Winter 1-31-1994

Concurrent engineering and design for manufacture in the medical device industry

Martin A. Mathelier
New Jersey Institute of Technology

Copyright Warning & Restrictions

The copyright law of the United States (Title 17, United States Code) governs the making of photocopies or other reproductions of copyrighted material.

Under certain conditions specified in the law, libraries and archives are authorized to furnish a photocopy or other reproduction. One of these specified conditions is that the photocopy or reproduction is not to be "used for any purpose other than private study, scholarship, or research." If a, user makes a request for, or later uses, a photocopy or reproduction for purposes in excess of "fair use" that user may be liable for copyright infringement,

This institution reserves the right to refuse to accept a copying order if, in its judgment, fulfillment of the order would involve violation of copyright law.

Please Note: The author retains the copyright while the New Jersey Institute of Technology reserves the right to distribute this thesis or dissertation

Printing note: If you do not wish to print this page, then select "Pages from: first page # to: last page #" on the print dialog screen

ABSTRACT

Concurrent Engineering and Design for Manufacture in the Medical device Industry

by
Martin A. Mathelier

Concurrent Engineering (CE) is an approach to product development in which engineers work on design and manufacturability at the same time. The ultimate goal of concurrent engineering is to reduce the time-to-market while improving quality. This thesis goes into details about the tools necessary to achieve successful product development in the Medical Device Industry. The novelty of this thesis is not in the tools themselves but rather in the way that they are applied to the medical device industry. The need for the CE approach is of utmost importance because of the vast competition in the medical device industry.

The times now require changes. These changes are depicted in detail early in this thesis. This latter suggests that manufacturing is to be perceived like another science. The axiomatic approach to manufacturing answers these needs. A new way of designing a product and collecting data is relevant. It is known as the technique of Quality function Deployment (QFD). Finally, all these tools are managed with the phase approach to management. I sincerely think that this thesis will constitute an invaluable tool for managers and engineers in the medical industry.

CONCURRENT ENGINEERING AND DESIGN FOR MANUFACTURE IN THE MEDICAL DEVICE INDUSTRY

by
Martin A. Mathelier

A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
In Partial Fulfillment of the Requirements for the Degree
of Master of Science in Manufacturing System Engineering

Manufacturing Engineering Division

January 1994

APPROVAL PAGE

Concurrrent Engineering and Design for Manufacture
In the Medical Device Industry

Martin Antoine Mathelier

Dr. Sanchoy Das, Thesis Advisor — Date
Assistant Professor, Department of
Mechanical & Industrial Engineering, NJIT

Dr. Raj Sodhi, Committee Member — / / Date
Director of Manufacturing Engineering Program
Associate Professor, Manufacturing Engineering
Division, NJIT

Dr. Clarence Mayott, Committee Member — Date
Assistant Professor, Department of
Mechanical and Industrial Engineering, NJIT

BIOGRAPHICAL SKETCH

Author: Martin Mathelier

Degree: Master of Science in Manufacturing System Engineering

Date: January 1994

Undergraduate and Graduate Education

- Master of Science in Manufacturing System Engineering,
  New Jersey Institute of Technology,
  Newark, New Jersey, 1994

- Bachelor of Science in Mechanical Engineering
  New Jersey Institute of Technology
  Newark, New Jersey, 1990

Major : Manufacturing System Engineering

Professional Positions Held:

Process Engineer, June 1988 - November 1989, Becton Dickinson Immunodiagnostic System, Orangeburg N.Y.

R&D Engineer, November 1989 - May 1992, Becton Dickinson, Medical Technique Products Division.

Senior R&D Engineer, May 1992 - November 1993 Becton Dickinson, Medical Technique Products Division.

This thesis is dedicated to my mother
Marie Therese Mathelier.

ACKNOWLEDGEMENT

The author wishes to thank his thesis advisor, Dr Sanchoy K. Das for patiently reviewing the progress of the thesis at every stage and helping him to plan it efficiently. This thesis would not have been successful but for his invaluable guidance and concern.

Special thanks to professors Dr Sodhi, and Dr Mayott for serving as member of the committee.

The author is also grateful to Becton Dickinson and Company for their support throughout this project.

Thanks also are due to the librarians at Becton Dickinson for their help in the survey of research papers on the subject of my thesis.

Lastly, a thank you to Director Joe Gregg of Becton Dickinson & Company for his understanding and support.

TABLE OF CONTENTS

Chapter	Page
1 INTRODUCTION	1
1.1 Introduction: The Purpose of Concurrent Engineering	1
1.2 The Importance of Upper Management Involvement for Successful CE and DFM Implementation	5
1.3 Design for Manufacture Concept	7
1.3.1 The Meaning of DFM in the Medical Device Industry.	13
1.3.2 Design for Assembly a Key Attribute of DFM.	13
1.4 Concurrent Engineering as a Competitive Advantage	16
1.5 Concurrent Engineering Strategy and Benefits in the Medical Device Industry.	16
2 THE AXIOMATIC APPROACH TO MANUFACTURING.	20
2.1 Definition of Terms.	20
2.2 Description of the Axiomatic Approach to Manufacturing.	20
2.3 A Methodology for Developing Manufacturing Axioms	22
2.3.1 Hypothetical Axioms.	22
2.3.2 Corollaries.	23
2.4 Disadvantage of the Axiomatic Approach to Design	24
2.5 Rating of a Product Design Using DFA Tool.	25

TABLE OF CONTENTS
(Continued)

Chapter	Page
3 FDA REGULATIONS AND CONSTRAINTS.	27
3.1 Medical Device Technology in General An Overview of Products and the Industry.	27
3.2 Regulation (Constraints) of the Medical Device Industry	33
3.2.1 United States Regulations (FDA)	33
3.2.2 Product Classification.	35
3.3 Product Approval Process	36
3.3.1 Pre-market Notification	36
3.3.2 Pre-market Approval.	37
3.4 The Importance of Accurate Documentation in the Medical Device Industry	40
4 QUALITY FUNCTION DEPLOYMENT.	43
4.1 Quality Function Deployment (Patient Driven Engineering in the Bio-medical Industry)	43
4.1.1 The House of Quality	43
4.2 The Voice of the Patient (Through the Physician)	45
4.3 The Voice of the Engineer	46
4.4 The Importance of Quality Function Deployment in CE	47
4.5 The Meaning of Quality to the Patient	48

TABLE OF CONTENTS
(Continued)

Chapter	Page
5 PHASE APPROACH TO CE & DFM.	50
5.1 A Dual Approach in the Development of a New Product in the Medical Device Industry	50
5.2 The Phase Approach to Concurrent Engineering	50
5.2.1 The Phase of the New Product Development	52
5.2.2 Responsibility of Different Group at Each Stage	54
5.3 Phase Description of New Product Development	54
5.3.1 Application of DFM and CE in the Development Phase	56
5.3.2 Prototyping for Medical Device.	57
5.3.3 Engineering Testing of Medical Device	58
5.3.4 Mfg Process Capability Development	58
5.3.5 Production Process	61
6 TOOLS OF DFM.	64
6.1 Tools of Concurrent Engineering.	64
6.2 The Third-generation Tools Approach to Product Development.	66
6.3 Philosophical Tool of DFM.	68
6.4 Simplification of the Axiom of Manufacturing as Design Tools.	69
6.4.1 Illustration of DFA as a Design Tool	70
6.4.2 The Taguchi Method: A Tool Necessary to Meet the Requirement in the Medical Device Industry	71

TABLE OF CONTENTS
(Continued)

Chapter Page

6.4.3 A Process Driven Manufacturing 72

6.5 The Importance of a Good Software Selection 73

7 A DFM EXAMPLE 77

7.1 B-D PULSITAINER (Blood Containment Device) A DFM Example . . . 77

7.1.1 Rationale 78

7.2 An Interfunctional Product Development Team 78

7.3 The Voice of the Physician in the Development of the Pulsitainer 79

7.4 Pulsitainer's Cost Target 80

8 REFERENCES 84

LIST OF TABLE

Table		Page
1	DFM Tools	12
2	Fastest Growing U.S Manufacturing Industries in 1993	29
3	U.S. Research and Development (R&D)	30
4	FDA Original Inv. Device Exemptions	39

LIST OF FIGURES

Figure		Page
1	Concurrent Engineering Chart.	2
2	DFM Process.	10
3	Core Team.	17
4	Product Proposal	18
5	Purchasers of US medical products.	31
	5.1 US Medical Products Exports.	32
6	U.S. Medical Products Imports	34
7	Quality function Chart.	44
8	The Phase Approach to DFM and CE.	53
9	Spinal Needle Insert Mold Sterile.	62
10	PULSITAINER Phase Implementation.	81

CHAPTER 1

INTRODUCTION

1.1 The Purpose of Concurrent Engineering

A classical definition of Concurrent Engineering (CE) is the earliest possible integration of a company's overall resources, knowledge, experience in design, development, manufacturing and sales. The basic idea is to create successful new products with high quality and low cost while meeting the customer expectations. The most desirable result of using CE is to shorten the product life development cycle. The product concept, design and development process should be parallel instead of sequential.

In the medical device industry, the current manufacturing system method used to achieve shorter product development cycle is the changing of part drawings their tolerances and the modification of existing line-ups. The aforementioned system updates documentation such as part lists, configurations and assembly drawings. This method also reworks the tooling and renegotiates with the component's suppliers. After the product is on the market, the Marketing and Quality Assurance groups report customer complaints on product use and performance against the advertised specifications.

In many cases these reports are usually distributed throughout the organization. The current system does not provide for a product champion initiating a new venture to learn from the previous product manager's mistakes. Communication links are not established to make the design and development departments aware of previous deficiencies. Those deficiencies should not be in the next generation of the product. **Figure 1** illustrates all the information that should be readily

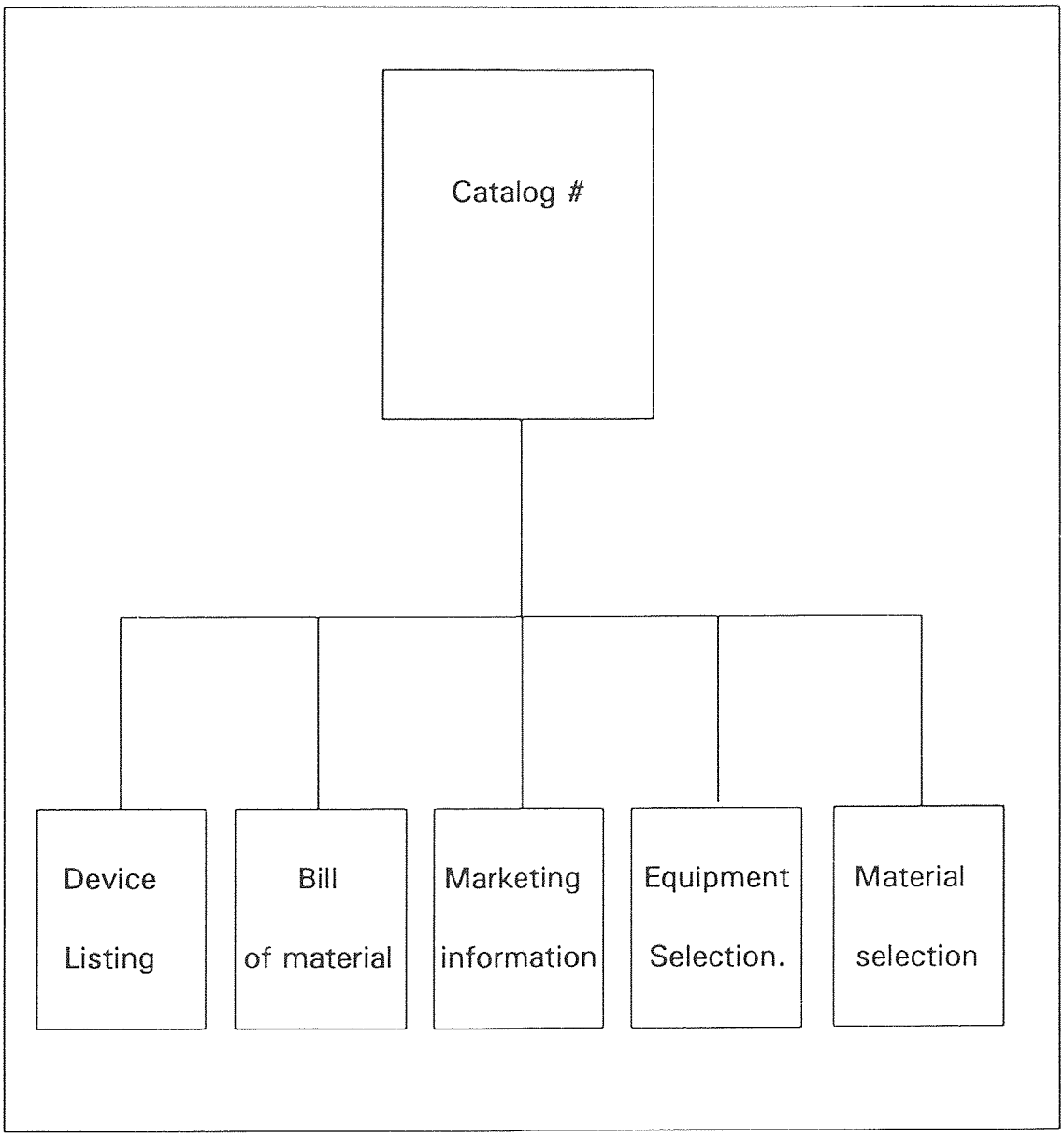

Figure 1 Concurrent Engineering Chart

available for each product in the company catalog. All this information (Device Master Listing - a matrix where all the specifications and all Drawings are listed, Bill of material, Marketing information, Equipment selection, Material election) would prevent the product developers from solving the same problem a number of times. The availability of this information would put the developer in a good starting position. In turn, the development cycle time would be reduced considerably.

At present, only one section of the aforementioned chart (The Device Master Listing Section) is available in the development of a new product. The proposed CE integration method can be implemented using the tool of Design For Manufacture (DFM) discussed later in this thesis. Also, the crucial importance of the functional attributes of a design in the medical device industry was causing the designer often to neglect the axiomatic approach to manufacturing. This approach is discussed later in this thesis. It is simply a set of rules forcing the Designer to make correct manufacturing decisions early in the design process. The need to reduce development time was not a problem until recently, when competition began to increase in the medical device market. One of the problems is that many companies do not have the managements skills, the resources or tracking system necessary to identify these deficiencies.

The new products have the same level of customer satisfaction quality as the previous one. The cause is that engineers are solving the same problems for every new product. Most companies in the medical device industry do not have a structured phase implementation system in the development of a new product. The activities to developed a new product are not structured in the most efficient manner. The order that the process steps are done varies from one project engineer/manager to another. Of course, in a few cases the manager is

knowledgeable of the new Concurrent Engineering techniques available. In those limited cases, successful product are produced. The point is that companies that are currently producing successful products in a short amount of time are mostly doing so because of the skills of their managers, not because of a system in place. The solution to this imbalance, is to have a well structured system where anybody in this industry should be able to follow a set of standardized steps to come up with a successful product in a relatively short time. The trained individual only has to follow the guidelines that this thesis illustrates.

As of now, even though there exists competition in the medical device industry, it is not as rigorous as in the other industries such as the automobile, electronics and appliances industries. The regulations of the Federal Drug Administration to enter this market are very strict. Nevertheless, only the company willing to use the new DFM and CE technique will remain the major player in the Medical Device industry. In the worldwide and domestic competitive arena, companies have to react quickly with new products in order to respond to customer trends, technological advances and competitors products. Medical Device companies need new products to continue to grow by opening new markets, creating new customer demand and increasing their market share.

The key to success in this industry is a company's ability to create new products quickly by doing development manufacturing and delivering customer satisfaction "right the first time". A point of importance is that due to the nature of this industry the release of a badly designed product could be detrimental to the entire organization. The medical device industry deals with human life. The designer has only one chance to make the best product to meet patients needs. Concurrent Engineering can play a significant role in the effective realization of this aim. The techniques and tools of CE concentrate on the product concepts in

order to meet market and customer desires and reduce the time and iterations of new product development. This is achieved by producing prototypes that are made to specifications and meeting the company's manufacturing requirements.

The tools and techniques of Concurrent Engineering were used first in world class companies like Ford, AT&T and Hewlett Packard. All these ideas have become well established and are proven to be successful in many instances. Hewlett Packard has the highest number of new successful products in the past two years. This thesis focuses on applying those well established concepts to the medical device industry. It is predicted that unless a company is willing to adopt those new techniques it will not be able to stay in business.

In the implementation of Concurrent Engineering in the medical device industry, the values of teamwork, the sharing of ideas and their goals beyond their immediate assignment and departmental loyalty are of imperative importance.The successful new product interdisciplinary teams are the ones that are focused on aggressive but achievable goals for CE and DFM. The characteristics of teamwork and cooperation can be rewarded by making them an integral part of the performance evaluation process for engineers.

One of the most important elements in understanding the complexities of introducing new products is the use of the tools of structured analysis to describe the different processes and information flow inherent in a complex medical device plant. The structure chart methodology, which was developed for the software industry, can be used here to describe and clarify those processes.

