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# Design of an effective and timely product development process for medical devices

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# ABSTRACT

## DESIGN OF AN EFFECTIVE AND TIMELY PRODUCT DEVELOPMENT PROCESS FOR MEDICAL DEVICES

by
**Jean Benoit Almonor**

Effective product development process is one of the most critical issues facing medical devices manufacturing today. There is a need to search for ways to improve or solve the cross organization and company boundaries to enhance the faster release of new medical products to the market. This thesis presents an integrated set of perspectives on the process of new product development of medical devices with dual goals of achieving marketing speed and meet customer satisfaction.

The Attribute Driven Specifications approach described in this thesis, is one of the most valuable tools in the approach to effective product development in medical devices.

This thesis aims to promote effective management of product design and development of medical devices by addressing the inherent complexity and operational reality of the development process of medical devices. Also presented are approaches to product design and development employed by some successful medical device industries.

# DESIGN OF AN EFFICIENT AND TIMELY PRODUCT DEVELOPMENT PROCESS FOR MEDICAL DEVICES

by
Jean Benoit Almonor

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## APPROVAL PAGE

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This thesis is dedicated to
my father Antoine J. Almonor
and
my mother Philomene E. Almonor

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# CHAPTER 1

# INTRODUCTION

## 1.1 The Need for New Products

In this era of global competition and accelerating product life cycles, the need to get new products to market faster is more compelling than ever. There is an old saying, "Time is Money", this statement couldn't be any truer in the present age. Time-to-market is crucial as competitive pressure increases. What was once considered fast development is now a commonplace.

New products determine the future of manufacturing companies. Without well-designed, effectively developed new products, a company's prosperity is limited. A lack of introduction of successful new products can even threaten companies whose prior product success was legendary. Wang Laboratories' information-based office systems and Polaroid's instant photography are two examples. Counting on the continued rewards from existing products can be a recipe for failure. Although a stream of incremental improvements to existing products may prevent disaster, it is usually not long before competitor initiatives and shifting customer needs make a firm's existing products obsolete.

Companies try to respond to market changes and competitive pressure by introducing new products, but this requires more thought and effort than usually invested by companies. Product design and development is an ongoing company activity and should be consistent with the overall business strategy of a company.

In the past several years, rapid product development has become increasingly popular through industry. With this rise in popularity we find some companies that are pursuing rapid development simply because they believe that fast time to market is universally good. Fast time-to-market is worth money, sometimes a great deal of money, but it is not universally so. The only way to determine which actions are appropriate in pursuing development speed is to know what cycle time is worth in financial terms. Since your competitors are also getting faster, a sloppy approach to pursue rapid development will become more expensive.

This thesis provides the necessary tools to achieve more efficient product development cycle time in the medical devices industry. This thesis strives to present a balanced and integrated view of product development. Although it goes into depth about the regulatory requirements for medical devices, the greatest gains are to be made by how integrated disciplines are used to contribute in an effective manner in the product development process. The primary goal is to describe the basic product development process for medical devices and to provide techniques such as the approach to the Attribute Driven Specifications described in chapter 4, as a basis for improvement. Also presented is a practical approach to the development process. This thesis presents an integrated set of perspectives on the process of new product development for medical devices, with an emphasis on new ways of achieving speed to market and meet customer satisfaction.

## 1.2 Concurrent Engineering

The overwhelming conclusion of everyone who has researched into Concurrent Engineering (CE) is that the bulk of the leverage occurs in the product's conceptual design. Here we make the basic design choices that will determine a product's possible manufacturing processes. We can view our design choices as having to meet the needs of both engineering and manufacturing. When a design fails to meet the needs of either of these groups, rework is required. The key difference in rework that comes from manufacturing issues is that it is expensive and late in comparison to rework originating from engineering issues.

By increasing the number of design choices that meet the needs of manufacturing in advance we reduce this rework. The problem with most design processes is that they first design to meet the needs of engineering and then assess manufacturability. This means that the needs of manufacturing are poorly served until late in the design process. A better approach is to address the needs of manufacturing and engineering simultaneously. This reduces the number of design decisions that fails to meet the needs of manufacturing.

Sports analogies have been widely used to distinguish between sequential and simultaneous approaches. The more traditional sequential approach is portrayed as a relay race, in which only one player runs at a time and a baton is passed in one direction from one runner to his or her successor. If any one runner stumble, or if the hand-off is bobbled, the entire effort is delayed. Simultaneous engineering, in contrast, is likened to a game of rugby. Here, the entire team runs down the field at the same time, repeatedly

passing the ball and forth among players. Since the two sports events are different, the analogies that can be drawn between them are limited, but the image is clear.

### 1.3 What is Concurrent Engineering?

Concurrent Engineering (CE) is also known as simultaneous or parallel engineering. It represents a structured, logical framework, which supports a systematic approach to the integrated. **Figure 1** shows an example of CE or parallel engineering.

This method is intended to ensure that developers consider all elements of the product life cycle from conception through to final disposition, including quality, cost schedule, and user requirements. CE focuses on customer satisfaction and teamwork as well as on design for manufacturing, design for assembly and quality issues.

CE is very much a team-management, people, communications, sound technology and culture issue. It is about thinking of the total design and manufacturing cycle, and implementing it using appropriate technologies and excellent people equipped with multi disciplinary skills.

The heart of the problem is that engineers in design, manufacturing, medical, quality assurance, and R&D do not speak the same language. Most of the obstacles are cultural and organizational. What this technology provides is fundamentally the excellent communications systems that the small family business always had, as well as new methods and tools for creating, analyzing, testing and implementing products that the customers need.

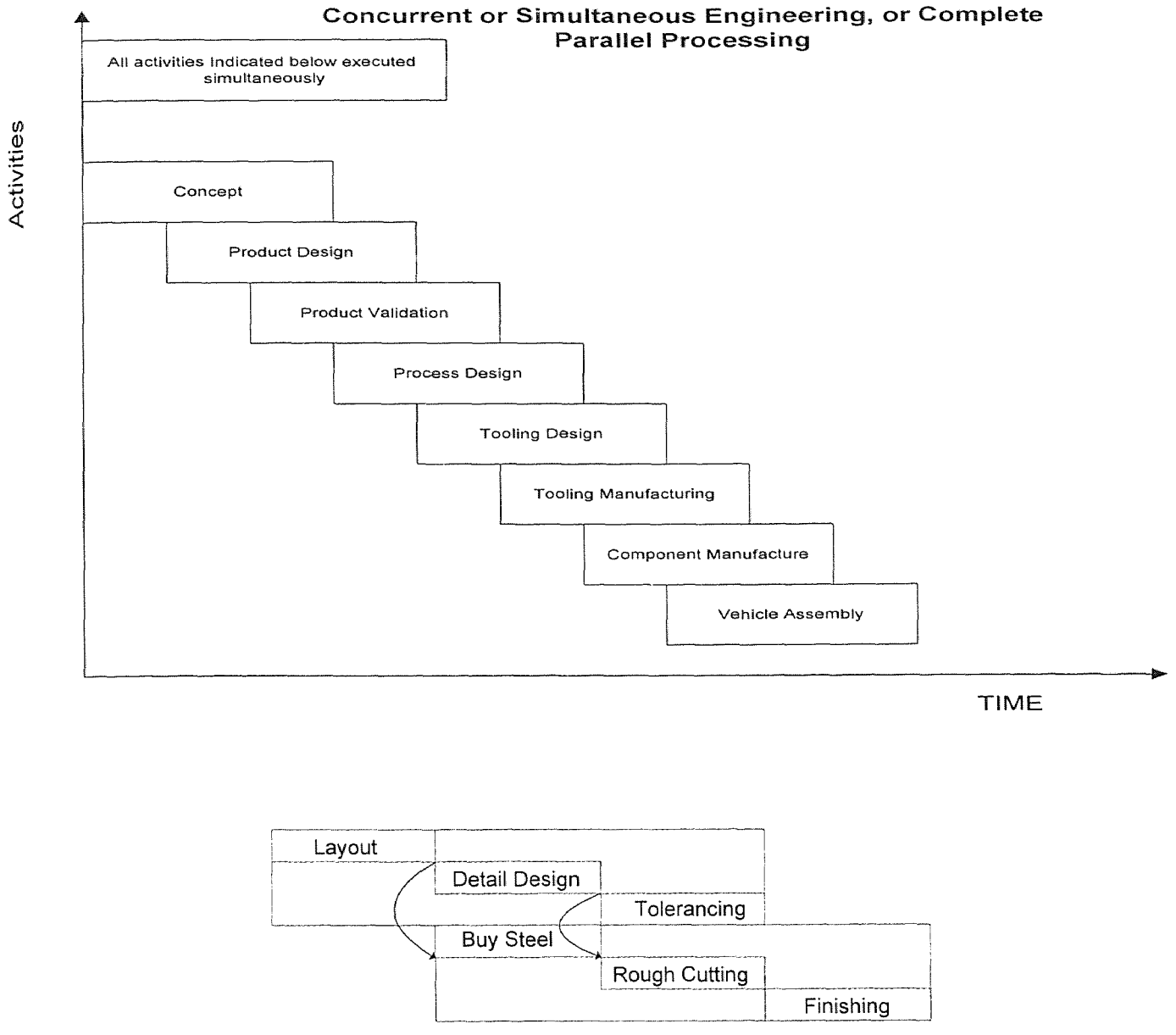






**Figure 1** The Principal Activities of the Commence Parallel and Concurrent Engineering
*Source: Paul G. Ranky – Concurrent/Simultaneous Engineering 1951*

## 1.4 Product Reliability is Key for Concurrent Engineering in the Development Process of Medical Devices

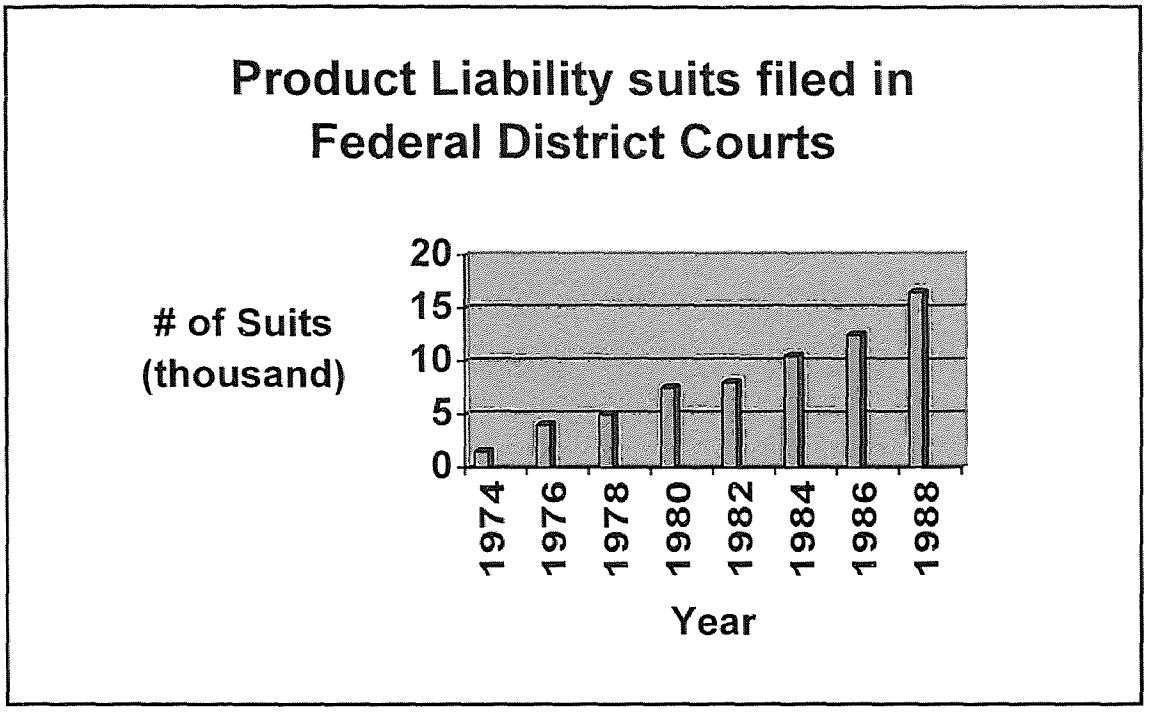
Reliability engineering is key to concurrent engineering through product development teams. Reliability engineering is one of these essential links, since reliability, as a product attribute, is an essential ingredient to the success of any product. Customers expect their products to work on demand. As devices functionally become more intricate, concerns arise regarding efficacy, safety and reliability. Both the user and the patient want the device to operate as specified, perform in a safe manner, and continue to perform over a long period of time without failure. To be successful, the designer and manufacturer of medical devices must ensure that all devices meet these requirements. Reliability assurance is an integral part of the product development process and of problem solving activities related to manufacturing and field failure. Reliability assurance is essential to the success of any medical device company. It helps develop a more profitable product, contributes to a more satisfied customer base, reduces the risk of liability and builds confidence in meeting the requirements of standards and regulatory organizations. Reliability is a characteristic that describes how good a device really is. It is a measure of the dependability of the device. It is a characteristic that must be planned for, designed and manufactured into the design. The inclusion of reliability in manufacturing is important, because no matter how well a device is designed, it will not be a success unless it is manufactured and serviced reliably.

When developing a medical device, it is of utmost importance to design the device to operate according to specifications, without failure for a maximum period of time. To do this, failure must be analyzed as to whether its occurrence will allow the

device to keep operating at a safe level, or whether the device should be shut down to avoid potential harm to the patient or the user.

If a product is found to be defective in the hand of the user the manufacturer may be liable for the harm that the product causes. This could have significant consequences. **Table 1** shows some of the liability suits filed in the federal district court in regards to product liability cases.

