to organisational computing demand* | |
| 5 | Resolving software applications problems. | All participants confirmed improvement. |
| 6 | Responsiveness to end-user questions and concerns. | All participants confirmed the good IS responsiveness to end-users, but 3 of 4 participants confirm improvement. |
| 7 | Implementing software application upgrades. | 2 out of 4 participants mentioned this aspect as strong and confirmed further improvement. |
| 8 | Resolving computer network problems. | Only one participant confirmed improvement by providing some examples. Others mentioned that this was already well developed before the project. |
| | *End-user training effectiveness* | |
| 9 | Formal class room training on existing IS. | All participants mentioned that formal training at the end of the project were given for the first time. |
| 10 | On-the-job training on how on existing IS. | 3 out of 4 participants confirmed improvement. |

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| | *End-user computing skill* | |
| 11 | High end-user productivity when using new installed IS. | All participants confirmed improvement and mentioned the new weighing system as an example for improving productivity. |
| 12 | End-user skills in the use of manufacturing information technologies and computer based-technologies. | 3 out of 4 participants confirmed some improvement, but these skills can be further improved. |
| 13 | End-user capability of completing routine work assignments requiring the use of new installed IS. | All participants confirmed improvement and this will further enhance due to the planned training. |
| | *Cross-functional involvement* | |
| 14 | Departmental involvement in the development of IS policies and procedures. | All participants confirmed improvement, but this is at an early stage. |
| 15 | Departmental involvement in the integration of IS planning activities. | All participants confirmed improvement, and the different departments are co-operative. |
| 16 | Departmental involvement in the prioritisation of IS related activities. | 3 out of 4 participants confirmed some improvement, but a top down approach is needed to involve the departments. |
| 17 | Departmental involvement in the integration of software applications. | All participants confirmed improvement due to the project meetings and this could be further enhanced. |
| 18 | Departmental involvement in solving software application problems. | All participants confirmed improvement and IT specialists mention the positive feedback from end-users. |
| | *End-user involvement* | |
| 19 | End-user involvement in the development of IS. | Although improvement was mentioned, only a few end-users are involved. |
| 20 | End-user involvement in the analysis and opportunities of IS. | All participants confirmed improvement, but they also mentioned that employees of the production and engineering departments are not involved. |
| 21 | End-user involvement in the testing of IS. | 2 out of 4 participants confirmed improvement and the others mentioned that this aspect already existed before the project. |
| 22 | End-user involvement in the development of IS application. | 2 out of 4 participant mentioned improvement. |
| 23 | End-user involvement during the company's IS project. | All participants confirmed improvement and more employees are involved. This will improve further. |
| | *Information systems performance* | |
| 24 | End-user satisfaction with new installed IS. | All participants confirmed improvement and mentioned that the end-users will see advantages of the new installed ERP system. |
| 25 | Enhancing decision making by using new IS. | All participants confirmed improvement. Data are more reliable enhancing decision making. |
| 26 | End-user recognition of new installed IS benefits. | All participants confirmed improvement. Training will further increase the acceptance of the end-users. |

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| 27 | Improvement of managing manufacturing activities by the use of new installed IS. | All participants confirmed improvement. The generation of shop-floor papers and weighing system have been improved. |
| 28 | End-user expectations of new installed IS. | All participants mentioned that the new installed ERP system is meeting the expectations of employees. |

Although the IT project was successful ended, the company's IS will develop further, for example the enhancement of the system's security system and the accuracy of the MRP system were planned for further improvement. It is expected that the integral thinking of the end-users will improve the end-user and cross-functional involvement during the further use of the new installed IS.

### 4.1.3 IMPLEMENTATION PHASE – QUALITY MANAGEMENT SYSTEM

The quality project started in November 2006 and ended after I have left the company, was part of the AR project to improve the Company's infrastructure. The objective of this project was to improve the quality management system in order to obtain the GMP manufacturing license for pharmaceutical products from the health authorities. This license was obtained in June 2008. Table 4.14 gives the major stages of the quality project when I left the company.

Table 4.14: Status of the Quality Project in October 2007

| # | Stage | Status |
|---|---|---|
| 1 | Reconstruction of premises and facilities. | Final stage |
| 2 | Quality manual and standard operating procedures. | Realised |
| 3 | Specifications of raw materials and finished products. | Realised |
| 4 | Generation of batch documentation according to GMP requirements. | Realised through IT project |
| 5 | Validation of machines, processes (including cleaning) and IS. | Preparatory stage |
| 6 | Training of employees. | Not started |
| 7 | Submission of the application for the manufacturing license to the health authorities. | Not started |

The managing director, the quality consultant, the quality manager and his assistant were interviewed in September 2007. Table 4.15 presents the results of the Likert-scale questions and Table 4.16 presents the results of the open questions with the information of the achieved improvements; see Appendix E for the questionnaire.

Table 4.15: Quality Management System Variable Characteristics of Case Company 1

| Construct | No. of items | Mean Scores | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| Top Management Support | 5 | 3.22 | 0.48 | 0.94 |
| Quality Information | 2 | 3.13 | 0.75 | 0.68 |
| Process Management | 7 | 3.20 | 0.71 | 0.84 |
| Product Design | 2 | 3.75 | 0.50 | 0.86 |
| Workforce Management | 5 | 3.45 | 0.75 | 0.92 |
| Customer Involvement | 3 | 3.25 | 0.57 | 0.80 |
| Supplier Involvement | 4 | 3.31 | 0.90 | 0.75 |

Table 4.15 shows that product design is the strongest element of the quality management system. The scores of other quality items suggest that there are no weak points, but the IRRs of the "quality information" and "supplier involvement" are low. RLJ notes and the minutes of the quality project meetings corroborate that supplier involvement and quality information are weakly developed. Only an overview of quality complaints are discussed in management team meetings and there is no feedback from the shop-floor.

Table 4.16: Results of the Semi-Structured Interviews on Achieved Improvements of the Quality Management System of Case Company 1

| # | Question | Responses on improvements made |
|---|---|---|
| 1 | Top management support for quality | 3 out of 4 participants confirmed some improvement, but the emphasis lies on the reconstruction of the production facilities and the changes are progressing slowly. |
| 2 | Quality seen as central theme within the organisation | 2 out of 4 participants confirmed some change, but quality is not seen as a central theme within the organisation. |
| 3 | Active role in quality improvements and communication by top management | 3 out of 4 participants confirmed that top management is actively involved and this has been improved. However, the actions for improvement are progressing slowly. |
| 4 | Organisational culture on quality | All participants confirmed that there is no organisational culture for quality. There are many improvements, but most of these improvements are initiated due to rapid growth of the Company rather than the company's focus on quality. |
| 5 | Rewards of quality results | 3 out of 4 participants confirmed that there is some reward by top management. This has not been improved. |
| 6 | Communication of quality results and feedback | All participants confirmed that there is some improvement. |
| 7 | Key performance indicators for quality | 3 out of 4 participants confirmed that there is no improvement. |
| 8 | Implementation of processes to prevent possible defects caused by employees | 3 out of 4 participants confirmed that there is no improvement. Investments in new machines may help to prevent defects due to automatic controlling devices to stop the process. |
| 9 | Quality control charts | 3 out of 4 participants confirmed that there is no improvement. The only improvement is that the shop-floor documents, including the control charts are issued automatically. |
| 10 | Validation of production machines | All participants confirmed that there is improvement, but the validation of equipment is still at the preparatory stage. |
| 11 | Authorisation to stop the production process | All participants confirmed that there is no improvement. |
| 12 | Cleanliness of machines and the shop-floor | There were some improvements mentioned, but the cleanliness is still insufficient. |
| 13 | Slow speed production process in order to guarantee quality | 3 out of 4 participants confirmed that there is only some slight improvement. |
| 14 | Development of new products | All participants confirmed that there is no improvement. |
| 15 | Role of customers and suppliers in the development of new products | 2 out of 4 participants confirmed that there is only some slight improvement. |
| 16 | New product development teams | 2 out of 4 participants confirmed that there is some improvement. Working in teams occurs, but it lacks structure. |

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| 17 | Quality meetings with employees | There were no improvements mentioned. |
| 18 | Recruitment and training of employees | There were no improvements mentioned. |
| 19 | Quality problem solving within small teams | There were no improvements mentioned. Problems are mainly discussed within the quality department. Production and engineering are rarely involved in solving quality problems. |
| 20 | Differences in treating employees | This aspect didn't change. |
| 21 | Employee flexibility in quality improvements | All participants mentioned that this aspect didn't change due to the increased production output and increased pressure on employees. |
| 22 | Customer requirements on quality | There were some changes mentioned. The requirements of customers are increasing. |
| 23 | Certification by customers | This was changed. Certification is performed by some customers and this will increase due to increasing quality requirements. |
| 24 | Exchange of information regarding production processes to customers | The Company is not eager to exchange information, but this is changing due to the increased power and requirements of customers. |
| 26 | Communication of specifications with suppliers | There were no improvements mentioned. |
| 27 | Quality as important criterion for supplier selection | There were no changes mentioned, price is still the most important criterion. |
| 28 | Certification and policy to select a small number of suppliers | All participants confirmed that there was an improvement. A classification scheme has been introduced and entered in the new IS. The increased quality requirements force the company to improve the quality of raw materials and certify suppliers. |
| 29 | Policy for keeping long-term relationships with suppliers | There were no improvements mentioned. |
| 30 | Main deviations of the quality system and bottlenecks of change. | 1. The increased production output and high growth of the company make quality improvements difficult.<br>2. The reconstruction of the production facilities is not finished.<br>3. The quality management system is not ready to enter the pharmaceutical industry.<br>4. More time is needed for training shop-floor employees<br>5. Lack of employees due to the high growth<br>6. There is no homogeneous culture on quality. |

Table 4.16 demonstrates that there are some improvements of the quality management made, but further improvements are progressing slowly. The project did not meet the scheduled end date. It was planned that the reconstruction of premises would be finished in July 2007 and the total quality project in October 2007. The organisational culture, increased production output and rapid growth of the company were mentioned as constraints for the development of the quality management system.

### 4.1.4 WORK SYSTEM PRACTICES OF CASE COMPANY 1

A survey was conducted on 14 informants from the shop-floor or who are acquainted with the shop-floor practices at the end of the AR project; see Appendix F for the questionnaire. Furthermore 74 participant observations were collected and stored in the RLJ. The objective of studying the work system practices is to find whether these practices are influenced through the company's infrastructure development as result of the IT and quality projects. Table 4.17 presents the results of the Likert scale questions.

Table 4.17: Work System Practices Variable Characteristics of Case Company 1

| Construct | No. of items | Mean Scores | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| Integration | 8 | 3.08 | 0.62 | 0.91 |
| Routine Use | 6 | 3.65 | 0.62 | 0.88 |
| Formalisation | 4 | 4.07 | 0.66 | 0.89 |
| Standardisation | 5 | 2.96 | 0.86 | 0.77 |

The results show that formalisation and routine use (repetitively performing tasks) are the best developed work system practices. RLJ notes corroborate that the formalisation improved due to the development of written operating procedures and other quality documents were developed during the quality project. The standardisation and routine

use improved through the IT project, since the production documents with standard instructions for making the products are automatically issued. However, the standardisation score was inaccurate due to the low IRR score. RLJ notes corroborate that the Company has a low standardisation in assessing the output performance, but a high standardisation of making products. There was a high agreement on the question relating to standardised methods of making products. 4 out of 5 questions of the standardisation construct relate to output measures and this may be the reason of the diverse responses. The Company has no culture of discussing problems in formal meetings and this may explain the relative low score on integration. This aspect improved due to the installed project meetings and new product development meetings, initiated during the AR project.

### 4.1.5 MANUFACTURING PERFORMANCE OF CASE COMPANY 1

The delivery dependability and the order cycle time were collected as manufacturing performance data and are shown in Table 4.18.

Table 4.18: Monthly Delivery Performance Data of Case Company 1

| Orders received in period | Total number of orders measured | Order Cycle Time (in weeks) | On-time deliveries (average time in weeks after promised delivery date) | On-time deliveries (% of orders on time) |
|---|---|---|---|---|
| May 2006 | 39 | 6.44 | 1.69 | 87.2% |
| June 2006 | 182 | 4.69 | 0.99 | 52.2% |
| July 2006 | 57 | 6.72 | 1.95 | 36.8% |
| August 2006 | 46 | 5.15 | 0.98 | 32.6% |
| September 2006 | 157 | 5.39 | 0.81 | 73.2% |
| October 2006 | 129 | 3.91 | 0.82 | 56.6% |
| November 2006 | 108 | 4.98 | 1.46 | 65.7% |
| December 2006 | 116 | 6.27 | 2.25 | 44.0% |
| January 2007 | 102 | 6.03 | 1.77 | 56.9% |
| February 2007 | 110 | 5.08 | 1.53 | 59.1% |
| March 2007 | 112 | 5.17 | 1.80 | 56.3% |
| April 2007 | 156 | 5.02 | 1.13 | 65.4% |
| May 2007 | 85 | 5.91 | 1.59 | 52.9% |
| June 2007 | 83 | 5.63 | 1.53 | 45.8% |
| Total period (weighed average) | 1482 | 5.29 | 1.38 | 57.1% |

The average cycle time is 5.3 weeks and 57% of the orders are delivered on-time with an average delay of 7 working days (1.38 week). Figures 4.1 and 4.2 present the time-series analysis of the order cycle time and delivery dependability and show, that there is no improvement of the two performance parameters observed during the AR project.

Figure 4.1: Time-Series Analysis of the Order Cycle Time of Case Company 1

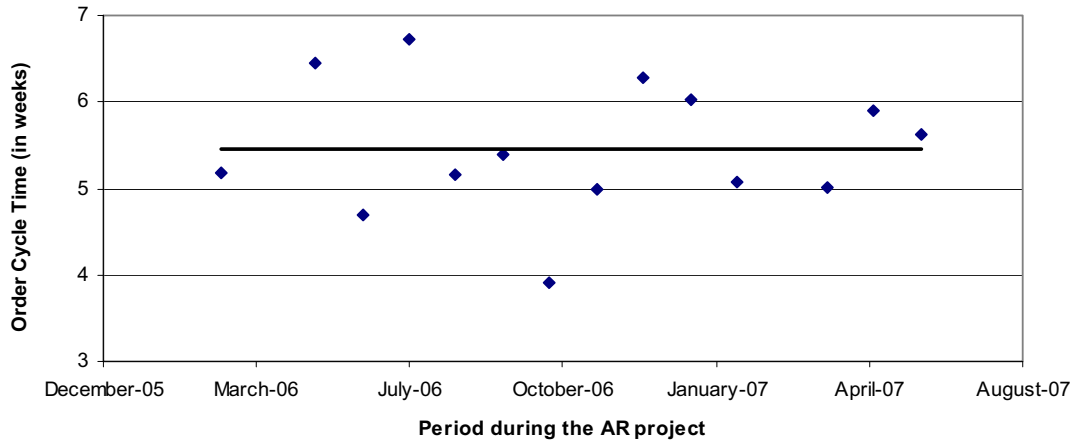



Figure 4.2: Time-Series Analysis of the Delivery Dependability of Case Company 1

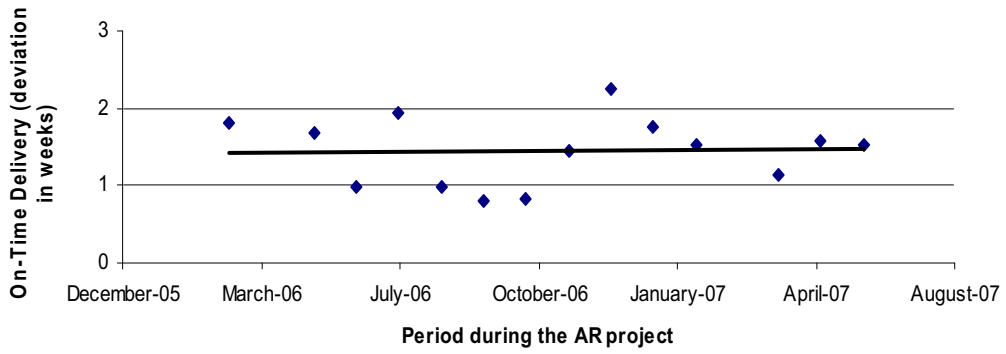
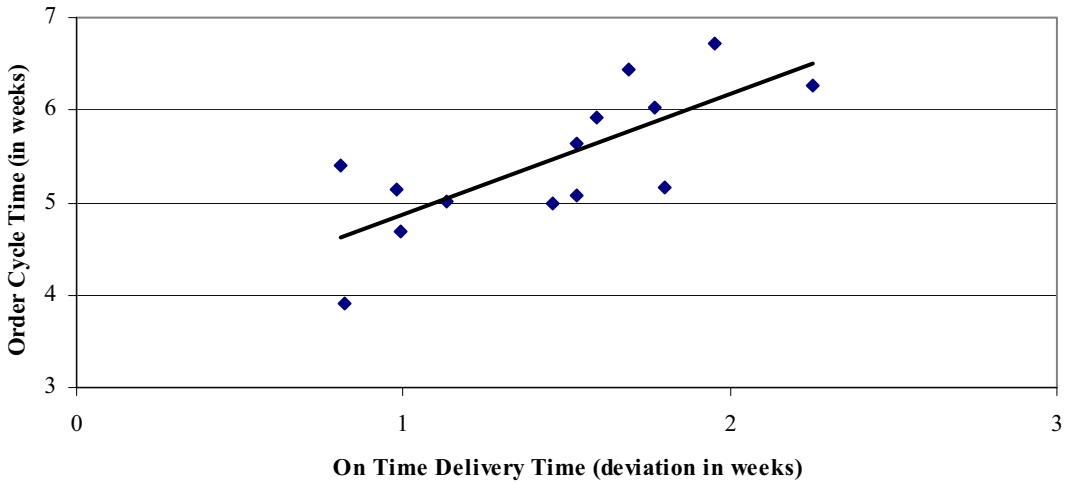



Figure 4.3 illustrates the relationship between the order cycle time and the delivery dependability, measured as deviation in time from the confirmed delivery time when the order is delivered too late to the customer. The following coefficients have been calculated:

Intercept/Regression coefficient (a) = 3.58
Regression coefficient (b) = 1.29 (significance level of the slope: $p < 0.005$)
Correlation coefficient (r) = 0.754
Coefficient of determination ($r^2$) = 0.569

Figure 4.3: The Relationship between the Order Cycle Time and Delivery Dependability of Case Company 1

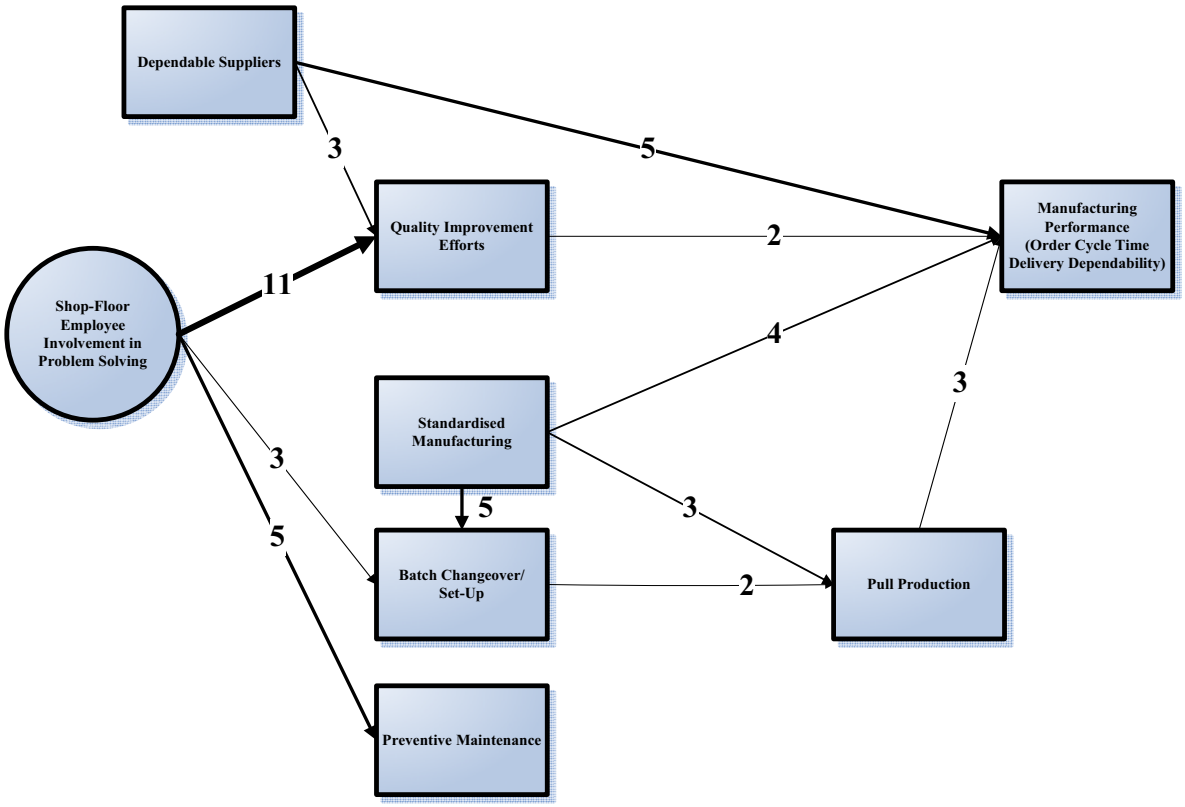



The correlation coefficient of *0.75* represents a high relationship between the order cycle time and delivery dependability and *57%* of the total variation can be explained by the relationship, as estimated by the correlation between the order cycle time and the corresponding deviation in time from the confirmed delivery date.

### 4.1.6 TBM FRAMEWORK OF CASE COMPANY 1

Figure 4.4 presents the TBM framework based on the open, axial and selective coding of all collected data at the end of the AR project. The numbers of axial codes between constructs are shown in the arrows of the framework.

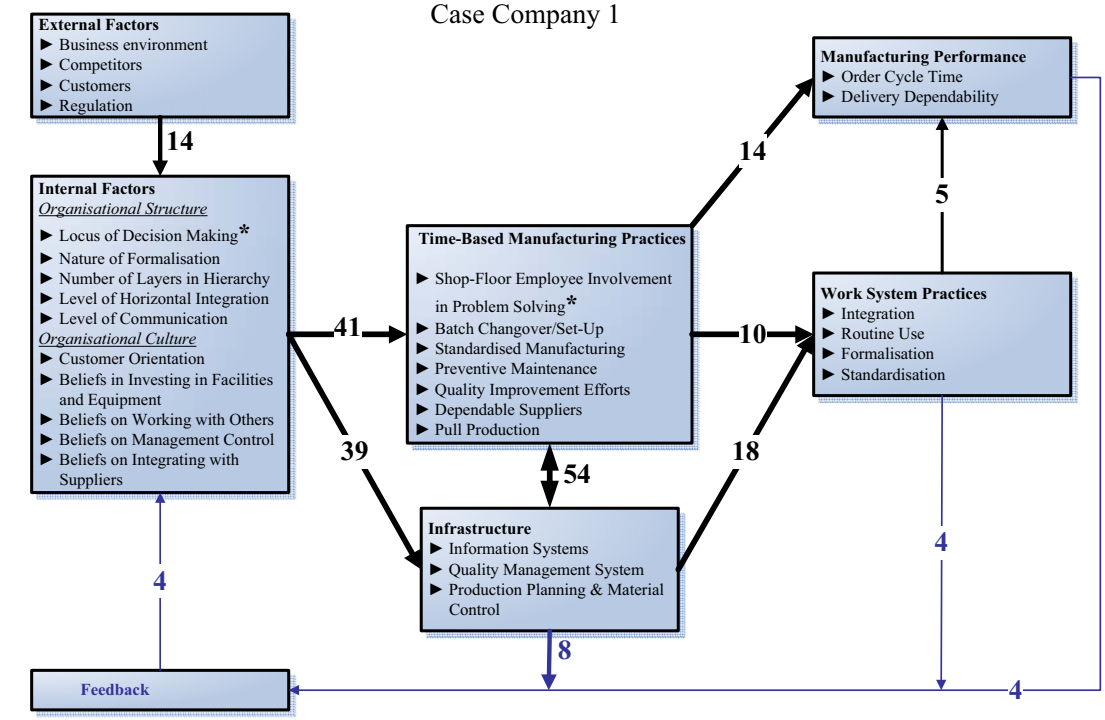
Figure 4.4: Framework of Time-Based Manufacturing Practices of Case Company 1




Most data representing the TBM framework were collected during the diagnosis phase and provided enough data to answer research question 1a by saturating the categories and constructs of the TBM framework. However, the implementation phases of the AR project were focussed on the infrastructure improvements and therefore little additional data and in particular axial codes could be obtained for developing the core TBM framework. The only exception is the improvement of the quality management system that provided more data of the "quality improvement efforts" construct, resulting for example in 11 axial codes representing the relationship with the "shop-floor employee involvement in problem solving" construct. The TBM framework in Figure 4.4 shows

10 propositions, provided by the selective coding technique. A proposition is considered to be valid if one axial code analysed in an observation or interview could be confirmed with a second event. The results demonstrate that shop-floor involvement in problem solving is the antecedent to three TBM practices, namely quality improvement efforts, preventive maintenance and batch changeover/set-up and no relationships are found with dependable suppliers, standardised manufacturing and pull production. There is also a relationship between dependable suppliers and quality improvement efforts. This finding is in accordance to the revised framework of Koufteros et al. (1999). There are relationships between pull production and two constructs, namely standardised manufacturing and batch changeover/set-up and there is no relationship found with preventive maintenance. This may be the result of the underdeveloped preventive maintenance of the Company. There is a relationship between standardised manufacturing and batch changeover/set-up. Events were found that the grouping of products with similar sizes and colour dimensions will reduce the batch changeover and set-up times of machines. The determinants of the manufacturing performance are dependable suppliers, quality improvement efforts, standardised manufacturing and pull production. Figure 4.5 shows the relationships between TBM practices and the contextual variables. Contextual variables are in this study the four work system practices, organisational structure, organisational culture, the infrastructure domain (information systems, quality management system and production planning and material control system) and the external factors. Observations of the Company's feedback on the manufacturing performance were also analysed and included in the framework. The TBM framework and the contextual variables will be presented latter in more detail when the comparative analysis of the two companies is discussed.

Figure 4.5: The Impact of Contextual Variables on TBM and Manufacturing Performance of Case Company 1




* The Locus of Decision Making domain covers the construct of Shop-Floor Employee Involvement in Problem Solving

## 4.2 CASE COMPANY 2

Table 4.19 illustrates the time-frame of the research project.

Table 4.19: Research Project at Case Company 2 – Time-Frame

| Phase of the AR project | Data collection method | Period |
|---|---|---|
| Diagnosis Phase (AR1)<br>Assessing TBM practices | Interviews<br>RLJ<br>Feedback on<br>Interim action research report | October – December 2007<br>January – December 2008<br>March - May 2008 |
| Implementation Phase (AR2 – AR5)<br>Improving TBM practices in 4 workgroups | Process maps<br>KPI workgroup meetings<br>Interviews<br>RLJ | January – July 2008<br>January – December 2008<br>November - December 2008<br>March 2006 –June 2007 |
| Information System | Interviews<br>RLJ | March – May 2008<br>October 2007 – December 2008 |
| Work System Practices | RLJ<br>Survey | October 2007 – December 2008<br>October – December 2008 |
| Delivery Performance Data | KPI data and feedback in KPI Circle meetings | October 2007 – December 2008 |

The findings to answer research question 1a "What are the TBM practices of the Case Company?" are according to the data accounting sheet complete; see Table 4.20 on the next page. The data collected during the implementation phase (AR2 – 5) provided additional evidence to research question 1a and these projects provided answers on research question 1b "how TBM practices can be improved". The other practices that can be applied to become a time-based competitor are in this study related to the infrastructure (research question 1c). The assessment of the IS and work system practices using the same instruments of the first Case Company provided comparative material relating to this research question**.**

Table 4.20: Data Accounting Sheet – Interview Data of Case Company 2

| Participants | Number of interviews | EM | BS | ST | PM | DS | QI | PP | IS |
|---|---|---|---|---|---|---|---|---|---|
| General manager | 2 | X | X | X | X | X | √ | - | - |
| Production manager | 4 | √ | √ | √ | √ | √ | X | √ | - |
| Engineering manager | 3 | √ | √ | √ | √ | √ | X | - | - |
| Production supervisors | 6 | √ | √ | √ | √ | √ | - | X | - |
| Engineering supervisor | 2 | √ | √ | √ | √ | √ | - | X | - |
| Quality assurance manager | 2 | X | X | X | X | X | √ | - | - |
| Quality control manager | 1 | X | - | - | - | X | √ | - | - |
| Quality consultants | 2 | X | - | - | - | X | √ | - | - |
| Logistics manager | 4 | - | - | - | - | √ | X | √ | √ |
| Purchase team | 6 | - | - | - | - | √ | X | - | - |
| Warehouse supervisor | 1 | X | - | X | - | - | - | X | - |
| Finance manager | 2 | X | - | - | - | - | - | - | √ |
| Marketing & sales manager | 1 | X | - | - | - | - | - | - | - |
| IT manager | 1 | X | - | X | - | - | - | - | √ |
| Business analyst | 1 | X | - | - | - | - | - | - | √ |
| TOTAL | 38 | √ | √ | √ | √ | √ | √ | √ | √ |

Legend:
√ = data complete
X = some information, but incomplete
- = missing data
EM = Shop-Floor Employee Involvement in Problem Solving
BS = Batch changeover/set-up
ST = Standardised Manufacturing
PM = Preventive Maintenance
DS = Dependable Suppliers
QI = Quality Improvement Efforts
PP = Pull Production
IS = Information Systems

Unstructured data collection, mainly participant observations and documents collected provided additional information of the internal and external factors influencing the implementation of TBM practices (research question 2). The change process of the implementation phase of the AR project provided data concerning the relationship between TBM practices and manufacturing performance (research question 3).

392 participant observations and documents were stored in the RLJ during the diagnosis and implementation phases. Table 4.21 shows the number of codes stored in the RLJ and divided in the various constructs according to the start list of codes; see Appendix A.

Table 4.21: Data Accounting sheet – Number of Open Codes Stored in RLJ of Case Company 2.

| Construct | Number of codes in RLJ |
|---|---|
| Shop-floor employee involvement in problem solving | 67 |
| Batch changeover/set-up | 21 |
| Standardised manufacturing | 23 |
| Preventive maintenance | 14 |
| Dependable suppliers | 36 |
| Quality improvement efforts | 86 |
| Pull production | 4 |
| Feedback to employees | 33 |
| Information systems | 36 |
| Work system practices | 71 |
| Quality management system | 91 |
| Internal factors | 110 |
| External factors | 21 |
| Change process | 185 |
| Total | 798 |

### 4.2.1 DIAGNOSIS PHASE OF CASE COMPANY 2

*Assessing TBM Practices – Interviews and RLJ*

The TBM practices were primary assessed by interviewing the key participants. The Tables 4.22 – 4.25 contain convergent interview data. RLJ data are used as secondary data to triangulate the interview data and are also included in these tables.