1.2 The Importance of Upper Management Involvement For Successful CE & DFM Implementation

A important part in the implementation of CE and DFM in the medical device companies is the acknowledgment that CE and DFM are important parts of the

company's competitive strategy. Concurrent Engineering and Design For Manufacturing should be included in the goals and objectives of the entire organization. Each group should have its own strategy matching the overall company plan. Upper management should be convinced that the application of Concurrent Engineering will result in selecting the best opportunities for development. This system will make developing competitively successful products easy. It will achieve more rapid time to market and will increase development productivity. Achieving world class product development using CE will increase revenue and profit. The key benefits are:

1) The reduction in cycle time (cost saving, increased revenue).
2) The product will match the customer's expectations.
3) The products will be designed better (cost saving, increased profit).
4) There will be better overall development.
5) There will be greater global coordination (for worldwide companies having manufacturing sites and distribution centers throughout the world).
6) A new generation of rapid response development process.

The institution of a Concurrent Engineering program requires serious commitment from every level of management. It also requires and a close look at the design, engineering and manufacturing process. Managing the proposed change in a medical device company will require careful planning to ensure success. The practice of CE and DFM should not belong to a specific group but should be shared among all. The role of the company management is to understand the implication of Concurrent Engineering. An example would be a longer initial development cycle with a reduction of the overall cycle for the entire project in question. Another illustration would be the measurement and continuous improvement of the current levels of product cost, testability, quality, reliability and

serviceability. It is also important that management understand the issues of Concurrent Engineering. Management should set operational goals and measures that are in line with the current product design and development practice. In establishing a new product development strategy it is imperative that each Concurrent Engineering plan and goal be clearly outlined. The goal statements and plans of action should be formulated with the cooperation of all appropriate departments. The milestone and checkpoint (describe as phases in the proposed solution) for new products should contain progress updates on Concurrent Engineering goals. Another important role of upper management is to support engineering suggestions of proposing long-range capital and process developments in the company.

The long range plans of manufacturing and information flow should be in line with plans for new products technologies. One major role of upper management should be to support appropriate departments in implementing credible concurrent engineering plans such as documenting process capability for the manufacturing process, determining the current level of warranty cost for the quality department and planning the service level for future products. Finally after a new product is released, production management should perform a retrospective analysis to compare actual results of the product performance after release to production with the original development project goal. The reasons for success or failure should be documented so the information can be fed back to new projects.

1.3 Design for Manufacture (DFM) Concept

Design For Manufacture (DFM) represents a new awareness of the importance of design as the first manufacturing step. As done in all the other industries including the automobile industry, the electronics industry and the appliance industry, the

medical device industry has to recognize that they will not meet quality and cost objectives with isolated design and manufacturing engineering operations. To be competitive in today's medical device marketplace requires a single engineering process from concept to production. The essence of the DFM approach is the integration of product design and process planning into one common activity. The DFM approach embodies certain underlying imperatives that help maintain communication between all components of manufacturing system and permit flexibility to adapt and to modify the design during each stage of the product's realization. The key among these is the team approach to simultaneous engineering, in which all relevant components of the manufacturing system including outside suppliers are made active participants in the design effort from the start. The team approach helps ensure that total product knowledge is as complete as possible at the time each decision is made.

Other imperatives include a general attitude that resists making irreversible design decisions before they absolutely must be made and a commitment to continuous optimization of product and process. The objectives of the Design For Manufacture approach are to identify product concepts that are inherently easy to manufacture to focus on component design for ease of manufacture and assembly, and to integrate manufacturing process design and product design to ensure the best matching of needs and requirements. Meeting these objectives requires the integration of an immense amount of diverse and complex information. This information includes not only considerations of product form, but also the organization and administrative procedures that underlie the design process. Because of the complexity of the issues involved , it is convenient to divide the subject of DFM into two considerations:

1) The DFM approach or process by which a product can be effectively designed

for manufacture and

2) The methodologies and the tools that can be used to help enable the DFM approach and to help ensure that the physical design meets the DFM objectives.

The proposed version of DFM to be used in the medical industry can be illustrated in **figure 2**. The four activities comprising this process are arranged in a circular fashion to emphasize the iterative nature of the process. Traditionally, many products have been designed by starting with functional optimization of the product design itself followed by detail design of each part to be made by a particular process, then simplification and finally design of a process to manufacture and assemble the product. As shown by the arrows, the progression of steps in the proposed DFM process is the reverse of the more traditional design approach.

The DFM process begins with a proposed process concept, and a set of design goals. All three of these inputs would be generated by a thorough product plan developed using the team approach. Design goals would include both manufacturing and products goals. Each activity within the DFM process addresses a particular aspect of the design. Optimization of the product/process concept is concerned with integrating the proposed product and process plan to ensure inherent ease of manufacture. The simplification activity focuses on components design for ease of assembly. This activity can often be rapidly effective because the integrated product and process requirements and constraints help to identify problem areas. The third activity ensures conformance of the design to processing needs. Finally functional optimization considers appropriateness of material selection and parameter specifications that maximize the design objectives. By reversing the process, the DFM approach helps ensure that all of the design

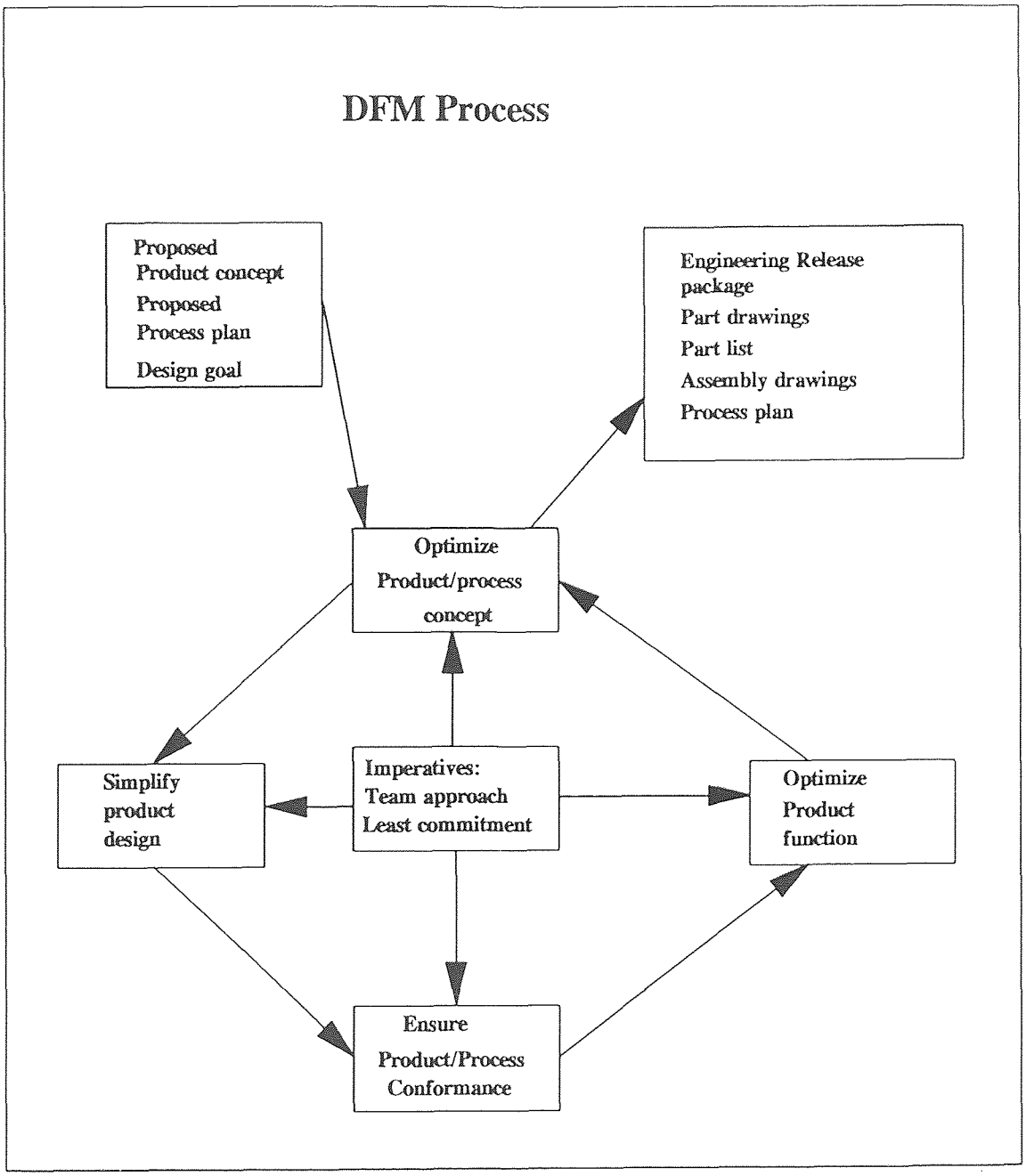

Figure 2 DFM Process

constraints, including assembly, material transformation processes, and material handling requirements are included as part of the functional optimization of the design.

In this, the DFM process enables the design team to consider all aspects of the product's design and manufacture in the early stages of the design cycle, so that design iteration and accompanying engineering changes can be made easily and cost effectively. Finally, by integrating the product and process design, it is possible to include manufacturing recommendations and a process plan as part of the engineering release package. This has great advantages because it leads to few or no manufacturing surprises. Also both manufacturing and engineering share equally in ownership of the ultimate commitment to the design.

The development and use of design methodologies that help the design team achieve an optimized design solution is an important part of the DFM approach. **Table 1** provides a selected list of DFM methodologies and tools and indicates where they might fit into the proposed DFM process. Use of these design methodologies helps promote the objectives of DFM by guiding the design team in making better informed design decisions and providing systematic procedures that help ensure that all aspects of product function manufacture and operational support are considered from the start. For the medical devices industry the DFM design tools that are suggested because of the criticality of functional requirements are as follows: the Axiomatic theory of design, the DFM guidelines, the manufacturing process design rules and computer-aided DFM. A total evaluation of the aforementioned tool of DFM in the medical device industry will show the benefits of this new way of manufacturing.

Table 1 DFM TOOLS

	Optimize Concept	Simplify	Process Conformance	Product Function
Design axiom	☐	☐	☐	☐
DFM Guide.	☐	☐		
DFA Method		☐		
Taguchi Method	☐			☐
Mfg Process		☐	☐	
Design Toolkit			☐	
CAD DFM	☐	☐	☐	☐
Group Tech.	☐	☐	☐	☐
Fmea	☐			☐
Value Analysis				☐

1.3.1 The Meaning of DFM in The Medical Device Industry

In the medical device industry, Design for Manufacture (DFM) means different things to different people. For the designer whose task is to consider the design of a single component, DFM means the avoidance of component features that are unnecessary expensives to produce. Examples include the following: Specification of the surface to be smoother than necessary on a machined component necessitating additional finishing operations; Specification of wide variations in the wall thickness of an injection molded component; Specification of too-small fillet radii in a forged component. Alternatively, the DFM of a single component might involve minimizing material costs or making the optimum choice of materials and processes to achieve a particular result. For example, can the component be cold headed and finish-machined rather than machined from bar stock? All of these considerations are important and can affect the cost of manufacture. They represent only the fine-tuning of costs, however, and by the time such considerations are made, the opportunities for significant savings may have been lost. It is important to differentiate between component or part DFM and product DFM. The former represents only the fine-tuning process taken under once the product form has been decided upon without compromising the functionality. The latter attacks the fundamental problem of the effect of product structure on total manufacturing costs.

1.3.2 Design for Assembly (A Key Attribute of DFM)

Another key to successful product DFM is product simplification through Design for Assembly (DFA). DFA technique primarily aim to simplify the product structure so the assembly cost are reduced. Experience shows that the consequent reduction in part costs often far outweigh the assembly cost reductions. Even more important, the elimination of parts as a result of DFA has several secondary

benefits more difficult to quantify, such as improved reliability and reduction in inventory and production-control costs. DFA, therefore, means much more than design to reduce assembly costs and in fact is central to the issue of product DFM. In other words, part DFM is only icing on the cake; product DFM through DFA is the cake.

DFA derives its name from a recognition of the need to consider assembly problems at the early stages of design. It therefore entails the analysis of both product and part design. For some years now an assembly evaluation method has been in use at Hitachi. In this proprietary method, commonly referred to as the Hitachi method, assembly element symbols are selected from a small array of possible choices. Combinations of the symbols then represent the complete assembly operation for a particular assembly operation for a particular part. Penalty points associated with each symbol are substituted into an equation, resulting in a numeral rating for the design. The higher the rating the better the design.

Another quantitative method involves two principal steps: 1) The application of criteria to each part to determine whether, theoretically, it should be separate from all the other parts in the assembly, an 2) an estimate of the handling and the assembly costs for each part using the appropriate assembly process. The first step, which involves minimizing the part count, is the most important. It guides the designer toward the kind of product simplification that can result in substantial savings in product costs. It also provides a basis for measuring the quality of a design from an assembly point of standpoint. For instance, in the design of a blood containment device at Becton Dickinson & Co., the design team in cooperation with Manufacturing came up with the best design for manufacture where all the components snapped into place. During the second step, cost figures are generated that allow the designer to judge whether suggested design changes will result in

meaningful savings in assembly cost.

For business reasons, most medical device companies are seldom prepared to release their manufacturing cost information. One reason is that many companies are not sufficiently confident about their costing procedures to want manufacturing costs made public for general discussion. In such an environment, the designer of a medical device product will often not be informed of the cost of manufacturing the product that they have been designing. Moreover, engineers and designers do not have the tools necessary to obtain immediate cost estimates relating to alternative product design schemes. Typically, a product will been designed and detailed and a prototype manufactured before a manufacturing cost estimate is attempted. Unfortunately, by then it is too late. The opportunity to consider radically different product structures has been lost, and among those design alternatives might have been a version that is substantially less expensive to produce.

Currently, there is much interest in the medical device industry in having product DFM and DFA techniques available on CAD/CAM systems. By the time a proposed product design has been sufficiently detailed to enter it into the CAD/CAM system, however, it is already too late to make radical changes. A CAD representation of a new product is an excellent vehicle for making effortless details changes, such as moving holes and changing draft angles. But for considering product structure alternatives, such as the choice of several machine parts versus one die casting, a CAD system is not nearly as useful. These basic, fundamentally important decisions must be made at the early sketch in product design. A conflict thus exists. On the one hand, the designer needs cost estimates as a basis for making sound decisions. On the other hand, the product design is not sufficiently firm to allow estimates to be made using currently available techniques. The means

of overcoming this dilemma is another key to successful product DFM -namely early cost estimate. Now some Japanese companies are even establishing their target cost prior to designing the product.

1.4 Concurrent Engineering as a Competitive Advantage

The fact that these CE and DFM methods will bring product to market in a shorter amount of time than the conventional method of manufacturing gives the company a competitive edge. This method could be compared to a force multiplier except for this one three times the resources of the adversary (the competitor) is not necessary to be successful. Moreover, throughout the years, attributes such as quality, cost containment and shorter time to market has given many companies an edge on their competition. Concurrent Engineering and Design For Manufacture are the ways to conquer this very difficult market and to stay on top.

Because of diminishing product life cycles and rapid technological advancements, few firms can afford to adapt their manufacturing technology to the production needs of each new product. And because of increasing consumer sophistication and competitive pressure, still fewer medical device companies can afford to skimp on quality to avoid manufacturing trouble. That is the reason that in order to remain competitive, medical device companies are now turning to Concurrent Engineering and DFM methods to streamline production process and achieve high quality, low cost product.