**Table 1** Product Liability Suits Filed in Federal District Courts
*Source: Administrative Office of U.S. Courts*



## 1.5 The Impact of Regulations on Product Development of Medical Devices

Although there are many good tools to use when developing new product, there are also some problematic areas in the development process. One of these is the dilemma that occurs in writing specifications. For Medical Device industries, which are regulated by Food and Drug Administration, certain levels of quality are required, such as requirements of Good Manufacturing Practices (GMP). The Quality Systems (QS) in the current GMP require that domestic or foreign manufacturers have quality system for the design and production of medical devices intended for commercial distribution in the United States. The regulation requires that various specifications and controls be established for devices; that they are manufactured under a quality system; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems and that complaints be processed. Thus the QS regulation helps assure that medical devices are safe and effective for their intended use. The FDA monitors device problem data and inspects the operation and records of device developers and manufacturers to determine compliance with the GMP requirements in the QS regulation.

The medical device QS regulation requires an umbrella quality system intended to cover the design, production, and distribution of all medical devices. In most cases, it is left to the manufacturer to determine the best methods to attain quality objectives. In some cases, however, the QS regulation does specify the particular type of method to be used such as written procedures or written instructions.

## 1.6 The Food and Drug Administration

The Food and Drug Administration's (FDA) job is to see that the food we eat is safe and wholesome, the cosmetics we use won't hurt us, the medicines and medical devices we use are safe and effective and that radiation-emitting products such as microwave ovens won't do us harm. FDA also ensures that all of these products are labeled truthfully with the information that people need to use them properly. FDA is the United States' oldest consumer protection agency. FDA is a public health agency, charged with protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related public health laws.

If a company is found violating any of the laws that FDA enforces, FDA can encourage the firm to voluntarily correct the problem or to recall a faulty product from the market. A recall is generally the fastest and most effective way to protect the public from an unsafe product. When a company can't or won't correct a public health problem with one of its products voluntarily, FDA has legal sanctions it can bring to bear. The agency can go to court to force a company to stop selling a product and to have items already produced seized and destroyed.

## 1.7 What is a Medical Device?

There are as many different definitions for a medical device as there are regulatory and standards organizations. Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part, or accessory, which is

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them.
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
- Intended to affect the structure or any function of the body of man or other animals Which does not achieve any of its principal intended purposes through chemical action within or in the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes

The Medical Device Amendments of 1976 expanded the definition to include:

- Device intended for use in the diagnosis of conditions other than disease, such as pregnancy
- In vitro diagnostic products, including those previously regulated as drugs.

Medical devices are classified and regulated according to their degree of risk to the public. Devices that are life-supporting, life-sustaining or implanted, such as pacemakers, must receive agency approval before they can be marketed. FDA's investigation does not end when a drug or device is approved for marketing; the agency collects and analyzes tens of thousands of reports each year on drugs and devices after they have been put on the market to monitor for any unexpected adverse reactions. Medical devices are important part of health care. Yet they are an extraordinarily miscellaneous category of products. The term "medical device" includes such technologically simple articles as ice bags and tongue depressors on one end of the expansion and very sophisticated articles such as pacemakers and surgical lasers on the other. **Figures 2, 3 and 4** illustrate some currently marketed medical devices by Becton

Dickinson VACUTAINER Systems. These tubes are used to collect blood for diagnosis of the patients and allow the doctor to provide proper treatment.

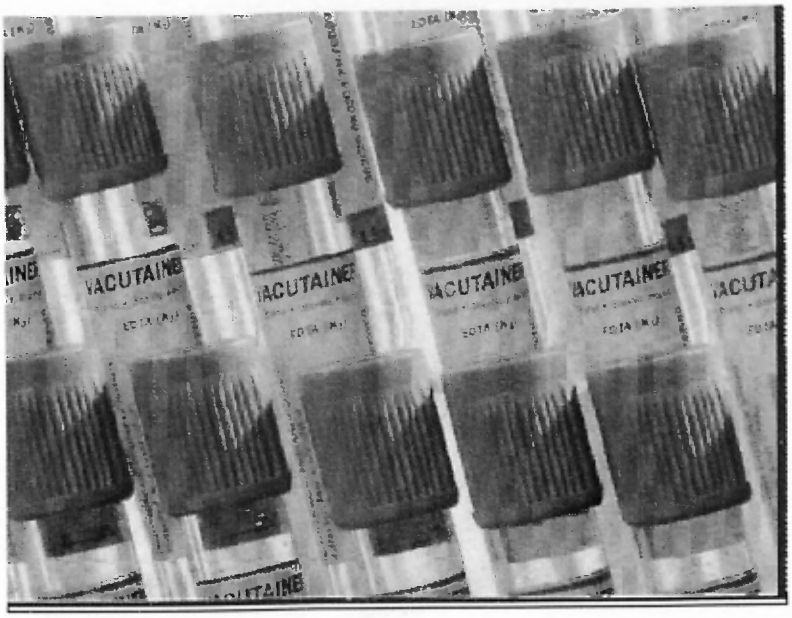



**Figure 2** Becton Dickinson VACUTAINER® $K_3$ EDTA Tube

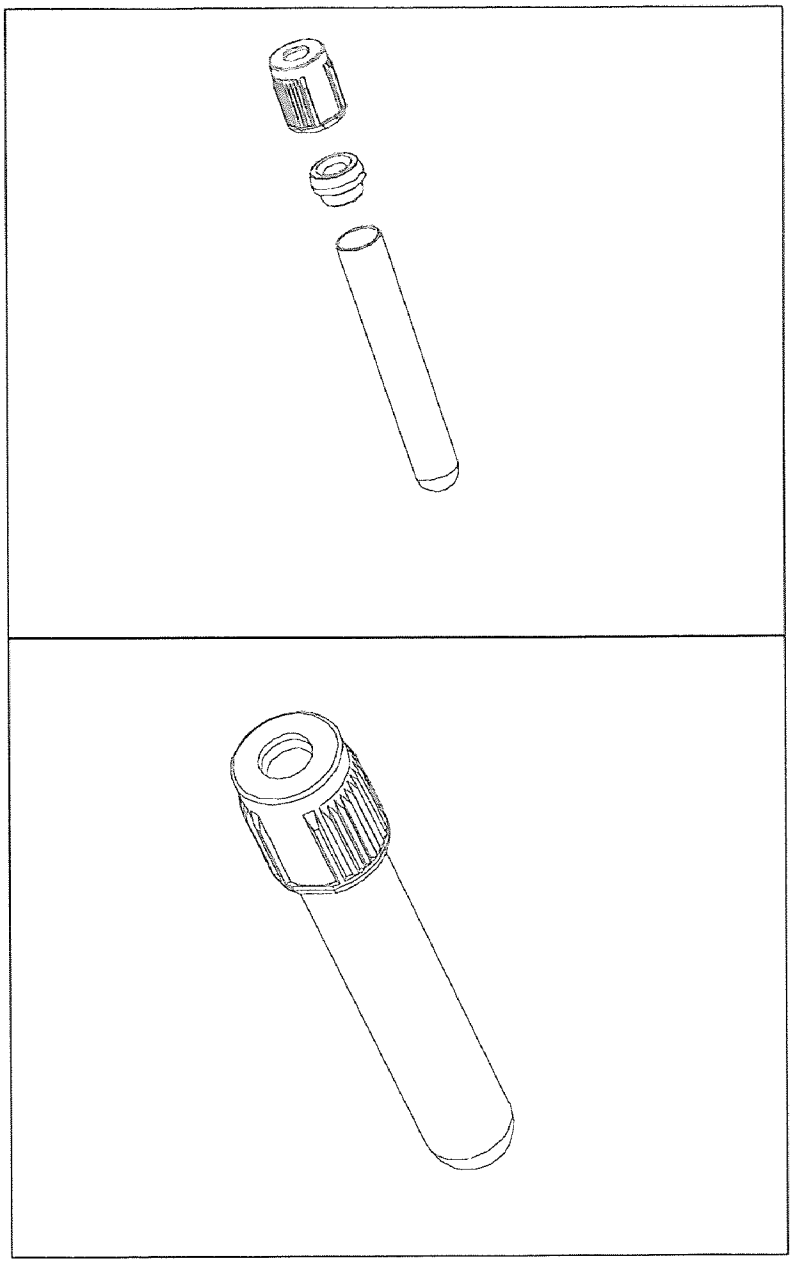


**Figure 3** VACUTAINER® Evacuated Blood Collection Tube

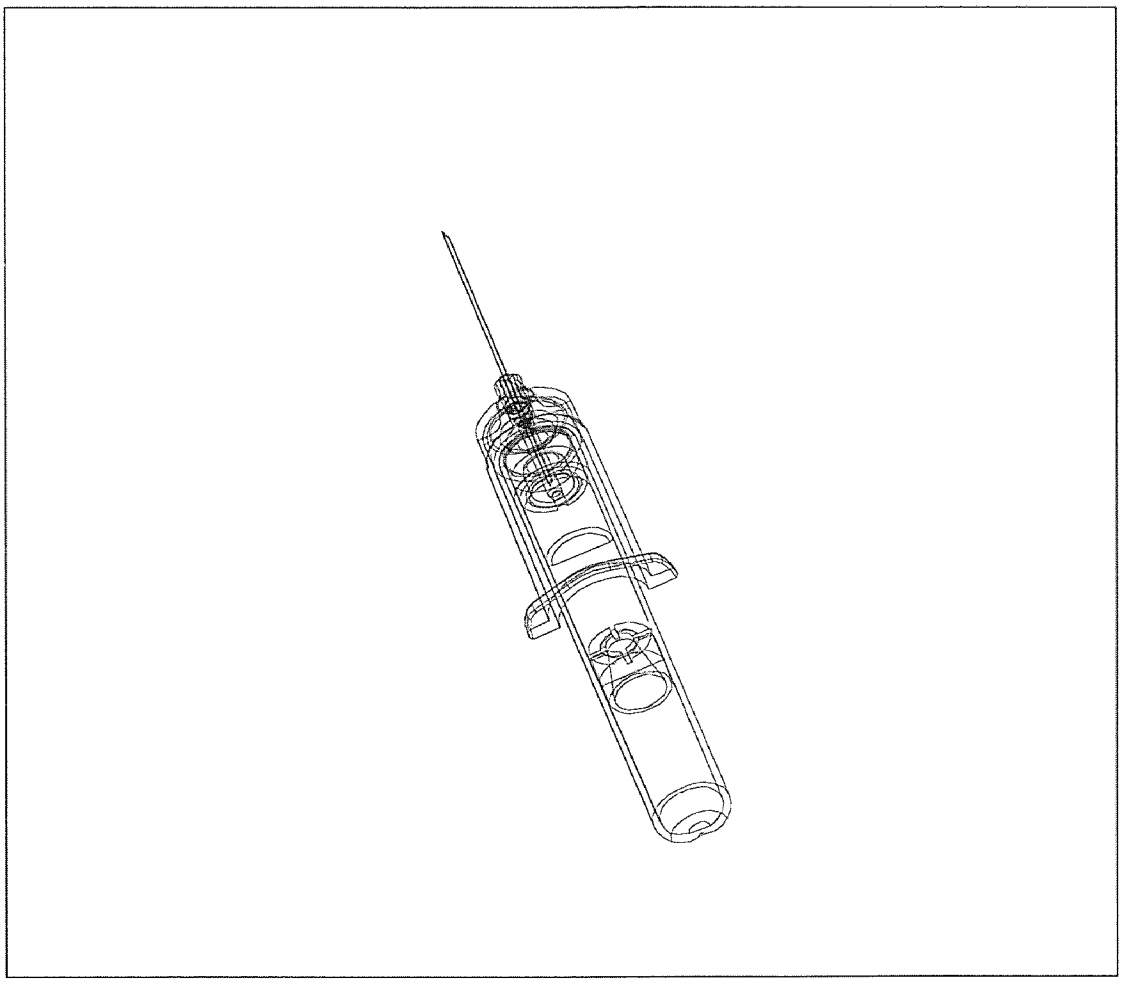


**Figure 4** VACUTAINER® Next Generation Evacuated Blood Collection Device

Perhaps it is this diversity of products coupled with the delicate number of different devices that makes the development of an effective and efficient regulatory scheme a unique challenge for domestic and international regulatory bodies.
The complexities of the FDA's regulations, along with the current regulatory, make the decisions concerning the medical devices approval strategy all more important. Although medical devices may vary in size, weight, complexity, and functionality, they have one thing in common. All must be safe and effective for their intended use. To be successful in this business, the device is to be highly reliable. Making devices safe, effective and reliable begins at the earliest stages of product design and is a continuous process through production and maintenance.

Safety must always be the most important consideration in designing and developing a medical device. A device must never function or malfunction in a way that will cause harm to either the user or the patient. Safety is not optional, nor can it be attained solely through standards compliance; it must be integrated in the design.