Table 4.22 describes the results of the semi-structured interviews concerning the shop-floor employee involvement in problem solving and Table 4.23 on the next page describes the results of the semi-structured interviews concerning the Batch Changeover, Standardised Manufacturing and Preventive Maintenance as parts of the process design of Case Company 2 from the perspective of the participants; see Appendix C for the questionnaire. 6 participants from the production and engineering departments were used as key-informants to assess these constructs; see Table 4.20 for the functions of these participants.

Table 4.22: Results of the Semi-Structured Interviews on Shop-Floor Employee Involvement in Problem Solving of Case Company 2

| # | Question | Results - interviews and secondary data |
|---|---|---|
| 1 | Shop-floor employees involvement in solving problems | Production operators are rarely involved in solving problems. Only a few operators are trying to solve simple technical problems by themselves. Most operators are motivated, but there is a lack of training. The production operators are not well skilled to perform the set-up of complex high speed packaging lines. This leads to long set-up times and low productivity. Engineers are involved in helping the production operators with the set-up of the packaging lines and as consequence no regular preventive maintenance are performed by engineers. RLJ notes corroborate interview data of the weak technical skills of production operators and that the company is seeking for new technical skilled operators. The Company is willing to invest in training of its employees to improve the skills. |
| 2 | Shop-floor employees involvement in group meetings | There are no regular meetings held with production operators and therefore they are not involved in improvement programs or making new products. The supervisors have daily discussions with production operators involving them in solving problems. There is no |

| | | |
|---|---|---|
| | | motivation to improve the batch changeover times, although the production operators are motivated but they need training to shorten set-up times. |
| 3 | Shop-floor employees involvement in making new products | Only the production manager is involved in making new products and this have caused in some occasions technical problems. |
| 4 | Role of production management in the involvement of shop-floor employees | The production manager organises only twice a year an information meeting with all production employees. The production supervisors are discussing problems with operators and inform and coaching them on a daily basis. |

Table 4.23: Results of the Semi-Structured Interview on Process Design of Case Company 2

| # | Question | Responses and secondary data |
|---|---|---|
| | *Batch Changeover/Set-up* | |
| 1 | The activities during batch changeover | Set-up activities on the packaging lines are performed by more than one operator and therefore more set-up activities such as cleaning, receiving materials and removing machinery parts are done simultaneously. When similar products of the following batches are produced and hence no conversion of machines are required, the set-up times are much lower compared to the set-up times of different products. |
| 2 | Set-up time and activities when different moulds are used during a set-up | The conversion of the packaging machine is the most difficult set-up activity with the highest time needed. Most production operators need technical support from engineers during the batch changeover. The batch changeover is more difficult when the blister-machine is converted to another blister-size, but less complex when the blister-size is similar and easy when the new batch contains the same product as the previous batch. |
| 3 | Set-up time and activities if the same moulds are used with another product | Batch changeover times are also high since the packaging materials are not standardised. This causes problems in machine efficiency. A few millimetre differences in packaging size of different products are allowed, instead of choosing a few fixed sizes. Regular support from engineers is needed in the fine-tuning of the packaging lines during the start-up of the production run. |
| 4 | Set-up time and activities if the moulds are used with the same product | Set-up times are much lower if similar products of following batches are produced, compared to set-up times between batches of different products. |
| 5 | Support from engineering department | The supervisors are responsible for the line-clearance and coordinate the batch changeover such as seeking necessary assistant from engineers, collecting the production documents and materials of the new batch. |
| 6 | Motivation to improve set-up times | There is no motivation to improve the batch changeover times, although production operators are motivated but they need training to shorten set-up times. |

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|---|---|---|
| 7 | New set-up method of new machines and processes | There are no set-up methods developed for new machines. |
| 8 | Shop-floor employees improvement of set-up times | Production operators are not involved in improving set-up times. |
| 9 | Location of tools | The tools for the machine set-up are conveniently located, however some improvements are necessary. There is no system for storing the tools adequately with the consequence that some tools may disappear or moving to other packaging lines causing delays during the batch changeover. |
| 10 | Adjustment of equipment to shorten set-up times | Production operators regularly reconfigure machines with plastic tape or pieces of carton or plastic material to shorten set-up time or attempt to produce without troubles. This shows that the technical level of production isn't quite optimal. |
| 11 | Special tools to shorten set-up times | There are no special tools used. |
| 12 | Jigs or fixtures used to shorten set-up time | No jigs or fixtures are used. |
| 13 | Training of shop-floor employees to shorten set-up times | Training on the job at the packaging lines is only applied for new production operators. The engineering department has started to develop instructions for the complex high speed packaging lines for training purposes. Instructions of other machines will follow. |
| 14 | Role of production manager to shorten the set-up times | The production manager is involved together with the logistics department in making the weekly fixed production schedule, where he tries to cluster the orders of products with same sizes in order to diminish the batch changeover times. The supervisors are allowed to fine-tune the weekly production schedule together with employee scheduling. |
| 15 | Suggestions to shorten the set-up times | Some suggestions are given:<br>1) Increase the availability of all materials by improving the production planning system in order to group products with similar sizes prior to production;<br>2) Storage of dedicated tools for the set-up of machines;<br>3) Training and selection of the operators to improve the set-up and solving small disturbances of machines;<br>4) Development of set-up instructions and introduction of SMED techniques;<br>5) Development of a measurement system for production results (OEE measurement) on the shop-floor. |
| | *Standardised Manufacturing* | |
| 1 | Grouping in families of products on basis of similar shape or process requirements. | The products are grouped in families of products with the same packaging sizes on basis of blister size, number of blisters per carton and carton box size. The current problems of making a fixed production planning with all materials available make this grouping of products in practice difficult. |

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|---|---|---|
| 2 | Coding classification | There is a coding classification to group materials and products into families together with a numbering system for tooling. The numbers of the tooling are documented in the production documents. |
| 3 | Location of machines and equipment to group families of products | The high speed blister and packaging machines are placed on-line to form one packaging line. But the low speed blister and packaging machines are not placed together due to lack of space. The routing of products packed on the low speed machines is therefore not logic, causing unnecessary storage of intermediate blister products on the shop-floor. The routing of products can only be improved when the production premises will be reconstructed. RLJ notes corroborate interview data, that there is intermediate storing of blistered product on the factory shop-floor, causing problems. |
| | *Preventive Maintenance* | |
| 1 | Preventive maintenance on machines | Maintenance on the machines is regularly performed by engineers during the batch changeover and in case of problems. Maintenance consists mainly of lubrication with oil, machinery inspection and replacement of machinery parts during the batch changeover, which is more a pro-active and corrective approach. These maintenance activities are considered to be insufficient according to the production supervisors. |
| 2 | Performing preventive maintenance performed by production employees | Preventive maintenance is considered to be important, but it is rarely performed due to the lack of time of engineers. Besides the maintenance activities, engineers perform the following tasks on the production shop-floor (according to the engineering manager):<br>* Assistance of the set-up of the packaging lines (this contains 20-25% of the activities of the technicians, while this is considered as an activity that should be performed by the production operators);<br>* Solving disturbances of the packaging machines (small disturbances contain 20-25% of the activities, while big breakdowns rarely occur, only a few times a year);<br>* Adjustment of machines after the batch changeover (this activity contains 15% of the activities. |
| 3 | Preventive maintenance during non-productive time | Sometimes an external engineer from the supplier performs the maintenance on machines. |
| 4 | Emphasis on preventive maintenance | According to the engineering manager, engineers are performing many activities not belonging to their tasks due to the lack of technical skills of the operators. Not all tasks could therefore be performed, for example, preventive maintenance, daily inspections of machines, trailing of potential problems, registration of disturbances and recording the maintenance in the computer system are not completely performed. |
| 5 | Records of routine maintenance | There is a software system for keeping records of routine maintenance. Records of machinery disturbances, |

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|---|---|---|
| | | maintenance and set-up activities by engineers are stored in this system. |
| 6 | Regular maintenance of equipment | Maintenance of machines is regularly and proactively performed by engineers in case of a technical breakdown. New machinery parts are replaced during the set-up of the packaging lines. The production operators are not involved in the maintenance activities. |
| 7 | Occurrence of machinery breakdowns | Breakdowns and disturbances happen often. A technical breakdown and replacement of broken machinery parts occur regularly about once a week for each machine. The high speed packaging lines are sensitive for disturbances, occurring approximately one hour per shift. |
| 8 | Role of production manager in preventive maintenance | The production manager has no role in the preventive maintenance policy. |

Table 4.24 describes the results of the semi-structured interviews concerning quality improvement efforts and dependable suppliers from the perspective of the participants; see Appendix C for the questionnaire. The general manager and the quality manager were used as key-informants for assessing the quality improvement efforts and the logistics manager, purchase manager and two purchasers were used as key informants to assess the dependable suppliers. Six items are overlapping issues relating to both constructs and were asked to all six participants.

Table 4.24: Results of the Semi-Structured Interviews on the Quality Management System and Dependable Suppliers of Case Company 2

| # | Question | Responses and secondary data |
|---|---|---|
| | *Quality Management* | |
| 1 | Top management support for quality | There is top management support for initiatives to improve quality and quality is stated in the mission of the Company, however, there is a different opinion in how the quality management system must function. Both the general manager and the quality manager mentioned that the stage of the current quality management system is at the early "Quality Control" stage towards the move of the ideal TQM stage. However, the road towards TQM simultaneously meeting the pharmaceutical GMP requirements is not clear. The quality manager mentioned that there is a lack of quality staff available. RLJ notes corroborate interview data, that there is a lack of quality staff. |

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|---|---|---|
| 2 | Quality seen as central theme within the organisation | The current quality system has too many control steps and this is one cause that the quality management system introduces inflexible business processes, but this is also an industry wide problem. The current quality management system is now only a catching net for finding quality deviations and as consequence the quality system is seen by employees as a heavy burden. The current quality department is now understaffed and the organisation is lagging behind in training and education of its employees. Quality is under these circumstances only seen as a legal prerequisite. The result is that quality is not widely spread throughout the whole organisation and not seen as a central theme within the organisation. RLJ notes corroborate interview data by providing examples. |
| 3 | Active role in quality improvements and communication by top management | The general manager is convinced that quality and a flexible organisation can be equal partners and wants to support initiatives for further improvements, but the quality management system must be more than only meeting the legal GMP requirements. In fact, the quality management system is a reacting system on quality defects and problems. The KPI measurement system to improve the delivery dependability is not yet seen by the quality manager as an improvement tool for quality. |
| 4 | Organisational culture on quality | There is no organisational culture that is focussed on quality. The quality department is mainly performing operational related quality activities. Quality issues are only discussed within the quality department without involving other departments in quality improvement efforts. RLJ notes corroborate interview data, that quality department is only involved in testing materials without improving the quality management system. |
| 5 | Rewards of quality results | Quality results are not rewarded. Suggestions for quality improvements are supported by management by providing resources. |
| 6 | Communication of quality results and feedback | The production manager keeps the records of observed deviations. Observed deviations in production and external quality complaints are not discussed with the production operators. There is a lack of communication and feedback between departments, resulting that the same quality problems may occur again. RLJ notes corroborate the lack of communication. |
| 7 | Key performance indicators for quality | There are no KPIs for quality. There is only a system for keeping records of deviations and customer complaints. RLJ notes corroborate interview data. |
| 8 | Implementation of processes to prevent possible defects caused by employees | The processes are not designed to prevent errors caused by the employees. Quality control employees are taken samples after the packaging process, which is not a value-added step when the production process is under control. The lack of training and low technical skills of production operators are the main reasons of low efficiency of the production process and quality defects. |

| | | |
|---|---|---|
| | | RLJ notes corroborate interview data, that there is an ineffective change control process of packaging materials causing problems. |
| 9 | Quality control charts | Production documents contain quality control charts used to control the production processes, but these in-process controls are according to the quality manager not effectively executed by production operators. Products are often approved with problems or delay by the quality department. |
| 10 | Validation of production machines | Production machines are not validated to prevent errors. |
| 11 | Authorisation to stop the production process | Production operators are authorised to stop the production process in case of quality defects. The quality and production departments have no agreement how quality defects must be solved in production. Examples are mentioned of some conflicts between quality and production managers. |
| 12 | Cleanliness of machines and the shop-floor | Cleanliness of the production department is considered as important, although there is a lack of space on the production shop-floor. Intermediate products are stored on the shop-floor and the storage of tools is not well organised. |
| 13 | Slow speed production process in order to guarantee quality | The output of the production process is considered to be more important than having a process guaranteeing quality. |
| 14 | Development of new products | The development of new products is underdeveloped. RLJ notes corroborate interview data, that changing packaging materials cause problems. |
| 15 | Role of customers and suppliers in the development of new products | Customers are rarely involved in the development of new products. |
| 16 | New product development teams | No regular meetings for quality problems or new product development are being held. |
| 17 | Quality meetings with employees | There are no quality meetings with employees of different departments. RLJ notes corroborate interview data, that the first quality meeting is organised through the installation of the KPI workgroups. |
| 18 | Recruitment and training of employees | New employees with a technical background are recruited to enhance the skills for problem solving. There is no regular training of employees. |
| 19 | Quality problem solving within small teams | There are no teams with quality and production employees involved to solve quality related problems. The quality and production departments are not co-operating and have different opinions in solving problems and quality related issues. RLJ notes corroborate interview data by giving examples of many conflicts |
| 20 | Differences in treating employees | There are differences in treating production employees by production management. The HR department has developed a new assessment system in order to harmonise the treatment and assessment of employees. |

| | | |
|---|---|---|
| 21 | Employee flexibility in quality improvements | The majority of employees are in general flexible to quality improvements. There are also some production operators with low interest and involvement. |
| 22 | Customer requirements on quality | The Company takes care concerning the legal GMP requirements of the customers, but this happens not on a proactive basis by following the needs of customers. |
| 23 | Certification by customers | The Company is only occasionally certified through quality audits by customers. |
| 24 | Exchange of information regarding production processes to customers | The Company only exchanges brief information of the production processes to customers. Exchanging information with customers happens often through quality audits. |
| | *Dependable Suppliers and Quality* | |
| 25 | Communication of specifications with suppliers | The quality department has regular written communications in the form of quality contracts with quality specifications and instructions. However, there is no regular communication between the QA departments of the Company and its suppliers. Many problems and obscure understanding may occur due to the lack of communication, which is now daily practice. The printed packaging materials may be changes during the ordering process and due to the ineffective change control procedure problems occur with the ordering process. RLJ notes corroborate interview data and give examples of poor communication causing problems. |
| 26 | Quality as important criterion for supplier selection | Quality is a selection criterion, but the purchase price of materials is the most important selection criterion for suppliers. The suppliers must be audited for approval. |
| 27 | Certification and policy to select a small number of suppliers | Suppliers are certified through quality audits. Purchase price and delivery reliability are the two most important selection criteria and quality is less important. Other purchase decision criteria are good supplier relationships and the policy for obtaining strategic suppliers. There are no regular changes in suppliers, but there is no policy in keeping a small number of suppliers. |
| 28 | Policy for keeping long-term relationships with suppliers | The Company has a policy for keeping long-term relationships with suppliers. It is difficult switching to other suppliers due to the high regulations of the pharmaceutical industry. The Company has often long term supply agreements, however switching to other suppliers may be necessary in case of low supplier performance. The Company has in most cases low bargaining purchase power against his suppliers. The problem is that the source of active pharmaceutical ingredients and the manufacturing of the dosage forms are fixed in the marketing authorisation dossiers. Changes of the source must be approved by the health authorities, which take a long time awaiting for regulatory approval. |
| 29 | High quality materials from suppliers | The Company receives occasionally bulk of low quality, but these deviations (defects are mainly broken tablets |

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| | | causing problems during the packaging process) are mostly not severe enough for rejection and returning of the products to the supplier. Such deviations will only lead to sending quality complaints to these suppliers. The product rejections, which are exceptional (about 10 times a year) are due to out-of-specification results found by the QC testing laboratory. In very rare cases products are rejected during the packaging process. RLJ notes corroborate that quality problems may occur during the packaging process. Some examples are mentioned in the RLJ. |
| 30 | Supplier's ability to meeting specifications | The products receiving from suppliers meet in most cases the specifications of the Company. Products are only in exceptional cases rejected and returned to the supplier and there are only a few quality complaints. RLJ notes corroborate interview data and give some examples of quality problems of delivered products from suppliers. |
| | *Dependable Suppliers* | |
| 31 | Purchase of (bulk)materials from manufacturers and intermediate suppliers | There are three different kinds of suppliers: 1) manufacturers belonging to the same international organisation; 2) external contract manufacturers and 3) intermediate companies. Furthermore, the company has six suppliers of packaging materials and one contract packaging company as back-up to increase volume flexibility. The headquarters has a centralised corporate purchasing team for strategic suppliers for the whole international group. |
| 32 | Number of different suppliers | The Company has many different suppliers (about 90), including 30 strategic suppliers (both internal affiliates belonging to the international organisation and important external suppliers) and the remaining non-strategic 60 suppliers are handled by the local purchase department of the Company. |
| 33 | The company's requirements of suppliers | The following requirements in decreasing importance are important in purchase decisions: 1) low price, which is key in the competitive generics pharmaceutical market; 2) good delivery reliability, which means on-time deliveries with a throughput time less than 6 months and 3) quality in the sense that the supplier must meet the GMP requirements. The last criterion is due to the high regulations an order qualifier and the first two criteria are considered as order winners. |
| 34 | Delivery times of (raw)materials | The delivery time of bulk and finished packed products is 4 to 6 months, packaging materials 2 to 3 weeks for printed materials, like carton box and leaflets and 1 month for aluminium and plastic foils. However, the delivery dependability of suppliers is low and typically the mother company and its subsidiary in Ireland are the two most unreliable suppliers. These two companies have an average delivery time of more than six months. RLJ notes corroborate interview data the poor performance of these suppliers. |

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| 35 | Differences in delivery times among suppliers | There are clear differences in delivery performance among suppliers within Europe and between Europe and India. The suppliers of the southern part of Europe have longer lead-times and low delivery reliability compared to the suppliers in Belgium, Germany, UK and Scandinavia. The suppliers from India have the worst performance. The objective is to obtain lead-times from suppliers in EU countries of less than 80 working days and outside EU of less than 120 working days. Lack of good communication of the Indian, often caused by cultural differences is mentioned as the main reason of the low delivery performance of the long distance suppliers. |
| 36 | On time deliveries from suppliers | The purchased materials and products are not received in many cases on time. The estimate is that approximately 50% of suppliers are delivering on-time, but this performance may be also negatively influenced by the complex ordering system of the company. RLJ notes corroborate interview data, that may materials and products are not received on-time. |
| 37 | Flexibility of suppliers in meeting company's requirements | There are differences in flexibility among the many suppliers. Some contract manufacturers are very flexible, whereas the manufacturing plant of the mother company is very inflexible. The perception is that suppliers with short lead-times are more flexible than suppliers with long lead-times. |
| 38 | Flexibility of suppliers flexible in meeting unexpected demand | Most bulk manufacturers are inflexible to meet unexpected demand, due to the campaign production unless an increase of demand volume can be planned during the production campaign of the particular product. Sometimes, it is possible to decrease the lead-time with 3 weeks. |
| 39 | Delivery dependability on order quantities | The delivery reliability based upon ordered quantities is highly reliable in the pharmaceutical industry, since fixed standard batch quantities are a regulatory obligation. It is therefore very unusual that the Company receives products deviating from the quantities in the purchase order. |
| 40 | The delivery of the right type of materials from suppliers | The Company receives always the right bulk products from the suppliers with the exception of printed packaging materials. It may happen that superseded packaging materials are received which have been changed after placing the order. These changes are not well managed due to ineffective change control procedures. RLJ notes corroborate interview data that Indian suppliers are difficult to manage. |

The production manager and the logistics manager were interviewed to assess the pull production process, as provided in Table 4.25; see Appendix C for the questions.

Table 4.25: Results of the Semi-Structured Interview concerning Pull Production

| # | Question | Responses |
|---|---|---|
| 1 | Explanation of the company's pull production system | The Company has a mixed make-to-order and make-to-stock production planning system and this system is a push system. |
| 2 | The capability of the production system to react on the continuously changing demand of the customers | The problem of the push system is that the Company produces to schedule in anticipating of possible customer demand and consumes additional time due to quality problems. The problem is caused by the insecure forecast data and using them as trigger for entering orders into the planning system (even in case of make to-order products when customer orders are not yet received), long lead times of bulk products, the insecure status of packaging materials (due to the ineffective change control procedures) and no fixed customer order quantities are defined for starting production orders, while for bulk production orders standard batch quantities are required by suppliers. RLJ notes corroborate that the company has a complex business process for the order entry and issuing manufacturing orders. |
| 3 | The weekly planning for production, packaging and deliveries of finished products | The production planners are placing manufacturing orders based on the MRP information. The weekly planning is discussed with production management for scheduling the production lines. |
| 4 | PULL and PUSH planning and control system | There is also too much stock representing a value of 30% of the annual turnover of the Company. Despite this high stock level there are many items out-of-stock, about 4% of the product range is out-of-stock. The Company has problems to arrange a fixed production plan since it is difficult to get the materials on-time available to start the production order. |
| 5 | PULL and PUSH material flows | Production management has direct communication with the warehouse to pull the materials to production according to the weekly production plan and available stock of finished packed products packed. If the Company is able to prepare a fixed Master Production Plan with all materials available, production is more able to pull the materials to the production area directly from the warehouse. Production management has access to ERP system to view the inventory levels of finished packed products. The materials flow follows more a pull system because no orders are issued for intermediate blister products. The high speed packaging lines are on-line blister and packaging machines, so no intermediate storage is possible. The |

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| | | low speed machines are not connected and this results in intermediate storage of blistered product on the shop-floor waiting for final packaging. The off-line packaging machines are not located in the near of the blistering machines. RLJ notes corroborate that intermediate products are stored on the production shop-floor and this has caused problems due to a shortage of bins for storing the intermediate products. |

*Assessing TBM Practices, feedback and suggestions for improvements*

The interim action research report describes the diagnosed TBM practices, based on the interviews and RLJ, and provides suggestions for improvements. Feedback from participants of the KPI circle meeting was received after issuing the interim report in February 2008 and used as additional information for the diagnosis. The outcome of the diagnosis is that none of the seven TBM practices are well developed. However, the maintenance of machines is proactively performed by engineers, but the production operators are rarely involved in the maintenance activities. Although the Company must meet the high quality standards of the pharmaceutical industry, its quality management system is weakly developed towards a company wide system (Total Quality Control). The Company installed a KPI measurement system and this makes it possible to follow the progress of the manufacturing performance during the implementation of the TBM practices. Adopting lean practices by removing non-added value steps in business processes and moving towards Total Quality Control, training of employees, seeking cooperation with important suppliers and improving the ordering system are the first steps towards implementation of TBM practices. The suggestions for improvement including the instalment of the four workgroups were discussed and agreed in a meeting with all management team members involved in November 2007. These workgroups were installed in order to improve the total throughput time and represent the four main problem areas defined during the diagnosis, as shown in Figure 4.6.

Figure 4.6: The Major Areas for Improvement of the Entire Process Chain

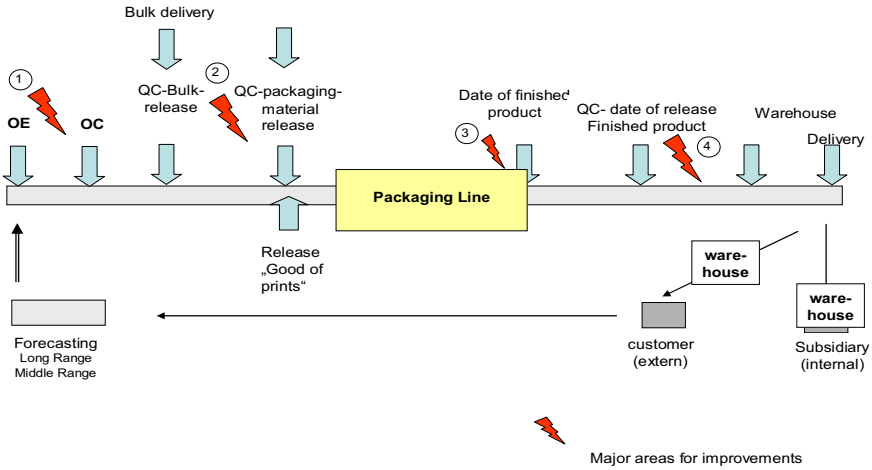


Table 4.26 presents 12 suggestions mentioned in the interim case report to reduce the throughput time by the workgroups.

Table 4.26: KPI Workgroups with Suggested Actions to Decline the Throughput Time.

| Workgroup | Objective | Actions |
|---|---|---|
| Workgroup WLD (logistics and document control departments) | Improvement of the order entry process | • Process mapping of the order entry process<br>• Integration of document control department within logistics<br>• Standardisation of packaging materials |
| Workgroup WLQ (logistics and quality departments) | Improvement the internal material flow until start production | • Sampling immediately after receipt of materials<br>• Reduction of the weighing of bulk products before packaging<br>• Increase of QC-laboratory capacity and reduction of QC-testing |
| Workgroup WPE (production and engineering departments) | Improvement of the production process | • Training of the production operators to improve set-up times, maintenance and quality<br>• Improving employee scheduling and utilisation<br>• Increase of efficiency of production lines<br>• Measuring OEE on production lines |
| Workgroup WPQ (production, quality and engineering departments) | Streamlining the process of releasing finished packed product | • Elimination of non-added value steps after production<br>• Developing a system for handling quality deviations for corrective and preventive actions |

### 4.2.2 IMPLEMENTATION PHASE OF CASE COMPANY 2

The implementation phase started in January 2008 with the instalment of the four KPI workgroup and ended in December 2008. The improvement path has been continued after my research and the KPI workgroups are still in operation, as the Case Company is aiming for continuous improvement.

Participants from several departments were interviewed to assess the improvement gains of the implementation phase at the end of the research project. The questionnaires contain also Likert-scale questions. Table 4.27 presents the results of the Likert-scale questions of 6 TBM constructs obtained from interviews of participants of the production, engineering and logistics departments.

Table 4.27: Results of the Likert-scale Questions of the Semi-Structured Interviews of Case Company 2

| Construct (number of interviews) | No. of items | Mean | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| Shop-employee involvement in problem-solving (n = 6) | 5 | 3.40 | 1.07 | 0.54 |
| Batch changeover/set-up (n = 6) | 9 | 2.98 | 0.27 | 0.95 |
| Standardised manufacturing (n = 6) | 8 | 3.98 | 0.30 | 0.94 |
| Preventive maintenance (n = 6) | 6 | 3.94 | 0.29 | 0.97 |
| Dependable suppliers (n = 4) | 16 | 3.19 | 0.25 | 0.99 |
| Pull production (n = 7) | 4 | 1.14 | 0.24 | 0.97 |

One question of the questionnaire relating to the preventive maintenance "*We have regularly breakdowns on our machines*" was excluded from the analysis. The answers

on the open question revealed that the Company has regularly breakdowns. This is not the result of poor maintenance of machines, but due to the lack of technical skilled and trained production operators. Thus this question relates more to the construct concerning shop-floor employee involvement in problem solving. Tables 4.28 and 4.29 present the results of the open questions with the information of the achieved improvements for shop-floor employee involvement in problem-solving and the three constructs of the process design; see Appendix G for the questionnaire. Six managers and supervisors of the production and engineering departments were interviewed in December 2008.

Table 4.28: Results of the Semi-Structured Interviews on Shop-Floor Employee Involvement in Problem Solving of Case Company 2

| # | Question | Responses on improvements made and secondary data |
|---|---|---|
| 1 | Shop-floor employees involvement in solving problems | 3 out of 6 participants confirmed that there is some improvement of the employee involvement in problem solving. Other participants mentioned that there are no improvements. Improvement was achieved due to the recruitment of new technical skilled operators, but the problem solving skills of the current employees didn't improve. RLJ notes and KPI workgroup minutes corroborate interview data that the problem solving skills of the production operators are weakly developed and therefore the Company is developing a training programme. |
| 2 | Shop-floor employees involvement in group meetings | All participants mentioned that group meetings take occasionally place and mentioned that this is insufficient. Examples of improvements discussed in these meetings are the introduction of reporting and documenting technical breakdowns and performing in-process controls before the restart of the process after breakdowns. KPI workgroup minutes corroborate interview data that the reporting of technical breakdown improved. |
| 3 | Shop-floor employees involvement in making new products | 2 out of 6 participants confirmed that there is improvement, but the others mentioned that there are no improvements made. |
| 4 | Shop-floor employees are involved in improvement efforts. | All participants mentioned that the production operators are increasingly involved in improvement efforts. Some examples were given by the participants. |
| 5 | Shop-floor employees are involved in problem solving teams. | 4 out of 6 participants mentioned that the production supervisors and engineers are involving the production operators when problems are being solved. This aspect has been improved. |

Table 4.29: Results of the Semi-Structured Interview on Process Design of Case Company 2

| # | Question | Responses on improvements made and secondary data |
|---|---|---|
| | *Batch Changeover/Set-up* | |
| 1 | Support from engineering department | 5 out of 6 participants mentioned that this aspect improved but the production operators still need technical support from engineering. The improvements are due to the recruitment of new skilled operators, the development of manuals with instructions for the set-up and the better organisation of the fixed production plan. |
| 2 | Motivation to improve set-up times | The participants mentioned that there is a start made for improvement, but the current production operators, except the new recruited ones are not motivated to improve set-up times. |
| 3 | New set-up method of new machines and processes | All participants mentioned that this has been improved and that manuals of all machines are made by the engineering department. Instructions will be made when new equipment are installed. RLJ notes and KPI workgroup minutes corroborate interview data that manuals and instructions of all machines, including new machines have been made. |
| 4 | Shop-floor employees improvement of set-up times | All participants mentioned that this has been improved by the recruitment of new skilled operators and the developed manuals. This is at the early stage, since production operators must be still trained to improve the set-up of machines. |
| 5 | Location of tools | All participants mentioned that this has been improved and that special closets for storing the tools needed for the set-up are placed in the near of each packaging line. It is mentioned that the operators must be trained to use the tools properly according to the SMED technique for further improvement of the set-up of machines. RLJ notes and KPI workgroup minutes corroborate interview data that the location of tools in the near of machines has been arranged. |
| 6 | Adjustment of equipment to shorten set-up times | Three out of six participants mentioned some improvement of the set-up times by giving an example of an adjustment of equipment. |
| 7 | Special tools to shorten set-up times | All participants mentioned that no special tools are used to shorten set-up times. |
| 8 | Jigs or fixtures used to shorten set-up time | Examples were given of fixtures, for example pushers and jigs to fasten, coding and open boxes during the packaging process and colour signs on equipment for easy set-up. |
| 9 | Training of shop-floor employees to shorten set-up times | All participants mentioned that production operators do not receive special training to shorten set-up times. The Company has developed a SMED list defining 28 activities during a set-up between two batches and this list will be used for the development of the training programme, beginning next year. RLJ notes and KPI workgroup minutes corroborate interview data that a |

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| | | SMED instruction for the high speed packaging lines has been developed. |
| | *Standardised Manufacturing* | |
| 1 | Grouping of products on basis of the shape or process requirements | All participants mentioned that significant improvements have been made in grouping products by improving the production planning and standardisation of materials. RLJ notes and KPI workgroup minutes corroborate interview data that efforts were taken for the standardisation of packaging materials. |
| 2 | Coding classification | All participants mentioned that improvements have been made by using coding for products, sizes and materials to cluster products in the production planning process. RLJ notes and KPI workgroup minutes corroborate interview data that the production planning process improved and a coding classification is used to group similar products. |
| 3 | Location of machines and equipment to group families of products | All participants mentioned that this aspect did not improve. The lay-out of the factory and location of machines did not change. |
| | *Preventive Maintenance* | |
| 1 | Preventive maintenance on machines | All participants mentioned that preventive maintenance has been improved. All machines are running with less technical breakdowns. Preventive maintenance will be performed every year. A routine checklist for preventive maintenance on the high speed production lines were developed with support of engineers from the machine supplier. KPI workgroup minutes corroborate interview data that preventive maintenance is regularly performed according to an annual maintenance plan. |
| 2 | Emphasis on preventive maintenance | All participants mentioned that this aspect has been improved. In the past the machines were in operation until a breakdown happened. Maintenance are now performed when a problem seems to occur before the breakdown can happen. Machinery parts are now regularly replaced. KPI workgroup minutes corroborate interview data that an annual preventive maintenance plan for all machines is developed. |
| 3 | Records of routine maintenance | Participants mentioned that the usage of computer system for storing maintenance data by engineers are only slightly improved. |
| 4 | Preventive maintenance during non-productive time | All participants mentioned that engineers are regularly performing maintenance during nights, weekends or when the machines are not in operation during regular production time. |
| 5 | Regular maintenance of equipment | 5 out of 6 participants mentioned that equipment are regularly maintained. The machines are every week lubricated with oil by engineers. RLJ notes corroborate interview data that engineers perform pro-active maintenance and inspections during the set-up in which parts are regularly replaced. |
| 6 | Occurrence of | All participants mentioned that the occurrence of |

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| | machinery breakdowns | breakdowns is declining through the recruitment of better skilled operators, grouping of products and development of standardised instructions for the set-up. The engineering department is still mostly involved to solve the technical disturbances, but production operators begin to solve small disturbances of machines. |

The quality assurance manager, the quality control manager and two quality consultants were interviewed in December 2008. Table 4.30 presents the results of the Likert-scale questions and Table 4.31 presents the results of the open questions with the information of the achieved improvements; see Appendix E for the questionnaire. Table 4.31 includes also the achieved improvements of the dependable suppliers from the perspective of the logistics manager and three purchasers from his department. Six items (no. 17 – 22) are overlapping issues relating to both constructs and were asked to eight participants from both the quality and logistics departments.