1.5 Concurrent Engineering Strategies and Benefits in the Medical Device Industry

The first concurrent engineering effort in a medical device company is the

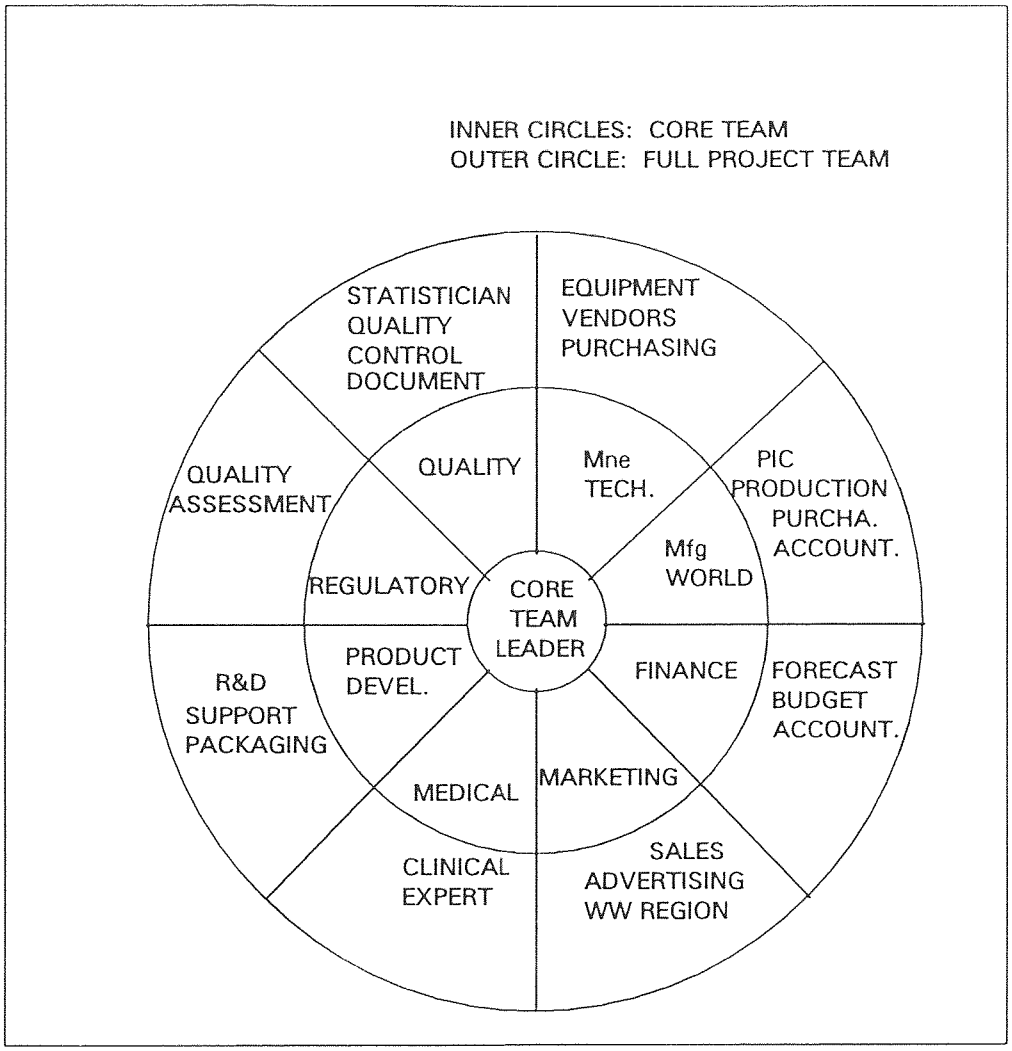

Figure 3 Core Team

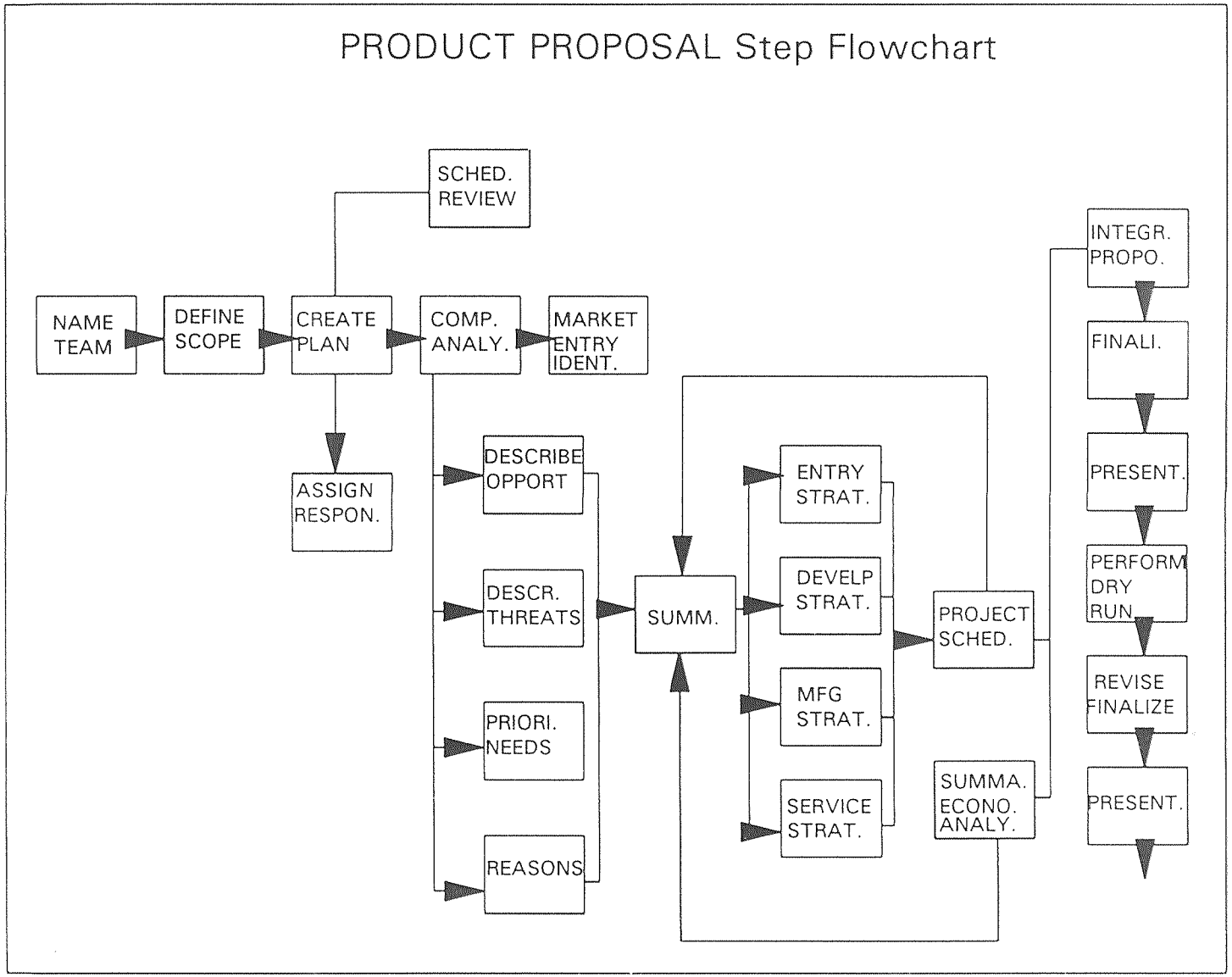

Figure 4 Product Proposal

formation of an interfunctional and interdisciplinary core team (figure 3) and an approval committee to facilitate new product development. The purpose of the team is to shorten the product development cycle, improve product reliability, and reduce cost through Concurrent Engineering and Design For Manufacture. At that point, it is desirable to set specific goals (a product proposal figure 4) for the effort. These goals should be aggressive but realistic for the company and should be based on the performance of current products. The strategy should be to combine the connectivity of CAD with the Design For Manufacturing and to get manufacturing involved early in the design of the product. The strategy's elements could be: a) Document the current manufacturing process capabilities and constraints. Structured analysis and data flow diagrams should be generated for the production processes and reviewed by the respective departments for elimination of redundant tasks and verification of the current process b) Have a data base where all information about a product can be stored; starting from conception to end. This would greatly reduce the development time and improvements could be implemented for a similar new product. c) Review all new parts and use DFM tool for the design of a new product. d) Use and develop software tooling whenever to allow manufacturing to build all prototypes. Manufacturing should treat prototypes as the highest priority of production.

CHAPTER 2

THE AXIOMATIC APPROACH TO MANUFACTURING

2.1 Definitions of Terms

The axiomatic approach that was mentioned earlier in this thesis will contribute a methodology for optimization of the manufacturing system in the medical device industry. The term axiom is used here in the same general sense as thermodynamic axioms, which provide basic guidelines to the study of thermodynamics. Specifically, an axiom is a proposition which is assumed to be true without proof for the sake of studying the consequences that follow from it. Manufacturing axioms should provide reference guidelines, which force decisions toward optimization of the entire manufacturing system when followed. Strictly speaking, an axiom must be a general truth, that is, a rule for which no exceptions or counter-examples can be observed. Similarly, an axiom cannot be proven, rather it must be assumed to be true until a violation or counter example can be found. An axiom must be general. For a manufacturing axiom to be useful, it must be applicable to the full range of manufacturing decisions. By implication, there should be a relatively small number of manufacturing axioms.

The term corollary is used here also in the mathematical sense. A corollary is an immediate or easily drawn consequence of an axiom or set of axioms. In contrast to axioms, corollaries may pertain to the entire manufacturing system, or may concern only a part of the manufacturing system.

2.2 Description of the Axiomatic Approach to Manufacturing

The first step in the axiomatic approach to "optimization" of a manufacturing

system is the specification of the functional requirements of the end product (for example the delivery of serum through syringe). The determination of functional requirements is discussed in Ellinger and Glegg at some length. Functional requirements are defined here as a minimum set of independent specifications that completely define the problem. Other examples of functional requirements are: kinematic and load requirements, expected life under a given set of temperatures, pressures and environment, efficiency, input power, etc. Functional requirements can be ordered in a hierarchial structure, starting from the primary functional requirement to the functional requirement of least importance.

In addition to these functional requirements, there may be the need to specify constraints. Constraints are defined as those factors which establish the boundaries on acceptable solutions. Constraints on the product may be in form of either acceptable cost, OSHA requirements or adaptability to existing systems. The difference between functional requirements and constraints is that functional requirements are negotiable final characteristics of a product, while constraints are not.

Once functional requirements and constraints are specified in a given product, the design of the product can proceed concept. During each stage of realization of the product, axioms can be to make decisions. Each decision must be guided by axioms and corollaries and must not violate them. A product designed by following the axioms, should yield a design which can be made more productively than otherwise. Similarly, the functional requirements constraints may be specified for manufacturing process and manufacturing process may be synthesized following a set of axioms again yielding maximum productivity for that specified product.

2.3 A Methodology for Developing Manufacturing Axioms

As described earlier, axioms have two fundamental characteristics:

1. They cannot be proven.
2. They are general truths; no violations or counter examples can be observed.

These characteristics naturally suggest a heuristic approach in development of axioms. The heuristic approach involves a positive initial set of axioms. Untested and untried, these "hypothetical" axioms can then be subjected to trial and evaluation in manufacturing case studies. The extent to which these hypothetical axioms affect the requirements for true axioms can be assessed. The evaluations can be used to expand, redefine and refine the original set of axioms. The process converges on a comprehensive set of axioms.

2.3.1 Hypothetical Axioms

To begin an axiomatic approach, a starting set of axioms must be stated. They are intended for use in the design of a product on processing and production. They are therefore stated as direct rather than as observations.

Axiom 1. Minimize the number of functional requirement constraints.

Axiom 2. Satisfy the primary functional requirement first. Save the others in order of importance.

Axiom 3. Minimize information content.

Axiom 4. Decouple or separate parts or aspects of a solution functional requirements are coupled or become interdependent to the designs or processes proposed.

Axiom 5. Integrate functional requirements in a single positive solution if they can be independently satisfied in the proposed solution.

Axiom 6. Everything being equal conserve materials.

Axiom 7. There may be several optimum solutions.

2.3.2 Corollaries

A large number of corollaries with more specific applications can be derived from the basic axioms. Eight are derived here for illustrative purposes.

Corollary 1. Part count is not a measure of productivity.

Corollary 2. Cost is not proportional to surface area.

Corollary 3. Minimize the number and complexity of part surfaces.

Corollary 4. If a solution satisfies more independent functional requirements and constraints than were originally imposed, the part or process may be overdesigned.

Corollary 5. A part should be a continuum if energy conduction is important.

Corollary 6. If weaknesses cannot be avoided, separate parts.

Corollary 7. If secondary functional requirements can be satisfied without violating primary requirements then integrate.

Corollary 8. Use standardized or interchangeable parts whenever possible.

The first of these arises out of axioms 4 (decouple to retain independence) and 5 (integrate where independence is maintained). Since axiom 4 increases part count while axiom 5 decreases it while both increase productivity, clearly part count alone contains no information about productivity. Axiom 3 (information) prevents a needless proliferation of parts.

Corollary 2 arises from the axioms constraining information (3) and material (6). Surface area measures neither mass nor information content and thus has little effect on productivity.

Corollary 3 follows from axiom 3, minimize information, and often from axiom

1 (minimize requirements and constraints) when a part is serving too many functions.

Corollary 4 is a consequence of axioms 1 and 7 dealing with minimizing functional requirements and constraints and the plurality of optimum solutions. It states the "no such thing as a free lunch" philosophy. If you are getting more than you need, you are probably paying for it.

Corollary 5 (continuum for energy conduction) results from axiom 5 (integrate). If two parts are to conduct energy in some form (heat, electricity, sound, light, etc) it is advantageous to make them one part to avoid contact resistance or reduced transmission. Axioms 1 and 2 avoid misuse of this corollary where functional requirements other than energy transmission are concerned.

Corollary 6 on avoiding weakness is derived from axiom 4 (decouple to avoid function dependence). If an "O"-ring grove provides a sealing function but weakens a structure, dividing the structure at the groove may reduce stress concentration by moving the stress elsewhere. It is assumed that other axioms are not violated in so doing.

2.4 Disavantage of the Axiomatic Approach to Design

Many experts in the medical device industry are proposing rule-based or axiomatic approach to product design. As describe above the axiomatic approach as applied to the medical device design is based on attempts to identify common properties of successful designs. These common properties such as how the design satisfies the functional requirements, were then proposed as axioms of good design. Design axioms can thus be viewed as global product guidelines that can co-exist with component guidelines for details such as hole spacings, fillet radii and draft angles.

However, axiomatic approaches have two major weakness when manufacturing

is considered in the early stages of product design. Both of these weakness are directly related to cost. First the aforementioned approach does not provide any means of making judgments between the centrally important tradeoffs posed by possible alternative choices of different materials and processes. Second, at the detail level, guidelines tend to lead designer in an essentially fruitless direction. This is because manufacturing guidelines are invariably intended to make individual processing steps as efficient as possible. Following such guidelines might lead to the avoidance of side hole or depressions in molded parts, the minimization of the number of steps in a part to be made by EDM machining it and so on. With this approach, the tendency is to design relatively simple individual components, which will invariably lead to high total fabrication and assembly costs.

The axiomatic approach is recommended but a designer working in a medical environment has to put the functional requirements as primordial concerns. Ultimately a DFM system must therefore must be able to predicts assembly cost, functionality requirement, and component manufacturing costs at the earliest stages of product design. Only in this way will it be possible to the design a product that takes maximum advantage of the capabilities of chosen manufacturing processes within the constraints imposed by functionality. In many situations this will simply mean providing the designer or design teams with the software tools that will enable them to make sound decision from a range of choices. These choices may involve designs necessitating increased tooling but fewer different parts and reduced assembly cost.

2.5 Rating of a Product Using DFA Tools

It is anticipated that medical device product DFM considerations will always start with DFA. To aid designers in implementing these techniques, many software have

been developed for to the medical device manufacturing market to establish an efficient assembly sequence for a proposed new product concept. The software then question the relationship between the parts and give an assembly efficiency rating, together with estimated assembly cost. The DFA process uses the assembly sequence as a vehicle for analyzing the product structure in order to force the design toward more integrated solutions with a reduced part count. This result of DFA is often the most important one in achieving total cost reductions. Thus, DFA analyses must be supported by techniques that will allow the design team to make early estimates of material, processing and tooling costs. Only in this way can designs, with different numbers of parts and perhaps using different materials and processes, be compared before detailed commitment is made.

The results of this DFA analysis, combined with early cost estimating methods, illustrate the kind of result that can be obtained by using DFA as the first step in a product DFM study. Of course, it is possible to achieve savings by considering changes in product design that are directed at reductions in individual part costs. The techniques of DFA and DFM can play a major role in reducing costs and increasing productivity in the design of a medical product. Recognition of this fact is also increasing the demand for cost estimating tools that allow design teams to make the necessary tradeoffs at the early concept stages of design. These technique and tools can play a significant part in helping US industry to keep its supremacy in the medical device industry.

CHAPTER 3

FDA REGULATIONS AND CONSTRAINTS

3.1 Medical Device Technology in General. An Overview of Products and The Industry

For the purpose of understanding the urgency of shorter development cycle, it is important to establish a clear definition of the medical device technology. Referred to as one of the country's more innovative industries, U.S. Medical device technology has been the focus of increasing attention in recent years. The reasons are many: the industry has produced significant new medical advance, from fiber optics to diagnostic imaging; it has become a world leader in medical product sales, contributing to $4 billion to the U.S. trade balance. At the same time this technology like every other aspect of the economy finds itself in the midst of one of today's most significant problem and debates, International and domestic competition and reform of the health care system.

Some organization use a broad definition of medical device technology encompassing most elements of health treatment, including pharmaceutical, medical devices, and medical procedures. This thesis focuses more on the medical devices, and diagnostic products. Medical devices range from relatively simple products, such as surgical gloves, gowns and bandage, to highly sophisticated products such as pacemakers. implacable defibrillator, laser, intraocular lenses fiberoptics, and infusion pumps. Diagnostic products are those that detect or diagnose specific diseases or injuries. They include X-ray machines, Computerized Axial Tomography (CT/CAT) scanners, blood or urine tests, automated laboratory tests, and home testing kits for pregnancy or a variety of illness.

By developing and marketing products of this kind, the health care technology

industry has generated a strong economic performance for many years. To illustrate, the commerce department identified four segments: (surgical and medical instrument, surgical appliance and suppliers, electromedical equipment, and X-ray apparatus and tubes - predicted to be the fastest-growing U.S. industry sectors for 1993 **(table # 2)**.