## 1.8 The Trend for Medical Devices

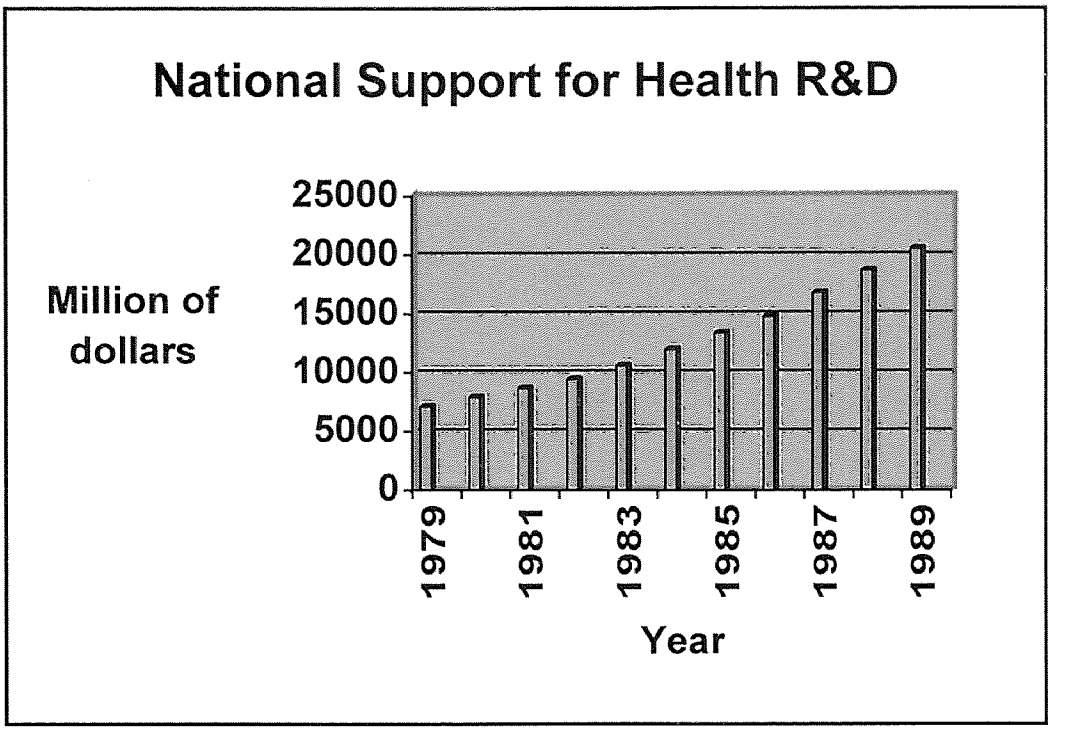
Medical care has become increasingly dependent on technology, and medical devices are the drivers of that trend. The modern hospital is full of complicate machinery. Tens of thousands of Americans depend upon artificial body parts for survival and to improve the quality of their lives, from hips to intraocular lenses to heart pacemakers. Even doctors' offices are full of new devices. Physicians use lasers to remove cataracts without the need for hospitalization. The allure of medical innovation is powerful, holding out the possibility of a perfect outcome, an amelioration of pain and possibly a postponement of

death. At the current rate of innovation, an analyst currently projected, by the year 2000 close to 100,000 new or enhanced medical devices will have been introduced into the marketplace. **Table 2** illustrates the value of this industry and **table 3** shows that over $20 billion in 1989 are being spent on R&D for the innovation of new medical devices.

**Table 2** Forecast Health Spending
*Source: M.S. Freeland et. Al., Health Care Financing Review 6*

| | YEARS | | |
|---|---|---|---|
| | **1984** | **1990** | **2000** |
| % GNP | 10.6 | 12.2 | 14 |
| **Value** | $387 billion | $660 billion | $1.9 trillion |

***Table** 3 National Support for Health R&D*
*Source: NIH Data Book, no 90-1261 (December 1989)*



## 1.9 Background

There has been numerous approaches to cycle-time reduction for new product development over the years. Martin Mathelier, a graduate from New Jersey Institute of Technology (NJIT) discussed in his master thesis (January 1994) " Concurrent Engineering and Design for Manufacturing in the Medical Device Industry" the principle of an axiomatic approach to manufacturing. He described how techniques such as Quality Function Deployment (QFD) could be used in the product development of Medical Devices. His thesis applied these tools in Concurrent Engineering (CE) to show success in the product development of Medical Devices.

In his 1951 book titled "Concurrent/Simultaneous Engineering", Paul Ranky used CE as key to the success of product development where he defines CE as a team management, people, communications, sound technology, and a culture issue. He emphasizes on thinking of the total design and manufacturing cycle, and implementing it, using appropriate technology and excellent people equipped with multi disciplinary skills.

Arthur D. Little, a consultant for medical device products (ref. 1998, Directory to Medical Products Manufacturing Consultant) also use the integrated approach; he works with the customer and coordinates team effort to create innovative product concepts and identify the best design. The team applies comprehensive product development process methodology, from market analysis to rapid prototyping to Design for Manufacturing and Assembly to manufacturing system design. The result of that process was the release of a 33 mm trocar which was develop in less than a year, met all qualities standards, and cost far less to produce than initial budget targets.

Medical device development is a complex process that requires the careful integration of diverse disciplines, technical activities, standards, regulatory requirements, and administrative project controls. The need for systematic approaches to product development and maintenance is necessary to ensure a safe and effective device for the user and patient, an economical and competitive success for the manufacturer, and a reliable, cost-effective investment for the user.

# CHAPTER 2

# CURRENT PRODUCT DEVELOPMENT PROCESSES FOR MEDICAL DEVICES

## 2.1 From Conceptual Phase to the Release Phase of Medical Devices Product Development Cycle

New medical device products come to the market through a process that first transforms ideas and concepts into working prototypes through detailed design and engineering, then tests and refines them to meet regulations, and finally prepares the product design and factories for commercial operation. The schematic of the development process illustrated in **figure 5** defines the way in which many medical devices industries propose and select concepts, and how these concepts converge to a specific product definition, design, and release to the market. The development process as defined in this chapter lays out the pattern of how to release a medical device product to the market.

The process described in this chapter provides tools and guidelines on how to develop and release medical device products. The Product Development Notification (PDN) process discussed is a very important part of the development process. It informs the organization of the new product that is about to be developed and released for sale. Furthermore, the Core Team approach discussed in this chapter is a good example of concurrent engineering.

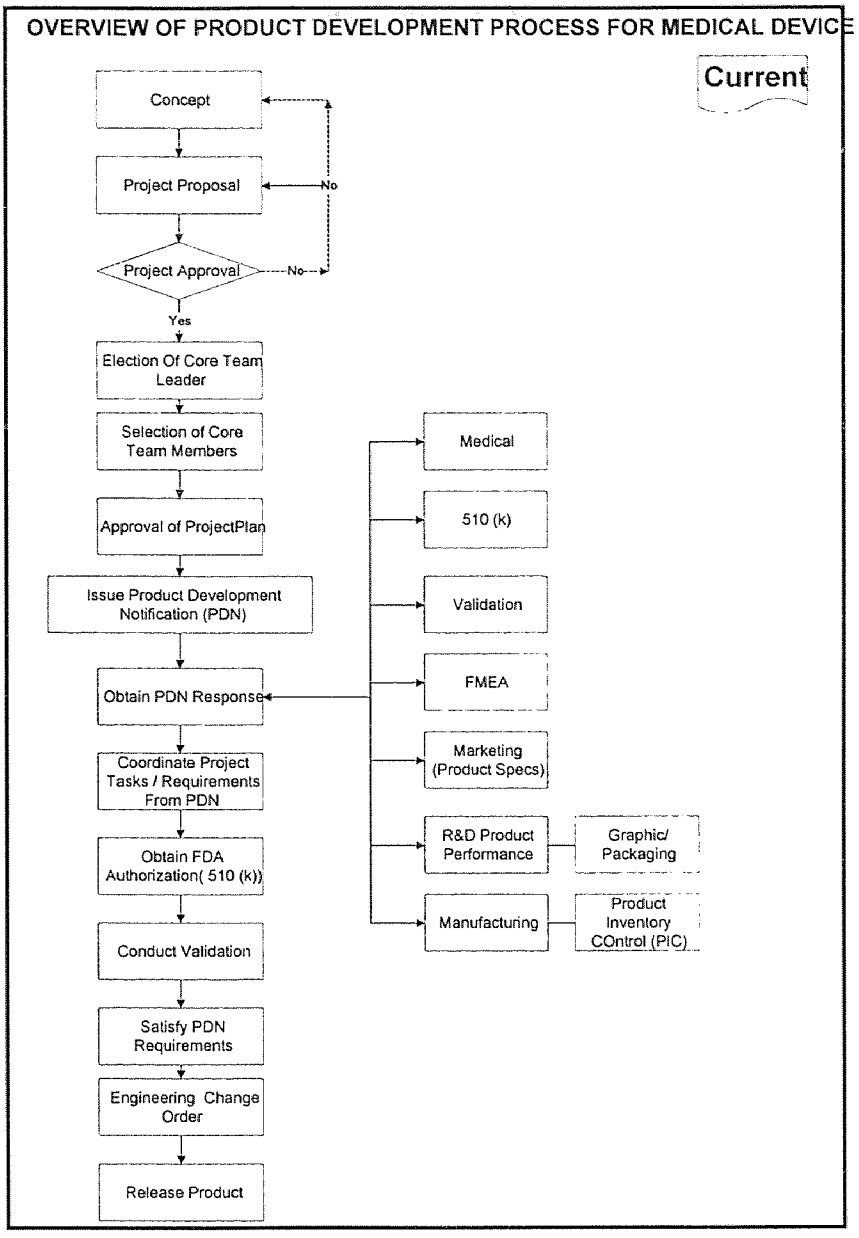



**Figure 5** Overview of Current Product Development Process for Medical Devices

## 2.2 The Development Process

### 2.2.1 How do you Get a Product Concept?

All new products start with a concept. If you don't already have a concept for a new product, then you will need to develop one. New product ideas are not simply born. Most good concepts begin with either a perceived or a measured need. New product ideas come from examining the needs of hospitals, nurses, physicians and other medical professionals as well as from sales and marketing personnel. It is important to talk with physicians and nurses to determine what their problems are and how they can be addressed. These problems generally represent good product opportunities.

There usually are several needs from which to choose. The one with the greatest impact on your customer is usually a good one to pick. After all, they are the ones that are going to buy your new product/service. Once the need has been identified, it is better to capture it in writing as clearly and concisely as possible. It is also a good practice to describe the need and why it exists, be sure to describe who the customer is.

Now, identify a customer need that you are not currently satisfying. Although you may have an idea of what is important to your customers, make sure you ask them for suggestions. Once you have thoroughly defined the need, summarize it and post it where most of your product development work will be conducted. Review the summarized need regularly as you develop your new product. This will keep you focused on the customer throughout the development process.

In addition to your customers and employees, there are other sources for new product ideas. Patent search is another good way of getting new ideas;

The Government-owned patents are a good way to start; call your local Small Business Administration (SBA) office or write to the U.S. Patent Office. The Patent Abstract Bibliography lists NASA-owned patents and can be ordered from the National Technical Information Service (NTIS). AEC-NASA Technical Briefs are 1 or 2 page descriptions of ideas, patents, concepts available to the general public. Government Reports Announcements and Indices are current awareness announcements. Both are also available from NTIS.

Private granted patents could be found in The Official Gazette published by the U.S. Patent Office on a weekly basis. The patent attorneys are also good resources. Large companies often have hundreds of patents for products that they haven't commercialized for one reason or another. Investigate patents held by large companies in your industry. They may be willing to license patent that could be a gold mine for you.

### 2.2.2 The Project Proposal/Approval Cycle

The product development process begins when an idea for a new product is presented to upper management. This latter is a cross-functional team made up of representatives of the senior management committee who determine the strategic business decisions for the project. If the idea seems promising, management instructs representatives from various areas within the company (e.g., marketing, engineering, medical, regulatory affairs, and manufacturing) to investigate whether it is feasible to develop the product.

Working along with others, representatives from the various departments attempt to determine the basic resources and requirements needed to complete the project successfully, and decide whether the benefits of producing it outweigh the risks. After

they have completed their research, department members produce a project proposal; a document recommending whether or not to develop the product and various conditions related to its manufacture. Management reviews the document and decides whether to go ahead with the project or cancel it. Once management decides that a project is worth pursuing, planning the development process can actually begin.

### 2.2.3 The Core Team Approach

Of all decisions management makes, none is more crucial to success than choosing a team leader. A strong leader will be able to overcome many other shortcomings and imperfect decisions, but a mediocre one will be puzzled by even small obstacles. The leader is often the buffer insulating the team from inappropriate management practices that run uncontrolled in the rest of the company. It is important to pick a leader carefully and announce the choice publicly. Everyone should know exactly who is responsible for successful completion of the project and what authority he or she has been granted by management. Selecting a good overall core team leader is crucial to the success of planning the project.

The role of a leader is to maintain overall responsibility and leadership for the project. The leader will set the tone for the project by providing motivation to the members of the team and keeping the team focussed on the plan. The leader has to set high expectations, take risks ands create team excitement about their participation on the project.

The Core Team leader holds the ultimate responsibility for the course of the product's development. Committee management of the project will not work; as the saying goes, "When everybody is responsible, nobody is responsible."
The core team leader should hold regular meetings with the project team to track the status of project planning. It is important not to underestimate the value of these meetings; they are the glue that holds various project activities together. Minutes of meetings should be published and distributed to notify team members of pending action items and provide project status information.

Once the team leader has been selected, the leader should recruit the team members. This is most commonly done by preparing a list of desired team members and negotiating with the functional owners of these resources for their time.

Core Team Members coordinate the project activities for their particular functions. They act as pipelines for communicating both functional needs into the development effort and project requirements back into the functional organization. Core Team members also manage the project resources for the activities that they have responsibility for. The purpose of the Core Team is to bring the necessary expertise to a project from a greater resource pool on an as-needed basis. An unlimited amount of personnel can serve on the project team depending upon the complexity. An illustration of a Core Team structure diagram is shown **figure 6.** With the Core Team approach, senior management makes the critical decisions regarding the product, but the Core Team members make all the implementation or tactical decisions necessary to develop the product.