Table 4.30: Quality Management System Variable Characteristics of Case Company 2

| Construct | No. of items | Mean Scores | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| Top Management Support | 5 | 3.15 | 0.34 | 0.92 |
| Quality Information | 2 | 3.75 | 0.50 | 0.86 |
| Process Management | 7 | 3.33 | 0.49 | 0.94 |
| Product Design | 2 | 3.33 | 0.41 | 0.96 |
| Workforce Management | 5 | 3.30 | 0.76 | 0.87 |
| Customer Involvement | 3 | 3.47 | 0.50 | 0.89 |
| Supplier Involvement | 6 | 3.32 | 0.26 | 0.96 |

Table 4.31: Results of the Semi-Structured Interview concerning Quality Management System and Dependable Suppliers

| # | Question | Responses on improvements made and secondary data |
|---|---|---|
| | *Quality Management* | |
| 1 | Top management support for quality | All participants confirmed that there is some support from top management for quality. The major support was the agreement to hire quality consultants. RLJ notes corroborate interview data. |

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| 2 | Quality seen as central theme within the organisation | All participants confirmed that there is no improvement, quality is still seen as a burden. |
| 3 | Active role in quality improvements and communication by top management | Two participants mentioned that top management has a supportive role in quality improvements, but has no active role. The other two participants mentioned no improvement on this aspect. |
| 4 | Organisational culture on quality | All participants mentioned that there is only a small improvement and this is growing. |
| 5 | Rewards of quality results | All participants mentioned that this aspect didn't change. |
| 6 | Communication of quality results and feedback | Two participants mentioned that the communication and feedback on quality has been improved, but not all departments are involved. The developed deviation management system improved this aspect. RLJ notes and KPI workgroup minutes corroborate interview data that the communication improved through a deviation management system and KPI workgroups discussing quality results and problems. |
| 7 | Key performance indicators for quality | All participants mentioned that this was improved, but this is at an early stage. RLJ notes and KPI workgroup minutes corroborate that the Company has introduced a deviation reporting system, which can be used as quality performance indicator. |
| 8 | Implementation of processes to prevent possible defects caused by employees | Two participants mentioned that this was improved, but this is at an early stage. Some examples were given of initiatives to prevent employee's errors. RLJ notes and KPI workgroup minutes corroborate that the development and change process of packaging materials improved to prevent the use of superseded materials. |
| 9 | Quality control charts | All participants mentioned that this aspect didn't change. RLJ notes and KPI workgroup minutes corroborate that the company wants to improve the in-process controls during the production process in order to eliminate the quality inspection on the finished packed product after packing. |
| 10 | Validation of production machines | Two participants mentioned that this was improved. The engineering department started with the validation of machines. KPI workgroup minutes corroborate that the engineering department has developed a validation plan for machines and started with the validation. |
| 11 | Authorisation to stop the production process | Two participants mentioned that production operators are authorised to stop the production process in case of detected quality defects, but production operators must be further trained to improve this aspect. |
| 12 | Cleanliness of machines and the shop-floor | All participants mentioned that this aspect didn't change. |
| 13 | Slow speed production process in order to guarantee quality | Two participants mentioned that this aspect improved. RLJ notes corroborate interview data that the emphasis is to prevent quality instead of running at high speed production with quality problems. |

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| 14 | Development of new products | All participants mentioned that this aspect didn't change and this aspect is underdeveloped. There is only an attempt to bring more structure in the introduction of new products. KPI workgroup minutes corroborate that the improved process of developing packaging materials will help to bring more structure in the development of new products. |
| 15 | Role of customers and suppliers in the development of new products | All participants mentioned that this aspect didn't change and there are rarely contacts with customers on this aspect. |
| 16 | New product development teams | Two participants mentioned that there is some slight improvement in discussing new products in teams and this is at an early stage. |
| 17 | Quality meetings with employees | All participants mentioned that this aspect significantly improved. There is a workgroup installed to discuss quality relating issues and to introduce tools for quality improvement, for example reporting and handling quality deviations according to Ishikawa and reporting technical disturbances more accurate. Furthermore, there are regular meetings organised with managers from quality and production departments. RLJ notes and KPI workgroup minutes corroborate that this aspect significantly improved due to the aid of the quality consultants and KPI workgroups. |
| 18 | Recruitment and training of employees | All participants mentioned that the training of employees didn't improve. A training programme for production employees is under development. This training will start in January 2009. RLJ notes and KPI workgroup minutes corroborate interview data that there is a lack of skills and a training programme is developed to enhance the technical and quality related skills of production operators. |
| 19 | Quality problem solving within small teams | 3 out of 4 participants mentioned that this aspect improved with aid of the quality consultants. RLJ notes corroborate that quality problems are better communicated and solved within small teams due to the support of quality consultants. |
| 20 | Differences in treating employees | All participants mentioned that this aspect improved and that employees of different departments are simultaneously involved to solve problems through the introductions of the KPI workgroups. |
| 21 | Employee flexibility in quality improvements | All participants mentioned that employees are flexible to improve quality, although there was also mentioned that there are differences between departments. Some departments are less flexible. |
| 22 | Customer requirements on quality | 3 out of 4 participants mentioned that this aspect didn't change. |
| 23 | Certification by customers | All participants mentioned that the Company is rarely certified by its customers. |
| 24 | Exchange of | 2 out of 4 participants mentioned that this aspect |

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| | information regarding production processes to customers | approved. There are regular meetings organised with customers to discuss operational processes. |
| 25 | Bottlenecks of the quality system | All participants mentioned that the document management system, including SOPs and the training of employees as the main bottlenecks. |
| 26 | Barriers for further improvement of the quality management system | Lack of trained employees, insufficient documentation and poor management were mentioned as barriers for improving the quality management system. |
| | *Dependable Suppliers and Quality* | |
| 27 | High quality materials from suppliers | There are different opinions, some participants mentioned improvement, others mentioned no progress. |
| 28 | Supplier's ability to meeting specifications | All participants mentioned that this aspect didn't change. RLJ notes and KPI workgroup minutes corroborate interview data and provide examples that quality problems caused by suppliers have a negative impact on the delivery performance of the Company. |
| 29 | Communication of specifications with suppliers | All participants mentioned that this aspect didn't change. RLJ notes corroborate interview data that the Company performs double QC tests and supplier quality audits are rarely performed. Audits lead to better communication of the company's quality requirements and possibly the reduction of QC testing. |
| 30 | Quality as important criterion for supplier selection | All participants mentioned that this aspect didn't change. Price is most important and examples were given of suppliers with quality problems affecting the business despite the lower prices. |
| 31 | Certification and policy to select a small number of suppliers | Only one participant mentioned an improvement, but the others mentioned no progress. RLJ notes corroborate interview data that the Company doesn't regularly perform supplier quality audits. |
| 32 | Policy for keeping long-term relationships with suppliers | The participants of the quality department mentioned that this aspect didn't change, but the purchasers confirmed to strive for long-term relationships with suppliers. It is difficult to switch to other suppliers due to the high regulations of the pharmaceutical industry. |
| | *Dependable Suppliers* | |
| 33 | Number of different suppliers and reduction. | All participants mentioned that there is no policy to reduce the amount of suppliers; in fact the number of suppliers is growing. |
| 34 | The company's requirements of suppliers | All participants mentioned that this aspect didn't change and the Company has a low bargaining power towards its suppliers. The Company introduced recently a vendor-rating system. RLJ notes and KPI workgroup minutes corroborate interview data that the company has installed a vendor rating system and started to communicate the performance results with suppliers. |
| 35 | Lead times of (raw)materials | All participants mentioned that the lead-times of materials from suppliers improved. The purchase ordering process improved and resulted in increased |

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| | | supplier performance; orders are only placed if all necessary information is complete. The purchasers invested in acquiring good supplier relationships. Results of the Company's vendor rating system of December 2008 corroborate interview data that the supplier lead-times have been declined. The on-time delivery rates have only slightly been improved. |
| 36 | Differences in delivery times among suppliers | All participants mentioned that the differences among suppliers didn't change. RLJ notes and KPI workgroup minutes corroborate that contract manufacturers have better performance compared to the subsidiaries belonging to the same international group. |
| 37 | On time deliveries from suppliers | 3 out of 4 participants mentioned that the supplier performance improved. Results of the Company's vendor rating system of December 2008 corroborate interview data that the supplier lead-times have been declined. The on-time delivery rates have only slightly been improved. |
| 38 | Flexibility of suppliers in meeting company's requirements | All participants mentioned that this aspect didn't change. There are differences in flexibility of the different suppliers. RLJ notes and KPI workgroup minutes corroborate that companies belonging to the same international group are not flexible to meeting the requested changes to streamline the order processes and material flows. The suppliers of packaging materials are flexible to introduce EDI system and improving the design process of packaging materials. |
| 39 | Flexibility of suppliers in meeting unexpected demand | 2 out of 4 participants mentioned that the flexibility in meeting unexpected demand improved. |
| 40 | Delivery dependability on order quantities and right type of materials | All participants mentioned that order quantities and deliveries of the right materials are always accurate. |

Process maps were developed of the current and desired ideal processes. These process maps were used as input for several workgroup meetings for improving the business processes. Table 4.32 shows the mapped processes and the achieved improvements of the throughput process.

Table 4.32: Mapped Processes and Achieved Improvement Gains

| # | **Process** | **Major improvement gains** |
|---|---|---|
| 1 | Order entry process | A standardised process of the customer order entry with defined lead-times for each process step has been developed and agreed by all customers. This resulted in a clear and efficient order process and increased delivery reliability of the Company. |

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| 2 | Purchase of bulk product and packaging materials | The process of placing purchase orders has been simplified and this helped to improve the supplier performance. |
| 3 | Issuing manufacturing orders | The process of issuing manufacturing orders has been simplified through the reduction of internal lead-times, increase of the availability and clear status of the availability of materials, the security of complete information of customer orders and standardisation of lead-times. Further improvements will be achieved when the process of issuing manufacturing orders are designed according to the desired process map with the introduction of a new ERP system. |
| 4 | Starting new products - entry of master production data in ERP | The process of collecting and entering master data has been improved for products of external customers according to the new process map, by entering the data as soon as available by the departments involved instead of entering the data by one central document control department later in the process when all data are gathered. This process led to a reliable process and it speeded up the starting of new products. The process is also better coordinated by the logistics department. The process of starting up new products for the internal customer (make-to-stock products) didn't change and this is still under consideration. |
| 5 | Changing printed packaging materials | The improvement of changing printed packaging materials is better under control resulting in increased material availability and less repack of products with superseded packaging materials. |
| 6 | Incoming bulk product | This process has been improved by the workgroup WLQ; see table 4.33 |
| 7 | Process after packing until shipment | This process has been improved by the workgroup WPQ; see table 4.33 |

26 KPI circle meetings for identifying problem areas in the throughput process and 81 KPI workgroup meetings for implementing improvements took place during the AR project. Table 4.33 presents the improvements identified in the minutes of these meetings and the RLJ data.

Table 4.33: Improvement Gains Obtained through the KPI Workgroups

| Workgroup | Major improvements |
|---|---|
| Workgroup WLD (21 meetings) | • 26 process maps of (sub)processes and material flows were developed and identified improvement areas, as presented in Table 4.32.<br>• The integration of the logistics and document control departments |

| | |
|---|---|
| Improvement of the order entry process | for issuing production documents and developing printed packaging materials resulted in streamlined order processes, better handling of new products and product changes, increased availability of materials and reduction of suppliers lead-times.<br>• Packaging materials have been standardised resulting in lower batch changeover times, increased machine efficiency, decreasing purchase costs.<br>• The control of master production data, including a numbering system for issuing production documents has been improved, resulting in increased grouping of similar products. |
| Workgroup WLQ<br>(19 meetings)<br><br>Improvement the internal material flow until start production | • Streamlining the receipt of incoming goods and sampling of materials saved the Company two weeks of the internal throughput time. Shop-floor employees in the warehouse have direct contact with suppliers to plan and organise the receipt and sampling of materials in order to finish these activities within 24 hours after receipt.<br>• Elimination of the weighing of bulk product before the start of production improved the materials flow towards production. The quantities per container are known at the receipt and this avoids the weighing step of bulk, unless a low quantity less than one container is needed for a production order. This elimination saved the Company also a lot of working hours in the warehouse.<br>• Improvement of the QC testing throughput time due to the streamlined processes in the warehouse because 1) quality problems are identified early in the process; 2) fast sampling leads to better planning and clustering the QC testing. Release of the bulk product was a major bottleneck of the entire throughput process and this bottleneck has been eliminated without the need to outsource QC testing to contract laboratories, as originally planned. The internal QC throughput time reduced from 7 weeks at the top of the bottleneck to less than 3 week by the end of 2008.<br>• Instalment of a vendor-rating system in order to improve the purchase ordering process and supplier performance. |
| Workgroup WPE<br>(20 meetings)<br><br>Improvement of the production process | • Development of the training programme to improve the technical skills and quality knowledge of production operators.<br>• Development of a SMED list to be included in the training programme.<br>• Development of manuals for operating the production lines, including the set-up.<br>• Storing system for dedicated tools needed for the set-up.<br>• Engineering department performed validation and preventive maintenance of machines. Although the annual production volume increased by 25% in 2008 less technical breakdowns of machines occurred. |
| Workgroup WPQ<br>(21 meetings)<br><br>Streamlining the process of releasing finished packed product | • The instalment of a system for reporting quality deviations resulted that quality department improved the decision making for releasing the product when defects in productions are observed. The production department is forced through this system to investigate the problem and propose corrective and preventive actions during or immediately after production. This resulted in a decrease of 2 weeks of the internal throughput time by the end of 2008. |

| | |
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| | • Quality department approved the plan that production takes samples when the production operators effectively perform the in-process controls during the packaging process. This will eliminate the step of inspecting and sampling by QC personnel after packing. The improvement of in-process controls will be included in the training of the production operators, started beginning 2009. |

### 4.2.3 INFORMATION SYSTEMS OF CASE COMPANY 2

Four participants (IT manager, logistics manager, finance manager and the business analyst) were interviewed between March and May 2008 to assess the company's IS. 36 participant observations stored in the RLJ and 33 minutes of KPI workgroup meetings contain additional data of the IS. Table 4.34 presents the results of the Likert-scale questions and Table 4.35 presents the results of the open questions; see Appendix D for the questionnaire, including the corroboration with the data stored in the RLJ and minutes of the KPI workgroup meetings.

Table 4.34: Information Systems Variable Characteristics of Case Company 2

| Construct | No. of items | Mean Scores | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| I.S. strategic planning effectiveness | 4 | 2.56 | 0.85 | 0.83 |
| I.S. responsiveness to organisational computing demands | 4 | 3.31 | 0.77 | 0.83 |
| End-user training effectiveness | 2 | 2.25 | 0.29 | 0.86 |
| End-user computing skill | 3 | 3.25 | 0.50 | 0.91 |
| Cross-functional involvement (in I.S. related activities) | 5 | 2.75 | 0.87 | 0.75 |
| End-user involvement (in I.S. related activities) | 5 | 2.70 | 0.35 | 0.90 |
| I.S. performance | 5 | 3.60 | 0.28 | 0.94 |

IS performance, IS responsiveness to organisational computing demand and end-user computing skills and are the best developed IS practices, whereas the end-user training

effectiveness and IS strategic planning effectiveness are the weakest practices. The cross-functional involvement has a low IRR meaning that the participants have no common view in rating this construct. Table 4.35 gives some indication that the implementation of TBM practices will lead to improvements of the Company's IS.

Table 4.35: IS Characteristics of Case Company 2 - Results of the Semi-Structured Interviews

| # | Question | Responses – interviews and secondary data |
|---|---|---|
| | *Strategic planning effectiveness* | |
| 1 | IS strategy and objectives | There is no clear strategy defined which is linked to the business strategy of the company. RLJ notes indicate that the Company is developing an IS strategy which is based on the planned implementation of a new ERP system. A steering committee of the ERP implementation project has been installed. |
| 2 | Procedures and instructions defining the scope of IS functionalities | There are rarely procedures developed for the scope of IS functionalities. RLJ notes and minutes of workgroup meetings corroborate that this aspect is changing, for example process maps were made by some departments to define the future IS functionalities supporting the improved business processes, but procedures and instructions are not yet developed. |
| 3 | Improvement of business processes due to IT project | There were some examples given of improvements, for example the introduction of the master production plan to integrate the planning of the logistics and production departments. However, improvements are often stand-alone solutions without viewing the integrated approach and foreseeing the consequences for all business processing. RLJ notes and minutes of workgroup meetings provide examples of IS improvements. Issuing shop-floor production documents and the development of process maps of all operational processes giving an integrated approach of new business processes are examples. |
| 4 | Policies and procedures defining the scope of IS responsibilities | There are no written procedures developed for the scope of IS responsibilities. |
| | *Responsiveness to organisational computing demand* | |
| 5 | Resolving software applications problems | The IT department is able to solve problems and this is improved with the start of the helpdesk of |

| | | |
|---|---|---|
| | | the IT department for helping users. |
| 6 | Responsiveness to end-user questions and concerns. | The responsiveness to end-users in case of questions and problems is high and has significantly been improved. RLJ notes and minutes of workgroup meetings corroborate the improved responsiveness, for example the KPI data are automatically generated through the adjustment of the IS and the possibility of placing purchase order with EDI to suppliers and adjustment of the IS to support the integration of the receipt and sampling processes in the warehouse. |
| 7 | Implementing software application upgrades | Software updates are regularly installed. |
| 8 | Resolving computer network problems | There are rarely network problems, although users often complain of the low speed of the network. |
| | *End-user training effectiveness* | |
| 9 | Formal class room training on existing IS. | There are no formal class room training for existing and new software applications. |
| 10 | On-the-job training on how on existing IS | New employees receive on-the-job training from colleagues of the same department. There are rarely training manuals for on-the-job training available. |
| | *End-user computing skill* | |
| 11 | High end-user productivity when using new installed IS | There were examples given of higher user productivity, for example the introduction of the master production plan. The electronic system of managing quality documents has a low end-user productivity. RLJ notes corroborate interview data regarding the use of the KPI measurement system and master production plan and the ineffective operating quality documentation system. |
| 12 | End-user skills in the use of manufacturing information technologies and computer based-technologies. | The following examples were mentioned:<br>• Production planners have good skills to use the ERP system;<br>• The employees of the Print-shop have good skills, it is foreseen that the software for printing packaging materials will be connected with ERP system:<br>• The automatic weighing system in the warehouse is connected to the ERP system.<br>• Performance analyser software for measuring OEE on the production lines will be installed and connected to the ERP system.<br>RLJ notes and minutes of workgroup meetings corroborate the above examples of the interview data. |
| 13 | End-user capability of completing routine work assignments requiring the use | The production planners have good capabilities to perform routine work assignment with the new installed master production planning system. RLJ |

| | | |
|---|---|---|
| | of new installed IS | notes and minutes of workgroup meetings corroborate interview data. The weekly reporting system to measure the QC backlog of incoming goods and finished products after production is an example of a routine work assignment. |
| | *Cross-functional involvement* | |
| 14 | Departmental involvement in the development of IS policies and procedures | All participants mentioned that there is often a lack of departmental involvement. The laboratory information management system (LIMS) is given as an application not involving other departments. This resulted in the absence of the integrated approach and deterred the business processes of other departments. The KPI workgroups have a positive effect on the departmental involvement when IT solutions are proposed. RLJ notes and minutes of workgroup meetings corroborate interview data, for example that the warehouse employees have access to LIMS of the QC department. |
| 15 | Departmental involvement in the integration of IS planning activities | Departmental involvement in the integration of IS planning activities is low. There was an example given of the introduction of the master laboratory plan as extension of the master production plan. Several departments are involved in one of the KPI workgroups. It was mentioned that the planned implementation of the new ERP system will require an integrated approach involving all departments. RLJ notes minutes of workgroup meetings corroborate interview data that the departmental involvement is increasing. Examples are: the master production plan, involvement of users in the planning of the new ERP system and the integration of the receipt and sampling processes in the warehouse. |
| 16 | Departmental involvement in the prioritisation of IS related activities | There is no clear structure of involving departments for making priorities of IS activities. |
| 17 | Departmental involvement in the integration of software applications | The departmental involvement in the integration of software applications has been improved through the KPI workgroups. The following examples were mentioned:<br>• ERP and LIMS;<br>• ERP and software of the Print-shop;<br>• Vendor-rating system;<br>• Master production plan.<br>RLJ notes corroborate interview data by providing the same examples. |
| 18 | Departmental involvement in solving software application problems. | Departments are not simultaneously involved in solving software problems. RLJ notes and minutes of workgroup meetings do not corroborate interview data. Some examples of |

| | | |
|---|---|---|
| | | departmental involvement in solving software application problems are given. |
| | *End-user involvement* | |
| 19 | End-user involvement in the development of IS | There is some involvement of end-users in the IS development. Production employees are less involved. RLJ notes corroborate interview data, but the involvement is increasing. For example, meetings with IT department occurred to discuss the installation of OEE software on packaging lines. |
| 20 | End-user involvement in the analysis and opportunities of IS | There is low end-user involvement in the analysis and opportunities of IS. RLJ notes and minutes of workgroup meetings corroborate interview data, but this is changing. End-users are involved to investigate the possibilities of using new software to lower development time of printed packaging materials in co-operation with the supplier. |
| 21 | End-user involvement in the testing of IS | End-users are not always involved in testing new IS. Sometimes new IS are installed and tested by the IT department without end-user testing. RLJ notes corroborate interview data, but an example is given of testing IS in a pilot project of issuing automatically issuing expiry dates from LIMS into ERP system by end-users. |
| 22 | End-user involvement in the development of IS application. | Standard software is in most cases installed with low end-user involvement. Departments are only involved with the development of interfaces between systems. This aspect has been improved through the KPI workgroups. RLJ notes corroborate interview data, for example the inefficient operating quality documentation system. |
| 23 | End-user involvement during the company's IS project | There were examples mentioned high end-user involvement in the IS project. The end-users are only in some cases involved in selecting the software application but they rarely involved in the technical implementation resulting in lower effective use of the IS application. RLJ notes do corroborate interview data. |
| | *Information systems performance* | |
| 24 | End-user satisfaction with new installed IS | End-users are generally satisfied when using new installed IS. RLJ notes corroborate interview data. The new vendor rating system and the master production plan are good examples with satisfied end-users. |
| 25 | Enhancing decision making by using new IS. | The introduction of a new master production planning system is a good example of improved decision making of the production planning department. RLJ notes corroborate interview data and the installation of the KPI and vendor-rating systems will enhance user decision making. |

| | | |
|---|---|---|
| 26 | End-user recognition of new installed IS benefits. | End-users do not always recognise the benefits of new installed IS. RLJ notes do not corroborate the interview data. For example, it was well recognised that the integration of the processes in the warehouse needed to be supported with IS to obtain the benefits. |
| 27 | Improvement of managing manufacturing activities by the use of new installed IS. | Production is rarely automated. The production planning, including the issuing of production shop-floor documents is an example of improving manufacturing activities. |
| 28 | End-user expectations of new installed IS | End-users often expect more improved results when using new installed IS. |

### 4.2.4 WORK SYSTEM PRACTICES OF CASE COMPANY 2

A survey was conducted on 13 informants from the shop-floor or who are acquainted with the shop-floor practices at the end of the AR project; see Appendix F for the questionnaire. 69 participants observations stored in the RLJ and minutes of the workgroups were also collected which provided additional detailed information. Table 4.36 presents the results of the Likert-scale questions.

Table 4.36: Work System Practices Variable Characteristics of Case Company 2

| Construct | No. of items | Mean Scores | Standard deviation | Interrater reliability (IRR) |
|---|---|---|---|---|
| Integration | 8 | 3.28 | 0.30 | 0.93 |
| Routine Use | 6 | 4.20 | 0.34 | 0.96 |
| Formalisation | 4 | 3.98 | 0.72 | 0.73 |
| Standardisation | 5 | 3.10 | 0.65 | 0.86 |

The results show that routine use (repetitively performing tasks) and formalisation are the best developed work system practices. However, the formalisation score is inaccurate due to the low IRR score. Since the Company must meet the pharmaceutical requirements, many standard operating procedures exist. There is a lack of training of these procedures and this may cause unawareness of these procedures resulting in the low IRR score. The high score of the routine use may be explained, because the

Company has a simple production process, in which the production operators perform the same work on a daily basis. RLJ notes corroborate that the integration improved due to the several KPI workgroups involving different departments simultaneously. Standardisation has the lowest score, but the Company has a high standardisation of making products and this has been improved due to the developed operating manuals for machines and equipment. RLJ notes corroborate that the Company has low standardisation in assessing the output performance of the production shop-floor. OEE measurement of machines, worker and production management productivities are not measured.

### 4.2.5 MANUFACTURING PERFORMANCE DATA OF CASE COMPANY 2

The delivery dependability, the order cycle time and the throughput times of the value – added business processes were collected as manufacturing data on a weekly basis as manufacturing data and discussed in the KPI circle meetings twice a month. Table 4.37 presents the average performance data measured in 2007 and 2008.

Table 4.37: Delivery Performance Data in 2007 and 2008

| Period | Order cycle time (in weeks) | Aggregated throughput time (in weeks) | On-time deliveries (average time in weeks after promised delivery date) | On-time deliveries (% of orders on time) |
|---|---|---|---|---|
| 2007 | 22.6 | 29.4 | 2.1 | 60.8% |
| 2008 | 20.6 | 26.0 | 0.6 | 85.3% |

The average cycle time is 22.6 weeks in 2007 and 60% of the orders are delivered on-time with an average delay of 10 working days. The delivery performance improved in 2008 with an average order cycle time of 20.6 weeks and 85% of the orders are delivered on-time with an average delay of 3 days. The aggregated throughput time was measured of all make-to-order and make-to-stock orders together by aggregating the days needed for each order from purchasing materials until receipt, from receipt and

testing the materials by quality control, from packing the product and releasing the final product either for shipment to the external customer (make-to-order) or replenishment of stock in the warehouse (make-to-stock). Figures 4.7 and 4.8 present the time series analysis of the order cycle time and the aggregated throughput time, showing that improvements were made in the last months in 2008 compared to 2007.