There are many reasons for such success. First, medical device technology has provided significant innovations in health care delivery in decades. With an aging population, troubling conditions like cancer and heart disease, emerging new illness such as Acquired Immune Deficiency Syndrome (AIDS) and growing concern over good health and improved quality of life, such innovation has found a receptive market. In addition, such products has proven to be successful in global market. As industrialized and emerging nations attend to the growing health needs of their population, this demand for products should continue to increase. The success of the industry can also be attributed in part to its aggressive innovation and intensive commitment to research and development (R&D). In 1991, for example the industry invested 6.3% of sales in R&D **(table # 3)**. This level far exceeded the percentage invested in R&D by the aerospace and chemical industries, as well as 5.8% investment of the high-tech electronics industry. When compared to all U.S industries, R&D spending in health technology industry was almost double the national average.

Such innovation has allowed the industry to capture, and dominate, important world markets. For the period 1987 to 1991, U.S. exports of medical products grew more than doubling in total dollar value, reaching $7.9 billion in 1991 **(figure 5.1)**. Over the past decade, the purchasers of U.S. medical product exports have remained largely the same **(figure 5)** In 1990, for example, the European community, Japan and Canada received two-third of products exports, up slightly

Table 2 Fastest Growing US Manufacturing industries in 1993

FASTEST-GROWING U.S. MANUFACTURING INDUSTRIES IN 1993

(Percent based on constant-dollar shipments)

SIC Code [a]	Industry	1992-1993
3674	Semiconductors	12.0
3841	Surgical and medical instrument	8.5
3842	Surgical appliances and supplies	8.5 [b]
357A	Computer and peripherals	8.2
3845	Electromedical equipment	7.8
3711	motor vehicles and car bodies	6.8
3633	Household laundry equipment	6.7
3632	Household refrigerators and freezers	6.5
371A	Automotive parts and accessories	6.1
3844	X-ray apparatus and tubes	5.6

a Standard Industrial Classification

b Percent change based on current-dollar shipments.

Source: US Department of commerce, International Trade Administration 1993 US Industrial Outlook.

Table 3 U.S. Research And Development R&D

U.S. RESEARCH AND DEVELOPMENT (R&D)

As a percentage of sales in medical products and other industries, 1988-1991

Industry	1988	1989	1990	1991
All industry average	3.4	3.4	3.4	3.6
Health Care	8.2	8.6	8.7	9.0
Medical Products & Services	6.2	6.2	6.2	6.3
Drugs & research	10.0	10.1	10.3	10.8
Aerospace	4.1	4.1	3.7	3.8
Automotive	3.2	3.4	3.7	4.2
Chemicals	3.6	3.8	3.9	4.1
Electrical and electronics	5.3	5.4	5.5	5.8

Source: Business Week, "R&D Scoreboard", 1989-1992

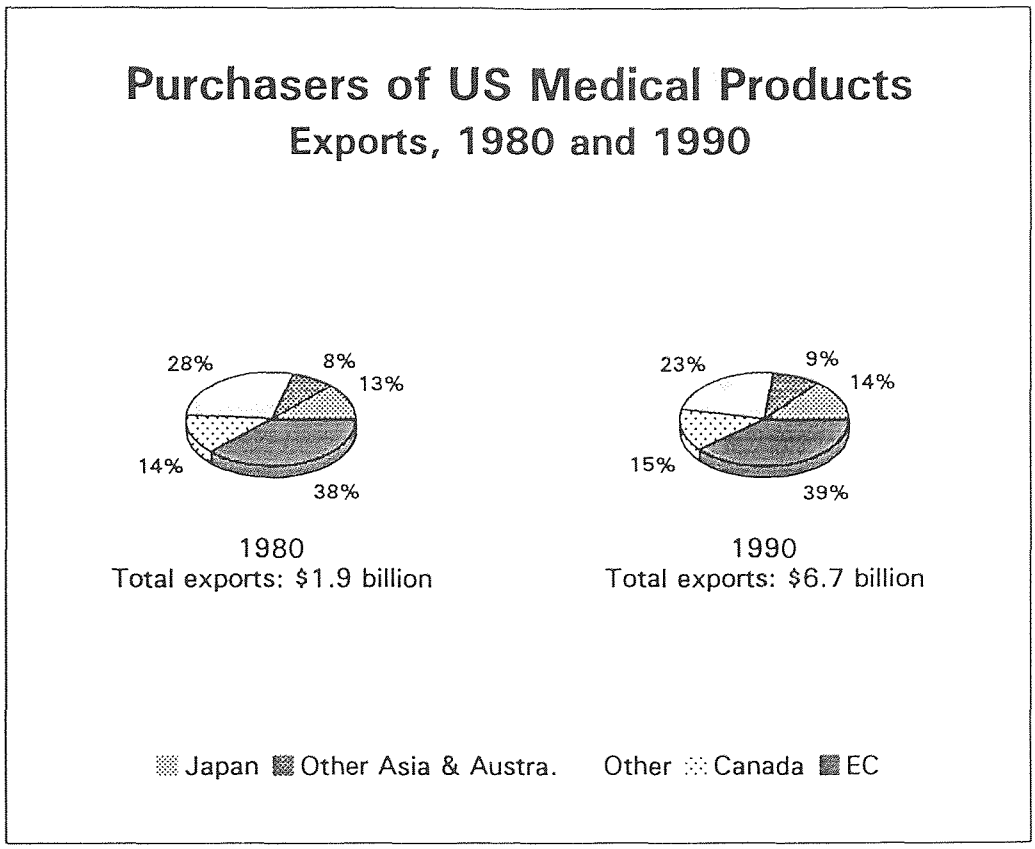

Figure 5 Purchaser of US Medical Products

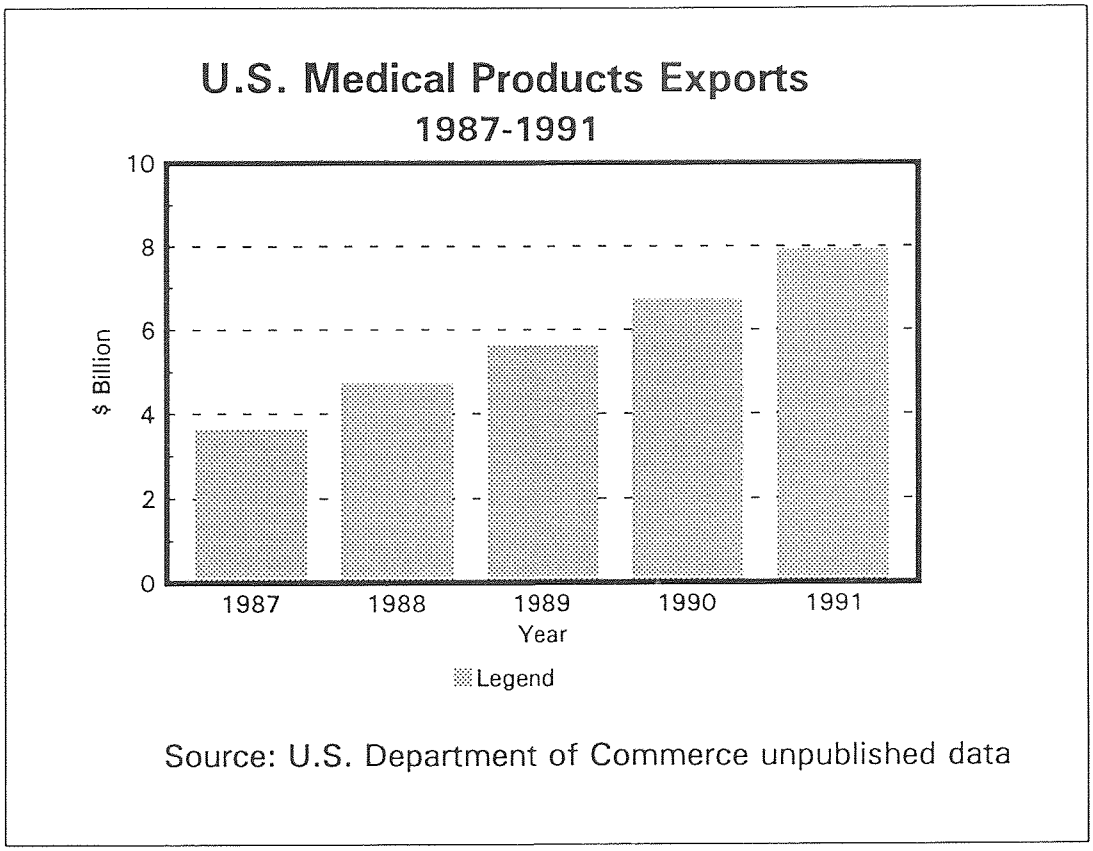

Figure 5.1 U.S Medical Exports

from 1980 export levels. Imports of medical products into the U.S. grew at an average annual rate of 12 percent for the period 1987 to 1991, reaching $4.1 billion in 1991 (figure 6). The EC and Japan supplied 70 percent of US imports in 1990, representing a decline from 1980 levels. This decline was primarily attributable to changes in the level of imports from Germany, which fell from 35 to 25% of U.S. imports during the period 1980 to 1990. In this same period, imports from Japan increased from,18 to 24%. Combined imports from Germany and Japan totalled $818 million and 794 respectively, which accounted for nearly half of total U.S. imports of medical products in 1990.

In 1991 global production of health care technology totalled 70.9 billion. U.S. production accounted for 48% of the total or $33.7 billion. These figure clearly shows that competition is increasing and that unless the U.S. can achieve shorter development time this industry could be in jeopardy.

3.2 Regulation of the Medical Device Industry

Because of the health care technology industry manufactures products for both domestic and international use, it must comply with product safety, and environmental regulation here and abroad. In the U.S. The food and drug administration (FDA) regulates medical products for safety and effectiveness. International regulation of health care technology varies by country, focusing largely on safety.

3.2.1 United States Regulation (FDA)

The most direct form of medical device technology regulation in the U.S. is conducted by the FDA and is designed to assure that all medical devices and diagnostic products are safe and effective. This agency's regulatory duties fall into

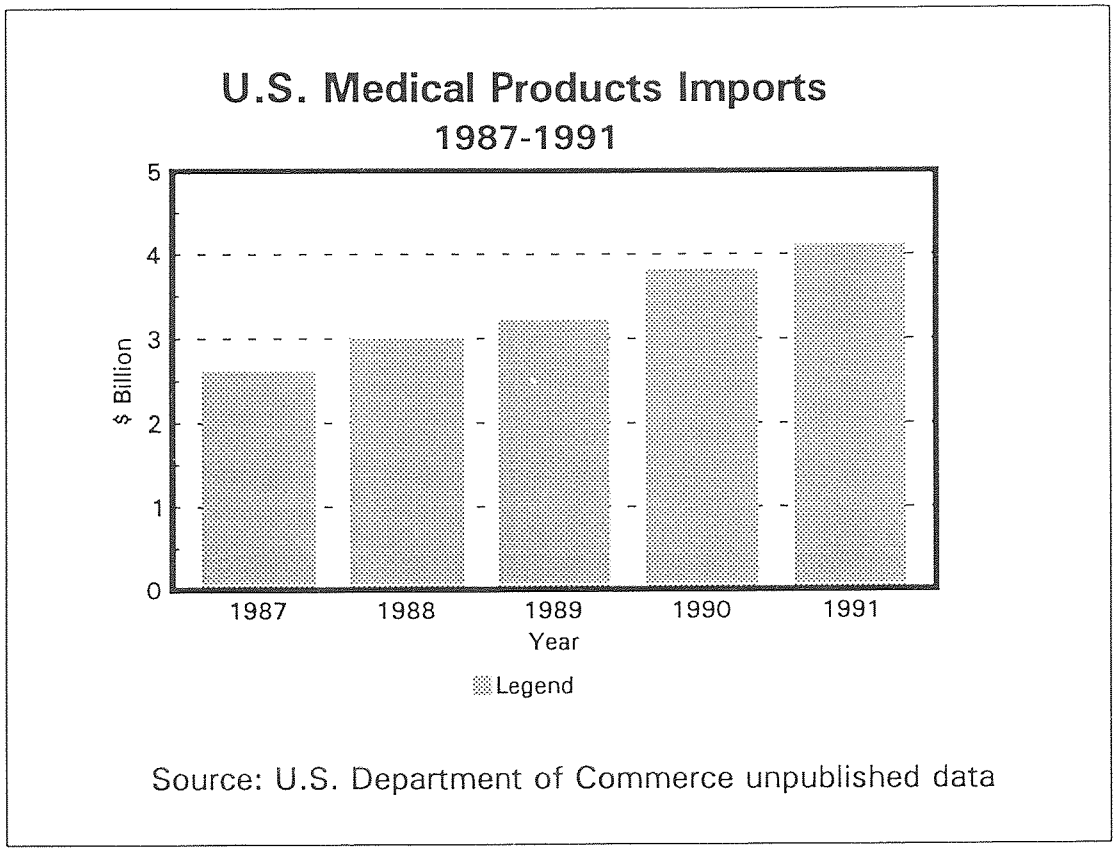

Figure 6 U.S Medical Imports

two general categories: review of a device before it reaches the market; and postmarked control after it has been cleared by the FDA. The type of pre-market

review a medical device undergoes depends, in large part, upon the potential risk it present to the patients. In cases where a device is not substantially equivalent to a legally marketed device and pose significant potential risk, companies must often gather extensive data, including results of testing in humans.

In cases where a product poses a less substantial risk, and is substantially equivalent to a legally marketed device, a company must notify the agency it intends to market the product and assure FDA that it meets certain basic standards. Postmarked controls are designed to keep the agency informed of any potential problems associated with a technology and to permit prompt action to address such problems should they arise.

3.2.2 Product Classification

The degree of regulation a medical device undergoes largely depends, as noted upon the degree of potential risk it poses to humans. After Congress passed the Medical Device amendment of 1976, the legislation that introduced systematic pre-market regulation of medical devices, the FDA classified devices into three categories. Each of the categories, or classes, imposes an increasing level of control over devices and establishes requirements that companies must meet before introducing products onto the market.

- Class I: Products in this category represent devices that pose the least risk. They include product such as simple elastic bandages, enema kits, and pipeting and diluting systems for clinical use. Class I devices must meet certain general controls that assure, among other things, that the product is not adulterated or misbranded,

that it is properly labelled, that is manufactured in a manner to assure that the finished device meets all the specifications, and that the FDA is notified prior to marketing.

- Class II: Products in this category pose a moderate degree of risk and include hearing aids, catheters and hypodermic syringes. In addition to meeting the general control that apply to Class I products, Class II devices must meet any standards or other special controls developed by the agency for that type of device.

- Class III: Products in this category pose the most significant potential risk and are subject to the most stringent controls. Examples of devices in Class III include cardiac pacemakers, extended-wear contact lenses, and replacement heart valves. In addition to complying with the general controls that apply to both of the other Classes of products, these devices must undergo detailed and often lengthy pre-market evaluation to determine if they are safe and effective.

3.3 Product Approval Process

Regardless of the class a product falls into, FDA must conduct a pre-market review of all medical devices before they can be introduced in the market. This is done through detailed pre-market review of the device or a more routine pre-market notification, depending upon the category into which the device has been classified.

3.3.1 Pre-market Notification

If a company intends to market a product that is "substantially equivalent" to an earlier, legally marketed device, it can submit a pre-market notification application, often called a 510(k) application, to the agency. This can be done for class I and II and for devices in class III which the FDA has not required a more detailed pre-market approval (PMA) submission, as will be discussed later. The company must

show that the device has the same intended use as the earlier device and that it represents the same technological characteristics. If it represents different characteristics, then the company must show that it is just as safe and effective as the earlier device.

Once the company receives clearance from the FDA, it can market the product. The fundamental behind pre-market notification is to expedite incremental adjustments in health care technologies through the regulatory process. the reasoning is that if a product represents a modification in a device already been used, whose risk, reliability, and quality are already known, FDA generally needs less information on the device before clearing it for marketing. This has traditionally meant that 510(k) used to be processed relatively quickly often in less than 90 days. Prompted by new legislation passes in 1990 as well as changes in agency practices, however, FDA has recently begun to require more information in 510(k) applications. In some cases the agency requires more extensive data including data from product testing in humans. As a results of these changes, the average total review time for pre-market notification applications has increased steadily during the period fiscal year (FY) 1987 to 1991. Total review time grew from 69 days in FY 1987 to 102 days in 1991, an increase of 48%. In addition the total number of 510(k) decision issued by the agency, as well by the total number of 510(k) clearance (in which the FDA agrees that a device is substantially equivalent to an earlier version) are their lowest levels in recent years.

3.3.2 Pre-market Approval

FDA conducts even more rigorous pre-market review on devices that present greater risk. These include Class III products, such as implantable devices, life-sustaining or supporting devices, or those which represent potentially unreasonable

risk of injury or illness. Class III products also include all products that are not substantially equivalent to an earlier device. That is, they represent a new kind of technology whose risk and reliability are unknown for that type of device or use. In these cases the medical device companies may be required to conduct a wide range of physical, scientific, biological, and engineering tests on the device and submit this information to the FDA in what is called a pre-market approval, or PMA, application. In most cases.