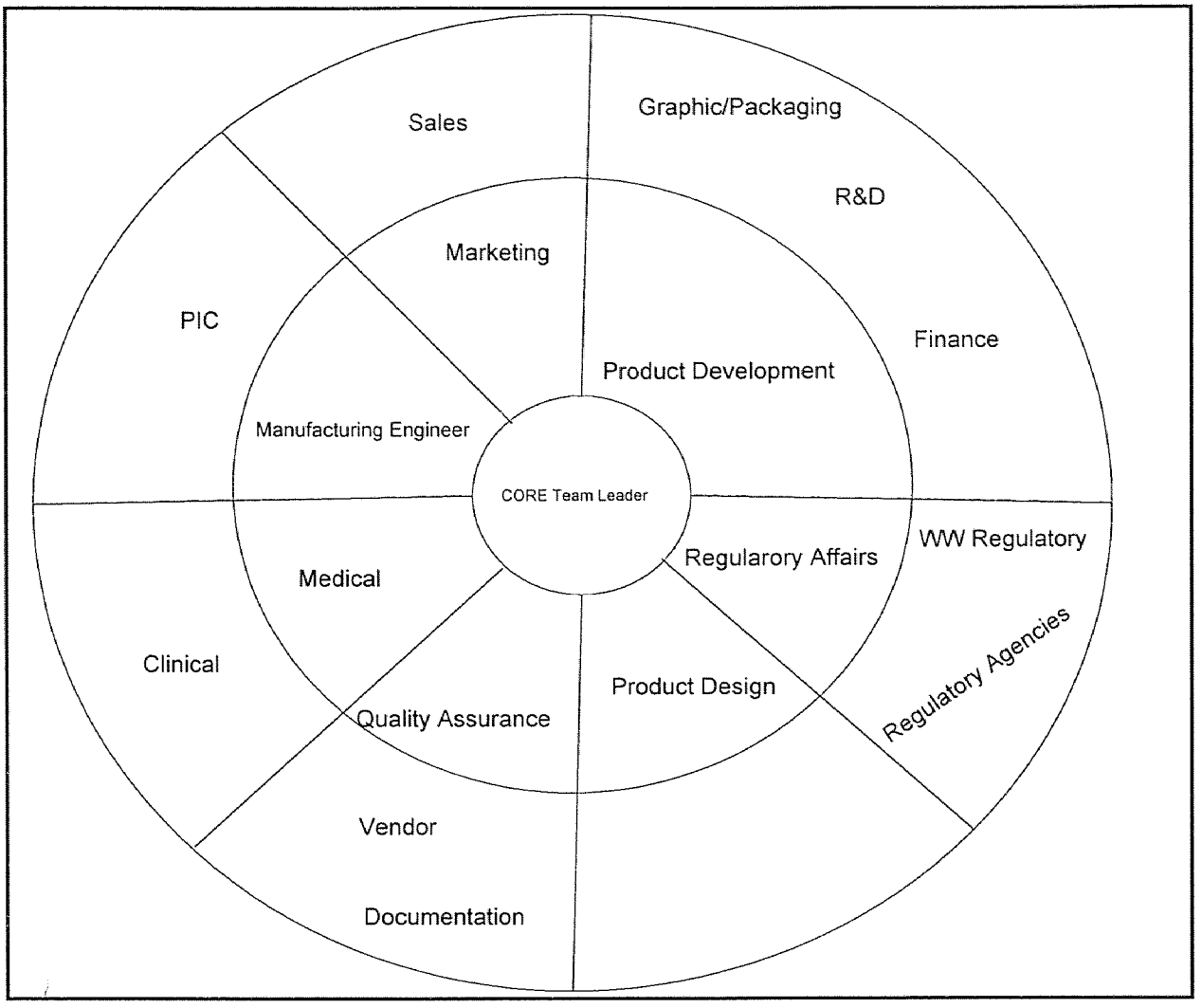



**Figure 6** Core Team

### 2.2.4 The Importance of the Project Plan

The first thing the Core Team leader and Core Team members must do is to draw up a systematic, overall project plan that identifies general terms, the network of activities, personnel, and resources that will be involved in the design and development process.

A project plan organizes and documents the development process and breaks it down into manageable chunks. Conceptually, project stages are distinct from one another, and ideally team members complete the activities in one stage before moving on to the next. In practice, however, activities in different stages sometimes overlap or are carried out concurrently. Also, activities in a given stage (for example a verification procedure) are sometimes repeated to refine the accuracy of the results.

To create the overall project plan, the Core Team leader and team members must look at the entire design and development process and decide what tasks need to be accomplished, in what order, how long they will take, which individuals and departments are needed to accomplish them, the best way to make use of people's time, and a general estimate of how much the process will cost. They must answer the same kinds of questions about materials and resources, and plot all these variables along a time line. They then select appropriate members for the project team, which includes people from almost every department in the company.

The overall project plan established the "big picture" of product development; the degree of detail in the overall plan varies depending on the product, the size of the company, its experience in developing products of this type, and so on. Later, as the project takes shape and the project team gets a better feel for the product, planning in getting detail is necessary, usually related to the completion of specific tasks.

For example, the overall planning phase might establish that the staff needs to begin planning for verification testing soon after actual design work begins, so that when product prototypes are developed, the test procedures are in place and there are no unnecessary delays or holdups. Later, in the actual design phase, specific details about verification testing can be altered if necessary.

Deciding how broad the scope of a project plan should be and how much detail it can specify is one of the biggest challenges facing project management. The more planning that can be done early on, the easier it is to anticipate potential problems and minimize delays further down the line. The trade-off, however, is that those decisions made too soon may have to be changed, possibly wasting time and resources.

To help deal with these concerns, some type of planning procedure or set of flow diagrams (such as the program evaluation and review technique (PERT)), maybe used to create a project schedule and keep track of project progress. These procedures can take the form of manuals and books, and a number of software applications for desktop computers are also available to make preparation of the design plan and project management easier.

Planning procedures encourage a project team to take a disciplined approach to design planning by presenting a structured set of questions that must be answered. They enable project management to create standard operating procedures that can be applied to all areas of product development as the project proceeds.

Developing an overall project plan is a major undertaking and can require considerable time. The Core Team must decide whether it is wise to begin actual design work before the overall project plan is completed. The R&D and engineering

departments will sometimes do preliminary research, before a project plan is finished, to test the feasibility of an element in the project proposal, especially if a new, unproven, or high-risk technology is involved. In some cases, the core team may deem it is important to get started with the design quickly to stay ahead of the competition, or to take advantage of a marketing opportunity. Other companies, however, take a hard line and refuse to begin work until the project plan is completed and management signs off on it.

Before the project plan is submitted to management, the Core Team leader should hold a final meeting with everyone on the team to ensure that the plan is completed to his or her satisfaction. Some companies develop a checklist of critical items that must be addressed before the plan is approved. When management has approved a comprehensive plan outlining the entire project, planning for the actual design work of product development can proceed.

### 2.2.5 Product Development Notification Process

Product Development Notification (PDN) is a cross functional communication process that is designed primarily for engineers and scientists to detail the product and process introductions, product design or product/process changes that impact product performance. The way the PDN works is as follows:

- The originator filled out the PDN form and addresses it to the Medical Department.
- The PDN coordinator from the Medical department distributes copies of the PDN to the Medical Director, Division Quality Assurance (QA), Regulatory Affairs (RA), R&D, Manufacturing, Marketing etc. for review.

- The Medical Director is a expert in physiology and medical assigned to a particular division to provide medical, technical and ethical oversight. He provides definition of evaluations necessary to document product safety and efficacy for all PDNs.

### 2.2.6 Obtain PDN Requirements

If the PDN is for the development of a new medical device, (e.g. a blood-evacuated tube) the Medical Director knows what is required to make a quality blood-evacuated tube, would require the originator to perform clinical functional testing on the tube before releasing it to the market. This may include testing for a variety of clinical analytes or the use of products during phlebotomy procedures. The Quality department could require that Design and Process Failure Mode Effect Analysis (FMEA) be performed to ensure that the design is safe before going out to the customer. Also, they could require that a process validation be conducted to assure that the process would be able to make products consistently within specifications. The Marketing department could require that an End User Assessment should be conducted before product launch. The R&D department could be required to perform different material testing, to ensure that the materials used are safe and will not leach into the blood sample or interfere with performance; the R&D department could require that a product validation is to be conducted, shipping tests are to be performed and functional engineering tests to be done before release. The regulatory Department will dictate the labeling content, FDA notification, 510 (k) requirements, etc.

Upon receipt of the PDN form the coordinator, the manager of that department could additionally chose to circulate the PDN to experts in the appropriate field in order

to get further requirements. These requirements are sent to the medical department which summarized them and issues a response to the originator.

### 2.2.7 Coordination of the Project Requirements

The early phase of development, when attention is focussed on establishing overall objectives, setting target design parameters and meeting PDN requirements, is a good time to start prototyping. There are different methods to have rapid prototyping. If designing a plastic part, methods such as Stereolithography (SLA), which is a printing process which produces copies of solid surface models in plastic can be employed. Other techniques like CAD/CAM and Selective Laser Sintering (SLS) are also good methods for rapid prototyping.

Human factors should be carefully evaluated during this phase in the development. A study conducted at Brigham and Womens Hospital in Boston in 1989 attempted to determine the causes of medical device failures within the hospital environment over an 11-month period. The results of the study indicated 41% of the device problems or failures were caused by user problems or errors. The misuse of a medical device is therefore seen to have an important impact on the overall reliability of the device. The methodology that addresses such user issues is Ergonomics or Human Factors.

Human factors is defined as the application of the scientific knowledge of human capabilities and limitations to the design of systems and equipment to produce products with the most efficient, safe, effective and reliable operation.

### 2.2.8 The Pre Market Notification - 510(k)

The Pre Market Notification Process 510(k) is one the regulatory pathways for device approval. Premarket notification is documentation submitted by the manufacturer that notifies the FDA that a device is about to be marketed. 510(k) notification assists the agency in making a determination about whether a device is substantially equivalent to a previous marketed predecessor device. The 510(k) premarket notification process was designed to give manufacturers the opportunity to obtain rapid market approval of these non critical devices by providing evidence that their device is substantially equivalent to a device that is already marketed. The device must have the same intended use and the same or equally safe and effective technological characteristics as a predicate device. The decision is based on premarket notification information that is provided by the manufacturer and includes the intended use, physical composition, and specifications of the device.

Device Classification

In 1976, with input from the Cooper Committee, the FDA proposed the Medical Device Amendments to the FFD&C Act, which were subsequently passed into law. The purpose of the amendments was to assure that medical devices were safe, effective and properly labeled for their intended use. To accomplish this mandate, the amendments provided FDA with the authority to regulate devices during most phases of their development, testing, distribution and use.

The Cooper Committee concluded that the many inherent and important differences between drugs and devices necessitated a regulatory plan specifically adapted to devices. They recognized that some degree of risk inherent in the development of

many devices, so that all hazards cannot be eliminated. All devices were placed into classes based upon the degree of risk posed by each individual device and its use.

Class I Devices were defined as not life sustaining, their failure poses no risk to life, and there is no need for performance standards. Basic standards, however, such as 510(k) premarket notification, registration, device listing, good manufacturing practices (GMP), and proper record keeping are all required. Nonetheless, the FDA has exempted many of the simpler Class I devices from some or all of these requirements. For example, tongue depressors and stethoscopes are both class I devices, both are exempt from GMP. Tongue depressors are exempt from 510(k) filing, whereas stethoscopes are not.

Class II devices were defined as not life sustained. However, they must not only comply with the basic standards for Class I devices, but must meet specific controls or performance standards.

Class III devices were defined in 1976 as either sustaining or supporting life so that their failure is life threatening. For example, heart valves, pacemakers and PTCA balloon catheters are all Class III devices.

It is necessary that the preparation of the Premarket Approval must actually begin early in the process before it will be submitted. It is only after the company has the results of all of the laboratory testing, pre-clinical animal testing, failure mode analysis and manufacturing validation that their proof of safety and efficacy can begin, in the form of a clinical study under Investigational Device Exemption.

*Types of 510(k)*

There are several types of 510(k) submissions that require different formats for addressing the requirements. These includes:

- Submissions for Identical Devices
- Submissions for Equivalent but not Identical Devices
- Submissions for Complex Devices or for Major Differences in Technological Characteristics
- Submissions for Software-Controlled Devices

The 510(k) for simple changes, or for equivalent devices should be kept simple and straightforward. The submission should refer to one or more predicate devices, it should contain samples of labeling, it should have a brief statement of equivalence, and it may be useful to include a chart listing similarities. The representation shown in **figure 12** is the FDA Substantial Equivalence Process.

Submissions for complex devices or for major differences in technological characteristics is the most difficult type of submissions, since it begins to approach the point at which the FDA will need to consider whether a 510(k) is sufficient or whether a Pre-Market Approval Application (PMAA) must be submitted.

As a general rule, it is often a good idea to meet with FDA to explain why the product is substantially equivalent, to discuss the data that will be submitted in support of a claim of substantial equivalence, and to learn the FDA's concerns and questions so that these may be addressed in the submission.