Figure 4.7: Time-Series Analysis of the Order Cycle Time of Case Company 2

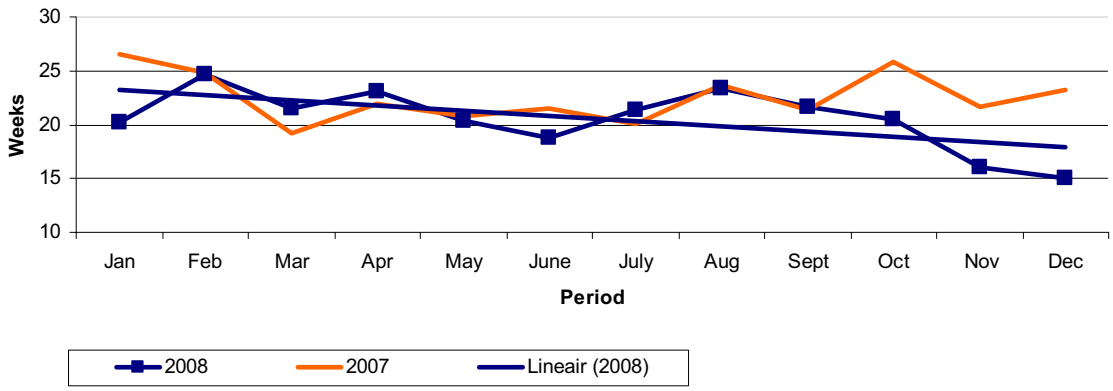



Figure 4.8: Time-Series Analysis of the Aggregated Throughput Time of Case Company 2

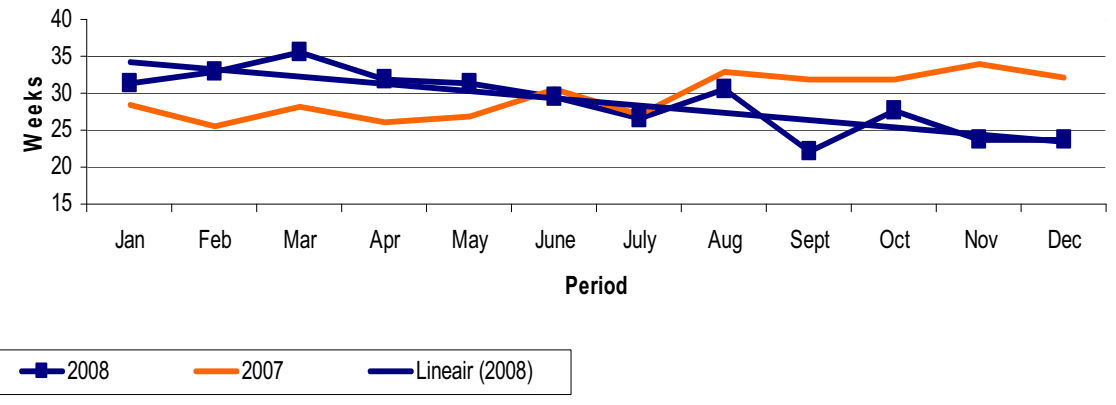
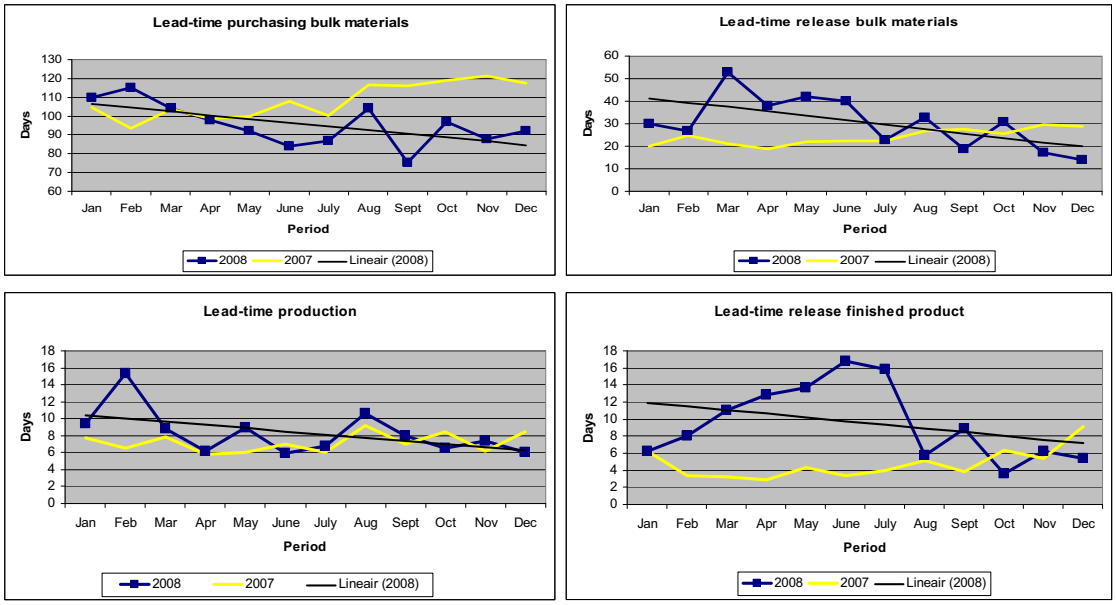



Figure 4.9 shows the pictures of the time-series analysis of each business process. Major improvements were made in the purchase of materials from suppliers.

Figure 4.9: Time-Series Analysis of Throughput Times of Value-Added Business Processes




The other business processes also show a decreasing trend in 2008, but the improvements of the lead-times made at the end of 2008 were small compared to the lead-times of 2007. Quality consultants were hired between May and December 2008 for solving a major bottleneck in the Quality Control department and this resulted in the declining trend of the release times both bulk materials and finished packed products. The lead-time of production also slightly improved. Figures 4.10 – 4.12 demonstrate the improvements of the delivery dependability measured as the deviated time of the shipment and percentage of on-time deliveries of orders after confirmed delivery date.

Figure 4.10: Time-Series Analysis of Delivery Dependability of Case Company 2 in 2007

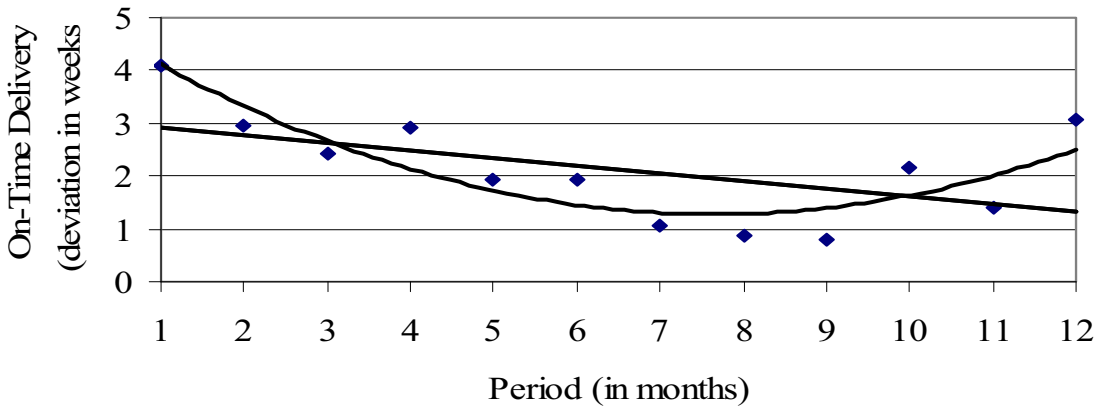


Figure 4.11: Time-Series Analysis of the Delivery Dependability of Case Company 2 in 2008

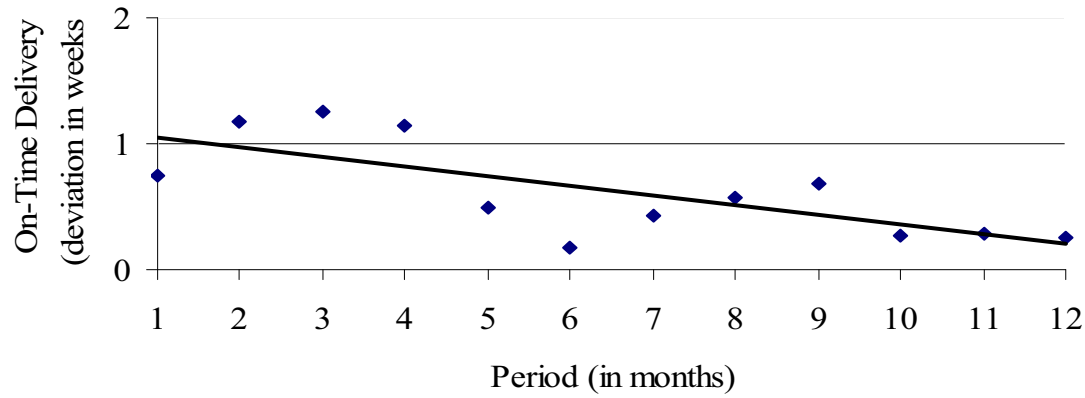



Figure 4.12: Time-Series Analysis of On-Time Deliveries of Make-to-Order Products of Case Company 2

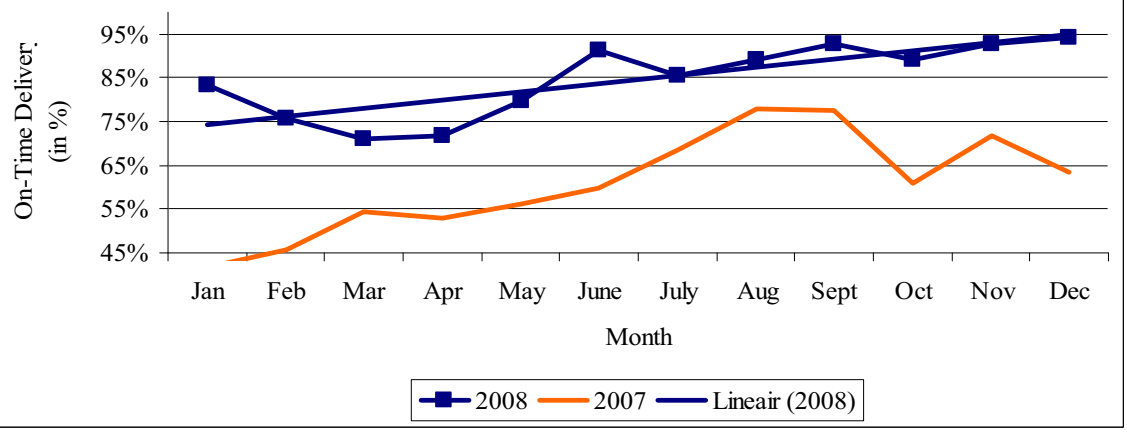



Figure 4.13 presents the on-time deliveries of the make-to-stock products and shows a small increasing trend but no significant improvement was made in 2008.

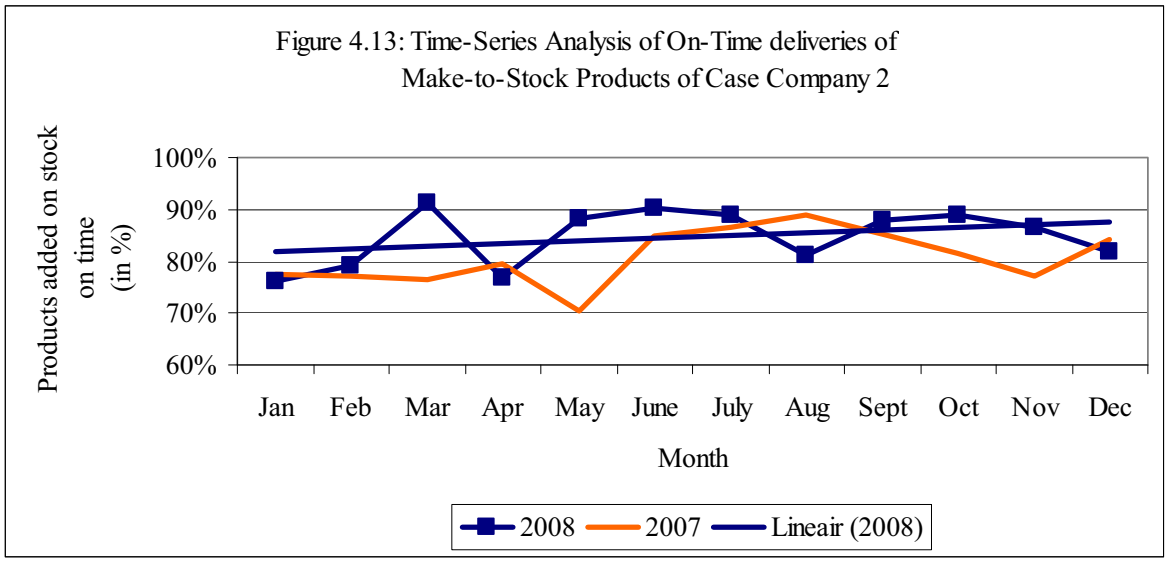



Table 4.38 shows the correlation coefficients of the time series analysis with the calculated significance levels. Five correlations were found to be statistical significant meaning that the manufacturing performance was improved in time. The improvement trend of the delivery dependability and on-time delivery was already observed in 2007 and progressed further in 2008. The improvement trend in 2008 appeared to be stronger due to higher correlation coefficients compared to 2007. However, the make-to-stock on-time delivery has a non-significant low trend in 2008. The order cycle and the aggregated throughput times improved significantly in 2008 with a high correlation trend of the aggregated throughput time and high significant level.

Table 4.38: Time-Series Analysis of Manufacturing Performance in 2007 and 2008

| Time series analysis | Correlation coefficient (r) | significance of the slope |
|---|---|---|
| Order cycle time in 2008 | -0.573 | $p < 0.025$ |
| Aggregated throughput time in 2008 | -0.841 | $p < 0.0005$ |
| Delivery dependability (deviation after confirmed order date) in 2007 | -0.522 | $p < 0.05$ |
| Delivery dependability (deviation after confirmed order date) in 2008 | -0.725 | $p < 0.005$ |
| Make-to-order - On-time deliveries in 2007 (in %) | 0.776 | $p < 0.002$ |
| Make-to-order - On-time deliveries in 2008 (in %) | 0.817 | $p < 0.001$ |
| Make-to-stock - On-time deliveries in 2008 (in %) | 0.333 | $p < 0.10$; NS |

NS = non statistical significant level of the t-test $p < 0,05$

Figures 4.14 and 4.15 illustrate the relationship between the order cycle time and delivery dependability measured in 2007 and 2008. The corresponding correlation coefficients of 0.51 and 0.69, as shown in Table 4.39 represent moderate and high relationships. A fairly high relationship is also found as shown in Figure 4.16 between the aggregated throughput time and delivery dependability in 2008, whereas this relationship could not be observed with data of 2007. These relationships suggest that compressing time will lead to higher delivery performance and improved customer service.

Figure 4.14: The Relationship between the Order Cycle Time and Delivery Dependability of Case Company 2 in 2007

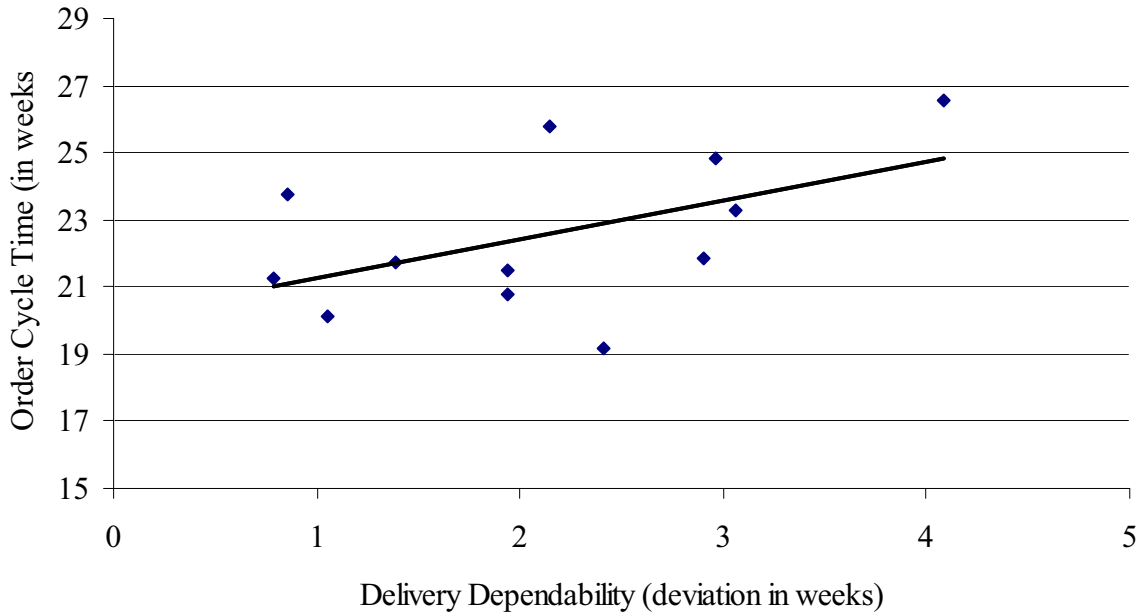


Figure 4.15: The Relationship between the Order Cycle Time and Delivery Dependability of Case Company 2 in 2008

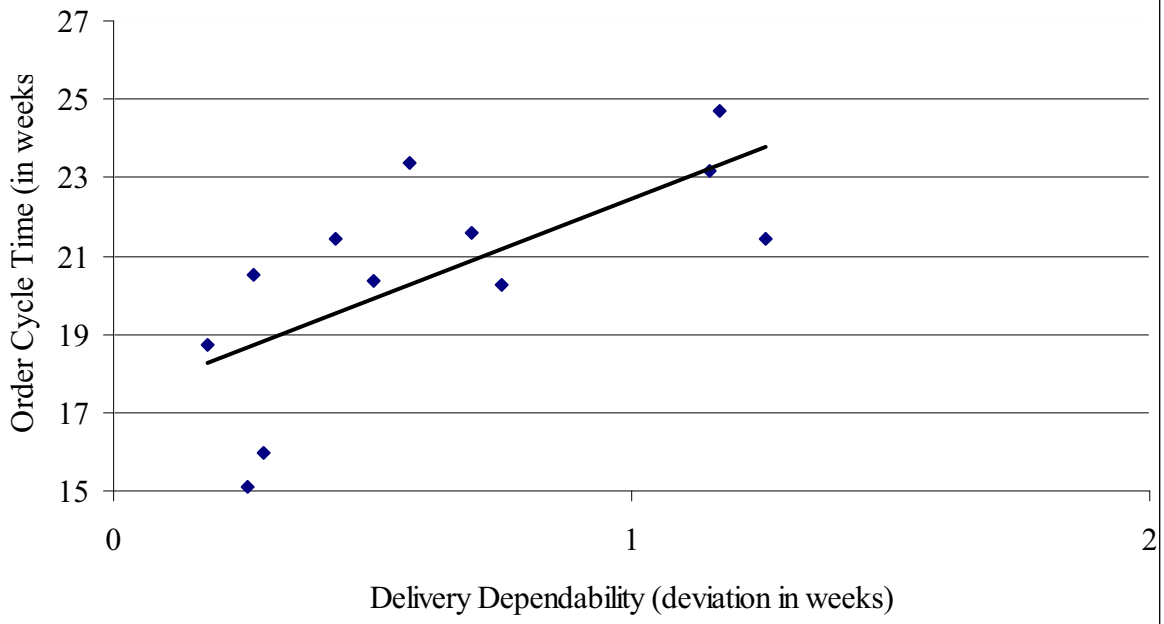



Figure 4.16: The Relationship between the Aggregated Throughput Time and Delivery Dependability of Case Company 2 in 2008

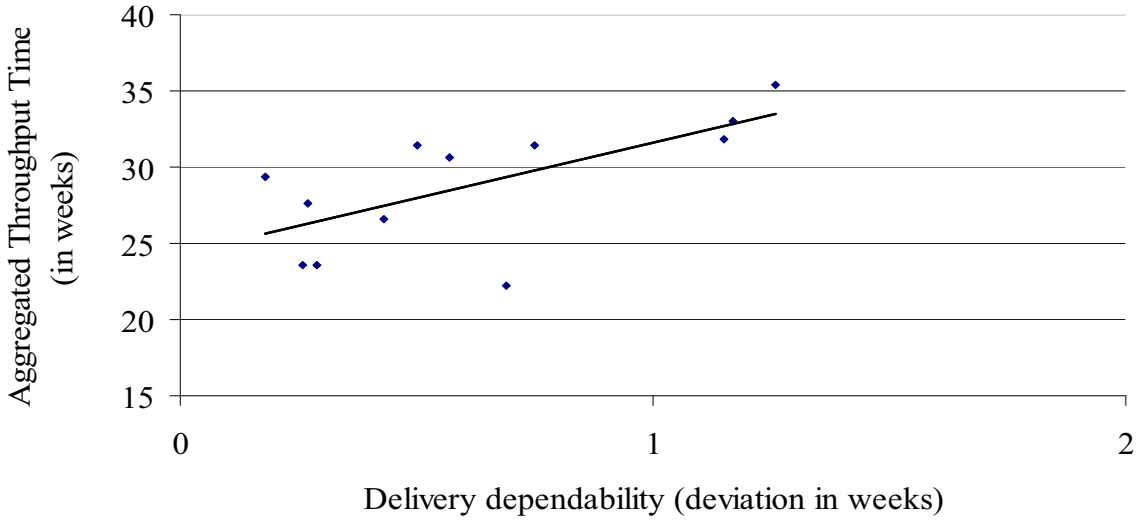
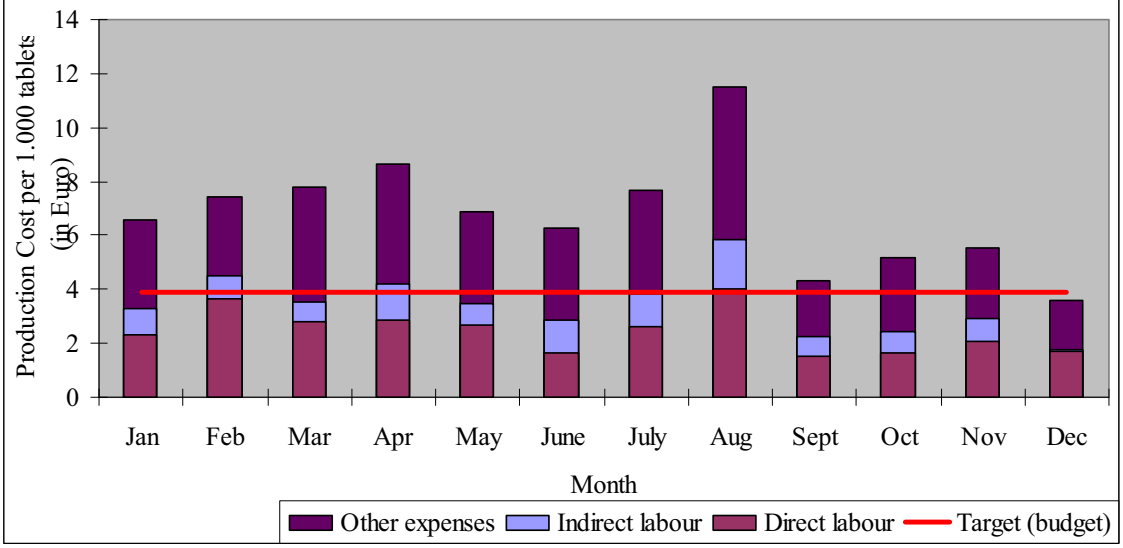


Figure 4.17 shows the monthly production costs in 2008. These costs are calculated as the total expenses of the production department divided by the total amount of tablets in a month. The production costs obviously declined during the last four months in 2008. Figure 4.18 presents a statistical significant relationship between the aggregated throughput time and production costs with a correlation coefficient of 0.68. 46% of the total variance can be explained by this relationship. There may be a direct cause-and-effect relationship, but obviously this is a spurious indirect relationship, indicating that implementing TBM practices has reduced both the throughput time and production costs simultaneously. The production volume increased during the last 4 months of 2008 with nearly a doubled monthly output compared to the first half year of 2008. This was the main reason of the lower production costs, but the manufacturing performance also improved despite the higher production volume with equal production means. This indicates that the manufacturing system was able to handle the higher production volume due to achieved improvements of the business processes during the AR project.

Figure 4.17: Monthly Production Costs in 2008



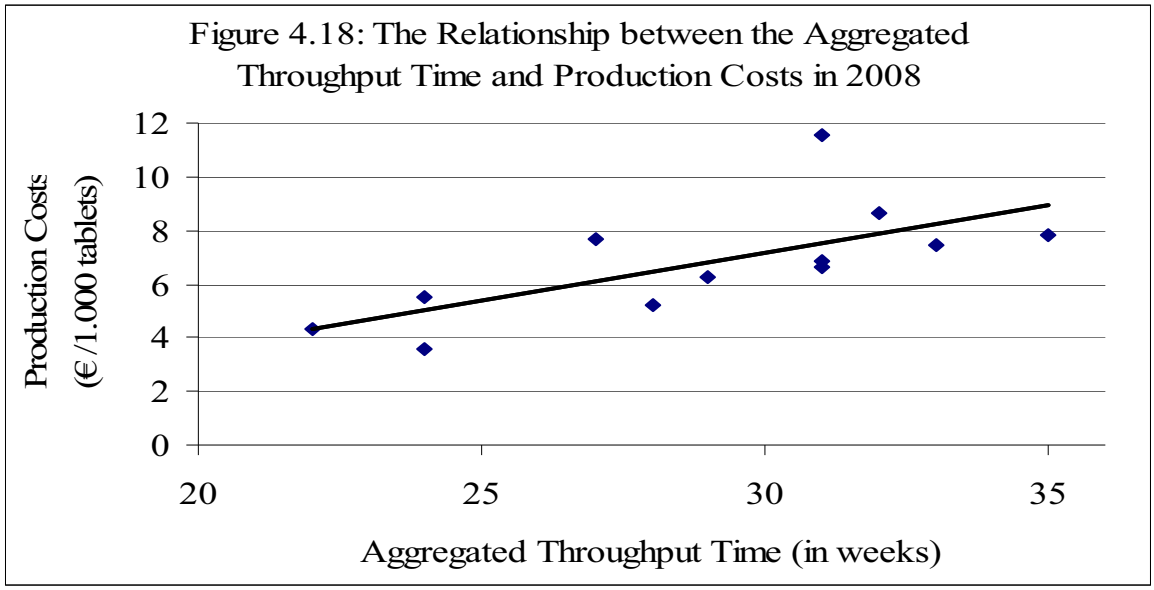


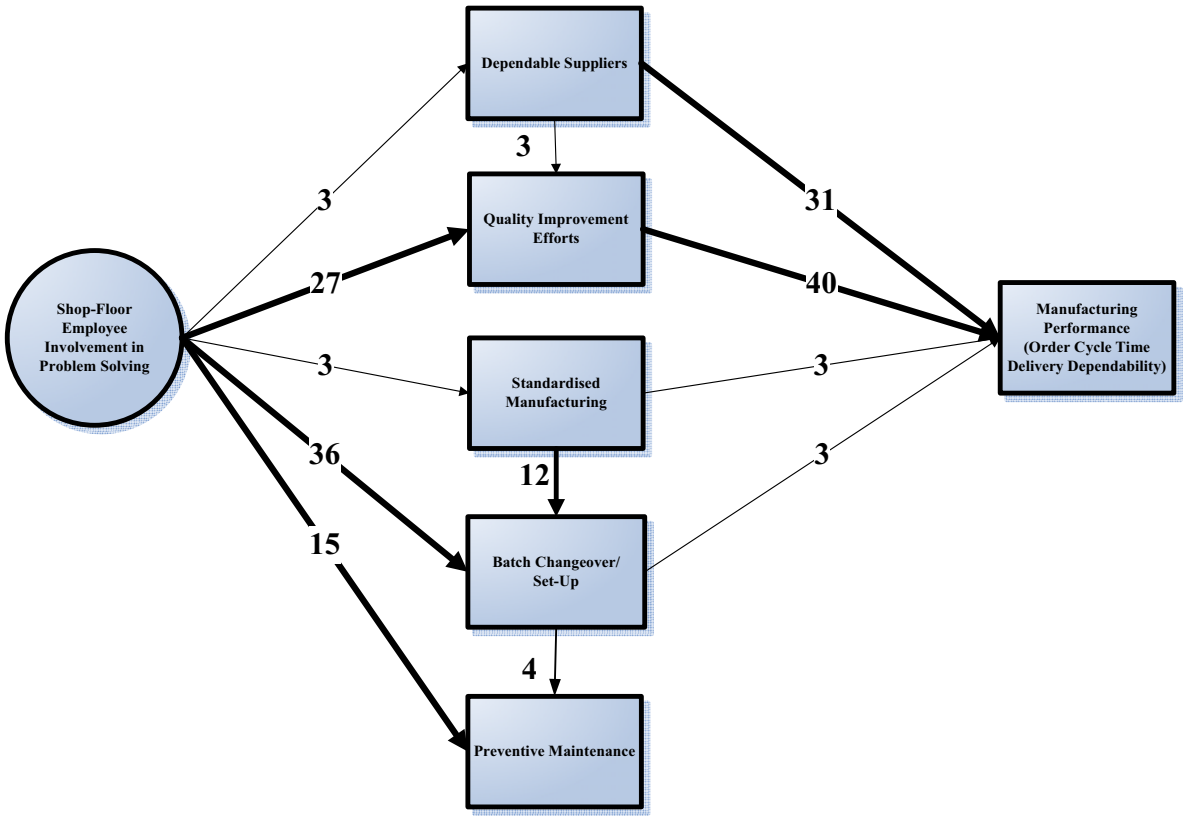

Table 4.39: Relationships between Manufacturing Performance Variables

| Relationship | Correlation coefficient (r) | Coefficient of determination ($r^2$) | Significance of the slope |
|---|---|---|---|
| Order cycle time and delivery dependability in 2007 | 0.511 | 0.261 | $p < 0.05$ |
| Order cycle time and delivery dependability in 2008 | 0.692 | 0.479 | $p < 0.01$ |
| Aggregated throughput time and delivery dependability in 2008 | 0.668 | 0.446 | $p < 0.01$ |
| Aggregated throughput time and production costs in 2008 | 0.678 | 0.460 | $p < 0.02$ |

### 4.2.6 TBM FRAMEWORK OF CASE COMPANY 2

Figure 4.19 presents the TBM framework based on the open, axial and selective coding of the collected data during the diagnosis and implementation phases of the AR project. The selective coding provides 12 propositions in the TBM framework.

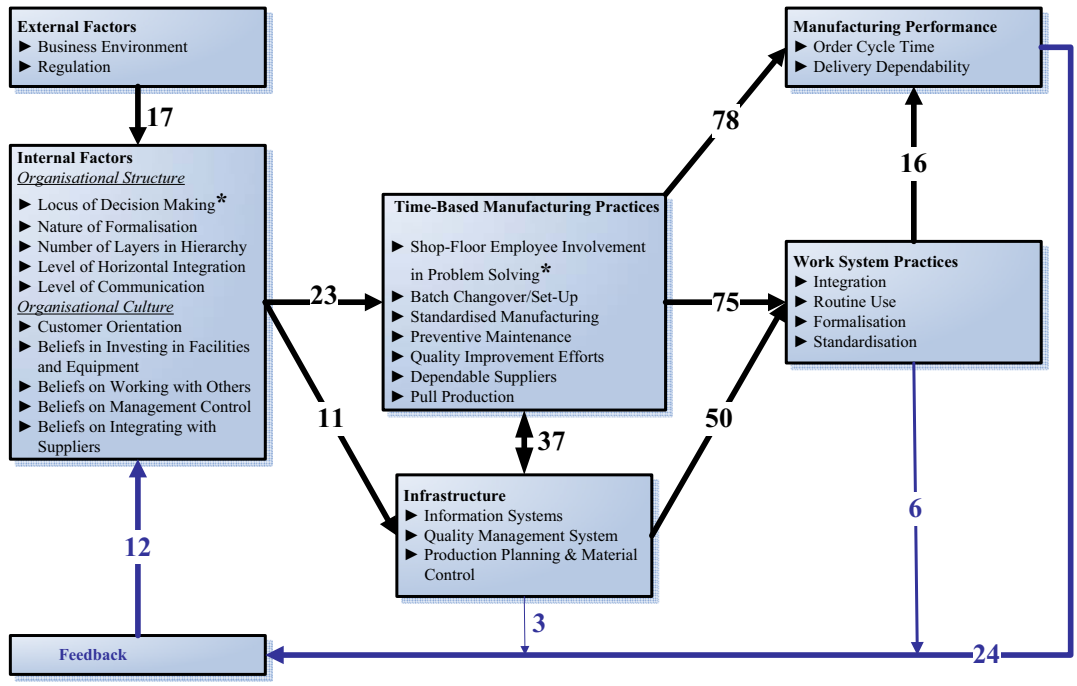
Figure 4.19: Framework of Time-Based Manufacturing Practices of Case Company 2




The framework shows that shop-floor involvement in problem solving is the antecedent to five TBM practices, namely dependable suppliers, quality improvement efforts, standardised manufacturing, batch changeover/set-up and preventive maintenance. This confirms the original study of Koufteros et al. (1998) with the same 5 propositions. Relationships between dependable suppliers and quality improvement efforts and between standardised manufacturing and batch changeover/set-up are also found. These two propositions are in accordance to the findings of the first Case Company. As pull production is nearly absent in the second Case Company, no relationships are found

with other TBM practices and manufacturing performance. The determinants of the manufacturing performance are dependable suppliers, quality improvement efforts, standardised manufacturing and batch changeover/set-up and this is also in accordance with the earlier findings if pull production is not considered in the framework of the first Case Company. There is also a relationship found between batch changeover/set-up and preventive maintenance. When production operators are able to set-up the machines during the batch changeover independent from engineers, the Company is able to emphasise preventive maintenance, as discussed earlier in this Chapter.