Such applications must also include the results of product testing in humans. Before humans tests can begin on devices that represent significant risks to patients, however, the medical device company must obtain approval of an institutional review board (IRB). A panel of medical experts at the institution that will oversee the study. For these devices, the company must also submit a to the FDA explaining among other things, how it will conduct the test, what type of patients it will use, what results it expects, and what risks and precautions it believes are involved. If the agency considers the request to be sound, it will grant an investigational device exemption, IDE.

The IDE allows for the device to be used in patients for the purpose of gathering data. As **table 4** indicates the number of IDEs received each year during the period FY 1987 to 1991 has remained relatively constant, with a slight increase in the years FY 1988 to 1990. Average FDA review time has experienced only minor changes for the period as well. Once the study is complete, the company must assemble, and present the data to the FDA in the PMA application. The agency reviews the application carefully and may request additional information or testing. Once the FDA is satisfied that the application shows that the products is safe and effective, it approves the device for marketing.

The law requires that FDA evaluation of PMA must be completed within 180

Table 4 FDA Original Inv. Device Exemptions

FDA Original Investigational Device Exemptions (IDE), Fiscal Year 1987-1991

	FY 87	*FY 88*	*FY 89*	*FY 90*	FY 91
# received	218	268	241	252	213
# of decisions Appr.	60	79	89	95	72
Not approved	153	172	143	146	141
Other	11	9	13	7	7
Total	224	260	245	248	220
Average review Days	28	27	29	29	29
% decis. in 30 days	97	99	100	99	99

Includes deletions, withdrawals,
Sources:Data and footnotes From FDA office of device Evaluation Annual report

days. Because of the changing process within the FDA, however, review times have increased significantly in more recent years. For example one measure of review times, average lapsed time for FDA approvals, grew from 415 days in FY 1990 to 633 days in FY 1991, an increase of 53% for that year. At the same time the number of devices approved by the agency declined by 43%. It can clearly be seen that the FDA is a constraint is the development cycle of a new product. fortunately in the solution to obtain shorter development cycle, offered by the phase approach, discussed later, starting the interphase with FDA is done at almost the beginning of the development cycle to allow for delay in dealing with the FDA.

3.4 The Importance of Accurate Documentation in the Medical Device Industry

In the medical device industry, documentation is an integral part of the design and manufacture of a product. The Food and Drug Administration (FDA) patrols the medical sector to safeguard the public from hazardous devices. Good records allow manufacturers to show the safety and efficacy of their products. Documents are used internally to help companies keep track of products from beginning to end. Other documents are required by the FDA to approve medical products for release. The following paragraphs go into depth about the type of documents used by medical companies to show and maintain the integrity of their products.

Internal company documents have various names but produce the same results. They keep track of a medical device from conception to final use. Various forms are utilized to inform key company personnel of new designs or changes to existing design.

One such form is used by engineering to submit new designs. All pertinent information about the design is included in the form. This information consists of what the design is, why it is needed, and how will it be manufactured. Once this

form is adequately filled out, it is circulated to the medical and regulatory experts in the company. The medical experts determine if the product is useful in the medical field. They also assist in determining whether biological tests and/or clinical trials are required for the product. The regulatory experts check to see if all regulations are adhered to. The approval from the medical and regulatory is an essential ingredient to continue work on the project. The engineer can develop the design during the time the form is being circulated, but if any issues arise, they must be dealt with to successfully complete the project.

Another document sometimes necessary during the early stage of product design is a patent. In order to apply for a patent, one of the important factors is to keep track of all design work in a laboratory notebook. This notebook can be used in court if someone else is applying for the same type of device. The company law department or an outside consultant can assist in determine if a device is patentable. Whether or not the device is patentable does not necessarily effect if the device will go into production. Sometimes manufacturers decide not to patent a device to keep it secret.

Regardless of what is decided, the flow of information continues. Once the design is completed, other documents are generated to release and record that design. A technical report is sometimes completed to record the design. The technical report allows other people to gain from any new discoveries. A formal release document also needs to be completed. This document is a type of engineering release form. The engineering release form includes all documentation required to manufacture and sell the product. This paperwork can sometimes include a very long list of documents. This list includes product drawings, product specifications, packaging drawings, packaging specifications, manufacturing drawings, manufacturing specifications, sterilization specifications, quality

assurance specifications, and any reference material such as memorandums and initial design approvals. After all these documents are satisfactorily completed, the engineering release form is sent to different functional areas for approval. These functional areas consist of engineering, marketing, quality assurance, and manufacturing. If any issues develop, they must be dealt with to get the product to market.

If internal experts decide approval is needed from the FDA to get the product to market, a pre-market notification, known as a 510(k), will have to be complete.

CHAPTER 4

QUALITY FUNCTION DEPLOYEMENT

4.1 Quality Function Deployment (Patient driven engineering)

"House of Quality," (HOQ) is a product development technique that had long been used in Japan and that was gaining popularity in the US. Since 1988, over a hundred U.S. firms have adopted the technique for part or all of their product development activities. The House of Quality, which is part of Quality Function Deployment (QFD), has evolved through use. The formal charting techniques have been way to sophisticated market measurement, and firms have modified QFD to work within their corporate culture. The same rationale can be used in the medical device industry.

4.1.1 The House of Quality

Mishubishi's Kobe shipyard developed quality function deployment in 1972. Ford and Xerox brought it to the U.S in 1986, and, in the last five years, it has been adopted widely Japanese, U.S. and European firms. In some applications, it has reduced design time by 40 percent and design cost by 60 percent while maintaining and enhancing design quality. QFD helps an inter-functional team of people from marketing, R&D, manufacturing and sales work together to focus on product development. It provides procedures and processes to enhance communication by focusing on the language of the customer. QFD uses four "houses" to integrate informational needs. Applications begin with the HOQ, which is shown conceptually in **figure 7**.

The team uses the HOQ to understand the voice of the patient and to translate

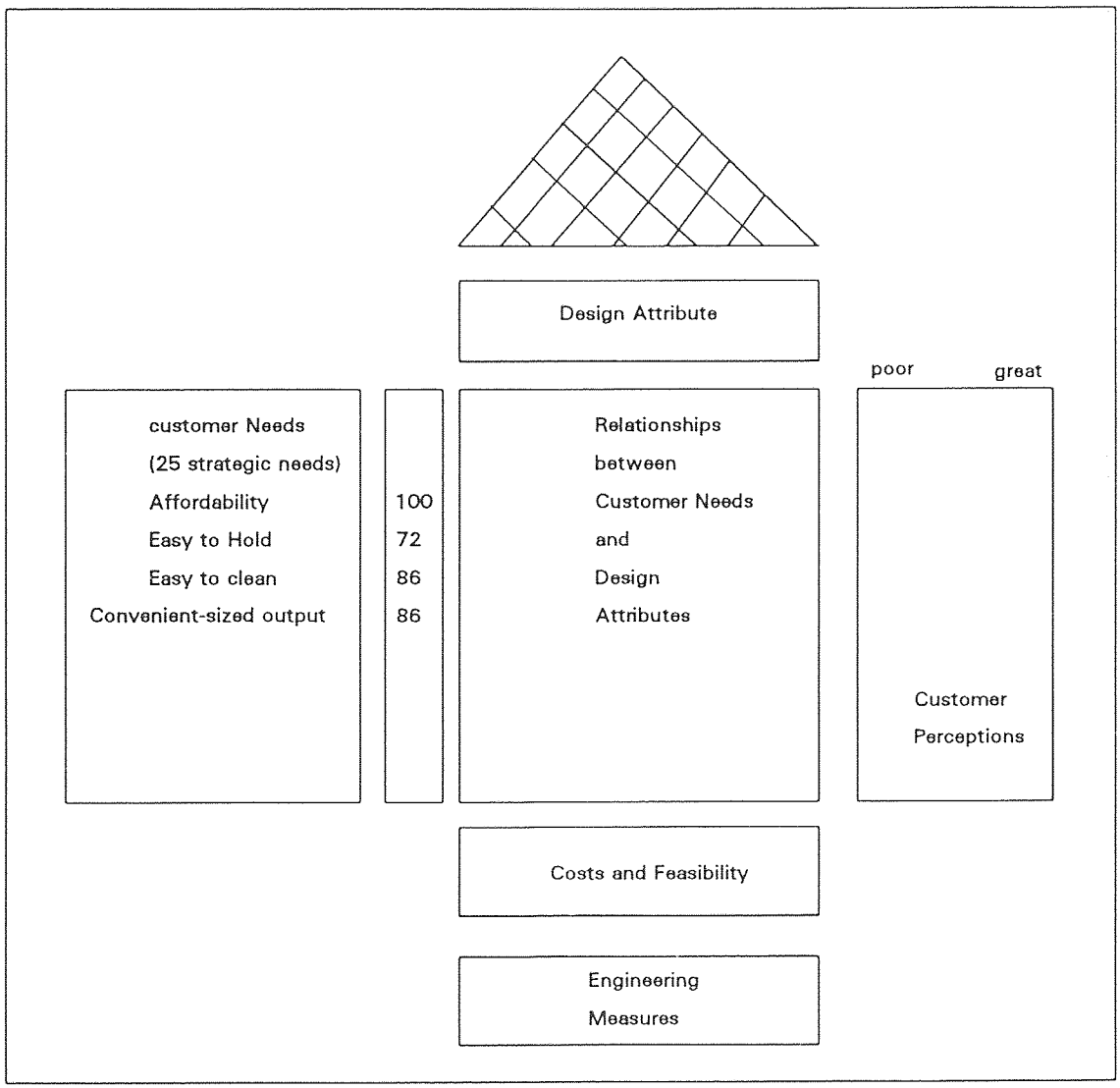

Figure 7 Quality Function Chart

it into the voice of the engineer. Subsequent houses continue to deploy the choice of the patient through to parts characteristics and production requirements.

4.2 The Voice of the Patient (Through the physician)

Identifying the patient needs. The first task is to identify patient needs, which are descriptions in the physician own words of the benefits they want the product or service to provide. These needs are usually determined by personal interviews and/or focus groups, which bring together six to eight physician for a facilitated discussion. Physicians typically identify one hundred to four hundred needs, including basic needs (what they just assume the product will do), articulated needs, (what they say they want the product to do) and excitement needs (which, if they were fulfilled, would delight and surprise customers). However, it is difficult for a team to work with so many patient needs simultaneously.

Structuring the needs. To manage the patients needs, the team has to structure them into a hierarchy. The primary needs, also known as strategic needs, are generally the five to ten top-level needs that set the strategic direction for the product. "Ease of use" might be a primary need for a product. Secondary needs, also known as tactical needs, are the elaborations of the primary need; each primary need is usually divided into three to ten secondary needs. These needs indicate more specifically what can be done to fulfill the corresponding strategic or primary need. For example, the primary need " ease of use" might be described further as " easy to say up" easy to operate," and "fast to use". In most cases, the secondary needs are further subdivided into detailed tertiary needs. These indicate specifically how the design team can fulfill the secondary needs.

Prioratizing the needs. Physician wants their needs fulfilled, but some needs are more important than others. Prioritizing helps the QFD team balance the cost

of fulfilling a need with the benefit to the patient. For example, if fulfilling two needs is equally costly, then the need that is more important to the patient should have higher priority. Theses priorities are normally determined through direct market research with the physician. The first room of the House of Quality thus contains the list of primary, secondary, and tertiary needs, in priority order. A second room lists the priority or importance ratings.

Comparing Physician Perceptions. Other patient-related information appears in another room in the house. Physician perceptions of how well the company's current product and competitive products fulfill customer needs are useful for guiding product design. By understanding which products fulfill patients needs best, how well those customer needs are fulfilled, and whether there are any gaps between the best product and the company's product, the QFD team can identify goals and opportunities for products design. This information is obtained through surveys of physician.

4.3 The Voice of the Engineer

Identifying Design Attributes. The other rooms in the house involve translating patients needs into engineering concerns. The team needs to identify measurable requirements.

- Design Attributes - that will fulfill patients needs. For example, design attributes relating to ease of use might include "time to perform the task," "initial set up time," and " time for a new operator to perform task." These attributes need to be assigned physical measurement units (e.g., number of minutes) that then become targets for an R&D or engineering design. However the attributes are not product solutions. If solutions are specified too early, the R&D process becomes constrained by existing solutions. New creative directions may be missed.

Comparing Engineering Measures. Just as the team measured competitive products with respect to customer needs, it now needs to compare competitive products on the physical units specified by the design attributes. For example, the time for a new operator to complete the task using each competing product must be measured and compared with the others.

Developing the Relationship Matrix. the QFD team now judges which design attributes influence which patients needs and how much. The idea is to specify the strongest relationships while leaving most of the matrix (60 percent to 70 percent) blank.

Developing the Roof Matrix. This matrix, symbolized in **figure 7** by the cross-hatched roof, quantify the physical relationships among the design attributes. For example, if two design attributes are "speed of printing" and "quality of hard copy output," then the roof matrix would indicate that improving one might degrade the other. However, when possible, the design team will seek creative solutions that improve both.

Making Other Estimate. In addition to the above, the team often estimates cost, feasibility and technical difficulty for changes in each of the design attributes. Developing a House of Quality can be time consuming. The team can spend a number of months just preparing to begin design work. But that time should be well spent. By identifying and quantifying customer needs, the team helps the company avoid unnecessary and costly redesigns and other rework. The total process should be shorter, less costly, and more effective.

4.4 The Importance of QFD in Concurrent Engineering

It is known that at the heart of CE are the capabilities of a company's technical workers. But many companies have found that innovation, manufacturing, and

quality can fit comfortably in Quality Function Deployment. QFD enhances Total Quality Management (TQM) by emphasizing that quality in the medical device industry is defined by the physicians and that is best achieved when a product or service is designed to increase customer satisfaction. QFD shifts quality from a "find and fix" mode to one of prevention. QFD is a team function; it's not just for engineers.

Because design engineers in the medical device industry have traditionally been isolated from the marketplace, they often have produced technically driven designs that were unduly complicated and out of sync with the patient needs. Using QFD, designers can convert customer needs into specific engineering requirements. A patient driven QFD matrix can help concurrent engineering teams translate such patient needs as " painless procedures". It is almost safe to predict that soon in the medical device industry QFD training will be a condition for employment.

4.5 The Meaning of Quality to the Patient

We must remember that in the medical device industry, quality is much more than meeting specifications. The physician point of view on quality is key. A survey conducted by an american research company identified that the physician defines quality in a medical device as reliability, durability, easy of maintenance for reusable products, easy to use, a trusted brand name, and a low price with high value.

The voice of the physician is the key element of Quality. From the perspective of the physician, quality is not just quantitative, it is an assessment, a verdict, an opinion. In short, it's something hard to pin down. The physician feels that the patient will be willing to pay more for vquality if they believe that they are getting more value. The proposed solution in the medical device industry will utilize the

seven stage quality build-up approach. Instead of beginning in stage one with the inspection function after production, audits, and problem solving activities, or the next stages including quality assurance during production, using employee education and training, product and process design optimization, and quality loss function, the approach of choice is to work in stage one.

This is where the voice of the patient through the physician is defined and carried throughout the value added chain, including the design of the part and the design of the manufacturing process (discussed in the next chapter). to define the voice of the patient in stage seven, we use as mentioned above QFD. This later considers the voice of the patient throughout the total process, from design through marketing. It's a technique that translates the customer requirements in all phases of the product' development and use. QFD assures that the voice of the end user is considered and his satisfaction assured.

As a designer in the medical industry, a high quality low cost segment of the matrix is a good position to be in. The high-quality, high-cost position is for selected high price market niches. The low-quality, high-cost segment will obviously lead to a bad business position. And the low-quality, low-cost segment is relegated to products like those coming from Japan 20 years ago (junk). Quality does not have to cost money. In opposition, the lack of quality can be expensive. The cost for non-conformance with quality specifications in the medical device industry is equivalent to the astronomical figure of 25% of total sales. As one can see QFD requires a change in attitude. Recognizing that quality defects are an opportunity to improve the manufacturing process by analyzing causes as a team. we have modern tools to optimize quality, improve the manufacturing process, and work to improve the service and price of the product.

CHAPTER 5

PHASE APPROACH TO CE & DFM

5.1 A Dual Approach in the Development of a New Product in the Medical Device Industry

In the medical industry one will encounter many difficulties to integrate design, manufacturing, engineering and marketing without changing the basic approach to management of new product development. The barriers to the integration can be locations, background, budgeting practices and performance measurement system to name a few. At present cross-functional teams are the most frequent way to cut through barriers for integration of design and manufacturing.These teams should have representative of design manufacturing marketing and quality.

However the team is only the beginning. Design for manufacturing (DFM) as explained in chapter # 2 Quality Function Deployment (QFD) as describe in chapter # 4 are necessary step to integrate design, manufacturing engineering, and marketing. DFM, a design discipline, consist of management tools and techniques, design principles and methodologies, and a philosophy of design integration and optimization. Application of DFM aids smooth transition from development to production where as QFD in the medical industry help to provide "better medicine". However DFM, cross functional team and QFD are only three conditions necessary for integration of design and manufacturing. The fourth and fifth are the a phase approach in concurrent engineering and a product-process development approach.