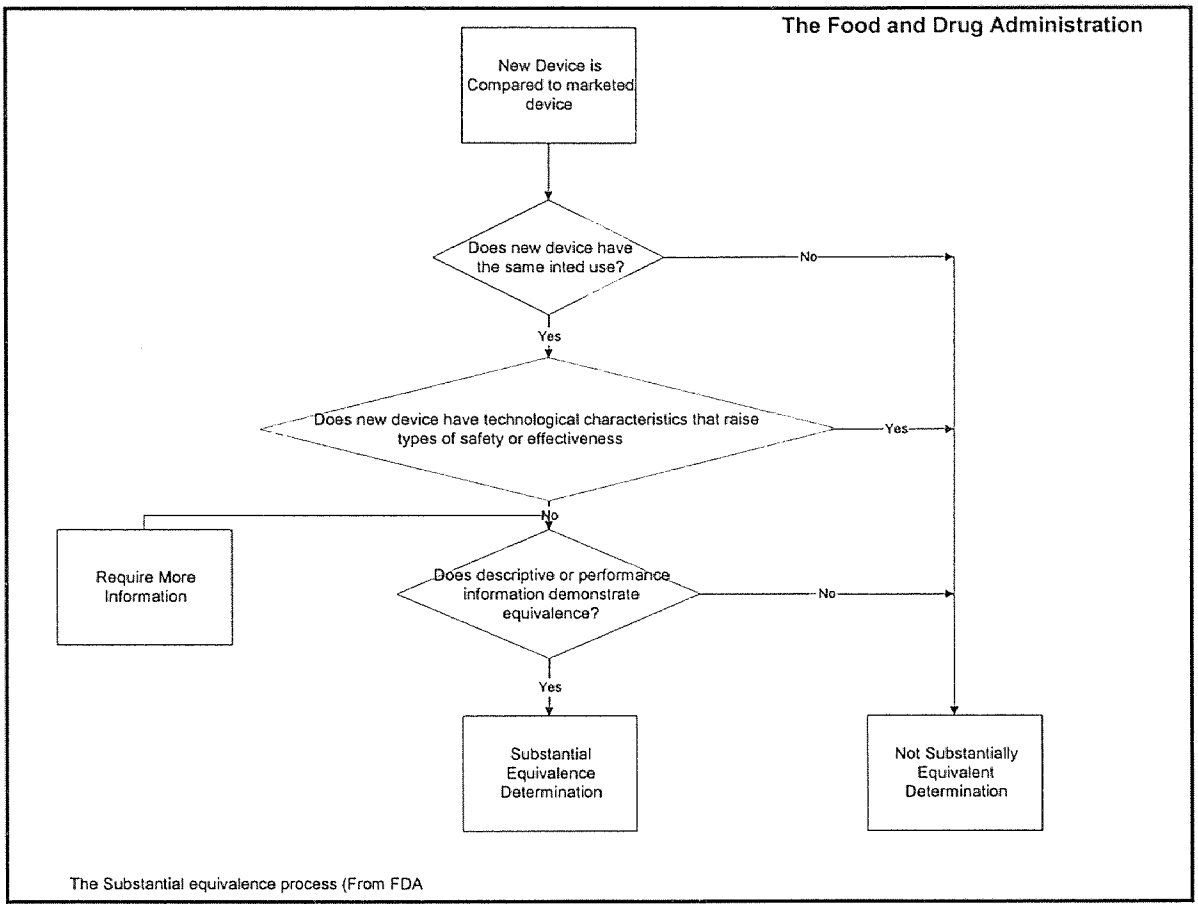



**Figure 7** FDA Substantial Equivalence Process

### 2.2.9 The Importance of the Validation

Customer expectations and international competition have increased the pressures to produce goods of the highest quality at a reasonable cost. Medical device products must be safe and effective at any cost. Testing final product for compliance to predetermined specifications is no longer enough to assure quality. One must determine and control the quality of the raw materials for the manufacturing event and the quality of the manufacturing process. In the complex environment of the modern manufacturing facility with new technology products, assuring quality is a difficult task. Validation should be designed to maximize the assurance of quality and minimize testing.

Validation, along with Good Manufacturing Practices, was mandated for the pharmaceutical manufacturing industry in the mid-1970s in response to numerous problems with the sterility of large volume parenterals. Prior to this time, validation had been routinely applied only to analytical test methods in a laboratory setting. Validation is a fundamental building block that supports corporate commitments to quality assurance. Validation must be carefully planned to ensure that regulatory requirements are met and that corporate philosophies are maintained in a reasonable and cost-effective manner. Poorly planned validation and poorly understood commitments to validation can result in excessive use of time and resources. Validation in the medical device manufacturing is appropriate and indeed often required in order to move a product from development to commercial production in the product life cycle. Validation confirms that product of predetermined quality and performance characteristics can be built reliably and reproducibly within established operating limits of the manufacturing process at the commercial manufacturing site. Validation is the process of evaluating a

product or a manufacturing process during or at the end of the development process to determine whether it satisfies specified requirements. A validation establish documented evidence which provides a high degree of assurance that a specific product/process will consistently produce a product/process meeting its predetermined specifications and quality attributes. There is a section in the medical device GMP regulation that is often cited as FDA's mandate for requiring process validation.

It is important to prepare a well-written validation protocol and report which specifies the procedures (tests) to be conducted, the data to be collected and the analysis that will be performed. An industry axiom says, "If it hasn't been documented, it hasn't been done." Similarly, conclusions drawn from a poorly documented validation study report are nothing more than corporate rumor.

### 2.2.10 Engineering Change Order (ECO)

The ECO is a documentation process that ensured all design or process changes have been properly documented. The ECO package must contain all the documentation required to define the change of the design documents which represent the item being changed. The ECO package is usually done at the end of the development process.

For the release of a new product, the ECO should contains all the PDN requirements, FDA clearance 510(k), validation reports, clinical evaluation reports, manufacturing specs, packaging graphics, medical release, material specs, process capability reports, DMR, etc. The ECO package usually gets circulated to upper management for their approval.

### 2.2.11 Product Release

The release of the product for sale is authorized when these requirements are met after the ECO is approved.

- Registration of the device with the FDA. Registration must be done when first beginning to manufacture medical devices and must be updated yearly.
- The logistics department will dictate when to start manufacture the product. They will make sure that the products go to the appropriate distribution center. They will be working with the manufacturing plant to review the production progress against their schedule.

## 2.3 Disadvantages of the Process

Some of the disadvantages in this process is time wasted waiting for an activity to be accomplished before proceeding to the next. In the PDN process, for example, the originator has to wait for the requirements from the other functions after issuing the PDN. If the originator disagrees with the requirements, PDN amendments have to be issued and rerouted to the same reviewers. Further, with new ISO regulations emphasizing on design control, it could make this process more cumbersome to release new products.

The product requirements usually come from marketing, who is closest to the customer. The problem with that is these requirements are always changing, which makes the design process longer than it should be. In the medical device world, any change in the design, has to be documented and released through the documentation process (i.e. ECO).

The level of documentations in the development and manufacture of medical devices is tremendous and makes the process lengthy, specially at the early stages in the development process. An efficient method to capture the product specifications will reduce the development cycle time.

# CHAPTER 3

# THE NEW APPROACH TO AN EFFICIENT AND TIMELY PRODUCT DEVELOPMENT PROCESS FOR MEDICAL DEVICES

## 3.1 The New Approach and its Advantages

The illustration in **figure 8** provides an overview of the proposed approach to product development for medical devices. This approach evolved from the approach described in chapter 2, with an emphasis on, the core team approach for the reduction of cycle time by using concurrent engineering in the Attribute Driven Specifications (ADS) process for the development of medical devices.

The purpose of this new approach is to accelerate and continually improve the efficiency and the effectiveness of the product development for the medical device industry. The Attribute Driven Specifications (ADS), which is the focus of the new product development process, is discussed in details in chapter 4 of this thesis. The new approach is also designed to fit well within the new domestic and international regulations which are the driving force of this business. Too much control could inhibit speedy development. The technique in this process is a fast, systematic and well understood approach to planning, and tracking the product development history without sacrificing overall control of the process. The International Standards Organization has done an outstanding job of writing minimum logical requirements for a quality operation. It is significant to note that the vast majority of the 9000 series of standards are Document Control (ref. Watts, Engineering Documentation Control Handbook, 1993). ISO rightfully places high emphasis on product specifications. The key nature of product specifications is discussed throughout chapter 4.

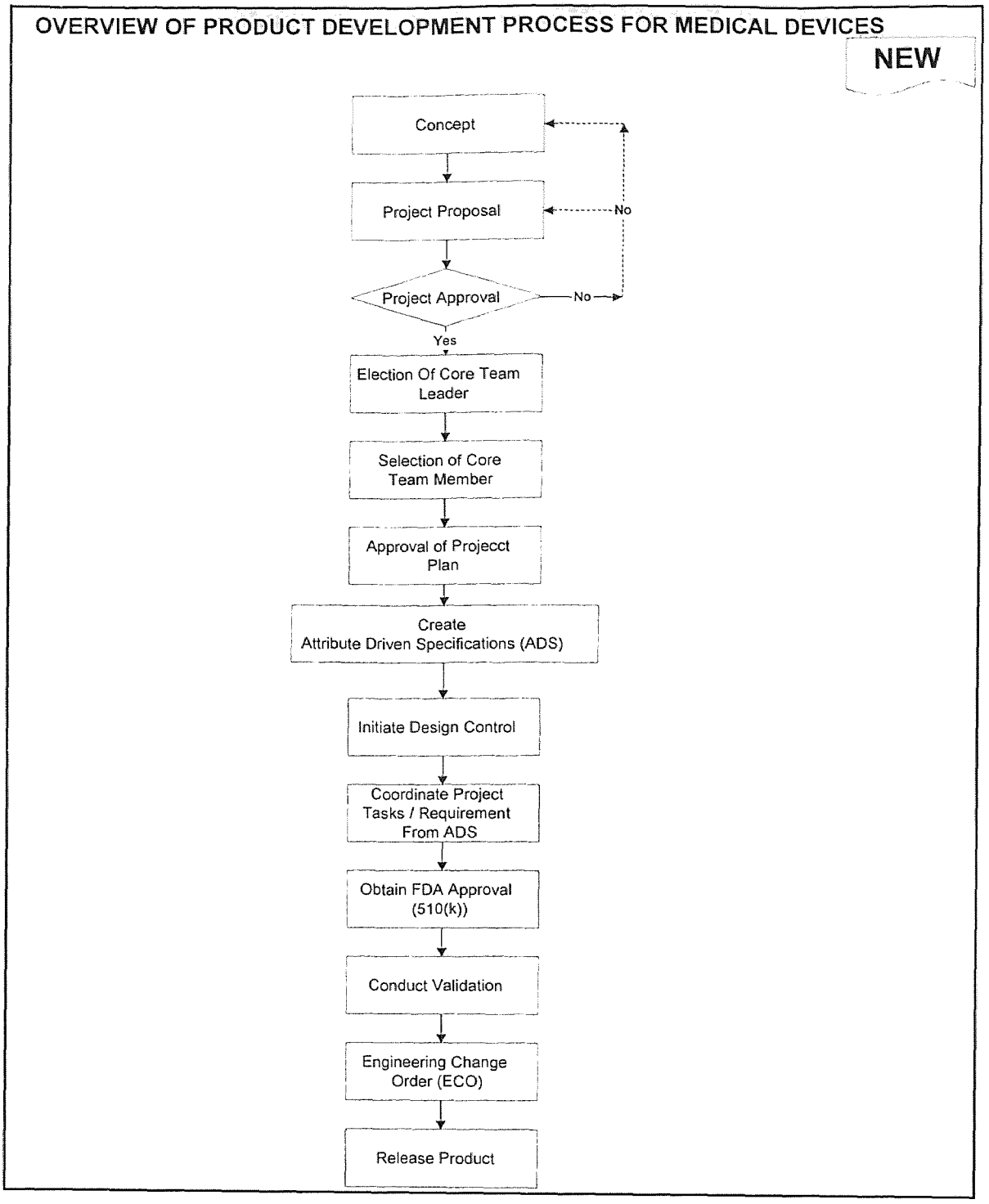



**Figure 8** Overview of New Product Development Process for Medical Devices

Other advantages of this new approach are how the ADS is used to satisfy some of the critical elements of design control. This is one of the most important elements of the revised GMP. Some medical device manufacturers already consider the design control program as a method for improving the product development process, while others consider it as a necessary step to selling products in the European Community (EC). Both the ISO and the GMP requirements call for a documented procedure to ensure that the design requirements are properly established, verified, and translated into design specifications.

The ADS process is an excellent method for cycle time reduction that could be used in most parts of the design control. It is a good tool for traceability of the product and process development. Its revision levels helps keep track of the development process history. In comparison to the PDN process, the ADS reduces the cycle time because it involves, at an early stage of the development process, the different functions that are affected.

## 3.2 The ISO 9000 Series of Standards

ISO9000 is a series of international quality standards prepared by the International Organization for Standardization. These standards are intended to harmonize the quality systems requirements for industries involved in the design, manufacture and international distribution of products. In addition, revisions to the FDA Good Manufacturing Practice Regulation for Medical Devices will require conformance to design control aspects similar to those established in the ISO9000 series of standards.

Further, these standards specify a quality management system. They judge how well a business is run by their ability to deliver consistently a quality product. They deal with all aspects of a business and how controls are managed and improved. They describe a basic set of elements by which an organization can develop and implement a quality management system. Registration to the series of standards is accomplished through a third party audit by a Notified Body, which must be approved by an international certification organization.

### 3.3 The Design Control

Design Control is a documented and controlled procedure to ensure the product and process design requirements are properly established, verified, translated into design specifications and transferred to production. Design Controls are an interrelated set of practices and procedures that are incorporated into the design and development process. In other words it is a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements and discrepancies between the proposed designs and requirements are made evident and corrected early in the development process. Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use.

### 3.4 Implementing Design Control

The fact that the medical device industry is a regulated industry. It is not always apparent to some observers and, at times even to supplier personnel. The medical device Act of

1976 resulted in the generation of regulations centered around the manufacturing of Medical Devices. Justification for this action was a study performed indicating that the majority of problems experienced by users of medical Devices were quality related, and that these quality related problems were associated with production.

Other reasons why it is necessary to implement Design Control are:

- Domestic Regulations (FDA)
- Safe Medical Device Act of 1990
- European Regulations (European Quality System)
- ISO 9001 complemented by the particular requirements for Medical Devices in EN46001

European focus is expected to be on the documentation of systems to comply with the European Quality System. FDA can be expected to review the operation as well as the documentation of the system. If, for example, a manufacturer views design control as a means of improving the product development process, it can introduce the discipline necessary to produce high-quality products, shorten development time, and reduce or eliminate the annoying defects and errors that often crop up when a new product enters full-scale manufacturing.

The up-front work expended in the ADS, establishing and evaluating the design, conducting rigorous testing, and developing effective and efficient manufacturing processes can pay big dividends toward meeting customer expectations, lowering manufacturing costs, reducing liability exposure, yielding better quality products, and increasing market penetration. The ADS is also one way to implement the design control

in the medical device industry, it is a reference for the design specifications and therefore control the design process from beginning to end.

The design control section of FDA's and the revised GMP regulations require device manufacturers to establish and maintain formal controls for their product development activities. These controls are intended to ensure that appropriate specifications for the device are developed and thoroughly reviewed, so that the device eventually manufactured can be used safely and effectively.