Figure 4.20: The Impact of Contextual Variables on TBM and Manufacturing Performance of Case Company 2




* The Locus of Decision Making domain covers the construct of Shop-Floor Employee Involvement in Problem Solving

Figure 4.20 shows the framework with the propositions between TBM practices, the contextual variables and the manufacturing performance. As this framework is nearly a copy of the framework of the first Case Company, the overall framework resembling the two Case Companies will be discussed latter in more detail when the comparative analysis is presented in next paragraph.

## 4.3 COMPARATIVE ANALYSIS OF THE CASE COMPANIES

This paragraph describes the comparative analysis by comparing the qualitative data of the TBM practices of the two Case Companies. Student-t test statistics is used for the comparative analysis of the Likert-scale questions of the surveys and semi-structured interviews. Finally analytic induction is used for the development of the TBM framework representing the set of multiple propositions consistent with the data of two Case Companies. Table 4.40 presents the descriptive data of the TBM practices for comparative analysis of the two Case Companies.

Table 4.40: Cross-Case Display of Descriptive data of the two Case Companies

| Variable | Case Company 1 | Case Company 2 |
|---|---|---|
| Shop-floor employee in problem-solving | *Diagnosis Phase*<br>• The motivation and spirit of the production operators are high and they are willing to help other operators during the set-up and solve simple problems. Bulk production operators are self-supportive, but packaging operators need assistance from the packaging supervisor or engineers.<br>• There are no regular official group meetings held with production operators for improving the production processes and quality. Production operators are only partly involved in the development of new products.<br>• Production management listens to ideas and initiatives from the shop-floor and production operators are involved.<br>*Implementation Phase/ improvements*<br>• No improvements were observed during the implementation phase | *Diagnosis Phase*<br>• Production operators are rarely involved in solving problems. There is no motivation to improve the batch changeover times, since there is a lack of skills to perform the set-up on the packaging lines. Operators often need help from engineers during the set-up or solving simple problems.<br>• There are no regular official group meetings held with production operators for improving the production processes and quality. Only the production manager is involved in making new products.<br>• The production supervisors are discussing problems with operators and inform and coaching them on a daily basis.<br>*Implementation Phase/ improvements*<br>• Improvement was achieved due to the recruitment of new technical skilled operators, but the problem solving skills of the current employees didn't improve. Production operators are increasingly involved in improvement efforts. The operators |

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| | | improved the reporting and documenting technical breakdowns and introduced additional in-process controls before the restart of the process after breakdowns.<br>• Development of a training programme for production operators to enhance technical skills and knowledge on quality.<br>• There is involvement of production operators by engineers and production supervisors in solving problems. |
| Batch changeover/ set-up | *Diagnosis Phase*<br>• Batch changeover times:<br>No conversion of machine:<br>15 - 60 minutes;<br>Small conversion needed:<br>30 – 90 minutes;<br>Big conversion of machines is not needed.<br>• Cleaning is the most important activity in time during the batch changeover, especially when active compounds are difficult to clean. Most tablets are coated and this has a positive effect on the cleaning activities during the batch changeover of the packaging machines.<br>• Bulk production operators don't need additional support from the engineering department during the set-up. The packaging employees are not completely self supportive and need technical support during the set-up of machines. Most blisters are manually packed into the final packs and this needs no technical support for the batch changeover.<br>• There is in the bulk production no motivation to shorten the batch changeover times, since the set-up times are already considered to be short. The packaging supervisor is motivated to improve the batch changeover to avoid assistance form the engineering department.<br>• New machines are investigated by the engineering department | *Diagnosis Phase*<br>• Batch changeover times:<br>No conversion of machine:<br>½ - 1½ hours;<br>Small conversion needed:<br>1 - 4 hours;<br>Big conversion needed:<br>3 - 8 hours.<br>• Conversion of packaging machines is the most important activity in time during the batch changeover. The batch changeover time highly depends on the complexity of machines, and if conversion of the packaging line is needed.<br>• Most production operators need support from engineers during the batch changeover. Instructions will be made when new equipment are installed. The supervisors coordinate the batch changeover such as seeking necessary assistant from engineers, collecting production documents and materials of the new batch.<br>• There is no motivation to improve the batch changeover times. Production operators need training to shorten set-up times.<br>• There are no set-up methods developed for new machines. |

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| | before usage in production, but a new set-up method for new machines is not usually developed.<br>• There is a system for storing tools, but this can be improved.<br>• Engineers design occasionally fixtures on machines to shorten set-up time. No special tools are used.<br>• Only new bulk production operators are trained.<br>• The production manager prepares the weekly production plan and organising the shop-floor papers. Standardised products are sequentially planned to keep the batch changeover times low.<br>*Implementation Phase/ improvements*<br>• No improvements were observed during the implementation phase | Production operators are not involved in improving set-up times.<br>• There is no system for storing tools adequately.<br>• No special tools, jigs or fixtures are used.<br>• Only new production operator are receiving training on the job.<br>• The production manager is involved in making the weekly fixed production plan by logistics. Standardised products are sequentially planned to decline the batch changeover times.<br>*Implementation Phase/ improvements*<br>• The set-up of machines improved due to the recruitment of new skilled operators, development of manuals with instructions for the set-up and the organising of a fixed production plan .<br>• A training programme for production operators is developed.<br>• A SMED method of the high speed packaging lines is developed and used for the development of the training programme.<br>• Special closets for storing the tools needed for the set-up have been installed. |
| Standardised manufactu-ring | *Diagnosis Phase*<br>• Products forming families are grouped by using only a few different seizes of punches on tablet compressing machines. The packaging machines use mainly one blister size.<br>• There is no coding classification used to group materials and products into families in bulk production. There is a coding system for moulding parts of the | *Diagnosis Phase*<br>• Products are grouped in families of products with the same packaging, but the complex production planning process makes this grouping of products in practice difficult.<br>• There is a coding classification to group materials and products into families together with a numbering system for moulding parts.<br>• The high speed blister and |

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| | packaging machines.<br><br>• The machines are not places together to form groups with similar routing requirements.<br><br>*Implementation Phase/ improvements*<br><br>• Reconstruction of production facilities improved the material flow due to:<br>- grouping of machines with similar processes;<br>- on-line packaging. | packaging machines are placed to form one packaging line. The low speed blister and packaging machines are not placed together, causing intermediate inventory on the shop-floor.<br><br>*Implementation Phase/ improvements*<br><br>• Grouping products improved through the optimisation of the production planning process, using codes for product and material sizes as planning parameters and standardisation of materials. |
| Preventive maintenance | *Diagnosis Phase*<br><br>• Preventive maintenance is rarely performed. An engineer will only inspect the machine when there is a breakdown. Production operators lubricate the machines every week and they are skilled to solve small technical disturbances. Solving technical breakdowns and replacement of parts are often done after production time. There is no emphasis on maintenance, since machines are not regularly maintained and preventive maintenance is considered not to be necessary. A machinery breakdown can be managed without loosing much time, compared with the time loss for preventive maintenance.<br><br>• The tablet compressing machines are not sensitive to disturbances. Packaging machines are more sensitive for disturbances and breakdowns often occur. Many problems occur due to adjustments of machines during the set-up.<br><br>• No records for maintenance are kept.<br><br>• The production manager has no role in the preventive maintenance policy.<br><br>*Implementation Phase/ improvements* | *Diagnosis Phase*<br><br>• Preventive maintenance is considered to be important, but it is rarely performed. Maintenance on the machines is regularly and proactively performed during the batch changeover and in case of a technical breakdown by engineers. Maintenance consists mainly of lubrication, machinery inspection and replacement of machinery parts during the batch changeover, which is more a pro-active and corrective approach. Production operators are not involved in the maintenance activities. Engineers often perform maintenance after regular production time.<br><br>• The high speed packaging lines are sensitive for technical disturbances. Breakdowns and disturbances happen often.<br><br>• Records of routine maintenance are kept in a software system.<br><br>• The production manager has no role in the preventive maintenance policy.<br><br>*Implementation Phase/ improvements* |

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| | • No improvements were observed during the implementation phase | • Preventive maintenance has been improved and machines are running with less technical breakdowns. The occurrence of breakdowns declined through the recruitment of better skilled operators, grouping of products and development of standardised instructions for the set-up. Preventive maintenance will be performed every year. A routine maintenance plan on the high speed production lines is developed |
| Quality management system | *Diagnosis Phase*<br>• There is some support from top management for quality, but top management has no active role to improve quality. Management is more output oriented and focussed on the rapid growth of the company then to support quality, making that there is no organisational culture for quality.<br>• Quality results are weakly communicated with the shop-floor, only the overview of customer quality complaints are discussed in management team meetings. There is no KPI system measuring quality results.<br>• Production processes which prevent possible defects caused by employees are not fully implemented. Quality control charts are used to control the production processes, but not all parameters are measured. The cleanliness of the machines and the shop-floor is weak.<br>• The development of new products is in most cases done by the Company. Raw ideas about a composition are received from customers. which will be developed further in the quotation stage. The composition of the product and the process are then developed during the production of the first batch. The development of new products is not organised in which employees are working in multidisciplinary | *Diagnosis Phase*<br>• There is top management support for initiatives to improve quality, but no active role. Management strives to obtain TQM, but the road towards TQM is not settled. There is a lack of quality staff available to improve the quality management system. There is no organisational culture that is focussed on quality.<br>• There is only a system for keeping records of deviations and external complaints. Observed deviations in production and external quality complaints are not discussed with production operators. There are no KPIs for quality defined.<br>• The processes are designed to prevent errors due to automatic control devices on packing lines. Production documents contain quality control charts to control the production processes, but the in-process controls are not effectively executed in production. QC employees are taken samples after the packaging process. The lack of training and low technical skills of the production employees are the main reasons of low efficiency of the production process and quality defects. The products are often approved with problems or delay by the quality department.<br>• The development of new products are already done by the customer. There are rarely meetings with customers to bring new products on the market. Effective meetings with |

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| | teams.<br><br>• There are no regular meetings to improve quality. Although the Company has a good recruitment, the new employees are not regularly trained. The employees are motivated and flexible, but due to the lack of training and knowledge, quality improvements efforts are not initiated.<br><br>• Requirements in quality vary per customer. There are close contacts with most customers to discuss the quality of design of new products. Customers do not certify their supplies to meet the quality requirements. The company is not eager to exchange detailed documented information of the production processes to customers.<br><br>*Implementation Phase/ improvements*<br><br>• Some improvements are realised, but it is progressing slowly. The organisational culture and rapid growth of the company are the main reasons for the slow improvements made.<br><br>• The quality manual and standard operating procedures have been developed meeting the pharmaceutical requirements.<br><br>• A system for generating batch production documents for the shop-floor meeting the pharmaceutical requirements have been implemented.<br><br>• Regular meetings of new products are organised, but the process is still weak.<br><br>• A validation plan to validate all production equipment has been developed. Validation is not yet performed. | different departments to bring new products on-time on the local market do not happen.<br><br>• There are no quality meetings with employees of different departments. Most employees are flexible to quality improvements. There are some production operators with low interest and involvement.<br><br>Customers occasionally certify the company through quality audits. The Company only exchanges brief information of the production processes with customers and happens often through quality audits.<br><br>*Implementation Phase/ improvements*<br><br>• KPI workgroups simultaneously involving employees from other departments improved the organisational culture for quality, since quality related issues are also discussed in these meetings.<br><br>• A system for reporting and handling quality deviations according to the Ishikawa root cause analysis has been installed. Technical disturbances are also better reported.<br><br>• Preventive maintenance and validation of equipment have been performed.<br><br>• Regular meetings are organised to involve customers in discussing operational processes. |
| Dependable suppliers | *Diagnosis Phase*<br><br>• The Company has 80 - 100 suppliers and 300 to 400 different raw materials are regularly | *Diagnosis Phase*<br><br>• The Company has about 90 suppliers. Bulk products are purchased from suppliers in Europe |

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| | purchased from 30 different suppliers. Raw materials are purchased in the Benelux countries, Europe and China.<br><br>• The delivery times of raw materials vary less then 4 weeks for European suppliers to 12 weeks from suppliers of China. Materials are not always received on-time, but in most cases there are no delivery problems. 80% of the orders are received on-time. Most suppliers are flexible enough to meet unexpected demand. Suppliers from China are less flexible. There are differences among different suppliers within Europe and China.<br><br>• Quality is an important criterion, but low prices are more important. The manufacturability is also important, but most raw materials are meeting this criterion. There is a selection program running, but most suppliers are not certified. Specifications are not always communicated with the suppliers when the materials are purchased.<br><br>• Quality is sometimes a problem, especially materials from plant origin and this may cause problems in production or deliveries. When a material meets the specifications, it will not guarantee the good manufacturability of the material. It is therefore important to purchase the raw materials from the same source.<br><br>*Implementation Phase/ improvements*<br><br>• The Company implemented a certification program for supplier selection. The increased quality requirements force the company to certify suppliers and improve the quality of raw materials. | and Asia.<br><br>• The delivery time of bulk products is 4 to 6 months. Packaging materials are delivered within one month. The delivery dependability of suppliers is approximately 50% . There are clear differences in delivery performance among suppliers within Europe and between Europe and India. The suppliers from India have the worst performance. There are differences in flexibility among the many suppliers. Some contract manufacturers are very flexible, but most bulk manufacturers are inflexible to meet unexpected demand due to campaign production.<br><br>• Purchase price and delivery reliability are the two most important selection criteria and quality is less important. The company strives for keeping long-term relationships with suppliers. Suppliers are certified through quality audits. The quality department has regular written communications with suppliers, but problems in communication occur.<br><br>• The Company receives products mostly without quality defects and products are only in exceptional cases returned to the supplier. Products are in very rare cases rejected during the packaging process. The Company has long term agreements with suppliers and switching to other suppliers is difficult.<br><br>*Implementation Phase/ improvements*<br><br>• The supplier performance improved. The lead-times of materials decreased and the flexibility in meeting unexpected demand improved.<br><br>• A vendor-rating system has been installed. |

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| Pull production | • The Company has make-to-order production planning and control system, based on a pull production system. There is no Kanban system, but there is good communication between the bulk production and packaging departments on the shop floor. Production is driven by the receipt of customer orders. Customer orders are given directly to the production manager for planning the shipment of products to customers, packaging and bulk production. Production management has direct contact with customers. The production system is well capable to react on the customer demand.<br><br>• The pull material flow follows more a pull system due to the type of products with a high standardisation grade in which the batch size is less important and fast batch changeover times. The intermediate bulk product is stored on the shop-floor before packing with a short storage period of 2 – 3 days. As the product will be delivered immediately after packing to the customer, there is very little inventory of finished product and sometimes the order quantities are divided in smaller quantities in order to deliver the product on-time. | • The company has a mixed make-to-order and make-to-stock production planning and system, based on a push production system. The production planners are placing manufacturing orders based on the MRP information. The weekly planning is discussed with production management for scheduling the production lines. Production management has access to ERP system to view the inventory levels of finished packed products. The Company has problems to arrange a fixed production plan since it is difficult to get the materials on time available to start the production order.<br><br>• The materials flow follows more a pull system because no orders are issued for intermediate blister products. Production management has direct communication with the warehouse to pull the materials to production according to the weekly production plan and available stock of finished packed products packed. The high speed packaging lines are on-line blister and packaging machines, therefore no intermediate storage is possible. The low speed machines are not connected and this results in intermediate storage of blistered product on the shop-floor waiting for final packaging. |
| Manufactu-ring performance & feedback | • The average cycle time is 5.3 weeks and 57% of the orders are delivered on-time with an average delay of 7 working days (1.38 week). The time-series analysis of the order cycle time and delivery dependability shows that there is no improvement of the two performance parameters observed during the whole AR project.<br><br>• A high relationship is found between the order cycle time and throughput time with a correlation coefficient of 0.75. | • The manufacturing performance is 22.6 weeks measured as the average cycle time and 60% of the orders are delivered on-time with an average delay of 10 working days during the diagnosis phase. At the end of the AR project the make-to-order cycle time was reduced to 15 weeks and 95% of the orders are delivered on time with an average delay of 1 day. The delivery dependability of make-to-stock orders was not significantly improved.<br><br>• Relationships are found between the order cycle time and throughput |

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| | • Regular feedback of manufacturing performance data was not possible due to the poor IS of the Company during the AR project. The implementation of KPI measurement system is now possible due to the successful implementation of the ERP system. | time with correlation coefficients of 0.51 measured during the diagnosis phase and 0.69 measured during the implementation phase.<br>• A KPI measurement system for regular feedback was already installed before the AR project. The ERP system was sufficiently developed to extract the performance data. Manufacturing performance is regularly discussed in KPI circle meetings. |

Case Company 1 has a low order cycle time of 5 weeks compared to Case Company 2 with an order cycle time of 15 weeks at the end of the AR project. However, the delivery dependability of Case Company 2 reached to higher levels then Case Company 1 during the AR project. Pull production was developed from the early start of Case Company 1 as result of high standardisation of products and fast batch changeover times, whereas Case Company 2 uses a push system. The delivery performance of the raw materials suppliers of Case Company 1 is higher with lower lead-times and higher on-time deliveries than the bulk suppliers of Case Company 2. The existence of a pull system and higher supplier dependability of Case Company 1 compared to Case Company 2 are the main reasons of the observed differences of the order cycle times and Case Company 1 has a higher level of TBM practices, despite the improvements made at Case Company 2. Improvement of the supplier lead-times is observed and resulting in higher manufacturing performance at Case Company 2. Both companies are focussed in obtaining low purchase prices with the selection of suppliers. The production operators of Case Company 1 seem to be better skilled in the machinery set-up, need less assistance from engineers and are able to solve small technical problems. The lack of skills of production operators is well recognised at Case Company 2 and as result a training programme has been developed to improve the problem solving skills, including the development of SMED instructions. Standardised manufacturing exists at

the two companies, for example Case Company 1 uses dedicated machines for each group of products with different tablet sizes and Case Company 2 has on-line packaging lines. Both companies have low inventory levels at the production shop-floor and made improvements in standardised manufacturing. The material flow of the Case Company 1 improved due to the reconstruction and expansion production facilities in which machines with similar processes are grouped together and the introduction of on-line packaging, whereas the standardisation of packaging materials improved the machinery set-up of Case Company 2. Preventive maintenance is far better developed at Case Company 2, but this is considered as less critical at Case Company 1, because it has less impact on the throughput time due to the excess of machines. The quality management system of both companies seems to be insufficient to support the TBM practices. Many conflicts have been observed between the quality departments and other operational departments at both companies. However, the situation at both companies clearly improved during the AR project through quality project and KPI workgroup meetings. Both companies made progress in improving the quality management system. However, the improvements must be further laid down to the shop-floor employees, wherein they are involved in quality improvement efforts and able to take initiatives for improvements on the shop-floor. Case Company 2 was clearly able to reduce its manufacturing performance through a KPI measurement system in a continuous improvement environment and started to improve the TBM practices. Although the shop-floor employee involvement in problem solving as antecedent of other TBM practices only slightly improved, preventive maintenance, standardised manufacturing through the standardisation of materials, dependable suppliers and quality improvement efforts through the implementation of a deviation management system improved significantly. Case Company 1 made improvements in the infrastructure of its manufacturing system through the implementation of an ERP system and improvement

of the quality management system, but it was not able to implement TBM practices at the shop-floor and improve the manufacturing performance.

Table 4.41 presents the comparison of the results of the Likert-scale questions obtained from the survey at Case Company 1 during the workshop at the beginning of the AR project and results from the semi-structured interviews at the end of the AR project at Case Company 2. The results of the semi-structured interviews regarding the quality management system of Case Company 1 were used for the comparison instead of the survey results of the workshop, because the quality improvement efforts were the only core TBM practices assessed during the implementation phase and also the survey finding of this construct has a low IRR. Although, the sample sizes were in all cases very small and the intension was to use these Likert-scale questions only for general comparison of answers, the comparative analysis using Student-t statistics provided some statistical meaningful information. The statistically differences of pull production and preventive maintenance are in agreement with the earlier interpretations of the descriptive data of the two Case Companies. Case Company 1 has faster batch changeover times then Case Company 2, but a significant lower score of the Batch changeover/set-up Likert-scale questions. This could be explained since Case Company 1 did not aim to improve its set-up times; some Likert-scale questions are related to the improvement of set-up methods and Case Company 2 has made some progress in the development of the training programme aiming to improve the set-up method. Standardised manufacturing is interpreted from the qualitative interview data to be well developed at Case Company 1, however Case Company 1 has more production steps involved, including bulk production and packaging processes, whereas Case Company 2 has only packaging processes.

Table 4.41: Comparative Analysis of Likert-Scale Items of TBM Practices between Case Companies.

| Construct | Case Company 1<br>Mean Scores ± Standard deviation | Case Company 2<br>Mean Scores ± Standard deviation | Significance<br>(Student-t test) |
|---|---|---|---|
| Shop-employee involvement in problem-Solving | 3.10 ± 0.59 | 3.40 ± 1.07 | NS |
| Batch changeover/set-up | 2.43 ± 0.53 | 2.98 ± 0.27 | $p = 0.05$ |
| Standardised manufacturing | 2.65 ± 0.54 | 3.98 ± 0.30 | $p < 0.001$ |
| Preventive maintenance | 1.94 ± 0.75 | 3.94 ± 0.29 | $p < 0.001$ |
| Quality management system | 3.33 ± 0.53 | 3.38 ± 0.29 | NS |
| Dependable suppliers | 3.47 ± 0.50 | 3.19 ± 0.25 | NS |
| Pull production | 3.76 ± 0.73 | 1.14 ± 0.24 | $p < 0.001$ |

This makes the comparison of the Likert-scale questions less meaningful to explain the differences. Table 4.42 shows that there are no significant statistical differences found of the quality managements constructs between the two Companies and this seems to be in consistence with the qualitative interview data. Both Companies made some improvements on the quality management system, but a continuous improvement mechanism involving shop-floor employees and all departments has to be further developed towards a company wide TQM system.

Table 4.43 presents the results of the Likert-scale questions of IS, showing that the IS of Case Company 1 has slightly better developed compared to the IS of Case Company 2. There is a low statistical significant difference for IS performance, but the differences of the other IS constructs are not statistically significant.

Table 4.42: Comparative analysis of Likert-scale items of the Quality Management Systems between Case Companies

| Construct | Case Company 1<br>Mean Scores ± Standard deviation | Case Company 2<br>Mean Scores ± Standard deviation |
|---|---|---|
| Top Management Support* | 3.22 ± 0.48 | 3.15 ± 0.34 |
| Quality Information* | 3.13 ± 0.75 | 3.75 ± 0.50 |
| Process Management* | 3.20 ± 0.71 | 3.33 ± 0.49 |
| Product Design* | 3.75 ± 0.50 | 3.33 ± 0.41 |
| Supplier Involvement* | 3.31 ± 0.90 | 3.32 ± 0.26 |
| Workforce Management* | 3.45 ± 0,75 | 3.30 ± 0.76 |
| Customer Involvement* | 3.25 ± 0.57 | 3.47 ± 0.50 |
| Total* | 3.33 ± 0,53 | 3.38 ± 0.29 |

* no significant statistical level of $p < 0.1$ with student-t test.

Table 4.43: Comparative Analysis of Likert-Scale Items of the Information Systems between Case Companies.

| Construct | Case Company 1<br>Mean Scores ± Standard deviation | Case Company 2<br>Mean Scores ± Standard deviation |
|---|---|---|
| I.S. strategic planning effectiveness | 3.00 ± 0.27 | 2.56 ± 0.85 |
| I.S. responsiveness to organisational computing demands | 3.72 ± 0.16 | 3.31 ± 0.77 |
| End-user training effectiveness | 2.25 ± 0.65 | 2.25 ± 0.29 |
| End-user computing skill | 3.17 ± 0.64 | 3.25 ± 0.50 |
| Cross-functional involvement (in I.S. related activities) | 2.90 ± 0.53 | 2.75 ± 0.87 |
| End-user involvement (in I.S. related activities) | 3.15 ± 0.62 | 2.70 ± 0.35 |
| I.S. performance* | 3.95 ± 0.09 | 3.60 ± 0.28 |
| TOTAL | 3.16 ± 0.24 | 2.92 ± 0.30 |

* a significant level of $p < 0.1$ with student-t test

Table 4.44 provides the Likert-scale results of the work system practices. Although there are more participants involved (13 and 14 informants from the two Companies) compared to the interviews, no statistical differences could be observed. The two Companies have the same profile in which formalisation and routine use are the best developed work system practices compared to the other two practices of standardisation and integration.

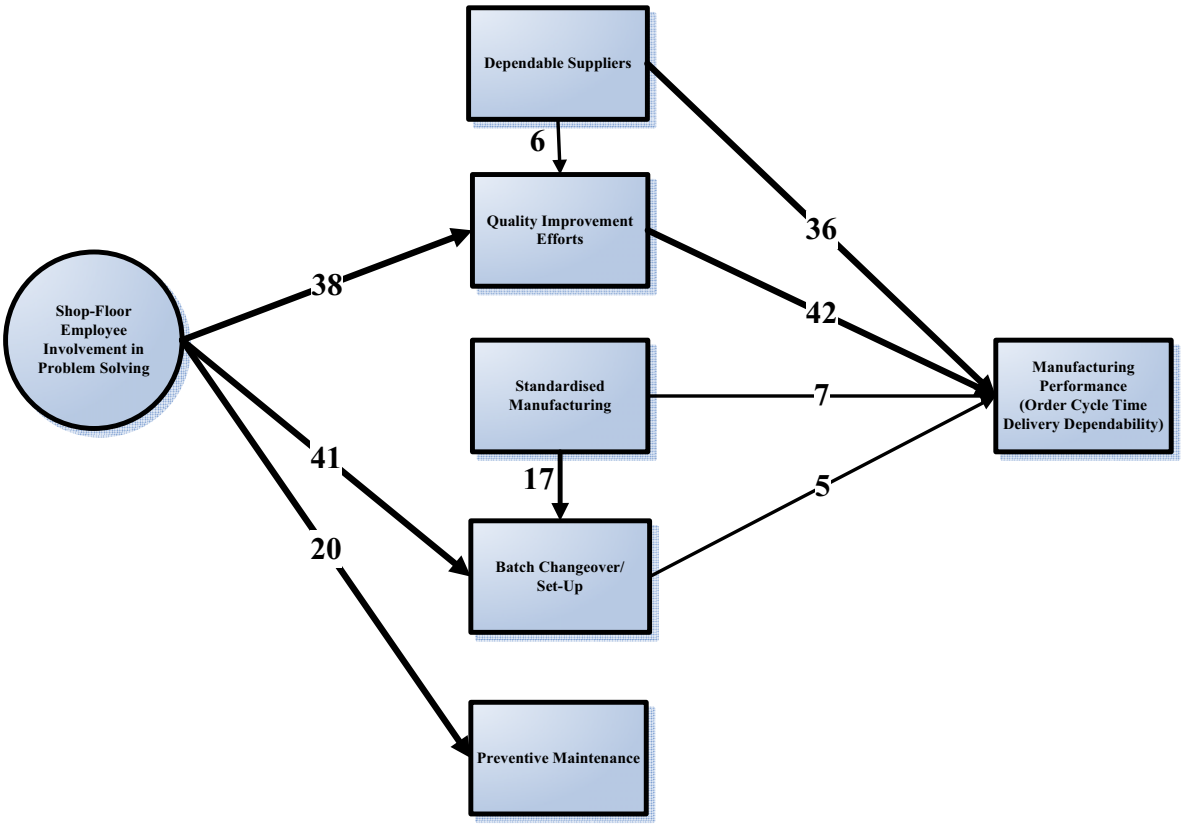
Table 4.44: Comparative Analysis of Likert-Scale Items of the Work System Practices between Case Companies

| Construct | Case Company 1<br>Mean Scores ± Standard deviation | Case Company 2<br>Mean Scores ± Standard deviation |
|---|---|---|
| Integration* | 3.08 ± 0.62 | 3.28 ± 0.30 |
| Routine Use* | 3.65 ± 0.62 | 4.20 ± 0.34 |
| Formalisation* | 4.07 ± 0.66 | 3.98 ± 0.72 |
| Standardisation* | 2.96 ± 0.86 | 3.10 ± 0.65 |
| TOTAL* | 3.44 ± 0.34 | 3.64 ± 0.26 |

* no significant statistical level of $p < 0.1$ with student-t test

Analytic induction to develop multiple propositions consistent with the data of the two Case Companies provides the TBM framework as presented in Figure 4.21. The framework contains only the relationships between constructs if they relationships are found in data of the two Case Companies. The observed relationships of Figure 4.21 are consistent with the two studies of Koufteros et al. (1998, 1999). Only the relationship between batch changeover/set-up and standardised manufacturing observed in the two cases is not consistent with the studies of Koufteros.