5.2 The Phase Approach To Concurrent Engineering

Over a number of product development projects, a teams learns to apply a product design in a way that reflects the company design philosophy. Individual team

members learn how to contribute to the philosophy through the creation of many informal communication networks. However, much of this learning is embodied in these individual, and is lost to the team with their departure from the team. Further, despite this design discipline, teams must still confront trade-off decisions on every projects, among cost, features and delivery.

Pressures and constraints associated with these decisions often dictate many aspect of product design, and make impossible to follow best practices or achieve the best design. As such, teams need a step-by-step management procedure, or approach, to discipline their interactions and to take members through these trade-off decisions that are in virtually every new product development project. In the medical industry the time is now for such a procedure. The phase procedure is introduced to manage the integration of new product development activities. It is to provide guidance to all divisions on identification and achievement of an evolving system of technical and commercial objectives at each stage of the new product development process. With the traditional financial control remaining in place, the new procedure will facilitate divisions into expanding their views of quality in new product development to include no defect, ease of manufacture and operation and timeliness of market availability.

From the start, planning for quality will be an integral part of the product development process. Development teams will catch and correct design deficiencies earlier. There is far more leverage in eliminating such defect early in the development process than later, when the product is in production or already in the market. Quality also means reducing product component to their simplest form for operation and manufacture. Unnecessary complexity will add extra cost and reduced product and process reliability. Simplicity, on the other hand will lead to improved manufacturability, market acceptance, and profitability. Finally, quality

means timeliness of product availability to the customer. Throughout the new product development the phase approach to CE will emphasize the achievement of delivery schedule. Frequent milestone and formal reviews, one of the characteristic in this approach will impress on the cross-functional team members the urgency of their work.

These reviews also will allow team members to foresee the impact of delays through the development process, and to control progress so that those dependent on deliverables late in the process will have adequate to meet their deadlines. This procedure will provide a basis for improving the performance of succeeding new product development projects. It will highlight cost, time, and quality objectives for each project and conducting formal reviews of progress at distinct stages. It will also correct the difficulties of unsuccessful projects by placing an increased emphasis on cost avoidance. The intention is to develop an environment in which divisions would experience continuous learning and adaptation. A illustration of this method as it applies to the medical device industry is described on **Figure 8**.

Within each of the step concurrent engineering technique could be applied. Shortening the overall decision loops by doing certain activity parallel whenever possible, and with a constant phase review process, are as important as shortening the loops with each activity. Each activity on this chart has a series of sub-activity which can be shortened by using CE and DFM technique.

5.2.1 The Phases of the New Product Development

In the medical device industry, the proposed phase approach will divide the new product development cycle into five major phases: Project proposal, Planning/Specification, Development, Evaluation & Manufacturing Implementation, Start-up and Product Launch. The different feature of this procedure is a series of

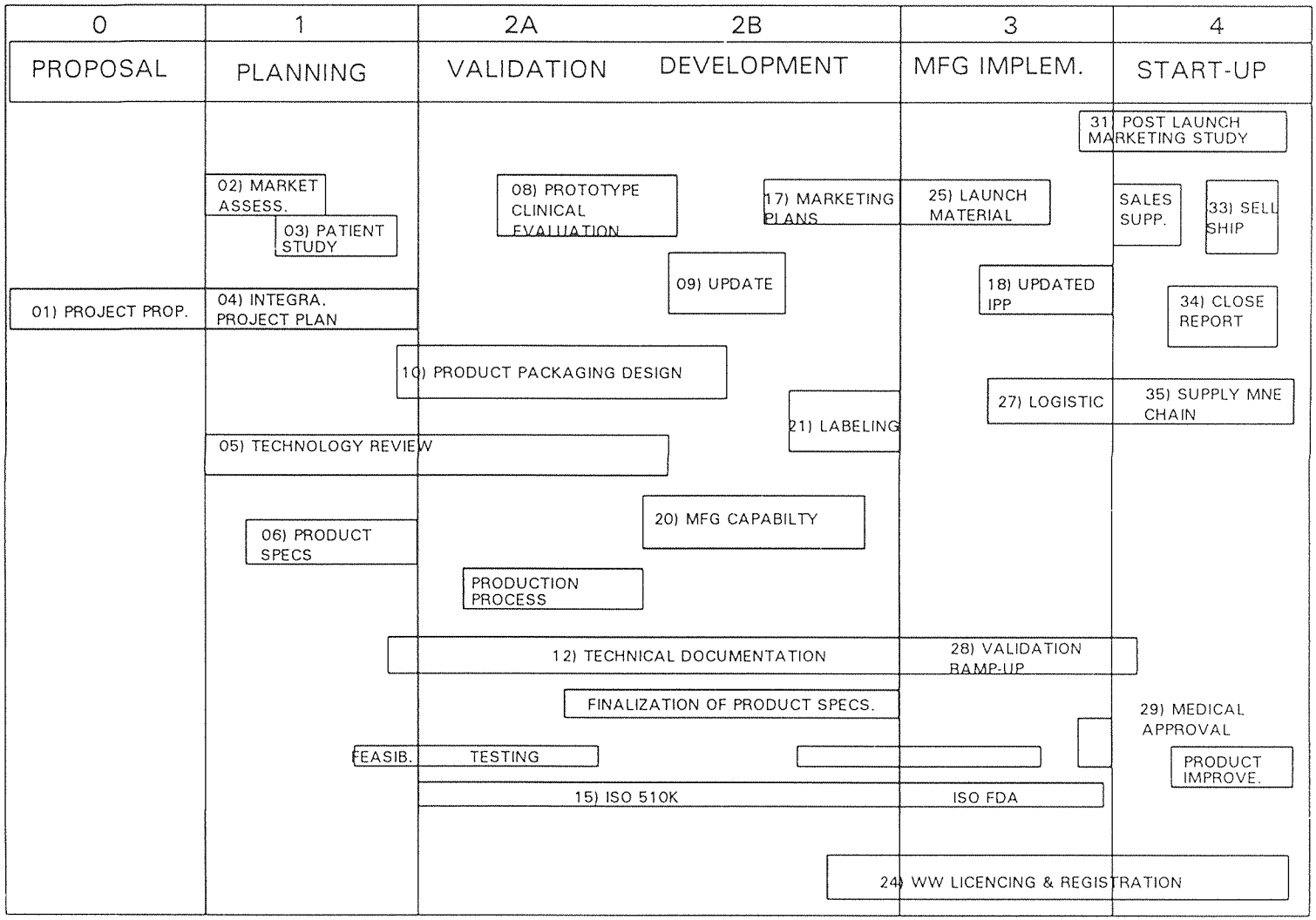

Figure 8 The Phase Approach to DFM and CE

reviews at each phase which occurred at the end of each development phase. In general a project could fail review at any phase. In such a case it can be cancelled,

reworked, and again presented for review. or if the reasons for failure were not perceived as major threats to the overall project, approval can be given to proceed to the next phase with existing inadequacies.

Phase reviews will tell just how far a project is from its targets, and will indicate what needs to be done to put it back on track before it become irreversibly late and expensive. Phase reviews should be carried by a panel of senior manager" appropriate to the level of importance of the project to the company". All functions involved in the product development are to be represented at the reviews, including marketing, design manufacturing, quality, customer service etc. The review panel focuses on the product development schedule, product function, quality, cost, and manufacturability. The panel will ensure that decisions made at earlier phase are implemented and that the project core team (**Figure 3**) will anticipate and will deal with down stream problems that may occur in volume manufacturing and the market.

5.2.2 Responsibility of different Groups at Each Phase

A different department will assume responsibility for completion of each project phase on time and to specification, marketing and design at earlier phases, manufacturing later. The transfer of each responsibility will take place at each phase, and should involve certified completion of project responsibilities by each functional group involved. Under this approach in the medical device industry, a department is to accept responsibility only when all preceding responsibilities are discharged.

5.3 Phase Description of New Product Development

Project Proposal Stage: The goal of the project proposal phase is to identify a new business opportunity, which is reviewed at phase 0, the formal beginning of the new product development process. Projects will go through two phases in this stage: Knowledge prebuilt, and concept development. At the knowledge prebuild phase, planning group, comprised of marketing and representatives, will match market opportunities and available technology. From the many opportunities identified each year perhaps a few with potential for developing into dominant designs will be selected for concept development.

A full time product manager and product designer will then analyze the market potential and concept, and then will develop draft specifications and plans for project management (**Figure 4**). At phase zero, senior and divisional management will evaluate the new business opportunity as a cost effective and innovative technological solution that could developed with sustainable margins on cost, revenues, and technology for a number of years.

The Planning/Specification Stage: Review of the product concept at phase one will mark the need of the next major stage in the new product development cycle. During this stage the product concept is defined, and marketing will set the context with which integration of design and manufacturing will occur. Commercial specification, outlining the functional and aesthetic features of the product, its price range and its market launch program, including launch date will be developed. These item will be commercial guideposts around which design and manufacturing engineering will designed the product form, fit and functions. The ultimate challenge for the development team will be to remain within these guideposts, and launching a price competitive product on time while achieving the cost and technological objectives set internally for the product. The review at phase one is

set up to answer the fundamental question: do the designers know what the customer actually requires? In the medical device industry a typical set of activities in this phase will be a market assessment, patient/professional study, technological review (patent search, license agreement) and a product/process specification.

The Development Stage: The development stage will end at phase 2. During this stage, the project core team will develop the detailed specifications of what the product will be, how it will perform, what it will look like, and how it will be used. At this point most of the tool and technique of DFM including The axiomatic approach to design as describe in chapter can be used. Here, product manufacturability is a major focus of the engineer from two perspectives. First the engineer will assess the readiness of the design for later prototype production and testing. Second, the assessment of the product design for attributes that will both avoid production line stoppages, rework costs, and aftersales problem, and also increase safety, quality of workmanship, cost savings and process capability. The focus on manufacturability will emphasize the design for cost avoidance through product development in preference to cost improvement after product launch.

5.3.1 Application of DFM and CE in the Development Phase

The Activities of the development stage in a typical medical industry company are:

Prototype fabrication; evaluation clinical, marketing

Product/packaging design

Mfg Process capability development

Production process Equipment

Labelling

Technical documentation

Finalization of product specifications

Finalization of product specifications

Engineering testing

Stability studies

Clinical

ISO/510k proposal and data collection.

With those activities DFM and CE tool and technique can be applied to only some the rest are constraint that have to be faced because of the nature of the industry.

5.3.2 Prototyping for Medical Device

One of the involvement of manufacturing in the design process should be the fabrication of prototype. Prototypes should be built as soon as possible to find problems not easily identified with computer modeling. Also functional testing with prototype should be done as soon as possible. Many functional problems can be identified and solved prior to the availability of final production hardware. Moreover a small pilot line should be started as early as possible. Many manufacturing process problems can b e solved utilizing early prototype. These activities provide information that is critical to avoiding design changes and assuring over all cycle time reduction.

Realizing additional cycle time reductions and quality improvement in the future will necessitate increased integration not only of internal organizations but of suppliers and customers as well. The efficiencies achieved through integration of design and manufacturing should be enhanced whenever possible by including suppliers and customers in the design process. Early and continuous involvement by manufacturing, marketing, supplier, and customer will lead to products that meet and exceed customer expectations.

5.3.3 Engineering Testing of Medical device

To assure an extremely high quality level product performance an a short product cycle, the device testing has to be done on a prototype design level. Existing test equipment capable of performing standardize test should available (ex: if the company makes needles, Tinous Olsen test apparatus should be readily available to the test the stiffness of the cannula.) This equipment should be set up in the lab to simulate the manufacturing line test equipment. Early decoction of problem will allow time to modify design and improve manufacturing quality before volume production begin. This simplified testing of the device will improved the quality of the product at significant cost savings.

5.3.4 Manufacturing Process Capability Development

Compliance, the accommodation of manufacturing error, should be designed into the medical device product to avoid excessive assembly force, rework and scrap. The relation of the manufacturing tolerance to the part specification limits is called process capability index. The reason for using this tool in the medical industry is simply that by focusing on the process capability index, there exist a commitment up-front to measuring and controlling manufacturing variability through statistical process control (SPC) tools and methods such as control charts. In addition it is an excellent tool for negotiating with and communication with suppliers to set the appropriate quality level and expectations.

The process capability index focuses on communication between the design development, and manufacturing parts of the organization. By managing the relationship of design tolerance to manufacturing specifications, it shifts attention away from a possible adversarial relationship between design and manufacturing

to a more constructive one where the common goal of achieving a particular index level facilitates negotiations and cooperation in a new medical product development. Medical device product usually are manufactured through materials and processes that are inherently variable. Design engineers specify materials and process characteristics to a nominal value, which is the ideal level for use in the product. The maximum range of variation of the product characteristic that will still work in the product determines the tolerances about the nominal value. This range is expressed as upper and lower specifications limits (USL and LSL).

The manufacturing process variability is usually approximated by a normal probability distribution, with mean of "U" and a standard deviation of "σ". The process capability is defined as the full range of normal manufacturing process variation measured for a chosen characteristic. Assuming normal distribution, 99.74% of the process output lies between -3σ and $+3\sigma$.

A properly controlled manufacturing process should make products whose output mean characteristic or target are set to the nominal value of the specification. This is easily achieved through control charts. If the process mean is not equal to the product nominal value, it can be shifted by recalibrating production machinery or inspecting incoming raw material characteristics.

The variation of the manufacturing processes (process capability) should be well within the product tolerance limits. The intersection of the process capability and the specification limits determines the reject level. Process capability can be monitored using control charts. The manufacturing process variability can be reduced by using optimized equipment calibration and maintenance schedules, increased material inspection and testing, and by using design of experiments to determine the best set of process parameters to reduce variability.

The classical design for manufacturing conflict of interests between design and

design engineers would prefer the narrowest possible process capability, so that they can specify the maximum tolerance specifications to ensure the proper functioning of their product. In contrast, the manufacturing engineers would prefer the widest possible tolerance specification, so that they can continue to operate the largest possible manufacturing capability to reduce the amount of rejects. The process capability index is a good arbiter of the two groups' interests.

The idea manufacturing process should produce clones of the production by performing replication of all fabrication and assembly materials, processes and movements. However, this can never be achieved, because of variations in manufacturing. As the production machines and processes continue to turn out the product, the characteristics of materials and tools in the process change as they are being consumed. Materials hardness can change from the supplier for different lots and still be within specifications; machinery, fixtures, and tools wear out; and even though they can be replaced, recalibrated, or resharpened in an ideal maintenance schedule, they can still result in variation in the product. Employees can be properly trained to perform production tasks, but will slightly alter production operations because of fatigue or human error. Conditions beyond the control of the plant management could result in variability, due to environmental and weather changes or changes in suppliers, which are further multiplied by their subsuppliers' variations.

Some or all of these conditions can cause product variability, which when added up at each level of production could cause some of the product to become defective even though it is within acceptable limits at each stage of production. This reject rate will adversely effect the quality, and hence the cost, of the product.

There are two ways to increase the quality level of new products: either increase the product specification limit and allow manufacturing variability to

increase the product specification limit and allow manufacturing variability to remain the same yet product fewer defects; or reduce manufacturing variability by improving the quality level of materials and processes through inspection, increased maintenance, and performing design of experiments to determine variability sources and counteract them. The ratio of the interaction of these two sources of rejects is called the process capability index, C_p: (Juran Quality Handbook)

C_p = specification width (or design tolerance)/process capability

C_p = (USL - LSL)/6σ(total range from -3σ +3σ)

where

USL = upper specification limit

LSL = lower specification limit

σ = manufacturing process standard deviation

The C_p value can predict the reject rate of new products by using normal probability distribution curves. A high C_p index indicates that the process is capable of replicating faithfully the product characteristics, and therefore will produce products with high quality.