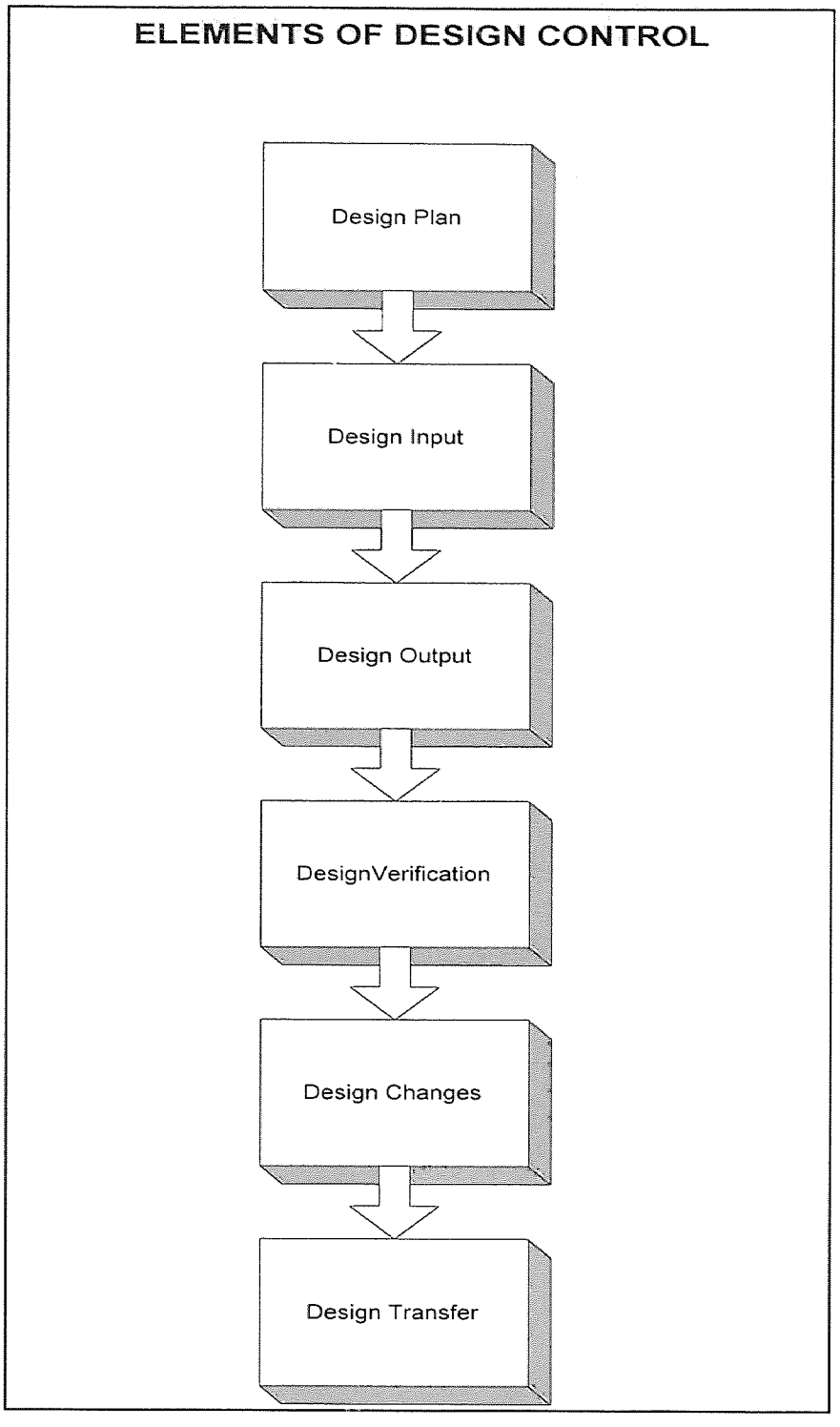



**Figure 9** Elements of Design Control

## 3.5 Elements of the Design Control are Integral Parts of the Development Process

**Figure 9** shows the major elements of the design control which are: design planning, design input, design output, design verification, design changes, and design transfer. These elements that are described below, are now integral parts of the development process in the medical devices industry.

### 3.5.1 Design Planning

The first phase of designing a new product is design and development planning, which is described in the design control section of the International Organization for Standardization 9001 standard. It requires manufacturers to draw up a plan that identifies and describes the activities necessary to design and develop a device and update it as the design evolves. Identify organizational and technical interactions that must occur among the company's departments and its suppliers, and establish mechanisms to ensure that necessary information is documented, transmitted, and reviewed as required.
Design and development planning makes clear what is going to happen, who is going to make it happen, and when it will happen. Design and development planning is critical because it establishes the groundwork for the design process.

Each description contains the assigned personnel from the Core Team and functional team areas of responsibility. This is inter-functional requirement for each activity. The assignment of these functions provides the indication of the input required from each of the functions for the specified activity

### 3.5.2 Design Input

The design input involves requirements relating to the device that should be specified and documented. These requirements should address the needs of the intended user. Design input should also include requirements for manufacturing, installation, maintenance and servicing. Both GMP and ISO call for the technical specification in this section. Physical and performance features and safety reliability are included. Environmental and regulatory requirements are also addressed in this specification; and finally, labelling requirements are part of this specification. Further, this requirement includes also, the project proposal, the integrated project plan, the market research and the Product /Process specifications. The resolution of conflicts, ambiguities, and incomplete requirements is accomplished through the employment of the design reviews and during the core team meeting.

### 3.5.3 Design Output

As the project progresses, product and process designs become more redefined, and the project team begins to create product and process documentation. The design output are documentation and specification in terms that allows an adequate evaluation of conformance to design requirements at each stage of the design process. This phase requires calculations, or analysis of the design to ensure that the product will meet the design input requirements. The international requirement in this area (ISO90001) is an analytical one looking for calculations and analysis against requirement.

This phase also calls for the creation of a matrix which would list each of the input requirements and a corresponding analytical methods used to demonstrate how the

product will meet the input requirement. The matrix will contain the reference test method used to demonstrate that the input requirement has been the corresponding results. A Failure Mode Effect Analysis (FMEA) could be used in this phase to assure product or process safety.

### 3.5.4 Design Verification

This part calls for planning, establish document and assign to competent personnel functions for reviewing and verifying the design output of each activity. Design verification shall be performed in a timely manner and shall established that design output meets the design input requirements. A recording shall be made of the design verification, including identification of the design verified, the date the person or the team performing the verification.

This section also deals with the feasibility Experiments, development and test of the demo process, molding technology development, prototypes evaluation etc...
The product and process specifications designate the verification method for each of the requirements. The results of the verification will become part of the project file.
The formation of matrix is a systematic method of ensuring that all input requirements are addressed.

### 3.5.5 Design Changes

This section calls for the review, evaluation, approval and documentation of all changes to the design during the development. While all proposed changes need not to be documented, all approved changes for incorporation into the design must be documented

and controlled. This section also calls for control documentation. Written procedure shall be established, implemented and controlled for the identification, review and approval of design changes. At appropriate intervals and at the conclusion of the design process, a formal systematic and documented review of the design results shall be conducted to assure the design meets the design input requirements. Design review shall include designated individuals representing all functions affecting quality. A written record of the design reviews shall be made.

### 3.5.6 Design Transfer

Activities that result in documentation that initiate a transfer from development to production would have to be reviewed to ensure they meet the intention of the proposed GMPs/ISO. They are validation, pilot study, molding technology, clinical for product validation, process validation labeling and packaging.

The design control concepts are applicable to process development as well as product development. The extent is dependent upon the nature of the product and process used to manufacture the product. The safety and performance of a new product is also dependent on an intimate relationship between product design robustness and process capability.

# CHAPTER 4

# THE ATTRIBUTES DRIVEN SPECIFICATIONS APPROACH

## 4.1 Introduction to the Attribute Driven Specifications Process

At the start of the development we attempt to capture the customer needs in a document often called product specification. This sounds simple enough but is actually a stumbling point for many medical device product developers, and the consequences of poorly written specifications show up as lost of time later in the project. Specifications provide input that is critical to both the product and the development process. The technique covered in this chapter will help avoiding writing specifications slowly or producing ones that are slow to win approval.

According to Haynes (ref. MDDI 1993), there is an approach to project communication that has been shown to work, and work effectively. It provides guidance from the start and avoids most conflict as the project progresses to completion. It is called Attribute-Driven Specification (ADS).

With the rapid design cycle inherent in Concurrent Engineering, effective specifications are needed at the outset of a project. Without early resolution of the target specifications, the project will suffer form communication problems. Confusion about the desired path to the goal is unavoidable.

This is a good tool to use in the development of medical device products. It could also be used to track product history by maintaining revision levels. The ADS is a good way to implement the Design Control of the project.

### 4.1.1 Definitions

- Attributes are customer descriptions of product characteristics.
- Engineering Parameters are a set of measurable, physical properties defining attributes.
- Specifications are sets of detailed and exact statements of requirements.
- Needs are features must be in the product.
- Wants are features that will help differentiate the product from competitors.
- Desires are innovative features that will appeal to the customers.
- Internal customers are any person or department within the company who is provided with a product.
- External customers are any person or organization outside the company who is provided with a product.
- Ideal performance level is the point beyond which little market value is achieved for the effort and risk involved.
- Limit performance level is the negotiated, absolute worst acceptable performance for the parameter which it is believed the customer will accept, assuming all other parameters are at goal.
- Goal performance level is the best estimate of achievable performance within the agreed upon ideal and limit performance levels.

## 4.2 Communication is Essential for Product Specification

As we know, Concurrent Engineering will not work without excellent communication among all parties, for beginning to end. Bad communication had been known as one of the main issue between Engineering, Marketing, Medical etc.

Numerous methods of obtaining new product information for medical devices exist. They include various ways of collecting data, such as internal sources, industry analysis, and technology analysis. The information is screened and a business analysis is conducted. The Quality Function Deployment (QFD) is a process where the voice of the customer is first hand in could be related to the process discussed in this chapter.

## 4.3 The QFD Approach

The QFD process has been applied for many years in different businesses including medical devices (ref. Akao, Yoji 1988). The Ford Company defines QFD as a planning technique for translating the customer's required quality characteristics into appropriate product or services features. QFD was developed in 1966 in Japan, and one of the first applications was credited in the early 1970s by Mitsubishi Heavy Industries. QFD is a systematic process which establishes customer requirements and accurately translates them into the appropriate technical design, manufacturing and production planning requirements. QFD is a matrix-based methodology which is effective in the hands of an experienced cross-functional team. The basic matrix of the QFD is the house of quality. It is called a house because of its shape, although it can look quite different if a large quantity of data is analyzed. QFD in many ways resemble the ADS process described in this chapter.

### 4.4 Difficulties in Writing Specifications

One complication in writing specifications is that many types of knowledge are needed, Engineering, Medical, Marketing, Quality, Regulatory Affairs and Manufacturing, to name a few. They will define the product and develop it. This means that all these different functions must interact to share information and reach a mutually satisfactory solution. One danger is having separate specifications. For example, marketing could write specifications from the sales and business perspectives, engineering could write about specifications that describes how the product is to work in considerable detail, and manufacturing could later try to interpret these specifications to produce what they thought the customer wanted.

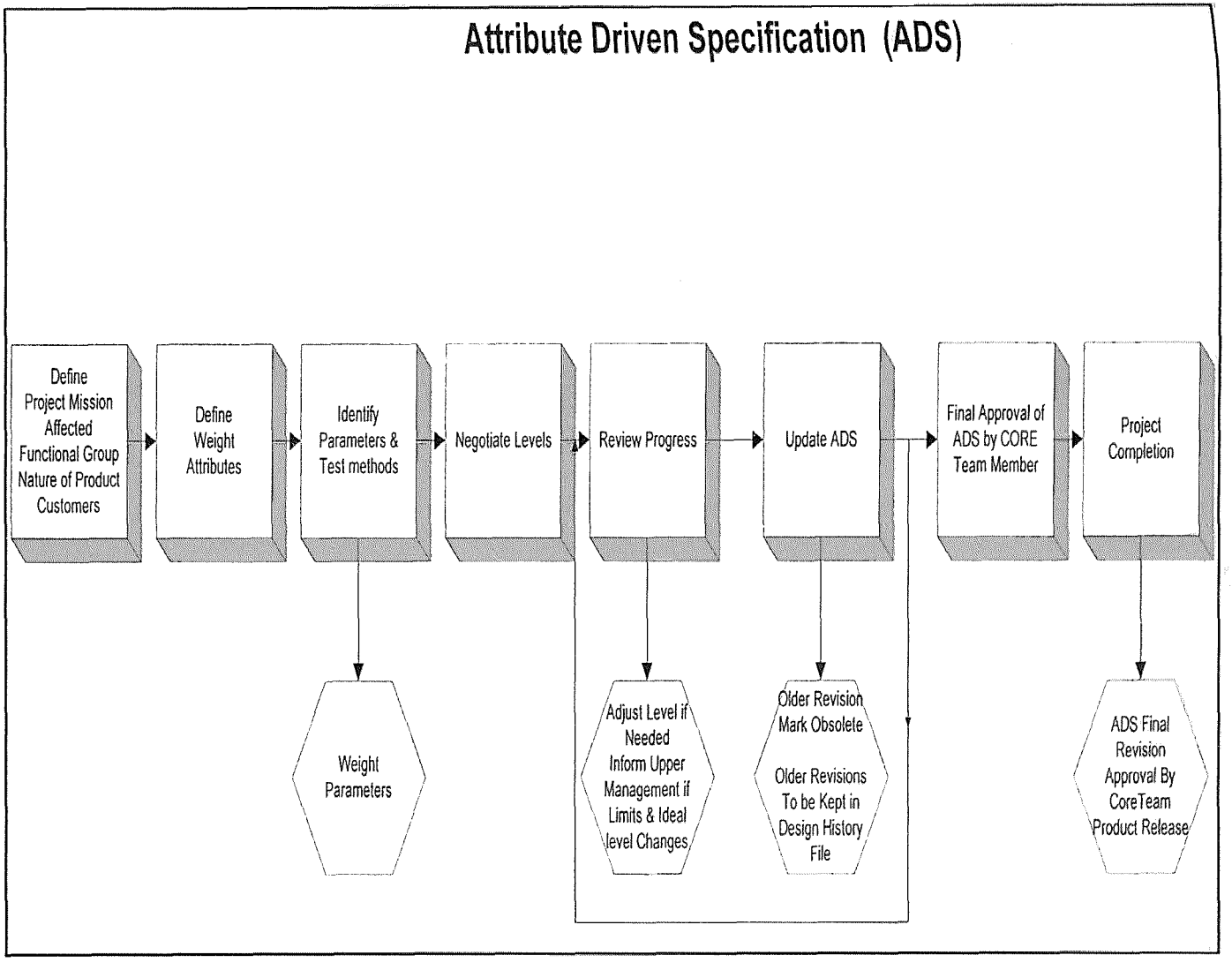



**Figure 10** The Attribute Driven Specifications Process

## 4.5 Requirements for Writing an Effective Specification

First and foremost, the specification must be the customer's voice to the development team. It must interpret the market needs which is to be filled by the product under development and it must define the project goal without ambiguity and in a verifiable way which guides design yet allows tradeoffs. It must point to a product goal which is competitive yet achievable, balancing risk vs. return, guiding all members of the product development team to pull in the same direction.