Figure 4.21: Analytic Framework of Time-Based Manufacturing Practices

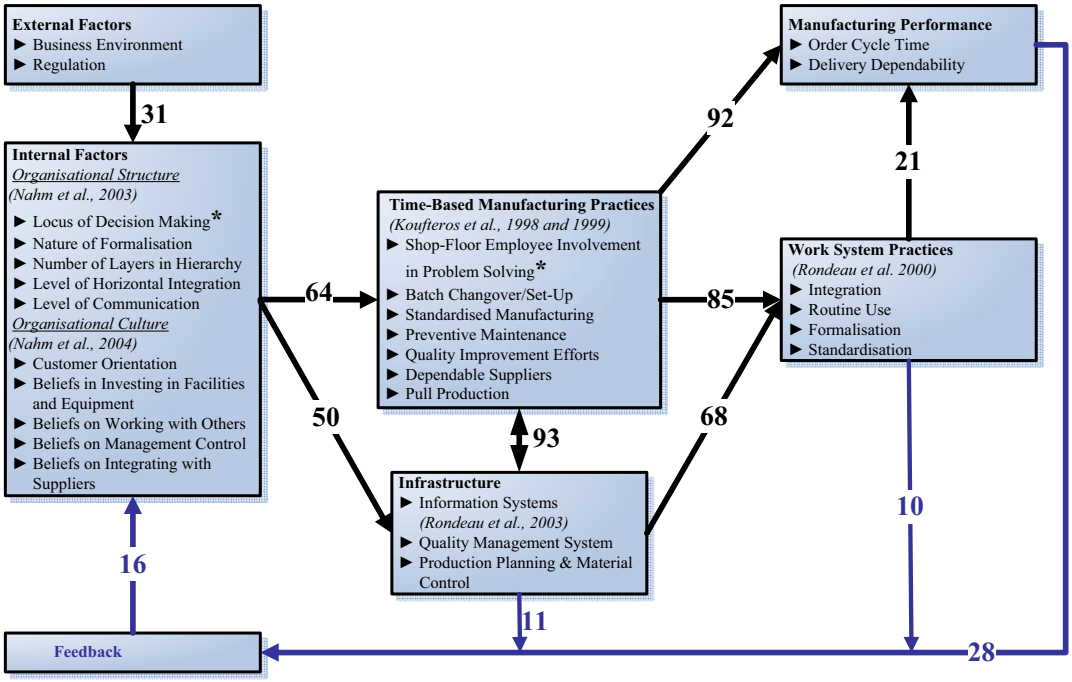



Standardised manufacturing, especially the grouping of materials and products are well developed in the two cases and many positive effects on the batch changeover process have been found. Pull production and its relationships with standardised manufacturing, batch changeover/set-up and manufacturing performance are only observed at Case Company 1. The relationship between standardised manufacturing and manufacturing performance have been found in both companies and relates in most cases to the factory lay-out and the grouping of machines with a direct influence on the throughput time. There was in-work progress inventory observed in the packaging department due to the off-line packaging process at Case Company 1 resulting in longer throughput time and pull production was more difficult to achieve. On-line packaging was introduced after the reconstruction of the production facilities and resulted in a decrease of throughput time. There is no direct relationship between standardised manufacturing and manufacturing performance if a company has an ideal pull production system with no

intermediate inventory. The relationships of shop-floor employee involvement in problem solving with dependable suppliers and standardised manufacturing are only found in Case Company 2. The shop-floor employees in the warehouse have direct contacts with suppliers to plan the receipt for streamlining the material handling in the warehouse, including the sampling by quality control employees. Enhanced shop-floor employee problem solving skills facilitate standardised manufacturing in Case Company 2. The connection of the blister and packing machines to form on-line production lines requires good problem solving skills to keep set-up times low due to the increased complexity of these production lines. The throughput time and inventory will decrease because intermediate stock will not appear at on-line packaging lines.

Figure 4.22 presents the contextual variables in relation with TBM practices, which are consistent with the data of the two Case Companies. TBM practices and work system practices have a direct positive effect on the manufacturing performance. The implementation of TBM practices will improve the work system practices. This finding corresponds to the study of Rondeau et al. (2000). Strengthening the infrastructure will improve the TBM and work system practices. The studied sub-dimensions of the infrastructure are IS, quality management system and production planning and material control system. The instalment of the infrastructure has a direct effect on the TBM and work system practices.

Figure 4.22: The Impact of Contextual Variables on TBM and Manufacturing Performance of the Case Companies




* The Locus of Decision Making domain covers the construct of Shop-Floor Employee Involvement in Problem Solving

For example, instalment of OEE software to measure performance on the production shop-floor will enhance standardisation. Quality management system consists of quality assurance and quality control. Quality assurance is concerned with the design of the company's management system, including a system for qualifying suppliers, machines and training of employees to assure that the products are designed and manufactured according to pharmaceutical requirements incorporating Good Manufacturing Practices. Quality control is concerned with inspecting, testing and releasing materials and products. The quality management system has an influence on TBM practices, for example testing materials will result in intermediate inventory of materials, or a deviation management system will result in quality improvement efforts on the production shop-floor. Both cases demonstrate also the opposite relationship that improving TBM practices will lead to initiatives to improve the infrastructure. Case Company 2 has initiated several IS improvements through the KPI workgroups as result of improved manufacturing practices. The internal factors in Figure 4.22 are related to the organisational structure and culture according to the studies of Nahm et al. (2003,

2004). These internal factors have in this study a direct effect on the TBM practices and the three sub-dimensions of the infrastructure. The locus of decision making is a sub-dimension of the organisational structure and stands for the degree to which decisions are made higher versus lower in the organisational hierarchy and covers the shop-floor employee involvement in problem solving (Nahm et al., 2003). Assessing manufacturing performance leads to feedback of results which is positively affected by the infrastructure and work system practices. This study demonstrates that the feedback of results will lead to initiatives to improve the manufacturing system by implementing TBM practices and enhancing the infrastructure, positively influenced by the internal factors. Case Company 2 developed a KPI measurement system with data extracted from the integrated ERP system and this system served as basis for the continuous improvement process. The instalment of the work groups has a positive effect on the level of communication and locus of decision making of the participants and this confirms the study of Nahm et al. (2003). This study shows that the business environment (i.e. market circumstances) and the high regulations of the pharmaceutical industry have effects on the TBM practices and infrastructure. These relationships are interpreted as indirect because the organisational structure is a direct result of the company's external environment (Nahm et al., 2003), subsequently leading to changes of the manufacturing system.

# 5 DISCUSSION AND CONCLUSIONS

The Discussions and Conclusions for both Case Companies and Recommendations for further research are described in this section. With respect to the AR framework presented in Table 3.2, the final part of the cycle is described whereby the actual results and processes are analysed and discussed (Final Reflective Cycle Analysis Phase: Diagnosing) and finally the recommendations for further research are made (Final Reflective Cycle Analysis Phase: Planning Action).

## 5.1 DISCUSSION

The aims of this AR project were, firstly, to improve the situation in two Case Companies by implementing TBM practices and enhancing manufacturing performance, and secondly to develop a theoretical model of these practices in relation to the manufacturing performance.

### 5.1.1 DISCUSSION ON THE RELIEF OF THE COMPANY'S PROBLEMS

The two studied manufacturing companies had similar problems and it was believed at the start of the research that implementing TBM practices would relieve the problems of the Companies, as described in the problem statements of the two Companies.

Problem statement of Case Company 1:

*The manufacturing performance (especially delivery performance and quality) is under pressure due to the rapid growth of the Company and must be improved to keep in pace with the growth of its industry and to enter the pharmaceutical market successfully*.

Problem statement of Case Company 2:

*The manufacturing performance (especially delivery performance and time to market of new products) is under pressure due to the rapid growth of the Company and must be improved to keep in pace with the growth of its industry*.

The AR project at Case Company 1 only improved the situation through the implementation of a new ERP system and enhancement of the quality management system, but the manufacturing performance did not improve in terms of speed and reliability. However, the study outcomes are satisfactory, since the participants succeeded to relieve the problem through the improvement of the company's infrastructure, which enabled the Company to enter the pharmaceutical industry. This is in light of the AR philosophy to find solutions to concrete functional organisational problems and by its agnostic nature meaning that the original planned actions can be changes during the AR process as happened in Case Company 1.

The AR project of Case Company 2 significantly improved the manufacturing performance. KPI workgroups were installed to reduce the throughput time, and to increase the delivery dependability. The throughput time, delivery dependability, and production costs improved at the end of the AR project. The problem of the Company was relieved at the end of the AR project, however, the AR project did not aim to improve the time-to-market of new products and this problem remained. The TBM practices improved with the exception of pull production and some improvements were made on the current IS as result of the improvement programme, and improvements of the order-entry process, the internal material flow, the production process, and the process of releasing the finished packed product and shipment to customers were

realised. This study also demonstrates the existence of the relationship between the delivery dependability and throughput time. Through this relationship reducing the throughput time was the right strategy to relieve the company's problem and thus justifying this AR project.

### 5.1.2 DISCUSSION ON THE FINDINGS ANSWERING THE RESEARCH QUESTIONS

The findings of the previous Chapter provide the answers on the research questions, as discussed below:

- 1a) *What are the TBM practices of the Case Companies?*

- 1b) *What other practices can be applied to become a time-based competitor?*

- 1c) *How can TBM and other practices be improved to reduce the throughput time?*

- 2) *What are the internal and external factors that influence the implementation of TBM practices of the Case Companies?*

- 3) *What is the relationship between TBM practices and manufacturing performance of the Case Companies?*

*What are the TBM practices of the Case Companies?*

Detailed and rich data were gathered to describe the TBM practices of both Case Companies. It can be concluded from these data that the seven TBM practices of the framework of Koufteros et al. (1998) are also applicable for the two Case Companies with exception of pull production. Elements of pull production were only observed in the first Case Company. The instruments used in the survey of Koufteros were re-

designed according to the characteristics of the Case Companies in context to the pharmaceutical preparation manufacturing industry. The questions of the semi-structured interviews concerning pull production, quality improvement efforts and dependable suppliers were made situational specific, but the questions are similar for both Case Companies. The answers on the questions of the survey of Koufteros used in the workshop of the first Case Company regarding pull production were not reliable and therefore the instruments of the semi-structured interviews were redesigned and made more industry specific by changing and adding elements of push production with some drawings of pull and push planning and control system, and material flows to visualise the differences between a push and pull production system. This was necessary, since participants had difficulties to understand the pull production mechanism, which is not familiar in the pharmaceutical manufacturing industry. The construct of quality improvement efforts has been extended according to the quality measurement instrument of Flynn et al. (1994). The extension of this quality construct was considered due to the high regulations of the pharmaceutical industry making quality management systems complex, which may hinder the implementation of TBM practices. The extended questionnaire includes top management support, employee training and involvement, and feedback to employees as additional quality dimensions of the survey items of Koufteros. The remaining items concerning the other TBM practices (e.g. shop-floor employee involvement in problem solving, batch changeover/set-up, standardised manufacturing and preventive maintenance) were modified using open questions due to the semi-structured design of the questionnaire and differences between discrete parts manufacturing and batch processing in pharmaceutical manufacturing, for example, the word “part” was changed in “material” or “product”. Although cellular manufacturing is not fully adopted in pharmaceutical manufacturing, the instrument concerning standardised manufacturing as opposed to cellular

manufacturing contains all items of the survey of Koufteros et al. (1998), since identifying, grouping and classifying of similar products and materials, and location of equipment are also applicable in the two Case Companies.

Based on the assumption that the instrument studying TBM practices must be handled differently across industries, this research has tended to be industry or firm specific. Koufteros et al. (1998) stated in his study that standardised instruments improve the theory development and further research is needed to determine whether the TBM measurement instruments are invariant across industries. The standardised instrument of Koufteros was the basis for the development of the instruments, and therefore this study has extended the development of generalised theory in TBM. The instruments of the semi-structured interviews used at the two Case Companies are similar and can be also used to study TBM practices in other case studies with pharmaceutical manufacturing companies.

*What other practices can be applied to become a time-based competitor?*

The core TBM framework of Koufteros et al. (1998) is mainly concerned with the processes on the production shop-floor representing the manufacturing cycle time, however, this framework does not consider other operational processes, which consume the waiting time of the overall throughput process and time spent manufacturing the product is typically only a small fraction of the total time spent of the overall throughput process. The waiting time reflects mostly the time consumed in the back office, and the volume of information flows and paper work often far exceed the product and materials flow. This applies especially in the high regulated pharmaceutical industry. Blackburn (1991) stated that a manufacturer must remove time from all segments of the delivery chain requiring efforts not only driven by a single function such as manufacturing, but

all functional departments in the organisation should be involved in the improvement process. The largest portion of cycle time reductions tends to come from removing the non-value adding activities and not from doing things faster (Blackburn, 1992). Thus the challenge of becoming a time-based competitor is much a white collar task as it is a factory task because time delays can appear every where in the value-delivery system. Squeezing time from the waiting processes is essential to reduce the overall throughput time to become a time-based competitor and therefore the other practices related to the infrastructure were also taken into account in this study to reduce the total throughput time.

The other practices are illustrated in the framework, presented in Figure 4.22, page 218. The dimensions related to the infrastructure (information systems, quality management system, production planning & material control systems), work system practices and the feedback of performance data to employees are the other practices that can be applied to reduce throughput time. In accordance to the study of Rondeau et al. (2000), this study demonstrates that employing TBM practices will lead to increased levels of work system practices, and additionally also the improvement of the infrastructure will lead to enhanced work system practices. For example, the development of written operating and quality control procedures as part of the company's quality management system will lead to higher formalisation, and the development of IS will lead to higher integration and standardisation, because IS facilitate cross-functional decision making and standardisation of output measurements. Thus this study shows that changes in the infrastructure must be considered when a manufacturer wants to become a time-based competitor due to its indirect effects to both TBM and work systems practices, and these two practices lead directly to throughput time reduction.

Value-stream mapping is another practice used in this study to remove waiting time from the total throughput processes, which is a technique in lean thinking to remove non-added value material and information flows (Womack and Jones, 1996). This technique was useful to redesign the infrastructure in both Case Companies. Process maps were used during the ERP implementation project to redesign the business processes of the first Case Company and this resulted also in reduction of non-added-value activities. The second Case Company succeeded to squeeze time out of the processes with little investments by making process maps of the throughput processes identifying the non-added value processes, and then systematically eliminating the redundant activities.

**Information systems**

This study is in accordance to the study of Davis (2002) describing that companies with an emphasis on cycle-time improvements and speeding up internal processes and operations are able to provide better service and these companies are likely to invest in IS in order to appropriately coordinate the link between the company's competitive strategy to its cycle-time efforts. This study demonstrates that it was necessary in both Companies to improve the infrastructure prior to the implementation and further enhancement of the core TBM practices of Koufteros. After the diagnosis of the first Case Company, it was decided to start with the improvement of the IS before the implementation of the core TBM practices, because the Company operated with a poor developed production planning system, whereas the Case Company 2 had already an ERP system running. The master production scheduling system and a KPI measurement system with the data extracted from the ERP system were already designed and installed by a consulting company before the start of the research project at Case Company 2.

**Production planning and material control system**

Case Company 2 uses a push production planning system for its conventional batch manufacturing, which is widely adopted in the pharmaceutical industry. The push system makes centrally computer control necessary. Case Company 1 adopts more a pull system and installed an ERP system to improve the production planning and material control system, but ERP systems are based on a push method. Therefore, it was important that the instalment of an ERP system did not change the existing pull system into a push system. This study provides a good example that an ERP system can work hand-in-hand with a pull call-off scheme, since the first Case Company succeeded to automate the existing pull mechanism by blending it with the planning strength of an ERP system. The new computer controlled production system uses a combination of push for material planning and a pull approach to prevent congestion. The starting point for production is the customer order which goes directly to the production department that order materials from the warehouse and to the packaging department that order materials from the upstream bulk manufacturing process. The new system triggers replenishment signals to the source of supply, in which the planning department is able to better anticipate to shifts in demand by aligning manufacturing and purchase orders to actual demand, so that both production and suppliers are constantly reacting to actual customer demand. However, this study is not able to demonstrate a possible effect of the successful implementation of the ERP system on the delivery performance because the AR project ended shortly after the implementation of the new system at the first Case Company.

**Quality management system**

The quality management system is an important part of the manufacturer's infrastructure. Quality assurance has the function to develop the quality structure with the responsibilities and activities, together with standard operating procedures ensuring that the company meets the agreed quality levels. It also determines the level of separation of quality control activities by employees completing their work and quality control employees given specific responsibilities for checking the quality afterwards and thus choosing whether the company adopts either a reactive or proactive approach to quality. The pharmaceutical industry tends to adopt a reactive approach due to higher manufacturing complexity caused by the high regulations of the pharmaceutical industry, leading to functional silos in the infrastructure due to the growth of the specialists' role and area of responsibility. However, this study shows that it is possible to adopt an emphasis on prevention in pharmaceutical production, rather than detection in quality despite the high pharmaceutical regulations. Although quality control testing can not be completely integrated into the production process avoiding necessary controls afterwards, pharmaceutical GMP regulations may also have a positive contribution to adopt a proactive role to quality, if the quality assurance system is designed to delegate quality related activities to employees completing their work.

Case Company 1 demonstrated that it is possible to adopt a pull production system and simultaneously meeting the pharmaceutical GMP requirements, whereas Case Company 2 was typically a traditional manufacturer adopting a reactive approach to quality at the beginning of the AR project. The AR project caused that the reactive approach of Case Company 2 is drifting slowly to a proactive and preventive approach through the introduction of a continuous improvement mechanism with workshops forming quality circles and improvement groups. The proactive approach leads to quality improvement

efforts initiated by shop-floor employees and thus enhancing TBM practices. The infrastructure of pharmaceutical manufacturers seems to be complex, but the development of the infrastructure may lead to inefficiencies of other supporting activities, as happened in Case Company 2 with an inefficient production planning and material control system at the beginning of the AR project.

Case Company 1 shows that the installation of IS was helpful to design an efficient production planning and material control system supporting the pull mechanism while meeting the GMP pharmaceutical regulations. Adopting TBM practices embodies the concept of continuous improvement and this reflects the TQM philosophy involving all functions within the company in order to satisfy customer requirements. This is adopted by the KPI measurement system and feedback in KPI circle meetings in the second Case Company involving all operational departments with the objective to improve customer service, resulting that the quality management system develops towards a proactive approach to quality.

*How can TBM and other practices be improved to reduce the throughput time?*

This study provides rich case material on how the TBM practices and the infrastructure can be improved. This study demonstrates that the AR methodology was suitable to improve the TBM practices in both Companies. The use of project groups and meetings was a key element to improve the situation at both Companies. Feedback based on performance measures recording continuous improvement is an essential element of TBM implementation and this should be in place to motivate the employees continuously. Case Company 1 succeeded only to implement an ERP system and to improve the quality management system by using two project groups, but it was not able to improve the manufacturing performance. The second Case Company has

installed a project organisation based on DMAIC improvement mechanism consisting of a team of process owners (i.e. the managers of the operational departments), and 4 multidisciplinary KPI workgroups in order to improve the throughput processes. DMAIC mechanism forms the basis in Lean Six Sigma programmes, but Six Sigma programmes are in most cases only based on process capability improvement efforts, whereas this AR project is based on the improvement of the total throughput process. This is a more holistic approach throughout the whole organisation.

The KPI measurement system of the second Case Company was an excellent tool, focussing on the reduction of throughput time and increase of the delivery dependability. Various actions have been executed to improve the manufacturing performance, such as streamlining the order processes, smoothing material and operational flows, development of a training programme for production operators, improvement of the set-up method through the introduction of SMED techniques, grouping of products by standardisation of materials, introduction of a preventive maintenance programme, introduction of a deviation management system and improvement of the supplier's performance. These actions have resulted in the observed improvements of the manufacturing performance at the second Case Company, but also leading to better compliance of pharmaceutical GMP regulations.

The first Case Company was not able to improve the throughput time, because the company did not have a KPI measurement system in place to measure the manufacturing performance; there was no total approach across the whole organisation; and the extension and reconstruction of production facilities were given a higher priority through the rapid growth of the company hindering the AR project. Top management support was also an issue as mentioned by Blackburn (1991: 20) that the company's motivation on time reduction must come from the top of the organisation and in many companies this requires a change in corporate philosophy and culture.

This study demonstrates that the following prerequisites should be in place for a successful implementation of TBM practices and improvement of manufacturing performance:

1) There should be a total vision and commitment of top management throughout the improvement programme;

2) There should be a total approach across the whole organisation and a holistic belief that TBM is more than manufacturing;

3) The improvement programme should include the diagnosis of the current stage and the implementation plan with proposed actions for improvement. There should be a clear link to the company's strategic goals;

4) A multidisciplinary project organisation should be installed covering all operational functions of the organisation;

5) The use of tools and techniques in particular a KPI measurement system for measuring manufacturing performance is necessary to assure the progress of improvement.

These conditions are much in common with recent studies of successful Six Sigma improvement programmes (Chakravorty, 2009; Guitierrez Guitierrez et al., 2008; Schroeder et al., 2008; Zu et al., 2008).

*What are the internal and external factors that influence the implementation of TBM practices of the Case Companies?*

This study relating to the organisational structure and culture is based on the earlier studies of Nahm et al. (2003, 2004). The factors of the organisational structure are the locus of decision making, nature of formalisation, number of layers in hierarchy, level of horizontal integration and level of communications and these internal factors were investigated in both Case Companies. The other internal factors are related to the organisational culture and the factors studied are the customer orientation, beliefs in investing in facilities and equipment, beliefs in working with others, beliefs on management control and beliefs on integrating with suppliers. This study confirms the earlier findings of Nahm et al. (2003; 2004) and shows that the organisational structure and the organisational culture have a direct relationship with TBM in both Case Companies. This study reveals also that the feedback from employees on manufacturing performance is stimulated when locus of decision making is low in the organisation; there exists a nature of formalisation encouraging autonomous work and learning; the number of layers in hierarchy is low; and both levels of horizontal integration and communications are high.

The external factors observed in this study are the business environment and regulations. This study shows that the changes business environment (i.e. market circumstances) and the high regulations of the pharmaceutical industry have effects on the TBM practices and infrastructure. Examples of the changes of the market circumstances are the entrance of pharmaceutical companies in the nutraceutical market at the first Case Company, and the increase of the price pressure due to the growth of the tender business in the generics pharmaceutical industry at the second Case

Company. The high regulations of the pharmaceutical industry have an impact on TBM practices. The quality control steps build in the throughput process creates intermediate inventory, since materials and products need to be tested in order to meet the pharmaceutical regulations. Intermediate inventory hinders the pull production mechanism. The quality management systems of pharmaceutical manufacturers are primarily a top-down approach and this is opposed to lean thinking of employee empowerment. However, as demonstrated in many Lean Six Sigma initiatives, cultural change programme relies on the site management to drive a true lasting cultural change, owned by all employees and most previous lean six sigma initiatives have occurred in unregulated industries (Basu, 2009: 291). Governmental regulatory issues cause that cultural changes are slow and as result the implementation of TBM practices of pharmaceutical manufacturers is more complex than for standard manufacturers in unregulated industries.

External changes may also have an impact on the organisational structure. For example, the second Case Company has decided to split the marketing & sales organisation and manufacturing organisation into two separated business units in order to better anticipate on the external environment. The manufacturing business unit will then be changed to a full make-to-order manufacturer receiving customer orders from all affiliates making the further development of TBM practices easier.

This study indicates that the company's size may have an influence in the implementation of TBM practices. Case Company 1 with less than 100 employees had more difficulties to improve TBM practices, whereas a larger company, namely Case Company 2 with more than 200 employees was able to improve the whole throughput

process at once by installing four work groups simultaneously. This finding is in line with other studies (Ahmed et al., 1991; Im and Lee, 1989; Hum and Ng, 1995; Shah and Ward, 2003 and White et al., 1999), stating that large plants are more likely to implement lean or JIT manufacturing practices extensively compared to small plants.

*What is the relationship between TBM practices and manufacturing performance of the Case Companies*?

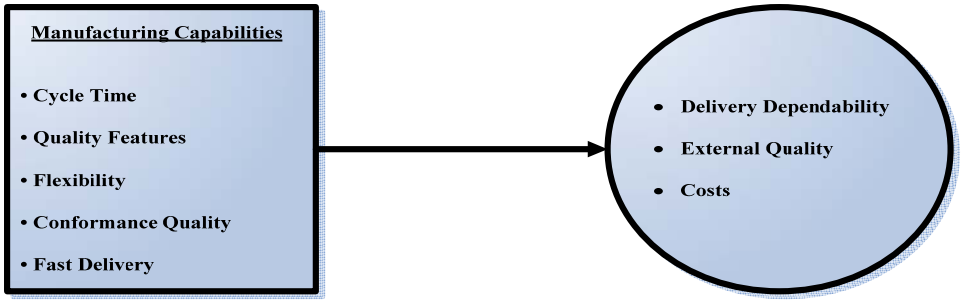
There is a relationship observed between TBM practices and manufacturing performance in only one Case Company. The first Case Company only succeeded to improve its infrastructure, but neither the core TBM practices nor the manufacturing performance improved. The second Case Company made significant improvements of some TBM practices during the implementation phase of the AR project. The quality improvement efforts through the introduction of a deviation management system, the improvement of supplier's performance, the implementation of a preventive maintenance programme, and the grouping and standardisation of products and materials were the major improvements of the core TBM practices. A small improvement of the employee involvement in problem solving and batch changeover/set-up were achieved due to recruitment of new production operators. An intensive training programme was developed during the AR project, but the training of the production operators has been started shortly after this study. Other significant improvements were the streamlined material flow and improved planning processes, as discussed earlier. Time-series analysis shows that the throughput time, delivery dependability and production costs improved during the implementation phase of the AR project. This shows that improvement of TBM practices, and other improvements

such streamlining planning processes and material flows lead to time reduction, substantial improvements in delivery dependability and declined costs.

Although the first Case Company did not significantly improve its manufacturing performance, an interesting strong relationship with a correlation coefficient of 0.75 between the throughput time and delivery dependability is observed. The correlation coefficients of the second Case Company representing the diagnosis phase are 0.51 and 0.69 for the implementation phase. The throughput time of the first Case Company was substantial lower than the throughput time of the second Case Company; 5 weeks compared to 15 - 20 weeks, despite the improvements made at the second Case Company. Koufteros et al. (1998, 1999) concluded in their studies that the primary determinants of the manufacturing throughput time are quality improvements efforts and pull production. They mentioned also that dependable suppliers are not significantly correlated with throughput time in the discrete parts manufacturing industry, but this may be explained by industry specific differences. If materials received from suppliers have low quality or are not received on-time, inventory will increase and production will create delays that immediately impact throughput time. However, this study indicates in Figure 4.21 that dependable suppliers are also a primary determinant in both Case Companies and this applies especially to Case Company 2 having long supplier's lead-times. Case Company 1 has a higher level of TBM practices compared to Case Company 2, since its manufacturing system is driven by customer demand (pull production) and its suppliers have lower lead-times. Case Company 2 has a push manufacturing system and has a lower level of dependable suppliers with long lead-times. These findings suggest that companies with high levels of TBM practices have low throughput times and the relationship between the throughput time and delivery dependability appears to be stronger when companies have low throughput times.

These findings confirm the earlier case studies of Blackburn (1991) and Stalk and Hout (1990) that companies with a focus on compressing time will achieve high productivity and high customer service. The detailed literature review of Sarmiento et al. (2007) studying the compatibility and tradeoffs relationships between the delivery reliability and other manufacturing capabilities supports the observed relationships between the delivery dependability and the throughput time.

Figure 5.1: The Relationship among Manufacturing Capabilities




Source: adapted from Sarmiento et al. (2007)

As Figure 5.1 shows, a manufacturer become more efficient when more outputs (delivery reliability and external quality) are achieved with lesser consumption of inputs (manufacturing costs). The efficiency of the manufacturer depends partly on some other manufacturing capabilities, such as cycle-time, fast delivery and flexibility.

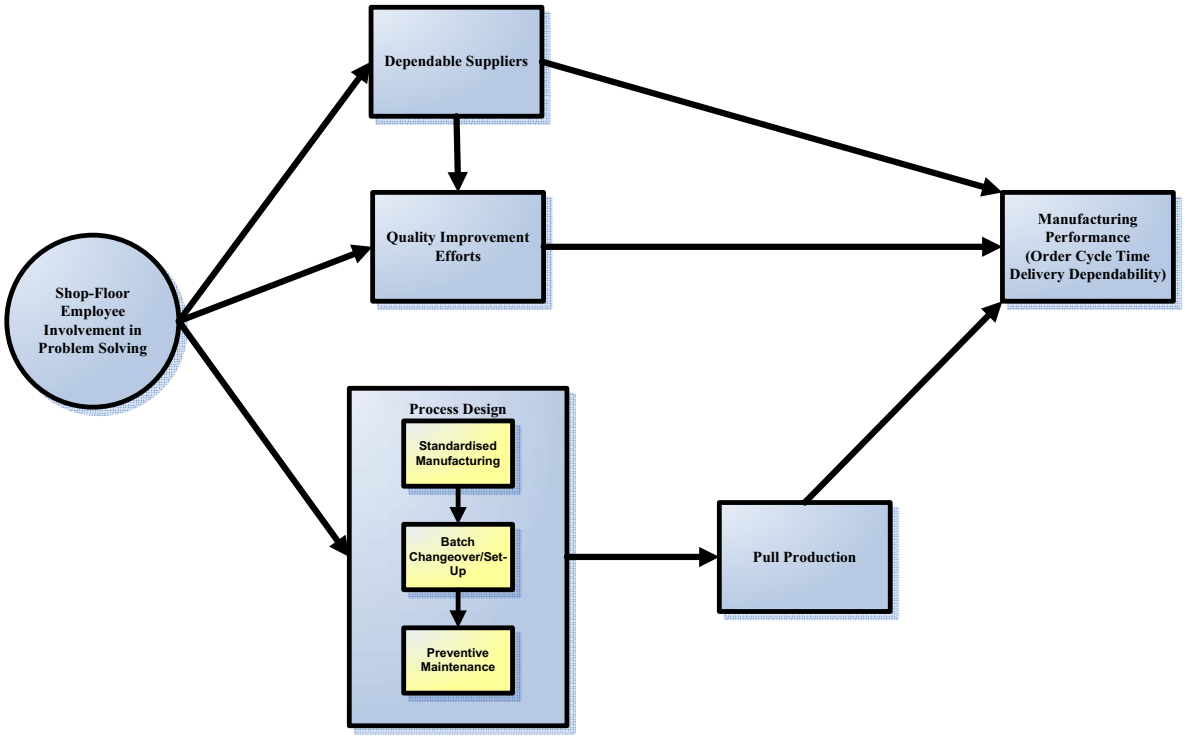
This study contradicts the earlier study of Handfield and Pannesi (1992) stating that the delivery speed and reliability are achieved through different means. They concluded that the delivery dependability is associated with the effectiveness of the manufacturer's production planning and inventory systems, such as MRP systems, whereas the delivery speed is achieved through process improvement. Case Company 2 was able to improve the delivery dependability prior to the AR study in 2007 through the improvement of its

production planning system by using an integrated master production plan, but the throughput time did not improve. This confirms the study of Handfield and Pannesi (1992), however the delivery dependability further improved during the implementation phase of the AR project in 2008 in Case Company 2 and simultaneously the throughput time declined. This shows that manufacturers may strive for both speed and reliability using the same improvement plan.

### 5.1.3 DISCUSSION ON THE TBM FRAMEWORK

Based on the findings of this study, it may be appropriate to reconfigure the framework presented earlier in Figure 4.21, because this framework is based on analytic induction with the objective to generalise theory. When analytic induction is done on more and more cases, it will lead to a generalised framework representing the industry as whole, but it is mentioned earlier in Chapter 1 that the pharmaceutical industry is lagging behind to other industries in terms of operational excellence. This AR study is situational based, and grounded in action, in which the TBM framework will change and extend when the research proceeds, as explained in the Methodology Chapter. AR and implementing TBM practices do not have defined end points to the direction in which the company continually move through the cyclic research process and continuous improvement mechanism. This infinite process will end towards the ideal case situation. It may be useful to develop a framework representing the ideal case situation, based on the experiences of the two Case Companies, which may be used as benchmark model for the implementation of TBM practices. Figure 5.2 presents the framework in the ideal situation in the pharmaceutical manufacturing industry.