The utility of the C_p index is that it shows the balance of the quality responsibility between the design and manufacturing engineers. The quality level is set by the ratio of the effects of both. The design engineer should increase the allowable tolerance to the maximum value that still permits the successful functioning of the product, and the manufacturing engineer should minimize the variability of the manufacturing process by proper material and process selection, inspection, calibration, and control, and by performing design of experiments

5.3.5 Production Process

Focus on the production process technology is important. How can an organization

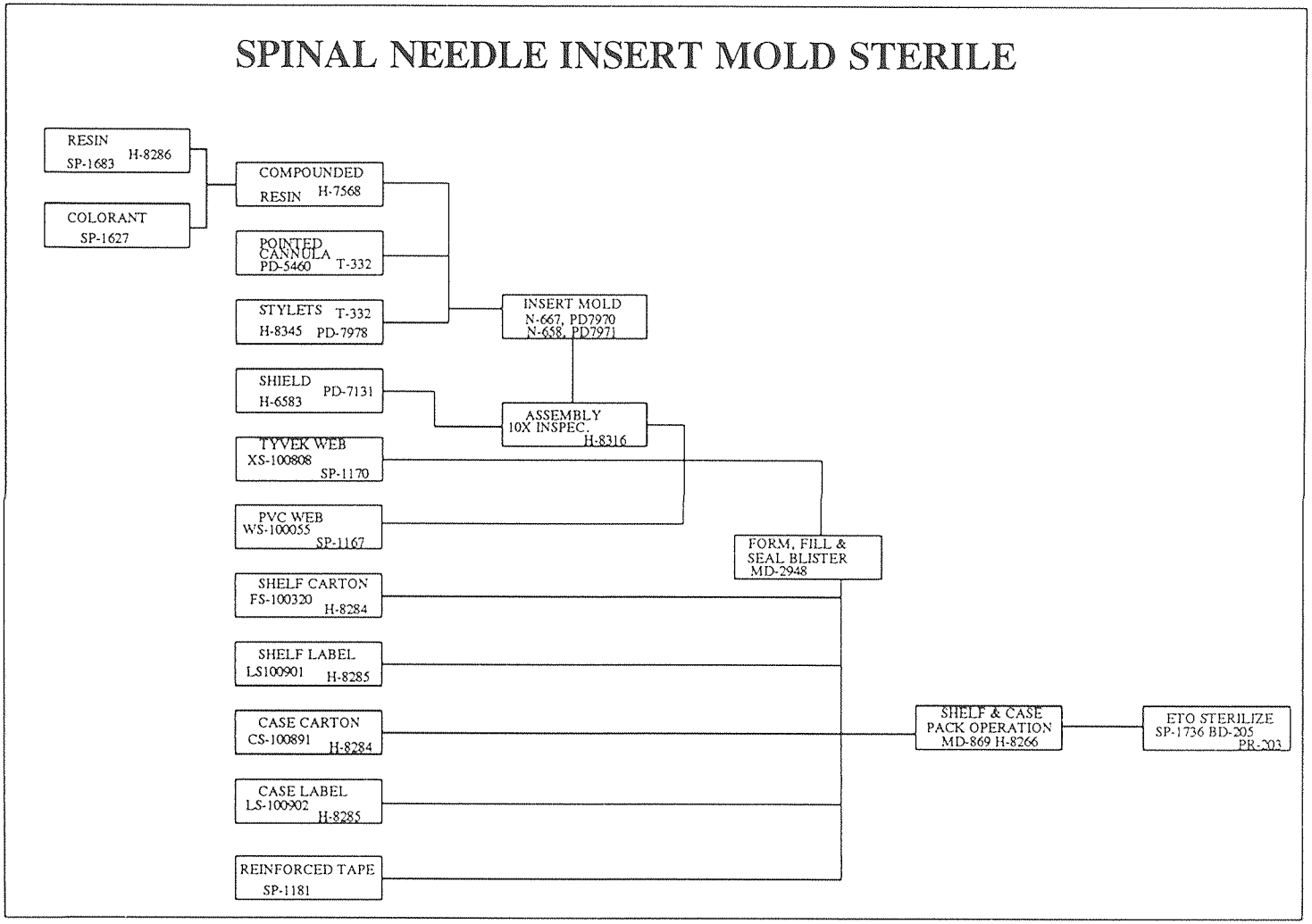

Figure 9 Spinal Needle Insert Mold Sterile

analyze its current activities and develop its unique approach to a mare change oriented, flexible, quick reflex business. The suggested approach for the medical device industry is called the work flow analysis. It is centered on diagraming or charting the path taken by new product programs during development and introduction and quantifying the activity effort been applied. Work flow analysis involves determining and plotting in sequence the existing steps in a particular process. Insight comes from using a technique of viewing each action step in term of input/action/output such as the output of a given action constitute the input of the next action. Bringing into view the numerous loops, sequences, approval chains and rework item that exist in the process of a medical device product.

Recognizing the complex actual path is a necessary first step in dealing with it. The next step is to make a concerted effort to reduce the detail times. A helpful method is to visualize the usefulness of activities in contributing value to the final product. Those activities that stand out as having low value should be questioned for elimination or combination. Certainly time elapse with no contribution does not add value. Another approach is that any activity that one can perform in an alternate or better way at less cost or time is not adding value and should be replaced by a better alternative. Using the work flow analysis an organization alignment and grouping is created where the work output of each work group is organized to be fully accomplished as input of the next group. A majority of support work can be moved offline or in parallel so that only necessary action are performed on the main line resulting in shortening the total development cycle. Example of this concept is illustrated in **figure 9.**

CHAPTER 6

TOOLS OF DFM

6.1 Tools of Concurrent Engineering

The traditional product development process is a series of specific tasks, often performed by a different group in the organization. The phases of product development (Ideas, Conceptual Design, Detailed Design, Analysis, Drafting and Manufacturing) must each be largely completed before the next begins. Since the late 1960s and early 1970s there have been software tools available to help with each stage of the product development process. Current software tools, known as second generation tools are aimed at automating a specific function. For example, a CAD tool helps drafters to draft better or mechanical engineers to design better, or manufacturing engineers to generate improved tools paths or to create efficient process plans. Because each second generation tool is a discrete product and has its own database, there can be no sharing of information between phases of the product development. Each task must be completed before passing off to the next phase.

This forces product development into running sequentially. In the traditional, serial product development process, parallel activities are often integrated only after they are completed. And that is when problems arise. For example, for a new device (safety Syringe) various subsystem are developed by individual groups: one group work on the lubrication of the barrel another on the barrel itself, still another on the plunger, etc. Although it looks like this approach saves time because development works takes place simultaneously, the pieces of ten fail to work when it comes time to integrate and test. Then redesign begins. And redesign is both

expensive and time consuming, especially if it takes place late in the product development process.

A study by Dataquest looked at the typical cost to make changes during different phases in the development of a major medical device products. A change that might cost $1000 in the design stage will cost $10,000 in design testing $100,000 during process planning, $1,000,000 during test production. With the traditional approach to product development, making changes is too difficult, even early-on in the development process. Second generation tools do not accommodate change. There is actually a negative incentive for change in sequential product development, even if changes in design could ultimately produce a better product. Consider for example a thin walled, molded plastic part which is well into the product development process. The parts and assemblies have been modeled on the CAD system, analyses performed, drafting created, molds modeled and analyzed, and some tool paths created. At this point the design engineer determines that there is a different material that would allow for a thinner part, an overall better quality design at a lower cost.

However the task of going back into all the CAD tools to update geometry, parts, assemblies, and drawings, create new finite element models and rerun the analyses, and to update the tool paths, mold information, etc. is overwhelming and a barrier to changing the design, even though the original is not the most competitive or most efficient design. Compounding the problem with second generation tools are multiple data structures at each stage in product development. These introduce the potential for loss of design integrity. Consider the situation from the molded plastic part for example above, where updates are started, but somehow not completed. Perhaps the drawing has been modified, but not the parts geometry or assemblies; the result is that potential fit problems in the assembly go

undetected, or there is incorrect geometry in the part. Maybe the analyses have not been re-run, or the molds and tooling not updated. The wrong prints may be used for tooling, leading to fit problems manifested only during the manufacturing or prototype stage. Or there may be failures in the fields requiring a product recall.

All of these problems with serial approach with second generation tools translate into lost dollars, lost work time and lost quality. There is no way that a company can hope to meet a target of first to market , cost effectively with a high quality product under these conditions. Even with the recent hardware and software advances providing more affordable and powerful hardware, memory advanced graphics capabilities, and telecommunication networks for distribution of information and communication, the current second-generation software tools don't go quite far enough. They are bound to a sequential, serial product development, by their multiple data base architectures and a general unfriendliness to change. Second generation tools limits a company's ability to achieve competitive leverage in today's medical device industry environment. Both second generation tools and sequential product process do not promote fast cycle time for high- quality products developed in a cost-efficient way.

6.2 The Third Generation Tools Approach to Product Development

To increase product quality and reduce cost while simultaneously improving the speed of product development requires a fundamental change in the development process itself and in the automation tools used for product development. That change is the third-generation approach an overlapped, concurrent, parallel, team product development process. And what makes this radically new approach to product development possible are the third generation automation tools. Thirds generation product development encourages a team approach and as such reflects

the early inputs of the various functions and ensure communication throughout the entire development cycle. For example, early participation by manufacturing ensures that manufacturing requirements and constraints are understood at the outset and taken into consideration in the design. Not only does this help engineers to avoid problems, costly mistake, and retooling, but also to manage affectively their machine tool and shop floor resources.

Overlapping, concurrent functions provide for and overall compression of the product development process, and hence, a faster time-to-market. And while overlap shortens the product development cycle, it also allows far the allotment of more time in certain phases. And more time spent considering design iterations or examining interference or fit problems or optimizing tool paths and mold flow and manufacturing process plans translates into a higher-quality product. The ability to fine tune the product model in the design phase also promotes cost savings by eliminating unnecessary mistakes and products delays at the a same time that quality of the product is being improved. What makes this type of product possible is a tool which incorporates input from all engineering disciplines through the use of a single database. It is because of the unified database that changes, key and necessary changes are propagated automatically to all project team members, all other engineering disciplines and phases. Everyone's work is updated, and all deliverables reflect the change, drawings, models, assemblies, manufacturing tools paths, mold flows, etc.

Reconsider the example of the thin walled molded plastic part where the design engineer determines late in the development process that there is a better material available. With only the second generation tools at hands, the designer opts to abandon a redesign because the task is intimidating. With third-generation tolls, however, the change is simple and straightforward, and updates of drawings

models and analyses are automatic and complete.

6.3 Philosophical Tool of DFM

The development and use of design methodologies that help the design team achieve an optimized design solution as describe in chapter 2 is an important part of the DFM approach. **table # 1** provides a selected list of DFM methodologies or tools and indicates where they might fit into the proposed DFM process. Use of these design methodologies helps promote the objectives of DFM by hiding the design team in making better informed design decisions and providing systematic procedures that help ensure that all aspects of product function manufacture, and operational support are considered from the start.

An axiomatic approach to design, explained in detail earlier is based on the belief that fundamental principles or axioms of good design exist and that use of the axioms to guide and to evaluate design decisions leads to good design. By definition, an axiom must be applicable to the full range of design decisions and to all stages, phases, and levels of the design process. Design axioms cannot be proven, but rather must be accepted as general truths because no violation or counterexample has ever been observed.

A study of many successful designs by several individuals in 1977 led them to propose a set of hypothetical axioms for design and manufacturing. Analysis and refinement of the initial axioms has shown that good design embodies two basic concepts. The first is that each functional requirement of a product should be satisfied independently by some aspect, feature, or component within the design. The second is that good designs maximize simplicity; in other words, they provide the required functions with minimal complexity.

Use of design axioms in design is a two-step process. The first is to identify

the functional requirements (FRs) and constraints. Each FR should be specified such that the FRs are neither redundant nor inconsistent. It is also useful in this step to order the FRs in a hierarchical structure, starting with the primary FR and proceeding to the FR of least importance. Once the functional requirements and constraints are specified for a given product or design problem, the second step is to proceed with the design, applying the axioms to each design decision. Each decision should be guided by the axioms and must not violate them.

Application of the design axioms to the analysis and design of products and manufacturing systems is not always easy or straightforward. Because the axioms are quite abstract, their use requires considerable practice as well as extensive on-the-job design and manufacturing experience and judgment. After reading this thesis, the axiom of manufacturing will be easy to understand.

6.4 Simplification of the Axioms of Manufacturing as Design Tools

DFM guidelines are systematic and codified statements of good design practice that have been empirically derived from years of design and manufacturing experience. Typically, the guidelines are stated as directives that act to both stimulate creativity and show the way to good deign for manufacture. If correctly followed, they should result in a product that is inherently easier to manufacture. Various forms of the design guidelines have been stated by different authors, a sampling of which follows:

1) Design for a minimum number of parts
2) Develop a modular design
3) Minimize part variations
4) Design parts to be multifunctional
5) Design parts for multiuse

6) Design parts for ease of fabrication

7) Avoid separate fasteners

8) Minimize assembly directions; design for top-down assembly (B-D Pulsitainer, our design example)

9) Maximize compliance; design for ease of assembly

10) Minimize handling; design for handling and presentation

11) Evaluate assembly methods

12) Eliminate or simplify adjustments

13) Avoid flexible components

DFM guidelines show the way, but do not replace the talent, innovation, and experience of the product development team. They must also be applied in a manner that maintains and, if possible, enhances product performance and marketing goals. Design guidelines should be thought of as 'optimal suggestions,' which, if successfully followed, will result in a high-quality, low-cost, and manufacture-friendly design. If a product performance or marketing requirement prevents full compliance with a particular guideline, then the next best alternative should be selected.

6.4.1 Illustration of DFA as a Design Tool

The design for assembly (DFA) method was developed by G. Boothroyd and P. Dewhurst while at the University of Massachusetts (Amherst). Details of the methodology are presented in Design for Assembly - A Designer's Handbook.

Based largely on industrial engineering time study methods, the DFA method developed by Boothroyd and Dewhurst seeks to minimize cost of assembly within constraints imposed by other design requirements. This is done by first reducing the number of parts and then ensuring that the remaining parts are easy to

assemble. Essentially, the method is a systematic, step-by-step implementation of the DFM guideline numbers 1, 7, 8, 9, and 10.

6.4.2 The Taguchi Method: A Tool Necessary to Meet the Requirement in the Medical Device Industry

The Taguchi method addresses the problems associated with determining robust design by using statistical design of experiment theory. Robust design implies a product designed to perform its intended function no matter what the circumstances. In particular, the Taguchi method seeks to identify a robust combination of design parameter values by conducting a series of factorial experiments and/or using other statistical methods. Termed parameter design by Taguchi, this step establishes the mid-values for robust regions of the design factors that influence system output. The next step, called tolerance (allowance) design, determines the tolerances or allowable range of variation for each factor. The mid-values and varying ranges of these factors and conditions are considered as variance factors and are arranged in orthogonal tables to determine the magnitude of their influences on the final output characteristics of the system. A narrower allowance will be given to noise factors imparting a large influence on the output.

In establishing the tolerance or allowance range for a particular parameter, Taguchi uses a unique concept defined as a loss function. In this approach, loss is expressed as a cost to either society (the customer) or the company that is produced by deviation of the parameter value from design intent. Because any deviation from design intent produces a loss, allowance or permissible deviation should be determined based on the magnitude of the cost associated with this loss. The concept of loss and other Taguchi concepts provide valuable insight into quality and the role design plays in determining the quality of a product or system.

6.4.3 A Process Driven Manufacturing

Process driven design seeks to ensure that parts and products are correctly designed to be produced using a particular production process or method. Design requirements for a given process are often stated in the form of design guidelines and rules of thumb. Typically, these guidelines are highly specialized for a particular industry, process implementation, plant, or equipment installation within a particular plant. Making the designer aware of these process requirements and constraints early in the design process, before concepts are finalized and lines are put irreversibly on paper, is a goal of design for manufacture. Design tools that help ensure product/process conformance and enable process-driven design can generally be classified as either process specific or facility specific.

Process specific DFM involves the design of parts to be manufactured using particular methods or processes such as casting, forging, injection molding, and stamping. Typically, these tools facilitate systematic application of specialized process knowledge in the form of codified statements of design guidelines and rules to the design of parts to be made using a particular manufacturing process or method. Examples include design for casting, design for injection molding, and design for total stamping.

Facility specific DFM tools facilitate correct design of products intended to be manufactured using highly specialized or unique advanced manufacturing facilities. Such tools, which could be aptly described as "designer toolkits," provide design rules, physical examples and models, various CAD design aids, and other specific information about a specialized manufacturing facility in a readily usable form to the designer.

Development of manufacturing facility specific DFM is, at present, in its infancy and is likely to advance very quickly as the relevance of this approach

becomes more widely recognized. Typical applications that could benefit greatly from the designer toolkit approach include such diverse situations as flexible assembly and manufacturing system concepts.

A major barrier to DFM is usually time. Design and manufacturing engineers are typically operating under very tight schedules and are, therefore, reluctant to spend time learning and using DFM approaches. Computer aided DFM helps simplify the effort and shortens the time required to implement DFM on a daily basis. Computer-aided DFM also enables the design team to consider a multitude of product/process alternatives easily and quickly. "What-if" optimization allows each alternative to be refined and fine tuned. Together, these capabilities greatly increase the probability of identifying the most desirable solutions during the early stages of design. When properly implemented, computer-aided DFM has the potential to vastly improve the quality of early product/process decisions and thereby enhance the design team's ability to design for effective quality, cost, and delivery. Another major benefit of computer-aided DFM is the way it fosters team building and the team approach.

A variety of proprietary computer aided DFM software packages is currently available. In addition, considerable effort is being directed toward the development of new computer-based and/or computer aided DFM methodologies.

6.5 The Importance of a Good Software Selection

A good third generation software package (PROengineer for example) will increased design productivity by 400 percent. A typical plastic one piece medical device molded part would take 40 hours of design time with our previous wire frame system. Now it can be done in 8 to 10 hours with a third generation software tool.

But the third generation software has done more than shorten the design cycle for many companies. It has also shortened product manufacturing time and improved product quality. And, when combined with superior graphics capability, produced a marketing tool which, in the words of one customer, "knocked their socks off."

It recommended that medical device company acquired the software after collaborating with their mold makers and vendors. Many design experts using Pro/Engineer explains that they can both be looking at 3D CAD systems at the same time, as their vendor. They selected the third generation tool approach because it is able to demonstrate a CNC connection with their equipment manufacturing controllers. Since this vendor builds many of our molds, their decision that was a large factor in our evaluation process.