## 4.6 The Attribute Driven Specification

All project or product specifications contain two key columns: the parameter to be specified and a valued to be achieved. If the specification is describing an evacuated blood collection tube, for example, the parameter might be blood volume with the value to be achieved 5 mL. This attention on engineering parameters is specific, clear and measurable, but often isolates the designer from the motivation behind the goal. Customers do not buy parameters, they select, differentiate and buy products based on attributes and their needs, wants, and desires. In our example of blood volume as the parameter, it is linked to the attribute cost.

Attributes are the customer's voice in the attribute-driven specifications (ADS). Each design parameter is related to an attribute desired by the customer; this ensures that the development will have a market-driven focus.

A major addition of the ADS is the use of the three levels of performance for each parameter; the design goal is bracketed by two other levels; an ideal performance level and a minimum acceptable limit. **Figure 10** illustrates the ADS process.

## 4.7 Creation of an ADS Step by Step

There are four defined stages in the process of developing and using the ADS: identify the elements, link them, negotiate the performance levels, and review progress.

### *Stage1-Identify the Key Elements*

The task: What is the proposed project and who is the customer

The Team: Who will be involved from each major functional group: R&D, Engineering, Manufacturing, Marketing, Medical, Regulatory Affairs, Quality Assurance

The Mission: What is the project target? E.g. define, develop, and deliver a safety next generation needle which could capture 20% of the regular needle in the market by December 1999 with a projected return on investment of 30% or more.

The Attributes: What are the key customer needs? This could be anything from quality, ease of use etc.

The Parameters: What are the Engineering/Scientific parameters which define the performance attributes.

### *Stage 2-Link the Parameters and Attributes*

Tie each parameter to an attribute and vice versa. Add additional parameters and/or attributes until all are linked. Parameters not linked to an identified attribute should be questioned.

*Stage 3-Negotiate the Three Performance Level*

This is the key stage. The successful completion of the project will be determined by these decisions. The team must reach a consensus on the three levels of performance for each parameter. At this stage, engineering could initiate the early negotiation with manufacturing for example, medical and regulatory affairs, etc.

*Stage 4-Review Progress, Goals and Limits*

As the project progresses, the Project Team should refer to the ADS in each regular project review. The Technical Team members should regularly update the Goal, always within the ideal and limit levels. The Marketing Team members may occasionally negotiate adjustments in the ideal or limits levels as external conditions change. With a well-designed ADS, participation by senior management may be unnecessary at this stage. **Figure 11** illustrates the four stages of the ADS process.

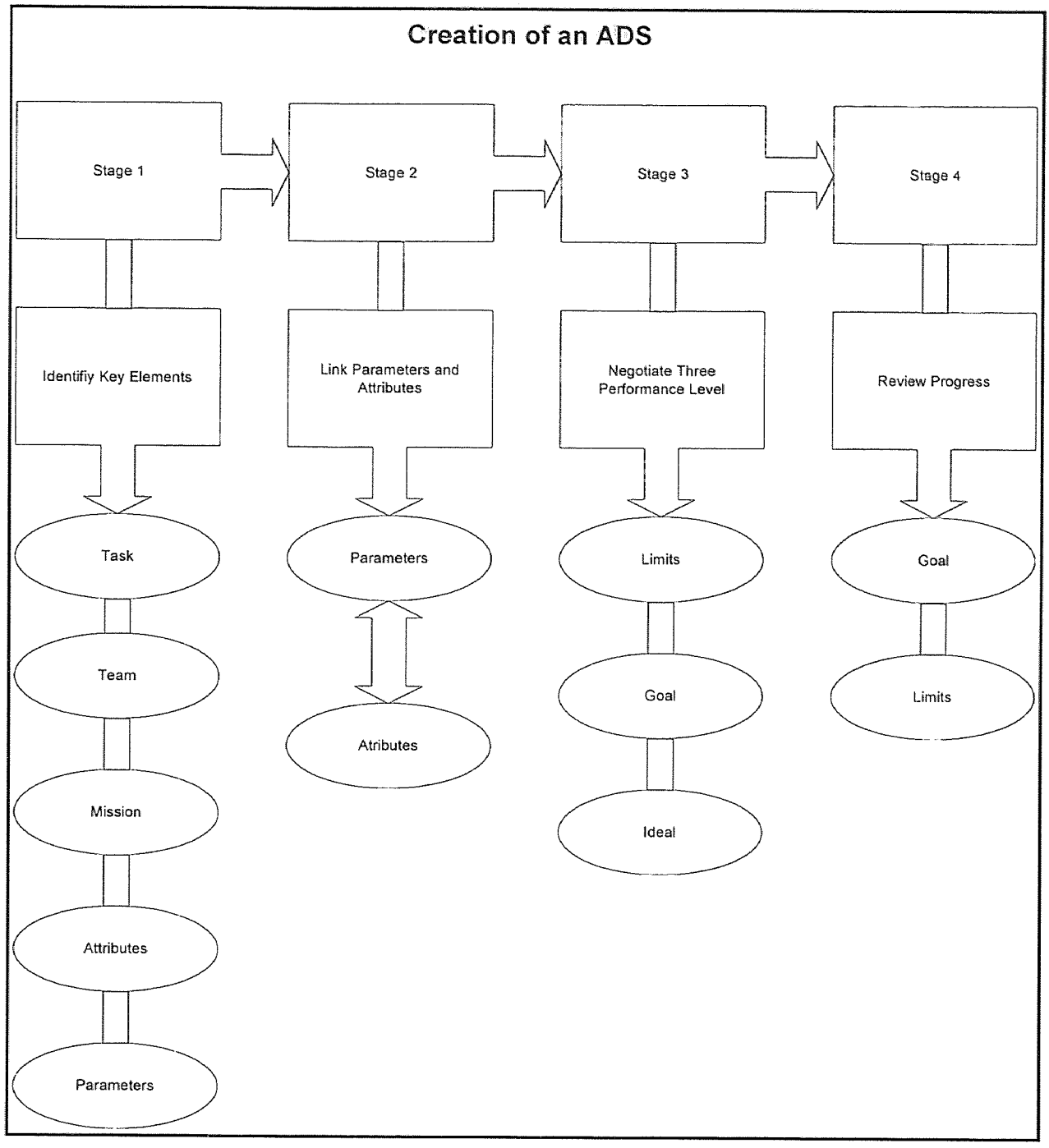



**Figure 11** Creation of an ADS Step-by-Step

## 4.8 Practical Suggestions for using the ADS Method

Identifying and linking attributes to parameters is demanding work. Several keys for stimulating this process are helpful. First, the general categories of attributes, utility, safety, etc. in the ADS help stimulate the team and organize their thoughts. The customer will place different weighting on these categories throughout the product life cycle.
The team should sort out the hierarchy of the attributes for the proposed product. Some attributes will be necessary to be a player in the market. Others attributes will be the basis of competition, the means of differentiating products, features which play to customer *wants*. The very innovative features and leaps in performance will appeal to customer desires.
During the negotiation of Stage 3, the hierarchy can serve to highlight the degree of flexibility which can be afforded in setting levels. Parameters linked to needs can seldom be compromised, those linked to wants can be more flexible, and those associated with customer desires can be afforded the greatest latitude.

In negotiating the limit performance level for a parameter in the desire grouping, it is important to assume that all other parameters are at their goal level, and push as hard as possible on the limit level, to find the absolute minimum acceptable performance. Only by providing this room for design tradeoffs will the marketing team members give the engineering team the flexibility to insure successful completion of the project. This approach minimizes the overall project risk by balancing the risks of market failure vs. technical failure.

The Attributes-Driven Specification approach ties together the process from attribute to parameter to specification; guiding design tasks, manufacturing process, and

maintaining market competitiveness while preserving flexibility for design tradeoffs. With a well define and negotiated ADS, with consensus on three level performances, there will be few surprises as the project progresses if the team participates in regular reviews.

Where consensus cannot be reached, the group may have chosen a project beyond their ability to deliver, and management needs to reconsider the fit with the group's mission.

Unlike other approaches, the three level method keeps flexibility for design tradeoffs, instead of setting up specifications "cast in concrete". Also, unlike other approaches, the ADS method insists on early and meaningful participation by management.

### 4.9 Who Should Sign the ADS?

One of the most debated issue in the change control system is the signature requirements. Everyone wants to sign. This is one of the biggest contributors to long throughput time. The ADS should be signed by the people the closest to the action; it should be signed by the core team, leader and members. If a Core Team member thinks he is not up to par to sign the document, it is his responsibility to seek the appropriate person, such as his functional manager, to sign the document. Doing so, reduces the cycle time of generating and issuing specifications and start the design control for the product.

The illustration in **figure 11** shows a reduction in cycle time with the ADS approach.

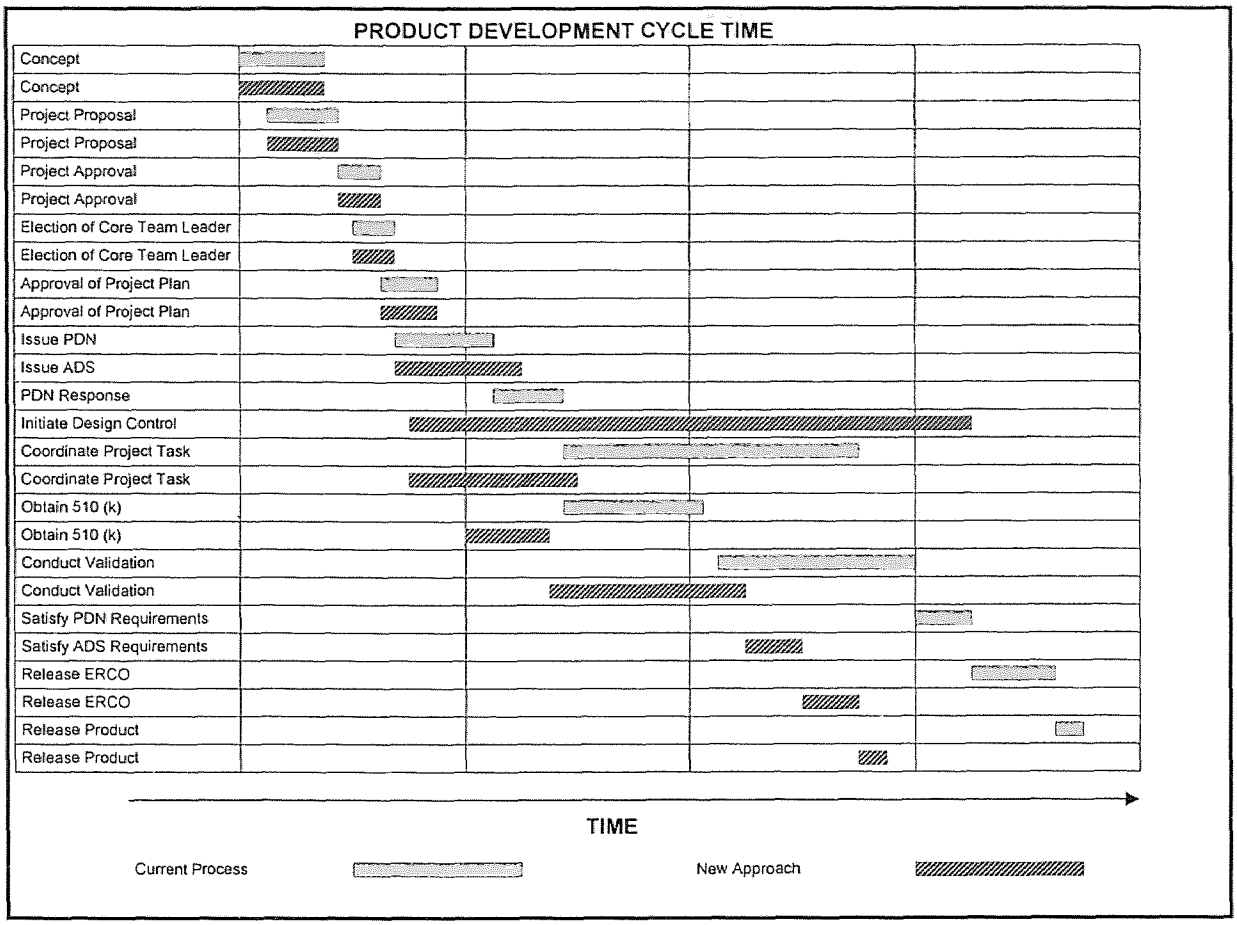



**Figure 12** Product Development Cycle Time

# CHAPTER 5

# EXAMPLE OF THE CURRENT PROCESS

## 5.1 The Need for a New Product

The example given in this chapter is for the development of a new medical device product that is being developed by Becton Dickinson Vacutainer Systems (BDVS) Division, where the tools described in chapter 3 for the new approach were used. This example is the best that could fit this model, although not every part of the process was used. The ADS approach used in this project resulted in a release of a high quality product for sale in less time than using the conventional product development process.