Figure 5.2: Ideal Framework of Time-Based Manufacturing Practices




The framework resembles the revised framework of Koufteros et al. (1999), but it has four additional relationships, which are presented in Table 5.1 and discussed further.

Table 5.1: Additional relationships of the ideal TBM framework compared to the framework of Koufteros et al. (1999)

| # | Additional relationships |
|---|---|
| 1 | Shop-floor employee involvement in problem solving >> Dependable suppliers |
| 2 | Dependable suppliers >> Manufacturing performance |
| 3 | Standardised manufacturing >> Batch changeover/set-up |
| 4 | Batch changeover/set-up >> Preventive maintenance |

Shop-floor employees may have direct contacts with suppliers to smooth the material flow of incoming materials. In the pharmaceutical industry materials must be sampled and tested before the material can be used in production, and this may result in an excess of inventory of materials. The lead-time in the warehouse can be reduced, if the activities are coordinated in the receipt area by the shop-floor employees and therefore

the direct communication with suppliers to plan the activities will smooth the material flow. There is a direct relationship observed between dependable suppliers and manufacturing performance. The supplier's lead-time is high in the pharmaceutical industry, and delayed and missed shipments, or a supplier's material has quality problems will create problems, that immediately impact throughput time when production is delayed. The findings presented here show that improvement of standardised manufacturing has a positive effect on the batch changeover/set-up time. Standardisation of materials and uniform instructions for the machinery set-up and measuring line performance will lead to improved batch changeover times and through the improvement of the batch changeover/set-up processes, more time will become available to perform preventive maintenance on machines.

## 5.2 CONCLUSIONS

This research builds on the study of Koufteros et al. (1998) and related studies of Nahm et al. (2003, 2004) and Rondeau et al. (2000, 2003), as well as on seminal work of time-based competition of Blackburn (1991) and Stalk and Hout (1990). This research extends the TBM practices with the pharmaceutical preparation manufacturing industry, and it provides information how to implement TBM practices in general. A theoretical rationale is provided for a set of TBM practices and instruments are developed to study the seven TBM practices, which are also applicable for the pharmaceutical industry. The study provided additional information concerning the relationships between TBM practices.

The company's infrastructure has an impact on the total throughput process and therefore the company's IS and quality management system, based on the study of Rondeau et al. (2003) and Flynn et al. (1994) respectively have been included in this research. As work system practices have also an impact on the throughput time, these practices have also been investigated. Through participant's observation and collection of secondary company data the earlier studies of Nahm et al. (2003, 2004) were used as the basis to study the impacts of the various aspects of the organisational structure and culture on TBM practices.

Comparative analysis of the two Case Company resulted in the design of two frameworks. One framework represents the core TBM practices of Koufteros et al. (1998), which is adapted to the context of the two Case Companies. The other framework represents the overall TBM framework with relationships between the contextual variables, including the core TBM practices, infrastructure, work system practices, organisational structure and culture, external factors, and manufacturing performance. This study clearly demonstrates in line with Blackburn (1991, 1992) that other functions than manufacturing must be included in the improvement programme to become a time-based competitor, especially in the high regulated pharmaceutical manufacturing industry in which most time is consumed in the back office.

### 5.2.1 KEY CONCLUSIONS

The following key conclusions can be drawn from the findings:

1) *TBM practices can be studied and adopted in the pharmaceutical preparation manufacturing industry*.

TBM practices can be applied by pharmaceutical manufacturers, despite the fact that cellular manufacturing and pull production are not widely adopted in this industry. Figure 5.2 indicates that pull production can be developed by specific process design activities. Short batch changeover/setup-times allow manufacturers quickly to changing customer orders. Standardised manufacturing reduces throughput time by grouping and standardisation of materials, streamlining material handling by placing different machines together and cutting batch changeover/set-up times. Preventive maintenance improves the reliability of the manufacturing system by reducing unplanned downtime. The study of the first Case Company shows that elements of pull production may be adopted in a make-to-order system by providing production management direct access to customer order data in order to react rapidly to shifts in customer demand.

2) *The design of the infrastructure is a key factor to become a time-based competitor.*

The infrastructure has at least an equal importance in reducing time compared to TBM practices. The production planning and material control system has to be designed with a pull approach in a decentralised production planning environment to prevent congestion of materials in the manufacturing system. While ERP systems widely used in the pharmaceutical industry are basically push planning systems, a pull production planning system can be automated and strengthened by using the planning strength of ERP systems, which means using the combination of push for material planning and pull for preventing intermediate inventory by keeping the pressure to produce the desired products and keep materials moving. Integrated computerised systems are

necessary for cross-functional involvement and feedback of performance data to employees. This resembles a recent article of Marchand and Raymond (2008), describing an IS perspective to performance measurement systems. The quality management systems of pharmaceutical manufacturers are often designed with a top-down and reactive approach to quality. The quality management systems of pharmaceutical manufacturers must be further developed adopting a Total Quality Management philosophy, using continuous improvement (kaizen) as basis for meeting customer requirements. The continuous improvement mechanism of TQM is needed to install TBM practices and reduce throughput time in which time is used as metric in KPI measurement systems.

3) *The organisational culture and structure have an impact on TBM practices.*

The organisational structure is influenced by the external environment. The pharmaceutical industry is becoming more dynamic, competition is intense and the regulations, especially the price regulations are constantly changing. These factors will have an impact on the organisational structure and thus on the extent of employee involvement in problem-solving. To become more flexible to these changes an organisational culture and climate have to be created that facilitate employee empowerment and participation, and these elements are key to successful TBM implementation. In turn TBM may help companies to develop manufacturing capabilities such as delivery speed and dependability, low costs and high quality which is needed in the increasing competitive environment.

4) *There is a relationship between the extent of TBM practices and manufacturing performance in pharmaceutical preparation manufacturers*.

The study demonstrates that the AR project at the second Case Company resulted in the improvement of the throughput time, delivery dependability and production costs. The quality improvement efforts through the introduction of a deviation management system, the improvement of supplier's performance, the implementation of a preventive maintenance programme, and the grouping and standardisation of products and materials were the major improvements of the core TBM practices. Other improvements relate to the infrastructure in order to reduce the waiting time. The improvements of the infrastructure, resulting in better material flow and planning processes, and dependable suppliers had the most impact on the increase of delivery speed and reliability.

5) *This study provides a continuous improvement infrastructure for TBM and shows that the AR methodology may help to increase the continuous improvement effectiveness.*

The problem of a successful initial implementation of manufacturing capabilities, such as lean manufacturing, or TBM is that most companies have problems to sustain or further improve initial deployed manufacturing capabilities (Anand 2009; Mendelbaum 2006; Pay 2008). Most attempts by companies to use TQM, BPR and Six Sigma have ended in failure (Easton and Jarrell, 1998). Companies have extremely difficulties to sustain even initially successful process improvement initiatives and for most companies to be the very best in their industry and stay there is a long journey, which needs a long-term improvement plan of say, 5 – 10 years (Basu, 2009). Continuous improvement is an ongoing activity of consistently improving current processes and applying new processes aiming to increase the level of organisational wide performance through incremental changes in processes and involves organisational learning (Anand et al., 2009; Ittner and Larcker, 1997; Mahoney, 1995; Schön, 1975). Organisational

learning reflects double-loop learning (Argyris and Schön, 1978). The effectiveness of continuous improvement depends on involving employees in double-loop learning challenging the existing ways of executing processes and improving them, but it also depends on creating an infrastructure to coordinate continuous improvement projects (Anand et al., 2009). As mentioned earlier in the Methodology Chapter, the spiral of AR cycles also finds expression in continuous improvement and this AR study has a double-loop learning element through the two stages process concerning the diagnosis stage with a collaborative analysis of the TBM practices by the participants of the Case Companies including myself and the second stage involves the collaborative change of the manufacturing practices. The second Case Company succeeded to install an effective KPI project organisation enabling to increase organisational wide performance (e.g. throughput time reduction), which can be seen as a successful example of a continuous improvement infrastructure. The implementation of actions and changes on the shop-floor in order to solve problems identified in the workshops adopt double-loop learning. This is the core AR project in which the progress of improvements and achieved results are reflected during the workshop meetings by the participants. The thesis AR project concerns with the reflection of the used AR methodology (or effectiveness of the continuous improvement infrastructure) done by the researcher (or programme leader), which is described as meta-learning in the Methodology Chapter. Thus it may be concluded that the AR methodology has a positive impact on the continuous improvement effectiveness, which can be explained by literature on organisational development (OD). This study resembles the following characteristics, which is like OD planned and long-term; it is problem-oriented; it reflects a systems approach; it is action oriented; it involves change agents; and it involves learning principles (Gibson et al., 1994; Lippitt et al., 1985). The two staged improvement approach of the AR methodology, namely the diagnosis phase using questionnaire data,

direct observations, interviews of selected key persons, workshops and examination of documents and records of the organisation, and the intervention phase driven by a change agent finds also its expression in OD (Kirkpatrick, 1985; Lippitt et al., 1985; Tichy, 1983).

6) *This study provides the route for improvement and implementation of TBM practices in the pharmaceutical preparation manufacturing industry*.

The process of becoming a time-based competitor can be long and arduous. According to Blackburn (1991), three years is the typical time required to transform most companies, although extremely complex companies may require more time. Therefore it may be helpful to have a roadmap for this long lasting transformation process requiring a continuous improvement infrastructure as discussed previously. There are basically five steps needed to become a fully operating time-based manufacturer that can be learned from this study. Improvement of existing and implementation of new manufacturing practices and systems by following the entire route of these five steps will lead to the adoption of the full TBM concept.

The first step is that the infrastructure should be further considered when manufacturers want to achieve significant time reductions. The infrastructure absorbs most of the overall throughput time of pharmaceutical manufacturers representing the waiting time that can be reduced through the redesign of throughput processes beyond the manufacturing process. Value-stream mapping is a tool that can be used to streamline the material and information flows and thus decreasing the waiting time. An integrated IS must be installed to control the overall throughput process, including an efficient production planning and material control system that has to be further developed to a

system supporting the KPI measurement system and pull mechanism, obtained in the following steps. The quality management system is a crucial factor in TBM and must be designed with a proactive approach to quality adopting continuous improvement and clear focus to customer requirements. Pharmaceutical manufacturers tend to design their quality management system just to be able in meeting the ever increasing high pharmaceutical regulations, resulting in a reactive system to quality. This may be changed towards a proactive approach when preventive elements are build in the quality management system, for example the use of an effective deviation management system involving employees in quality problems will lead to prevention.

The second step is to install a KPI measurement system using time as basic metric. The order cycle time and the throughput time of all individual processes of the value-stream can be extracted from an integrated ERP system. Other valuable KPI parameters, such as delivery dependability, quality and costs may also be measured and used in the improvement programme, in which time will positively influence these practices, as observed in this study and literature. The KPI measurement system should be served as basis for continuous improvement and used in the KPI workgroups.

The third step is to build a network of dependable suppliers and this is critical for manufacturing competitiveness. Suppliers are merely an extension of the company's manufacturing system and this study demonstrates that suppliers absorb most of the time of the total pharmaceutical supply chain. Suppliers and customers should therefore be linked into the supply chain, which is a critical entity in time-based competition.

The fourth step is to create a process design in which manufacturing should be focussed on fast batch changeover/set-up times, standardised manufacturing and preventive maintenance, instead of only focussing on inventory reduction and cutting costs. Manufacturers that achieve time reductions often obtain substantial benefits in customer service (on-time deliveries), quality and costs, while creating a manufacturing system that is more response to the needs of customers. This needs to be created through an organisational culture and structure that encourages employee participation and empowerment. The creation of cross-functional teams of shop-floor employees, middle and higher management and employees from other key areas to solving operating problems is an important prerequisite for success. These groups should be involved with developing and implementing systems to reduce set-up time, adopting standardised manufacturing, preventive maintenance and improving quality. The shop-floor employees must be involved in continuous improvement initiatives.

The fifth and last step is building a pull mechanism in the production planning and material control system. The TBM framework of Figure 5.2 indicates that batch changeover/set-up, standardised manufacturing and preventive maintenance can deliver pull production and throughput time reduction. A pull production system requires decentralised production planning. Customer orders are given to production line management having access to the production planning and inventory control modules of the ERP system, and this enables production to anticipate on the requested customer order delivery times, pulling the materials from the warehouse and issuing standardised shop-floor production documents for the execution of production orders, as organised in the first Case Company.

### 5.2.2 CONTRIBUTION TO PRACTICE

This research provided three gains which contributed positively to the practice of the Case Companies and this research may also be useful to managers of other companies.

1) This research improved the situation of both Case Companies. Although the first Case Company did not improve the core TBM practices and manufacturing performance, the Company improved the infrastructure through the implementation of an ERP system and further enhancement of its quality management system enabling the Company to enter the pharmaceutical manufacturing industry while remaining the pull production mechanism and short throughput times compared to other pharmaceutical manufacturers. The second Case Company improved TBM practices, the material and information flows, and the manufacturing performance. The literature examines TBM practices in the discrete parts manufacturing industry and this research fills the 'implementation' gap identified in the literature and provides practical means and guidance for successful intervention in TBM practices in the pharmaceutical manufacturing industry.

2) This research extends the existing theory adopted in the discrete parts manufacturing industry and demonstrates that TBM practices apply also in the pharmaceutical preparation manufacturing industry. Researchers studying pharmaceutical manufacturing companies and managers may find this interesting because many of the issues discussed are practically relevant to this industry. This research supports the recent literature describing the current trend that the pharmaceutical manufacturing industry is starting to reconfigure their processes and develop strategies towards "operational excellence"; see

Chapter 1. Planning a strategy for time-based competition and speculating on its strategic implications can be a refreshing process, particularly in an industry filled with pedestrian competitors as the pharmaceutical manufacturing industry. Deploying TBM practices may help a pharmaceutical manufacturer to differentiate from other pedestrian manufacturers.

3) This study shows how to reduce the throughput time and improve TBM practices by using a two staged process. The result that one can take a diagnosis of the company's manufacturing system and apply TBM to improve the manufacturing system is in general very useful to other manufacturers and this study provides an example of how it could be applied.

### 5.2.3 CONTRIBUTION TO KNOWLEDGE

This research provided five gains which may be useful to other researchers.

1) This study provides research instruments that can be used to study TBM practices in pharmaceutical preparation manufacturing companies. Instruments for conducting semi-structured interviews have been designed and used to examine TBM practices in two pharmaceutical manufacturing companies. Researchers implementing semi-structured interviews as their data gathering technique should be able to learn form this study and may use these instruments to replicate the study in a multi-case study within the pharmaceutical manufacturing industry.

2) This study describes additional relationships between TBM practices compared to the TBM framework of the original researchers (Koufteros et al. 1998, 1999). This provides an additional notion on the key interactions between TBM practices to other researchers. Standardised Manufacturing facilitates the batch changeover process to reduce time and this facilitates preventive maintenance, leading to increased equipment reliability and reduced waiting time in the pharmaceutical preparation manufacturing industry. Furthermore, the supplier's performance is more critical in the pharmaceutical industry compared to the discrete parts manufacturing industry, because this study demonstrates that it has a direct impact on the throughput time, while this relationship has not been observed by the original researchers.

3) This study describes how to reduce the throughput time and improve TBM practices through AR. Researchers studying manufacturing system improvement or manufacturing strategy implementation may find the study useful as it summarises the literature on the subject and provides an improvement methodology, whereby semi-structured interviews are undertaken with participants, triangulated with other data sources and after analysing the collected data, an intervention plan and continuous improvement infrastructure are developed and implemented to improve the situation. The AR methodology in this study may especially be used by other researchers carrying out AR within the company they work should not only find helpful advise in this research with respect to matters of research design and data collection but also interesting results that can advise the design of their studies.

4) Researchers studying manufacturing improvement programs may find this study interesting because it shows that reduction of the throughput time will also lead to improved delivery dependability and manufacturing costs by using the same improvement plan. Thus implementing TBM practices can also be used by researchers to improve other manufacturing capabilities, such as delivery dependability and low costs.

5) This study proves that there is a relationship between the throughput time and delivery dependability based on quantitative data in two cases. Researchers conducting manufacturing capabilities studies may find this interesting. This relationship existed also before the improvement plan was initiated in the two cases and this is an unexpected outcome. Comparative analysis of the cases also indicates that the relationship between the throughput time and delivery dependability will become stronger when manufacturers will reducing their throughput times.

### 5.2.4 LIMITATIONS

Despite the interesting results of this study, several limitations need to be emphasised as results of any research and its external validity have to consider limitations. Though precautions have been taken to avoid potential limitations, it is impossible to avoid all such concerns. Limitations of this study may include potential insider researcher's bias, lack of external validity, small company size, and duration of the intervention programme.

First, subjectivity is the main methodological weakness in this study, since the variables have been measured through a single researcher and his dual role as researcher and manager in the studied companies. The strength of the insider researcher is that he has access to hard evidence such as company performance data, whereas quantitative surveys relies often on a single respondent introducing possible bias, because the respondent may potentially present an inaccurate view of performance data. The potential researcher's bias was mitigated by having more subjects, using reflection for identifying areas of potential researcher's bias, and receiving confirmatory feedback from the participants on interview data, project meeting minutes and interim action research reports.

Second, AR is highly situational and each AR project is unique and this study considers data from only two Companies. However, case studies help control confounding factors like organisational structure. Yin (2003) suggests that case research can only be generalised to theory and not to a population. The lack of external validity was mitigated by comparing the findings with existing literature, through comparative analysis of data from the two Case Companies and analytic induction. Further replications are required to fully test the theory.

The third limitation of this study would be the firm size. The two Case Companies are small and mid-sized companies and the continuous improvement infrastructure may differ in large manufacturing companies.

The fourth limitation would be the duration of the intervention programmes in both Case Companies. A longitudinal study over a year is a good length of time to measure initial results of an improvement programme, but as mentioned earlier most manufacturers to become a time-based competitor will need a long-term improvement programme of several years and probably pharmaceutical manufacturers would need more time of 5 - 10 years. This study only demonstrates that the improvement programmes resulted in an initially success, but the two Case Companies have still a long journey to be become a real time-based competitor. The research would be stronger when it follows the entire route for improvement and implementation of TBM practices in the pharmaceutical preparation manufacturing industry, although this process will never end.

### 5.2.5 RECOMMENDATIONS FOR FURTHER RESEARCH

Clearly, future research can attempt to address each of the procedural problems identified in the limitations section. AR studies do not necessarily have a defined end, and can continue indefinitely, becoming embedded within the role of the researcher (Carr and Kemmis, 1986). This is now the case within my role within the Company and I have continued the continuous improvement programme to further develop the manufacturing system. The study results present opportunities for additional research for studying TBM in the pharmaceutical preparation manufacturing industry.

The development of the manufacturing system was at the end of this study still at an early stage towards a fully adopted TBM practices. More evidence will be gained when the research will be extended following the entire continuous improvement route from the involvement of shop-floor employees until a decentralised pull production planning system has been achieved. This may be achieved at my current employer at Case Company 2. The central theme is the continuous improvement by shop-floor employees, in which adequate training and motivation of employees are required to promote continuous improvement and to enable participation. Salient initiatives to capture process improvement ideas from shop-floor employees were not prevalent in the two Case Companies. However, these Companies regularly hold workshops for middle management to generate ideas for process improvement projects. Thus although these Companies do not explicitly use bottom-up idea generation practices, ideas from middle management are systematically captured. The research may be extended by involving the shop-floor employees directly in the continuous improvement process which will strengthen the TBM practices. Pull production may be facilitated by several TBM practices rather than a parameter that can be set directly. However, a Kanban pull system has the disadvantage that it requires inventory in the intermediate stages of the materials replenishment system. This applies especially in case, where there is a large number of products with infrequent demand, as observed in both Case Companies. Therefore, a fully operating pull production system using Kanban may probably not work in pharmaceutical preparation manufacturing. Aligning the existing ERP system with the TBM strategy using pull elements is probably the best approach to restructure the manufacturing system. Therefore, it may be interesting to study the transformation process of the push production system into a pull production system in future research.

**Starting points for other researchers**

This study provides several starting points for other researchers to extend theory with additional research. The possible directions elaborated in this section are focussed to the pharmaceutical industry, but can also be followed when studying other industries in order to generalise the theory of TBM practices of the original researchers and the findings of this study. Possible extensions of the research in the pharmaceutical industry are described hereunder and may have the following research questions:

*What are the relationships among TBM practices in the pharmaceutical preparation manufacturing industry*?

This study provides evidence of only two case companies and studying other case companies will increase the external and internal validity. This research may be extended studying other pharmaceutical manufacturers to confirm the findings of this research in a multi-case study. This research has provided the instruments that can be easily replicated in other pharmaceutical manufacturers and through analytic induction with other cases the TBM framework and founded relationships may be studied further and the research may also identify additional specific differences. The research may also be extended through a quantitative study using the survey questions of Koufteros et al. (1998) to test the relationships of the core TBM framework in this study. This study indicates that only small modifications of the measurement model of Koufteros will be needed, in which most questions may be used unchanged, but the measurement model must be further determined in the exploratory phase of the survey. Special attention must be paid for the pull production dimension, since pull production is not widely adopted in pharmaceutical preparation manufacturing.

*What are the relationships of TBM practices among the different types of pharmaceutical manufacturers (differences in market segments, size, or other criteria)*?

The pharmaceutical preparation manufacturing industry is segmented in different types of pharmaceutical manufacturers. This research may be extended by conducting a multi-case study with the different types of manufacturers and explore the differences and similarities of TBM practices and relationships between TBM practices. The different types of pharmaceutical manufacturers can be defined as the traditional pharmaceutical manufacturer producing a few products often in dedicated plants with large batch sizes, the biopharmaceutical manufacturer producing a few but very expensive products in dedicated plants with small batch sizes, the generic pharmaceutical manufacturer producing many products at lowest possible prices in multi-product plants with small batch sizes, the nutraceutical manufacturer producing many products with small batch sizes, but with lower regulation than other pharmaceutical manufacturers and the contract pharmaceutical manufacturer producing many products at competitive prices often with small batch sizes and operating in a make-to-order production system. Differences of make-to-order and make-to-stock manufacturing systems in relation to TBM practices may then also be explored. This study demonstrates that the infrastructure has an influence on the implementation of TBM practices. Therefore, this research may also be extended in a multi-case study by differentiating the types of pharmaceutical manufacturers, for example in low and high performing on IS, or in non- and users of performance measurement systems, or adopters of reactive quality management systems with emphasis on inspection and testing and pro-active quality management systems with emphasis on prevention. This reflects also the question "*What other practices can be applied to become a time-based competitor*?" Studying quality management systems in relation to TBM practices is especially relevant in additional research due to high regulations of the pharmaceutical industry and the

possible links to proactive quality management systems, like Six Sigma practices in co-existence with the stringent pharmaceutical GMP regulations.

A multi-case study may also be extended by differentiating the types of pharmaceutical manufacturers in low and high adopters of TBM practices in relation to the contextual variables of Figure 4.22, as contextual variables may moderate the relationships between TBM practices. This may provide also find possible answers why differences among pharmaceutical manufacturers in the adoption of TBM practices exist. This study has used some contextual variables, but other variables, such as business environmental dynamics (munificence, complexity and dynamism), or organisational variables (for example, human resources, personnel characteristics, process type, company size and -age, etc.) and strategic variables (for example, formal strategic planning, fit between manufacturing and business strategies) may be investigated in other multi-case studies.

*What is the relationship between TBM practices in the pharmaceutical preparation manufacturing industry and manufacturing performance*?

This study shows in two cases that there is a relationship between the extent of TBM practices and the throughput time, and that improvement of TBM practices will lead to reduced throughput time, increased delivery dependability and reduced production costs in one case. Researchers may conduct a multi-case study or a survey studying TBM practices and manufacturing performance by differentiating the pharmaceutical manufacturers in companies with low and high throughput times, as done in the study of Koufteros et al. (1999). Results of such study may confirm the findings of this study and the earlier findings of the original researchers. Other performance data, for example delivery dependability, manufacturing costs, inventory turnover, market share increase

or quality may be included to study additional possible relationships with time. Such study reflects the question "What are the relationships between throughput time and other manufacturing performance parameters?" As stated earlier on page 235, companies with high levels of TBM practices have low throughput times and the relationship between the throughput time and delivery dependability appears to be stronger when companies have low throughput times. This is an important finding, which may be replicated by additional research and extended with other manufacturing performance parameters, since TBM is considered as a strategic manufacturing paradigm in this study. Adopting SM is not mono-dimensional and must achieve a set of specific manufacturing capabilities focussing on more than one measure to obtain competitive advantage, and reducing throughput time though the implementation of TBM practices may achieve this.

*What are the time-based practices in the new product development process in the pharmaceutical industry*?

The examination of relationships between TBM and other time-based practices in the area of other business functions, such as new product development is needed to understand the full concept of time-based competition and its implications on pharmaceutical companies. Time-based competitors compete in both to producing existing products fast and fast to market of new products, but this research has only been focussed to study TBM practices in relation to throughput time reduction in manufacturing. Introducing new products fast to market is at least of equal importance compared to producing existing products fast in the pharmaceutical industry, since pharmaceutical firms seek a first-to-market strategy most of the time (Shah, 2004) and the pharmaceutical industry faces problems in the research and development process resulting in fewer launched patented products since many years (Friedli et al, 2006).

Fast-to-market emphases a reduction in design lead-time, which leads to increased market share and increased profitability. Adopting time-based practices in the new product development process may help pharmaceutical companies to mitigate the problems in the R&D process and to improve the business performance. Therefore, this research may be extended to study time-based practices of the new product development process in the pharmaceutical industry. A multi case study would be the most appropriate research design to study the new product development process of pharmaceutical companies.

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APPENDIX A: START LIST OF CODES

| Descriptive Label | Code | Code to the Research Question |
|---|---|---|
| **Internal Factors - Change** | **C** | |
| Management Team | C-MT | 2a |
| Planning Change | C-PC | 2a |
| Execution of Change | C-ES | 2a |
| Strategy | C-ST | 2a |
| Project Management | C-PM | 2a |
| Consensus Team – Difference | C-TD | 2a |
| Consensus Team – Agreement | C-TA | 2a |
| Change – Resistance | C-RS | 2a |
| Change-Cooperation/Motivation | C-CO | 2a |
| Change-Organisational Constraint | C-OC | 2a |
| **Performance Indicators** | **PI** | |
| Quality | PI-QI | 3 |
| Delivery performance | PI-DD | 3 |
| Costs/Productivity | PI-CO | 3 |
| Delivery Speed/Cycle Time | PI-CT | 3 |
| Flexibility | PI-FL | 3 |
| Time-to-Market of New Products | PI-TM | 3 |
| Financial Results: turnover | PI-TO | 3 |
| Financial Results: profit | PI-PR | 3 |
| Financial Results: inventory turnover | PI-IN | 3 |
| Customer Satisfaction | PI-CS | 3 |
| **External Factors** | **EF** | |
| Growth | EF-MU | 2b |
| Business Environment | EF-BE | 2b |
| Competitors | EF-CO | 2b |
| Customers | EF-CS | 2b |
| Regulation | EF-RG | 2b |
| **Work System Practices (infrastructure)** | **WS** | |
| Work System Practices - Standardisation | WS-ST | 1c |
| Work System Practices - Formalisation | WS-FO | 1c |
| Work System Practices - Routine Use | WS-RO | 1c |
| Work System Practices – Integration | WS-IN | 1c |
| **Internal Factors – Cultural & Organisational Aspects** | **IF** | |
| Growth | IF-GR | 2a |
| Nature of Formalisation | IF-FO | 2a |
| Number of Layers in Hierarchy / Egalitarian approach | IF-HL | 2a |
| Level of Horizontal Integration | IF-HI | 2a |
| Level of Communication | IF-CM | 2a |
| Customer Orientation | IF-CO | 2a |
| Investing in Facilities and Equipment | IF-IN | 2a |
| Beliefs in Working with Others | IF-WO | 2a |
| Beliefs on Management Control | IF-MC | 2a |
| Beliefs on Integrating with Suppliers | IF-IS | 2a |
| Top Management Support | IF-TM | 2a |
| Quality Management System | IF-QS | 2a |
| Production Planning and Material Control System | IF-PP | 2a |
| **Employees / Work Force Management** | **EM** | |
| Shop Floor-Employee Involvement in Problem Solving | EM-SF | 1a |
| Employees – Locus of decision making | EM-DM | 1a |
| Worker Screening | EM-WS | 1a |
| Job Training | EM-JT | 1a |
| Teamwork Training | EM-TW | 1a |
| Worker Flexibility | EM-WF | 1a |
| **Batch Changeover/Set-Up** | **BS** | |
| Batch Changeover/Set-Up - Improving Set-Up Times | BS-IM | 1a |
| Batch Changeover/Set-Up -Set-Up - Tools | BS-TO | 1a |
| Batch Changeover/Set-Up - Jigs/Fixtures | BS-JF | 1a |

| | | |
|---|---|---|
| Batch Changeover/Set-Up – Training | BS-TR | 1a |
| **Standardised Manufacturing** | **ST** | |
| Standardisation - Process Similarities | ST-PS | 1a |
| Standardisation - Grouping/Families of Products | ST-FP | 1a |
| Standardisation - Coding Classification | ST-CC | 1a |
| Standardisation - Factory Layout | ST-FL | 1a |
| **Quality Improvement Programmes** | **QI** | |
| Quality - Project | QI-PR | 1a |
| Quality - Identification of Causes of Problems | QI-IC | 1a |
| Quality - Automatic Stop | QI-AS | 1a |
| Quality - Process Design to Prevent Employee Errors | QI-PD | 1a |
| Quality - Design for Manufacturability | QI-DM | 1a |
| Quality - Design for Stability | QI-DS | 1a |
| Quality - Control Charts | QI-CC | 1a |
| Quality - Specifications Suppliers | QI-SS | 1a |
| Quality - Training | QI-QT | 1a |
| **Dependable Suppliers** | **DS** | |
| Dependable Suppliers - Raw Materials on Time | DS-RM | 1a |
| Dependable Suppliers - Meeting Specifications | DS-QS | 1a |
| Dependable Suppliers - Meeting Company's Needs | DS-CN | 1a |
| Dependable Suppliers - High Quality Materials | DS-HQ | 1a |
| **Preventive Maintenance / Process Management** | **PM** | |
| Preventive Maintenance during Non-Productive Time | PM-PT | 1a |
| Keeping Records of Routine Maintenance | PM-RR | 1a |
| Equipment Improvement | PM-EI | 1a |
| Proprietary Equipment | PM-PE | 1a |
| Testing/Validation of Machines and Equipment | PM-TM | 1a |
| Standardised Instructions | PM-SI | 1a |
| Cleanliness | PM-CL | 1a |
| Slower Run Speeds | PM-RS | 1a |
| **Pull Production** | **PP** | |
| Production Pulled by the Shipment of Goods | PP-SG | 1a |
| Production at Stations is Pulled by the Current Demand of Next Station | PP-DS | 1a |
| **Feedback of Information to Employees** | **FB** | |
| Quantitative | FB-QT | 1c |
| Qualitative | FB-QL | 1c |
| **Information Systems (infrastructure)** | **IS** | |
| Information Systems-Strategic Planning | IS-SP | 1c |
| Information Systems-Cross-Functional Involvement | IS-CI | 1c |
| IS Responsiveness to Organisational Computer Demand | IS-RD | 1c |
| End-User Involvement (in IS related activities) | IS-EI | 1c |
| End-User Training Effectiveness | IS-ET | 1c |
| End-User Computer Skill | IS-ES | 1c |
| Information Systems-Performance | IS-IP | 1c |
| **Pattern Codes** | | |
| Themes | PATT | |
| Causes/Explanations | EXPL | |
| Relationships Among People | NET | |
| Emerging Constructs | EMER | |

**Research questions:**

- 1a) *What are the TBM practices of the Case Companies?*

- 1b) *What other practices can be applied to become a time-based competitor?*

- 1c) *How can TBM and other practices be improved to reduce the throughput time?*

- 2) *What are the internal (2a) and external factors (2b) that influence the implementation of TBM practices of the Case Companies?*

- 3) *What is the relationship between TBM practices and manufacturing performance of the Case Companies?*

APPENDIX B: WORKSHOP – TBM SURVEY

PART A - Structured Questionnaire:

Each definition begins with “The extent to which.” The item scales are five-point Likert scales with 1 = not at all, 2 = a little, 3 = moderately, 4 = much, and 5 = a great deal

**Shop-floor employee involvement in problem solving**

1. Shop-floor employees are involved in problem solving.
2. Shop-floor employees are involved in suggestion programs.
3. Shop-floor employees are involved in designing processes.
4. Shop-floor employees are involved in improvement efforts.
5. Shop-floor employees are involved in problem solving teams.