Many major manufacturer of plastic parts, medical device, automotive parts, and pharmaceutical products, using a third generation tool proved to be the right decision. With software, they are able to do a lot of the development right on the computer rather than creating expensive prototypes. For example, It's assume we're designing a very, very intricate hinge for a dispensing cap, containing brand new ideas and technology. We can zoom in on it, and look at the cap from every angle. We can flex it, rotate the hinge elements and see exactly where it's going to go. We can make a lot of changes right in the computer, optimizing the design upfront.

A year ago, we would have made a guess at what we thought it should look like and made a mold. Six weeks later, we would have had something that probably didn't work. We would make some changes and go through the whole process all over again. We no longer waste time, effort, and money that way.

The consensus is to install an ENGINEER and a MOLDESIGN and Flow analysis version of the software used to mesh models for finite element and mold

flow analysis. FEA is used to optimize product weight vs. strength, to minimize cycle time, and maximize productivity of the mold. The cycle is related to molten masses, so "if we can thin area down, we can speed up the manufacturing process."

A fast manufacturing process and error-free design are critical since the typical production run for caps can run into the millions. A tooling error can be disastrous in terms of cost and customer service.

Some of the third generation out there are virtually flawless. One reason we will be so responsive to customer needs is because most of those software files can be used to make error-free stereolithography models and prototype molds. Often, we have service bureaus mail the SLA models direct to the customer, so they can have the part within 48 hours.

We are also going directly from 3D files to the mold, without going through the drawing stage. That's one of the things that used to slow us down, creating the blueprint. The mold maker really does not need a print. He uses the same for his cutter path to create the mold. Now, we just sent floppy disks to the mold maker.

This third generation software will allow the Medical device manufacturer to be customer responsive in other ways. One way is by delivering visualizations of a new product within three hours of the customer's initial request. With this tool, we can construct a solid model of a new cap within a couple of hours with a good workstations, one of which is equipped with superior Graphics. This configuration allows us to generate photo quality visuals on the screen, visuals so good that you can't tell it's not a real object.

We output the solid model off the screen and deliver them to the customer. At the same time that we send the photo-real images, we might very well get a stereolithography model made. The product visuals can be delivered within three hours and the stereolithography model within 48 hours of the time we receive the

customer request. The fast response to customer requests has been the only deciding factor in gaining recent new business but he does know it has greatly improved the way they develop and sell new products.

CHAPTER 7

A DFM EXAMPLE

7.1 B-D Pulsitainer™ (Blood containment Device) A DFM example

The best way to illustrate the concept of Concurrent Engineering and Design For Manufacture as applied to the medical industry is to analyze an actual project where the tools and techniques describe in this thesis were utilized. In this example, although every single tool or methodology that can be used in the design of a new product was not used. The one used illustrated the idea of Design for Manufacture and Concurrent Engineering technique in the medical device industry.

Marketing and Engineering personnel began to think about this design as a solution to a very serious problem in the health care industry. Health care workers are exposed every day to enormous danger because they are constantly in contact with patients who have transmitable diseases. Needle sticks and contacts to blood occur during medical procedures every day in the health care environment. That is the reason that medical device companies like Becton Dickinson and many others choose to adopt a strategy focusing on designing products that make the procedures in question safe for the individuals (nurses, doctors) performing them. Possible nosocomial transmission of blood-borne pathogens is a serious concern for health care workers and patients. Fears about physician-to-patient transmission of HIV have been heightened by reports of HIV transmission in medical practices. The risk of transmission from patient to health care worker after needle-stick injury has been examined in several recent reports. Fears persist because of the potential devastating consequences of infection. The device in question, B-D Pulsitainer Blood containment device is used during Invasive Radiologic Procedures. It is an

attachment to the needle used in the performance the procedure.

7.1.1 Rationale

The use of a device or system to encapsulate spurting of pulsating blood following arterial punctures seems to have been first reported 1988. With the increasing awareness of blood borne pathogens, and the increasing risk of infection to health care workers, there has been a number of preventive methods and techniques reported. Recently, there has been a growing concern with regards to procedures performed by both radiologists and cardiologist. However, unlike conventional methods to prevent percutaneous infection by needle sticks, the subject device would reduce the chance of exposure by containing spurting blood. Recent regulations promulgated by the Occupational Safety and Health Administration (OSHA) are relevant. Part of the Universal Precautions require that procedures involving blood shall be performed in such a manner as to minimize splashing, spattering and generation of droplets of blood.

While certain methods and products exist to aid in this effort, it is important that the basic technique not be compromised. Any new device should be compatible with the users technique. It should have the ability to collect, contain, and dispose of blood, with a minimum of effort. This should result in less exposure and a generally safer procedure.

7.2 An Interfunctional Product Development Team

QFD stressed that product development is more successful if there is good communication among all the people involved in designing, building, and delivering the product to the customer. A team drawn from marketing, customer service, sales , engineering, R&D, manufacturing, and management was put

together for this project. This team stayed together throughout the development of the new BD Pulsitainer Blood containment device and was involved in all the market research and all the technical design. In this way, engineering and R&D had first hand exposure to all the physician and patients needs; marketing, customer service, and sales understood the technology behind the product, how to use the technology, and what improvements where likely to be feasible in the future: The product was designed for cost-effective manufacture. All strategic decision were made with full knowledge of the physician and the technology and with the team support.

7.3 The Voice of the Physician in the Development of the Pulsitainer

The marketing personnel got in touch with all physician currently performing radiographic procedures. Through a combination of focus groups and telephone interviews, customers (radiologist and cardiologist) were ask to describe their experiences, and what is critical during the procedure, and how they made product decision. When a physician mentioned a need or experience, the interviewer probed the physician until he or she gained a deep understanding of that need from the physician perspective. The interviews were recorded, transcribed, and analyzed carefully. Team members looked for any and all needs that were mentioned, including basic needs, which they assume that any blood containment device should satisfy, and articulated needs, which the physician specifically raised. They also sought to identify any excitement needs. Those that if fulfilled would have delighted and surprised the physician but that were not yet available with any blood containment device. The findings were as follows:

1- The visualization of arterial access by clear blood spurt of the side holes in the collection chamber (articulated need).

2- Pre-loading the guidewire should be easy (exciting need)

3- The tactile feel of the physician cannot be compromised (articulated need)

4- Finally the blood should be contained after the procedure (basic need)

These four functional requirement were obtained after talking to many doctors. Most of them would not consider buying the product if requirements # 3 and # 4 were compromised. The questionnaire was done to design the best product that we know the customers would buy. Everything that was done from there was based on those requirements. This constituted the Quality Function Deployment part of the project.

7.4 Pulsitainer™ Cost Target

The next step was to establish a cost target. The customer even though they would buy this product were not willing to pay a lot for it. All the physician felt that even though the product is useful in preventing blood borne pathogen accident it does not simplify the procedure. Moreover they felt that the whole procedure was bloody anyway, therefore the elimination of the spurting of the blood during the initial stick does not constitute a big deal. All the aforesaid reasons were important to put a price tag on the product. Currently, Arrow sells a similar kind of product for $7.50, and Cook sells theirs for $8.50. Our target is to sell the B-D PULSITAINER for about $3.50. Also it is our intention to provide a superior product. Incidently, those same doctors that we questioned indicated to us that the competitor products did not meet the functional requirement. The competitor's products were designed without consulting the end user prior to designing them.

Now that functional requirement and cost target were set. It was possible to draft and applied a phase implementation approach as describe in Chapter 5. **figure 10** represents the phases in which the project was carried out.

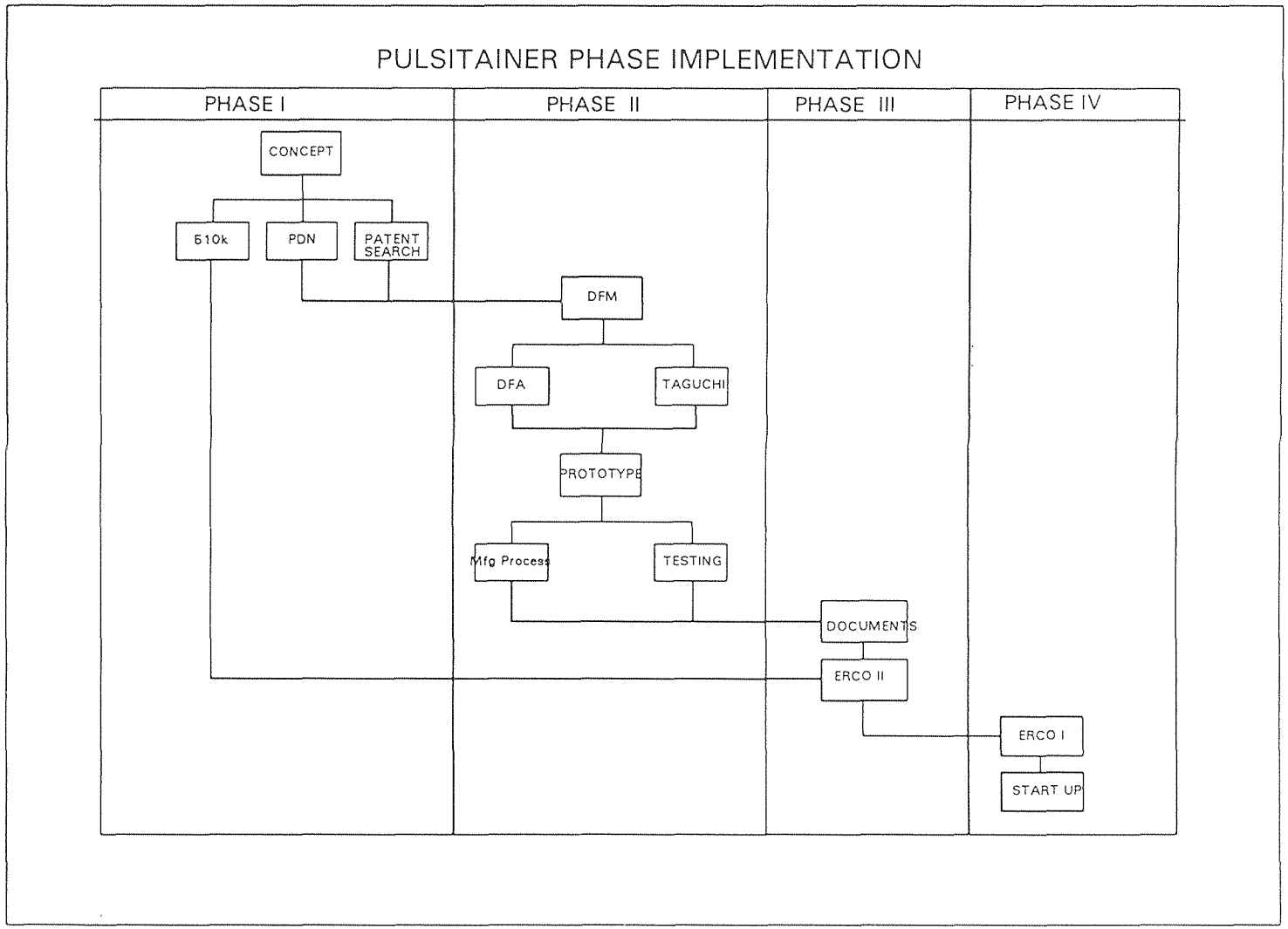

Figure 10 PULSITAINER Phase Implementation

PHASE # I

a) A 510k was submitted to the FDA early in the project to give them enough time to analyze our proposal.

b) At the same time a Product Device Notification (PDN) was submitted to our Medical division requesting approval of the design and approval of the materials and components involved. For instance, the toxicity level of all the material were tested to prevent the company from producing a device that could endanger the life of the patient.

c) Also at the same time, a patent search was initiate to make sure that our design was not infringing any other patents.

PHASE # II

a) Our initial design concept was then analyze with care using the DFM tool to come up with the best design for manufacture without compromising the functionality requirements

b) We then begun to work with our supplier for the components. We welcome their suggestions as long as that they did not compromised the functionality requirements for our product design.

c) We tried our best to use existing approved components and materials. The syringe barrel that we used is a standard item, the vent plug material was pre-approved for production in a different product. The plastic tubes were extruded by one of our manufacturing plant with a pre-approved resin.

d) After all the parts where designed, and the materials selected, in cooperation with our machine shop we build a series of show-and-tell prototypes. Those were shown to many physicians and to the marketing group. They were all

satisfied with the way that the prototype looked. It addressed all of their concerns. They only had small comments pertaining to the size and weight.

e) Our next test was then to make actual working prototype to be tested in a laboratory environment. An in-vitro model simulating an actual human heart rate was built to simulate the pulse that the device will see. Using the model, the device was tested for leakage. We even had a physician come and tested a our device using our in vitro model.

PHASE # III

At that point, all documents were generated and releases in an Engineering release order.

PHASE # IV

Finally, another engineering order was released to release the product for market. The difference between this Engineering order and the previous one is that in the latter all the cost information were included whereas in the

previous one only documents and drawings were released.

REFERENCES

1 Cutts, Structured Analysis and Design Methods. New York: Van Nostrand Reinhold, 1990, pp 12-14

2 Woodruff and Phillips " A smarter way to manufacture: How concurrent engineering can invigorate American industry." Business Week, April 30, 1990 pp 68-74

3 Andreasen, Kahler and Lung Design for Assembly Kempston: IFS Publication Ltd.,1983

4 Miles " Design for Assembly: A key element within the design for manufacture " Proceedings of the Institution for Mechanical Engineers, PP 203, 1988

5 Burr Engineering Statistics and Quality Control. New York: McGraw-Hill, 1953. pp 144

6 Chan Lai et al. " A new measure for process capability: C_p " Journal of Quality Technology. Vol 20, No. 3 1988, pp. 162-175

7 Clausing and Simpson " Quality by Design." Quality Progress " (Journal of ASQC), January 1990, pp 41-44

8 Kane " Process capability indices." Quality Technology Journal" Vol. 18 pp 41-52, 1986

9 Sinha " The successful use of the Taguchi methods to increase manufacturing process capability." Journal of Quality Engineering, Vol. III pp. 51-62

10 Young A. John " Technology and competitiveness: A key to the economic future of the United States. " Science Magazine, Vol. 241, 15 July, 1988.

11 Stuelpnagel Thomas "Total quality management." Journal of National Defense. November 1988, pp. 57-62

12 Spartz Management Vitality: The team Approach. Dearborn Mich.: Society of Manufacturing Engineers Press, 1988 pp. 14-24

13 Sullivan L.P. " Quality Function Deployment" Quality Progress, Vol XIX, No 6, pp. 39-50, June 1986

14 King Robert " Listening to the voice of the customer: Using the quality function deployment system." National Productivity Review, pp. 277-281, Summer 1987.

15 Kogure Masao and Akao Yoji " Quality function deployment and company worldwide quality control in Japan." Quality Progress, Vol XVI, No 10, pp. 25-29, Oct. 1983.

REFERENCES
(Continued)

16 Eureka, William and Ryan, Nancy. The Customer Driven Company. Dearborn,Mich.: ASI press, 1988

17 N.P Suh, A. C. Bell and D.C. Gossard. "On an Axiomatic Approach to manufacturing and manufacturing system." ASME Journal of Engineering for industry, Vol. 100 No. 2, May 1978

18 Whitney E Daniel " Manufacturing by design" Harvard Business Review, Vol 66, No 4, 1988.

19 Yasurahara M. and Suh N., "A quantitative analysis of design based on the Axiomatic Approach," in computer application and Manufacturing system,

20 ASME production Engineering division Publication, PED-2 1980.

21 Hayes H. Robert, Steven C. Wheelwrigth and Kim B. Clark, Managing Product and Process Development Projects, Dynamic Manufacturing, the free Press, New York 1988, pp. 304-339.

22 Lawrence P. and Lorsh W., Organization and Environment: Managing Differentiation and integration. Division of research Graduate School of Business Administration, Harvard University, Boston Mass. 1967.

23 S. Miyakawa and T. Ohashi, " The Hitachi Assemblability Evaluation Method (AEM)." Proceedings First international conference on product Design for Assembly April 1986.

24 G. Hock, " Designing for Productivity" Target (Summer 1987) p. 14

25 G. Taguchi, Introduction to Quality Control, Asian productivity Organization, UNIPUB White Plains N.Y. 1986.

26 George Box " An explanation and critique of Taguchi's contribution to Quality Engineering, Quality and Reliability Engineering International, Vol 4 pp. 123- 131.

27 US department of commerce, International Trade Administration, U.S Industrial Outlook'92 Business forecasts for 350 Industry.

28 Steward C. " A time and Place for Taguchi." Machine and tool book. December 1988, pp. 32-36

29 Vollman T.E., Berry W.L., and Whybark D.C. Manufacturing Planning and Control System, p30 Homewood, Ill.:Dow Jones-Irwin, 1988.

REFERENCES
(Continued)

30 Hollden Happy. " Six principles of automation in computer integrated manufacturing." Paper presented at 1986 Hewlett-Parckard CIM seminar, Cupertino, California, May 1986.

31 Berliner, C. and Brinson J.A. (eds.) Cost management for today's Advanced manufacturing: The CAM-I Conceptual design. Boston: Harvard Business Press, 1988.