**Batch changeover/set-up**

6. We have been working towards improving set-up times.
7. Standard set-ups are developed for new processes.
8. Employees work on set-up improvement.
9. Tools for set-up are conveniently located.
10. Employees redesign or reconfigure equipment to shorten set-up time.
11. Employees redesign jigs or fixtures to shorten set-up time.
12. We use special tools to shorten set-up.
13. Our employees are trained to reduce set-up time.

**Standardised manufacturing**

14. Products with design or processing similarities are produced together.
15. Products that share similar design or processing requirements are grouped into families of products.
16. Products are classified into groups with similar processing requirements.

17. Products are classified into groups with similar routing requirements.

18. A coding classification is used to group materials and products into families.

19. Our factory layout groups different machines to produce families of products.

20. Equipment is grouped to produce families of products.

21. Families of products determine our factory layout.

**Quality improvement efforts**

22. We use measurement reports or tools (for example fishbone type diagrams) to identify causes of quality problems.

23. The production line is shut down through an 'automatic' when defects are detected.

24. We aim for a process design which prevents employee errors.

25. We use design of experiments (i.e., Taguchi methods).

26. Our employees use quality control charts (e.g. SPC charts).

27. We communicate quality specifications to our suppliers.

28. We conduct process capability studies.

**Preventive maintenance**

29. There is a separate shift, or part of a shift reserved for preventive maintenance activities.

30. We emphasise good preventive maintenance.

31. Records of routine maintenance are kept.

32. We do preventive maintenance.

33. We do preventive maintenance during non-productive time.

34. We maintain our equipment regularly.

**Dependable suppliers**

35. We receive materials from suppliers on time.

36. We receive the correct quantity of materials from suppliers.

37. We receive the correct type of materials from suppliers.

38. We receive materials from suppliers that meet our specification.

39. Our suppliers accommodate our needs.

40. We receive high quality materials from our suppliers.

**Pull production**

41. We do not produce unless there is a demand in the next station.

42. Production is 'pulled' by the shipment of finished goods.

43. Production at stations is 'pulled' by the current demand of the next station.

44. We use a 'pull' production system.

PART B - Open Questions:

1) What do you consider as strong and weak points of the Company?

2) During the annual new years' company event, the following characteristics of the Company have been presented. Please describe briefly the Company's current situation concerning:
a) Customer satisfaction
b) Technology
c) Business processes
d) Satisfaction of employees

3) What are the problems or constraints of the Company for further growth?

4) Do you have any proposals, remarks or questions?

# APPENDIX C: SEMI-STRUCTURED QUESTIONNAIRE – TBM PRACTICES

## SHOP-FLOOR EMPLOYEES IN PROBLEM SOLVING

1) Are shop-floor employees involved in solving problems, how?

2) Are shop-floor employees involved in group meetings to discuss improvement programs?

3) How are shop-floor employees involved in making new products?

4) What is your role as supervisor to increase the involvement of shop-floor employees and the role of the production manager in this?

## PROCESS DESIGN - BATCH CHANGEOVER/SET-UP

1) What are the activities during a set-up between two batches?

2) When are different punches or moulds used during a batch changeover set-up, and what is the set-up time? What are the activities?

3) If the same punches or, moulds are used, but the machine must be switched on another product or granulate? What are the activities?

4) If the same punches or moulds will be used, but the machine must be switched on the same product of another batch. What are the activities? Only cleaning and changing the shop-floor papers?

5) Do your employees need support from the technical department? If so, when? If not, who else need technical support?

   When do your employees need support from the technical department and how often?

   What is your role as supervisor on the set-ups and the role of the production manager?

6) Is there any motivation or support to improve the batch changeover set-up times and how?

7) Is the set-up reengineering method re-developed in case of new machines and processes?

8) Do shop-floor employees work on improving reengineering set-up times?

9) Are tools for set-up conveniently located?

10) Do shop-floor employees redesign or reconfigure equipment to shorten set-up time?

11) Do we use special tools to shorten set-up?

12) Do employees redesign jigs or fixtures to shorten set-up time?

13) Are shop-floor employees being trained to shorten set-up times?

14) What is the role of the production manager to shorten the set-up times?

15) Do you have any suggestions to shorten the set-up times?

## PROCESS DESIGN - STANDARDISED MANUFACTURING

1) Are products grouped in families of products, how and where in the process?

2) Are products grouped on basis of the shape (for example, using the same machinery and moulding parts during production) of the product?

3) Is a coding classification used to group materials and products into families?

4) Are machines and equipment placed together to group families of products and are these products classified into groups with similar routing requirements?

## PROCESS DESIGN - PREVENTIVE MAINTENANCE

1) Is preventive maintenance performed on the machines? Which machines?

2) Besides the technical department, is preventive maintenance performed by production employees? If so, which activities are performed?

3) Do we perform preventive maintenance activities during non-productive time?

4) Do we emphasise our preventive maintenance, why?

5) Are records of routine maintenance kept?

6) Do we maintain our equipment regularly?

7) Do breakdowns happen often? If so, how often?

8) What is the role of the production manager in preventive maintenance?

## PULL PRODUCTION

1. Is there a push or pull production system at the Company? Could you explain how this pull mechanism works at the Company? How does this system work on the production shop-floor and are there a difference herein between bulk production and packaging?

2. Working according to the pull production system means that the production system reacts on the demand of the customers. Is the production system of the Company capable to react on the continuously changing demand of the customers?

   How?

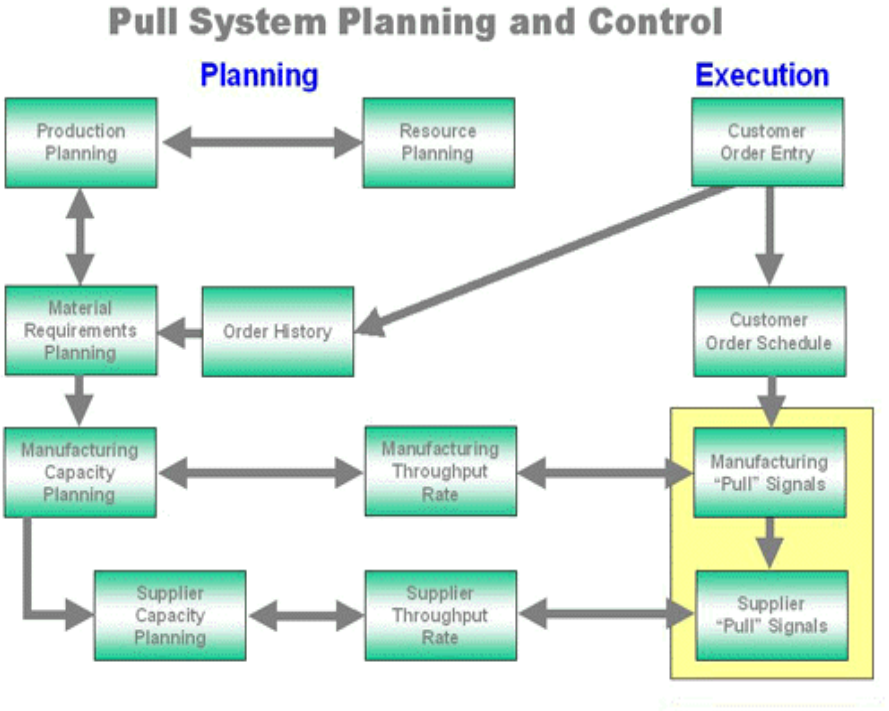
   Do you (as production manager) have direct contacts with the customer, or is only the logistics department involved? Are there any constraints or problems?

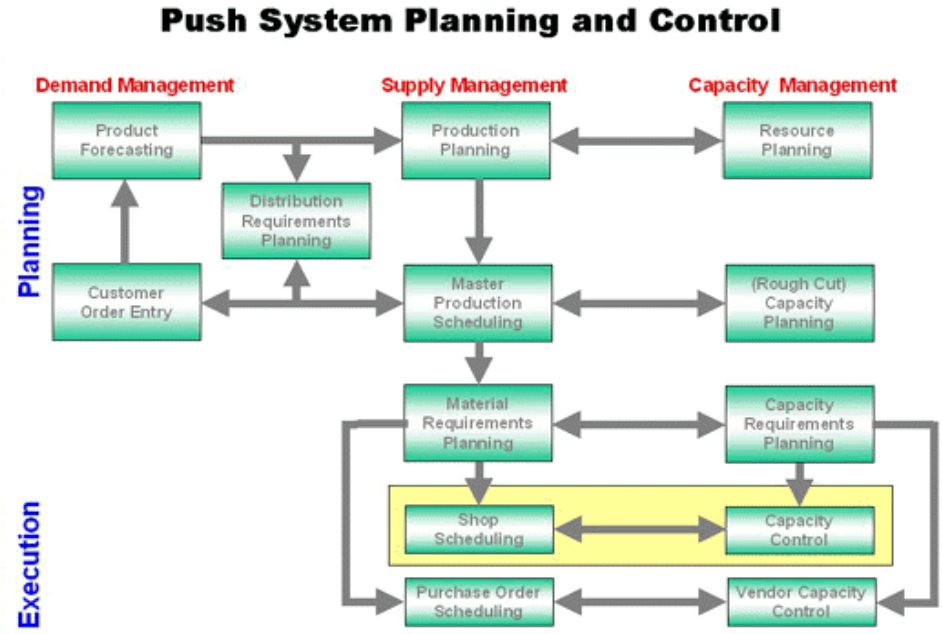
3. The person of the logistics department enters every week the received customer orders in the ERP system. Is this production plan a trigger for you to pull the materials from the warehouse and suppliers and to manage and control the production department?

   How?

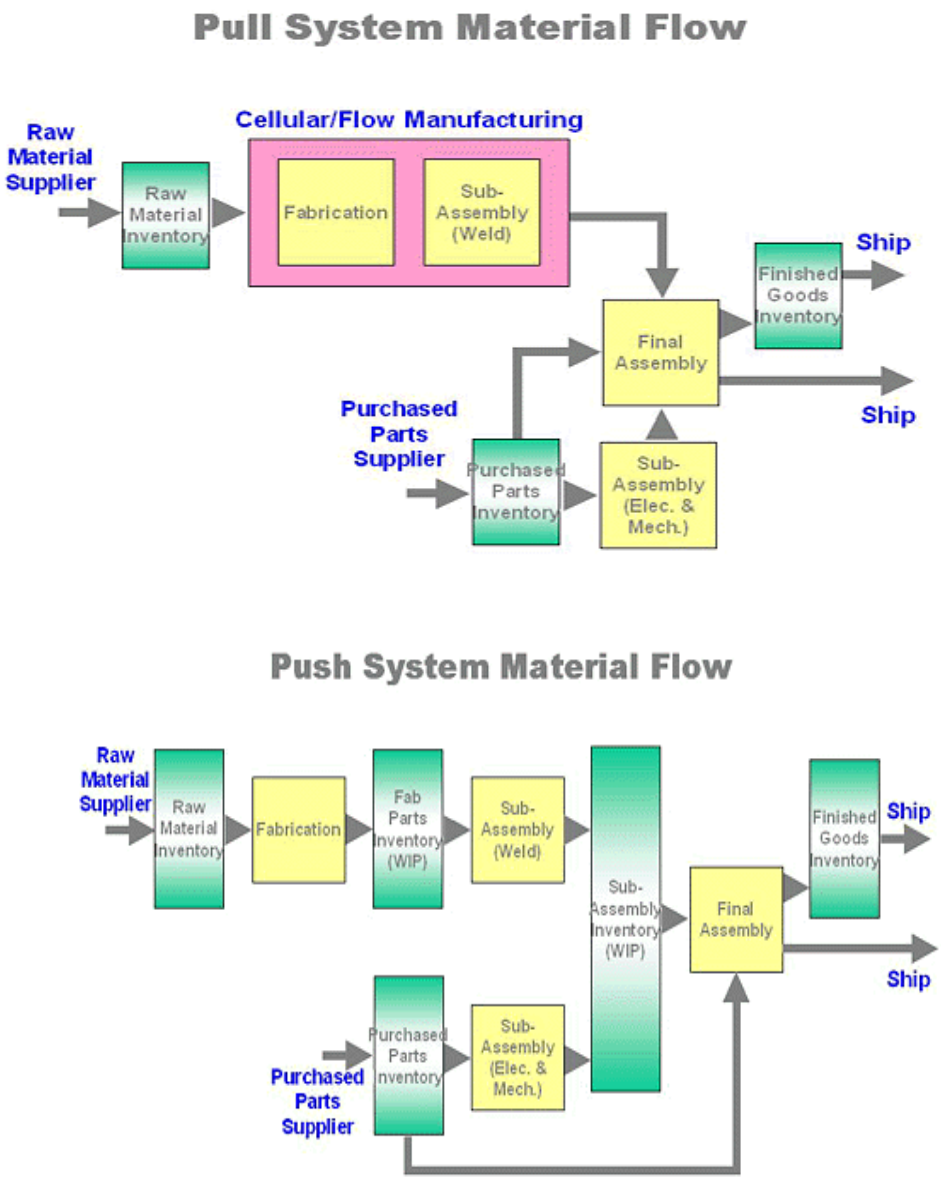
4. How is the weekly planning for production, packaging and deliveries of finished products to the customers organised?

5. I show you now below two figures of respectively a PULL and PUSH planning and control system. After we have discussed both figures, could you indicate the similarities and differences between these two systems and the system of the Company?




6. I show you now below two figures of respectively a PULL and PUSH material flows. After we have discussed both figures, could you indicate the similarities and differences between these two systems and the material flow of the Company?




source: http://www.mamtec.com/lean/building_pullKanban.asp

DEPENDABLE SUPPLIERS

1. Where do we purchase the (bulk)materials? Do we purchase the materials directly from the manufacturer or do we purchase them from intermediate companies?

2. Do we have many different suppliers?

3. What are our requirements of the suppliers?

4. Is there a policy of keeping a long term relationships with our suppliers?

5. What are the delivery times of (bulk)materials?

6. Are there differences in delivery times of among our suppliers? (for example, differences among suppliers of Asia, Europe and the Benelux countries)?

7. Do we receive our materials always on time?

8. Are our suppliers flexible to meet our requirements?

9. Are our suppliers flexible enough to meet unexpected demand (for example, speedy purchase orders)?

10. Do we receive always the exact ordered quantities from our suppliers?

11. Do we always receive the right type of materials from our suppliers?

12. Do we receive high quality materials from our suppliers, which are used without any problems in production?

13. Do we always receive materials from our suppliers which meet to our specifications?

14 (*). Do we communicate our specifications with our suppliers? How?
Is there often contact with our suppliers?

15 (*). Is quality an important criterion for the selection of our suppliers and is quality the most important criterion?

16 (*). Are our suppliers certified and is there a policy to select only a small number of suppliers?

17 (*). Is there a policy to have long-term relationships with our suppliers?

(*) these items are also used in the quality instrument (see also QUALITY IMPROVEMENT EFFORTS)

## QUALITY IMPROVEMENT EFFORTS

1) Is there sufficient support from top management for quality and initiatives to improve quality?

2) Is quality seen by top management as a central theme within the organisation?

3) Has top management herein an active role in quality improvements and are these improvement initiatives communicated by top management?

4) Has the Company an organisational culture that is focussed on quality?

5) Are quality results rewarded and how?

6) Are quality results communicated and is there a feedback from the organisation and from the shop-floor?

7) Are key performance indicators of quality measured and are these indicators communicated with the shop-floor?

The following parameters can be used as performance indicators:

Rework, number of deviations in production, deviations of meeting specifications, number of quality complaints, number of trained people, number of changes of the quality system.

Are these measurement instruments or any other instruments used to identify quality defects?

8) Are we aiming to implement our process which prevent as many as possible defects caused by employees? How? Can you give some of examples which parameters are measured during the production process?

9) Are quality control charts used to control the production processes?
Are these controls effective?

10) Are production machines validated to improve our processes?

11) Are shop-floor employees authorised to stop the production process in case of quality defects?

12) How important is the cleanliness of the machines and the shop-floor?

13) Is there a slow speed production process used to guarantee the quality, or is the speed of the processes more important?

14) How is the development of new products performed and how do we guarantee that the production is meeting the specification of the new developed product? Do we make pilot batches?

15) What is the role of the customers and suppliers in our development of new products? Do we have regularly meetings with customers?

16) Is the development of new products organised in such a way that the participants are working in teams?

17) Are there meetings with employees to improve quality?

18) Is there a good recruitment and training of (shop-floor) employees?

19) How are quality problems (within small teams) solved?

20) Are all employees treated equally, are there differences?

21) Are employees flexible to perform quality improvements?

22) Do we take care with the requirements of our customers regarding quality?

Do have herein a close contact with our customers?

23) Are we certified by our customers?

24) Do we exchange information of the production processes with our customers?

25 (*). Do we communicate our specifications with our suppliers? How?
Is there often contact with our suppliers?

26 (*). Is quality an important criterion for the selection of our suppliers and is quality the most important criterion?

27 (*). Are our suppliers certified and is there a policy to select only a small number of suppliers?

28 (*). Is there a policy to have long-term relationships with our suppliers?

(*) these items are also used in the supplier instrument (see also DEPENDABLE SUPPLIERS)

# APPENDIX D: QUESTIONNAIRE - INFORMATION SYSTEMS

## 1. INFORMATION SYSTEMS: STRATEGIC PLANNING EFFECTIVENESS (IS-SP)

**Question 1:**
**Our company has a well defined Information System Strategy and objectives, which are linked to the overall business strategy.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain how the Information Strategy and objectives are linked to the overall business strategy?

**Question 2:**
**Our company has developed procedures and instructions that clearly define the scope of Information System functional activities.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please describe the development of procedures and instructions defining the scope of IS functional activities?

**Question 3: The business processes of all departments have been improved by the use of IT systems.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Give some examples of improvements of business processes, which have been made.

**Question 4:**
**Our company has developed policies and procedures that clearly define the scope of Information System responsibility within the organisation.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain:

## 2. INFORMATION SYSTEMS: RESPONSIVENESS TO ORGANISATIONAL COMPUTING DEMAND (IS-RD)

**Question 5:**
**Does our company resolve software applications problems quickly?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give recent examples:

**Question 6:**
**Does our company quickly respond to end-user questions and concerns?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give recent examples:

**Question 7:**
**Does our company quickly implement software application upgrades?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give some examples of some software updates recently made:

**Question 8:**
**Does our company resolve computer network problems quickly?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give some examples of resolving network problems:

## 3. INFORMATION SYSTEMS: END-USER TRAINING EFFECTIVENESS (IS-ET)

**Question 9:**
**End-users receive formal class room training on how to use existing Information Systems.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) How is such training organised? Please explain:

**Question 10:**
**End-users receive extensive on-the-job training on how to use the existing Information Systems.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) How is such training organised? Please explain:

4. END-USER COMPUTING SKILL (IS-ES)

**Question 11:**
**Are the end-users highly productive when using the new installed Information Systems?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give any examples:

**Question 12:**
**Are the end-users highly skilled in the use of manufacturing information technologies and computer based-technologies?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Which manufacturing information systems do we use to support production and which persons are using such system? What is your opinion about the skills?

**Question 13:**
**Are end-users capable of completing routine work assignments requiring the use of new installed Information Systems?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give any examples:

5. INFORMATION SYSTEMS: CROSS-FUNCTIONAL INVOLVEMENT (IS-CI)

**Question 14:**
**Are the different departments simultaneously involved in the development of Information System policies and procedures?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give any examples:

**Question 15:**
**Are the different departments simultaneously involved in the integration of Information System planning activities?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give any examples:

**Question 16:**
**Are the different departments simultaneously involved in the prioritization of Information System related activities?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain:

**Question 17:**
**Are the different departments simultaneously involved in the integration of software applications?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please describe the involvement of departments in the integration of software applications:

**Question 18:**
**Are the different departments simultaneously involved in solving software application problems?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please describe the involvement of departments in solving software applications problems:

6. INFORMATION SYSTEMS: END-USER INVOLVEMENT (IS-EI)

**Question 19:**
**Do our end-users have a high involvement in the development or design of the company's Information Systems?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain:

**Question 20:**
**Do our end-users have a high involvement in the analysis and opportunities of the company's Information Systems?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give some examples:

**Question 21:**
**Do our end-users have a high involvement in the testing of the company's Information Systems?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give some examples:

**Question 22:**
**Do our end-users have a high involvement in the development of the company's Information System application?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain:

**Question 23:**
**Do our end-users have a high involvement during the implementation of the company's Information System project?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain:

7. INFORMATION SYSTEMS: INFORMATION SYSTEMS PERFORMANCE (IS-IP)

**Question 24:**
**Are the end-users generally satisfied with the new installed Information System?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give any examples:

**Question 25:**
**Are the new Information System helpful to make better decisions?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) How? Please explain:

**Question 26:**
**Do the end-users recognise the benefits of the new installed company's Information System.**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Please explain and give some examples:

**Question 27:**
**Does the use of the new installed Information System lead to better management of manufacturing activities?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) How? Please explain:

**Question 28:**
**Does the new installed Information System fail to meet the expectations of the end-users?**

a) □ not at all □ a little □ moderately □ much □ a great deal
b) Why, or why not? Please explain:

# APPENDIX E: QUESTIONNAIRE QUALITY MANAGEMENT SYSTEM & SUPPLIERS

## TOP MANAGEMENT SUPPORT

**1) There is sufficient support from top management for quality and initiatives to improve quality.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**2) Quality is seen by top management as a central theme within the organisation.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**3) Top management have an active role in quality improvements and are these improvement initiatives are communicated by top management.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**4) Our company has an organisational culture that is focussed on quality.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**5) Quality results are rewarded by top management.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

## QUALITY INFORMATION

**6) Quality results are communicated and is there a feedback from the organisation and from the shop-floor.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**7) Key performance indicators of quality (for example, number of deviations in production, complaints, deviations of meeting specification) are measured and used to identify quality defects and these indicators are communicated with the shop-floor employees.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

## PROCESS MANAGEMENT

**8) We are aiming to implement our process which prevent as many as possible defects caused by employees.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**9) Quality control charts are used to control the production processes.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*
**These controls are effectively executed by production employees.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**10) The production machines are validated to improve our processes.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**11) The shop-floor employees are authorised to stop the production process in case of quality defects.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**12) The cleanliness of the machines and the production shop-floor is important.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**13) There is a slow speed production process used to guarantee the quality, or is the speed of the processes more important.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**PRODUCT DESIGN**

**14) How is the development of new products performed and how do we guarantee that the production is meeting the specification of the new developed product?**
**Do we make pilot batches?**

**Which changes and improvements have been made in the development of new products?**

**15) Customers and suppliers have an important role in the development of new products and we have regularly meetings with customers.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**16) The development of new products is organised in such a way that the participants are working in teams.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**WORKFORCE MANAGEMENT**

**17) There are meetings with employees to improve quality.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**18) There is a good recruitment and training of (shop-floor) employees.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**19) Quality problems are often solved within small teams.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**20) All employees are treated differently and there are no hierarchical differences in the treatment of employees.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**21) Shop-floor employees are flexible to perform quality improvements.**

□ not at all □ a little □ moderately □ much □ a great deal

*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**CUSTOMER INVOLVEMENT**

**22) We take care with the requirements of our customers regarding quality and we have herein close contacts with our customers.**
□ not at all □ a little □ moderately □ much □ a great deal
*What changes and improvements did take place during last year regarding our involvement with customers? Please explain.*

**23) We are certified by our customers.**
□ not at all □ a little □ moderately □ much □ a great deal
*What changes and improvements did take place during last year regarding the certification of our customers? Please explain*

**24) We exchange information of the production processes with our customers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**SUPPLIERS: QUALITY**

**25*) We receive high quality materials and goods from suppliers, which are used without any problems in production.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has the quality of our suppliers been improved during last year? Please explain.*

**26*) We receive materials and goods from our suppliers that meet our specification.**
□ not at all □ a little □ moderately □ much □ a great deal
*What changes and improvements did take place during last year regarding the quality of suppliers? Please explain.*

**27) We communicate our specifications with our suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*What changes and improvements did take place during last year regarding the communication of specifications with suppliers? Please explain*

**28) Quality is the most important criterion for the selection of our suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**29) Our suppliers are certified and is there a policy to select only a small number of suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**30) There is a policy to have long-term relationships with our suppliers.**
not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

***) these questions are only used in Case Company 2.**

**GENERAL**

**31) What are at this moment the main bottlenecks of the quality management system?**

**32) What are the main barriers of the further improvement of the quality management system?**

**SUPPLIERS: PERFORMANCE (ONLY APPLIED IN CASE COMPANY 2)**

**1) We have many different suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**2) The amount of different suppliers has been declined during last year and this amount will be further reduced.**

□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**3) We demand high delivery performance from our suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**4) The lead-times of goods and materials of our suppliers has been improved and will shorten further.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**5) There are no clear differences in the delivery performance (on-time deliveries, short lead-time, quality) among most of our suppliers. Differences in the delivery performance of the different suppliers, for example from India, Europe and Benelux countries are small.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**6) We receive our goods and materials from our suppliers on time.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**7) Our suppliers accommodate our needs.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**8) Our suppliers are flexible to meet our unforeseen demand (for example rush orders).**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**9) We receive the correct quantity of materials from our suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

**10) We receive the correct type of materials from our suppliers.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been changes and what occurred last year to improve this? Please explain:*

APPENDIX F: SURVEY - WORK SYSTEM PRACTICES

Each definition begins with “The extent to which.” The item scales are five-point Likert scales with 1 = not at all, 2 = a little, 3 = moderately, 4 = much, and 5 = a great deal

**Integration**

1. Cross-functional teams are formed to solve problems.
2. Cross-functional teams frequently organise around projects and tasks.
3. Important decisions are often made by cross-functional consensus.
4. Cross-functional teams are formed to undertake special projects.
5. Cross-functional teams make important decisions on a regular basis.
6. Senior management values the input of cross-functional teams.
7. Cross-functional teams are an important source for new ideas.
8. Important cross-functional decisions are often made by consensus.

**Routine Use**

1. Production workers perform the same tasks each day.
2. Production workers operate the same. machinery and equipment each day.
3. Production workers operate the same kind of product(s) each day.
4. Production workers use the same set of tools each day.
5. Production workers follow the same set(s) of operating procedures each day.
6. First-line supervisors/managers perform the same tasks on a regular basis.

**Formalisation**

1. Written operating procedures specify the precise the precise sequence of steps required to perform each production process.
2. Production workers regularly follow written operating procedures.
3. Production workers regularly follow written quality control procedures.
4. Written policies/procedures specify how to assess product quality.

**Standardisation**

1. We use uniform methods of manufacturing.
2. Uniform methods are used to assess production worker productivity.
3. We use methods for assessing first-line supervisor/management productivity.
4. We use uniform measures of manufacturing performance.
5. We use uniform methods for assessing first-line supervisor/management quality.

# APPENDIX G: QUESTIONNAIRE SHOP FLOOR EMPLOYEES & PROCESS DESIGN

**SHOP-FLOOR EMPLOYEE INVOLVEMENT IN PROBLEM SOLVING:**

**1) Shop-floor employees are involved in problem solving efforts.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**2) Shop-floor employees are involved in suggestion programs.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**3) Shop-floor employees are involved in designing processes and tools that focus on improvement.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**4) Shop-floor employees are involved in improvement efforts.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**5) Shop-floor employees are involved in problem solving teams.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**BATCH CHANGEOVER:**

**1) Employees need support from the engineering department to set-up the production-line during the batch changeover.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**2) We have been working towards improving set-up times.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**3) Standard set-ups are developed for new processes.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**4) Employees work on set-up improvement.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**5) Tools for set-up are conveniently located.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**6) Employees redesign or reconfigure equipment to shorten set-up time.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**7) Employees redesign jigs or fixtures to shorten set-up time.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**8) We use special tools to shorten set-up.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**9) Our employees are trained to reduce set-up time.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**STANDARDISED MANUFACTURING**

**1) Products with design or processing similarities are produced together.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**2) Products that share similar design or processing requirements are grouped into families of products.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**3) Products are classified into groups with similar processing requirements.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**4) Products are classified into groups with similar routing requirements.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**5) A coding classification is used to group parts into families.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**6) Our factory layout groups different machines to produce families of products.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved. What occurred last year and there plans available or in development for future improvement? Please explain:*

**7) Equipment is grouped to produce families of products.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved. What occurred last year and there plans available or in development for future improvement? Please explain:*

**8) Families of products determine our factory layout.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved? What occurred last year and there plans available or in development for future improvement? Please explain:*

**PREVENTIVE MAINTENANCE**

**1) There is a separate shift, or part of a shift, reserved for preventive maintenance activities.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**2) We emphasize good preventive maintenance.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**3) Records of routine maintenance are kept.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**4) We do preventive maintenance.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**5) We do preventive maintenance during non-productive time.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**6) We maintain our equipment regularly.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**7) We have regularly breakdowns on our machines.**
□ not at all □ a little □ moderately □ much □ a great deal
*Has this aspect been improved and which activities occurred last year to improve this? Please explain:*

**PULL PRODUCTION**

**1) We do not produce unless there is a demand in the next station.**
□ not at all □ a little □ moderately □ much □ a great deal

**2) Production is 'pulled' by the shipment of finished goods.**
□ not at all □ a little □ moderately □ much □ a great deal

**3) Production at stations is 'pulled' by the current demand of the next station.**
□ not at all □ a little □ moderately □ much □ a great deal

**4) We use a 'pull' production system.**
□ not at all □ a little □ moderately □ much □ a great deal