The concept of the new product came from market research, by talking to the customer (laboratory technician) to find out what BDVS could do to improve the efficiency in the lab. Out of all the requests, one seems that could fit the business strategy more than the other. It is a need for a secondary tube that is used in the clinical laboratory.

The current laboratory work flow for analytical blood testing after the physician had ordered a test for a patient is as follows.

- The blood is drawn from the patient into an evacuated collection tube.
- The tube is than labelled with the patient ID.
- The tube is sent to the lab for testing (i.e. chemistry).
- Upon arrival of the collection tube, it is re-labelled properly with the patient identification.

- The technician confirms that the blood is clotted, and then places the tube in the centrifuge.
- After centrifugation, the tube is removed for the cup, there is now three different layers of separation in the tube. The red cells are located at the bottom of the tube, the gel is in the middle and the serum is at the top of the tube. The serum is what the technicians need to perform the test.
- Laboratory technicians usually pour off or pipette the serum sample into a secondary tube allowing for simultaneous testing of the primary sample.

The lab technicians use different secondary tubes with any closure that could fit. They are usually closed with a plug-type closure that must be removed before placement on analyzers, since most analyzers do not have cap-piercing abilities. Upon removal from analyzers, these tubes are often recapped with another closure. Hence the lab technician usually uses two closures per tube, because once removed, the closure is discarded for contamination purposes.

The vision of BDVS is to become the industry leader in specimen management, thereby becoming more integrated into the diagnostic processing chain. After evaluating this opportunity, BDVS wanted to commercialize a value-added secondary tube that replaces existing products and meets the needs of the existing manual and emerging automated lab markets. The new secondary Tube and Closure product will be a unique value-added offering that will differentiate BDVS in this large niche market. The new design is an integrated closure. The illustrations in **figures 13, 14, and 15** give a pictorial view of the new product that was developed based upon the need of the technicians. The

example given in this chapter will address how the ADS was a valuable tool in the development of this new product.

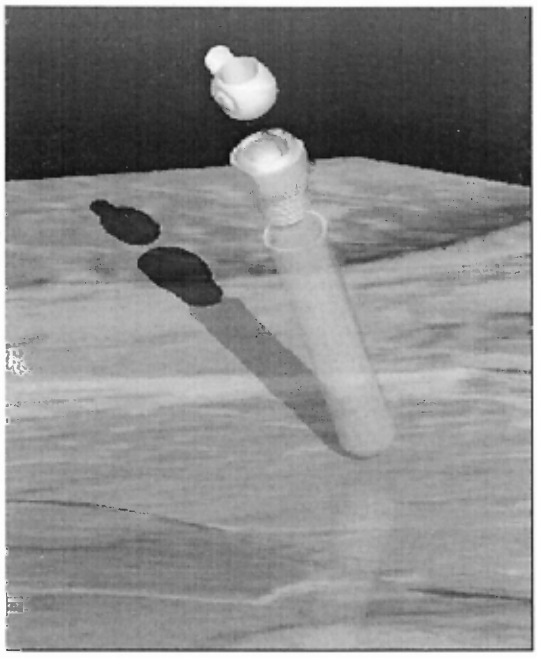


**Figure 13** BDVS Next Generation Secondary Tube with Closure

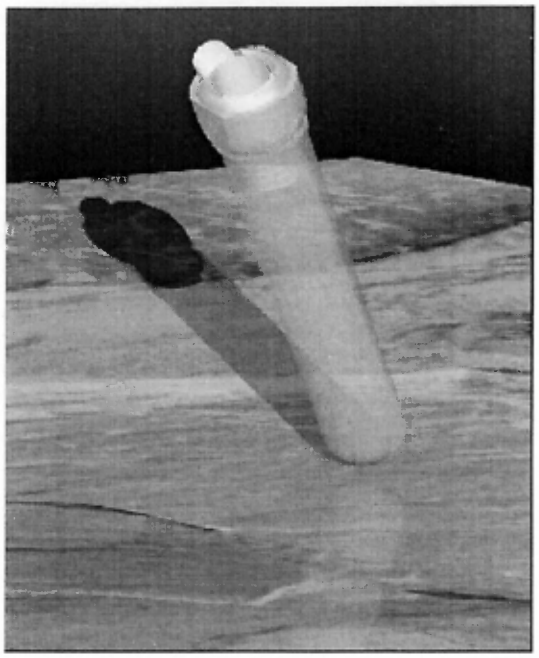


**Figure 14** BDVS Next Generation Secondary Tube with Closure

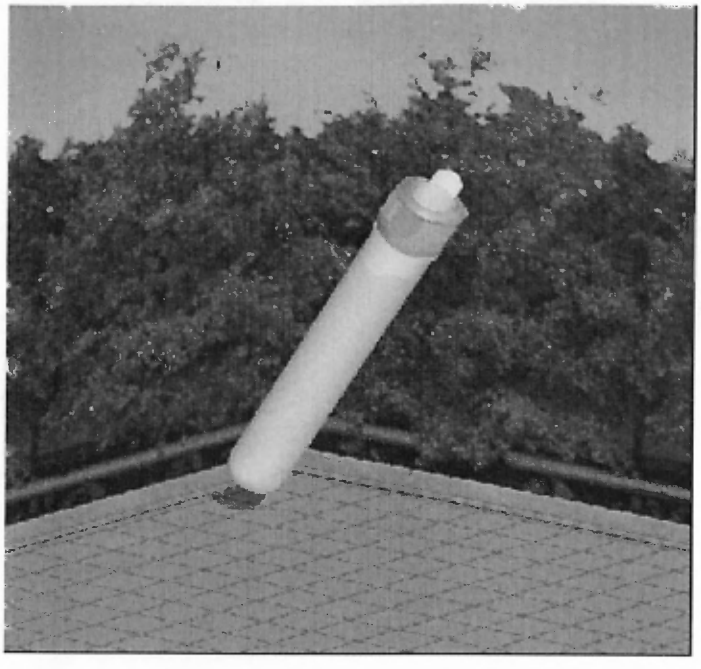


**Figure 15** Next Generation Secondary Tube with Closure

## 5.2 The Product Development Process

A Core Team leader, who came from the R&D functional group, was elected by the upper management. The Core Team members were carefully selected as discussed in chapter 2, with representatives from, Medical, Marketing, Manufacturing, Quality Assurance, R&D and Process Technology. An aggressive project plan was developed by the team and presented to the upper management.

## 5.3 The Development of the ADS

The attributes for the product came from market research and discussion with many customers, ease of use, automation friendly, safe, specimen quality and cost to name a few. Since this is the end-user attributes for the new product, the core team met to discuss how to design a product that could meet all these attributes. Some of the parameters for ease-of-use were defined as specimen transfer without closure removal; easy transfer from primary tube; easy manual operation and positive lock confirmation for open and close. The parameters for automation friendly were as follow: compatible with existing closure; bar code label compatibility; physical dimensions compatible with transport activities (carousel, rack, track); ability to recognize specimen; and compatible with automated closure operation. The parameters for safety were defined as: Ability to withstand an accidental drop within lab; closure functionality after multiple cycles and after freeze and thaw; ability to centrifuge the product; specimen should not leach; the ability to withstand world wide shipping conditions prior to use.

After the Core Team has reached a consensus on the design parameters, they then negotiated the different levels of specifications. The focus at first was on the end-user

attributes. Then the other requirements from the internal customers were developed. The ideal performance level is to have a high-speed process for assembling the finished molded plastic parts and then pack them. The design goal is to have a semi-automated process, and minimum acceptable limit is a manual process. The manufacturing requirements were to have a validated one-cavity mold for each component at initial release and then validate a high cavitation (64 cavities) in order to reduce the manufacturing cost.

The marketing requirements were similar to the end-user requirements, since for the most part they represented the external customer in the development process. One limitation was to conduct an end user assessment before the release of this product for sale. The three level specifications could be used for the marketing requirements with respect to the product sales price. The priced are justified because the current product sells for $0.04 - $0.06 for one tube and a closure, and multiple closures are generally used. This wasted expense is eliminated by the new design. The medical requirements were straight forward, since this is a secondary product, it has no contact with the patient and so no clinical evaluation was necessary. The Quality Assurance requirements were to validate the molding process to show its true capability and reliability. The Regulatory Affairs goal was no 510 (k) since this a class 1 device. The R&D requirements were to meet most of the attributes from ADS of the End User.

The internal customers of the ADS were not in the same scale as the external customers. The illustration in the **Table 4** shows in detail all the attributes of the product and the engineering parameters. The last column of the table displays the current status of the parameters.

**Table 4** Example of an ADS Process

| ATTRIBUTES | PARAMETERS | IDEAL | GOAL | LIMIT | CURRENT STATUS |
|---|---|---|---|---|---|
| Ease Of Use | Closure Open large enough to accommodate manual and automated specimen access | ID: 11.0 mm<br>Geometry: round | ID: 10.5 mm<br>Geometry: round | ID: 10.5 mm<br>Geometry: round | ID: 10.5 mm |
| | One hand Open and close | ≤2.0 lbs | ≤ 1.7 lbs | ≤ 1.3 lbs | ≤ 1.7 lbs |
| | Positive lock confirmation in open and closed position | Positive stop in open/close position | Positive stop lock | Positive lock | Tactical w/ lock in closed position. Visual status from top |
| | Maximum fill volume | 3.0 – 4.0 mL | 3.0 – 4.0 mL | 3.0 – 4.0 mL | 3.0 mL |
| | Visual tube sorting | 4 colors | 2 colors | 2 colors | 2 colors (Green & Gold) |
| | Design fosters easy pour in without closure removal | Cradles tube<br>Funnels specimen<br>Geometry: round<br>ID 11:00 | Cradles tube<br>Geometry: round<br>ID: 10.5 mm | Geometry: round<br>ID 10.5 mm | ID: 11.5 mm<br>Geometry: round |
| | Design fosters easy manual pour off without closure removal | Pouring feature<br>No dripping during high and low volume pour off (cup) | No dripping during high and low volume pour off | No dripping during high and low volume pour off | Single drop observed during manual pour off 100% of time |
| | Easy identification of specimen quality (hemolysis, lipemia, clots) | Equivalent to PLUS tube | Equivalent to Falcon tube<br>Polypropylene tube | Equivalent to Falcon tube<br>Polypropylene tube | Tube material:<br>Polypropelene PF533 |
| Ergonomics | Easy manual operation of closure | Ability to process 200 /hour<br>Compatible w/glove use<br>Forces: 1.5 ± .5 lbs | Ability to process 200 /hour<br>Compatible w/glove use<br>Forces: 2.5 ± .5 lbs | Ability to process 200 /hour<br>Compatible w/glove use<br>Forces: 4.5 ± .5 lbs | Compatible with gloves<br>Max (Blue closure)<br>Opening Force: 3. 5 lbs<br>Closing Force: 4.8 lbs |
| | Positive Identification of closure status | Audible (open; close)<br>Tactile (open; close)<br>Visual (viewed from top/side) | Tactile (open; close)<br>Visual (viewed from top/side) | Visual (viewed from top/side) | |

**Table 4** Example of an ADS Process (Continued)

| | | | | | |
|---|---|---|---|---|---|
| Compatibility | Equipment Compatibility (Carousels, rack, bar-code reading) | All systems w/ no incompatibilities or inconveniences<br>♦ Chemistry<br>♦ Immunochem<br>♦ Coag Systems<br>♦ Lab Automation Systems (IDS, Hitachi, Lab Interlink) | No incompatibilities or inconveniences w/ Chemistry:<br>♦ J&J, Hitachi<br>♦ Olympus<br>♦ Dade, Beckman<br>ImmunoChem:<br>Abbott, Ciba Cornin | No incompatibilities or inconveniences w/ Chemistry:<br>♦ J&J, Hitachi<br>♦ Olympus<br>ImmunoChem:<br>Abbott, Ciba Cornin | Not Compatible<br>Abbott AxSYM<br><br>Inconveniences<br>♦ Hitachi717, 911( barcode)<br>♦ Probe depth settings<br>♦ Olympus Rack ( barcode) |
| | Physical dimensions compatible with transport activities | Dimensions within 16x100 mm PLUS tube envelope (OD and height tube) | Dimensions within 16x100 mm PLUS tube envelope (OD and height tube) | Compatible with all instrument systems listed in preceding limit colum | |
| | Automation friendly closure operation | ➢ Linear (x) motion<br>➢ Easy/Positive Orientation<br>➢ Integrated Closure<br>➢ Compatible w/ currently systems | ➢ Linear (x) motion<br>➢ Capability for positive Orientation<br>➢ Integral Closure | ➢ Linear (x) motion<br>➢ Integrated Closure | ➢ Linear (x) motion<br>➢ Integrated closure<br>➢ Positive Orientation Possible<br>➢ Not compatible w/ current systems |
| | Bar-code label compatibility | Length: 60 mm<br>Adhesion: no lift<br>➢ 7 days @ 0°C<br>➢ 7 days frozen<br>➢ 12 hrs @ RT | Length: 60 mm<br>Adhesion: 13x75 mm polysterene equivalent<br>➢ 7 days @ 0°C<br>➢ 7 days frozen<br>➢ 12 hrs @ RT | Length: 60 mm<br>Adhesion: SKBCL Transport Tube equivalent<br>➢ 7 days @ 0°C<br>➢ 7 days frozen<br>➢ 12 hrs @ RT | Length: 60 mm<br>Adhesion: SKBCL Transport Tube equivalent<br>➢ 7 days @ 0°C<br>➢ 7 days frozen<br>➢ 12 hrs @ RT |

**Table 4** Example of an ADS Process (Continued)

| | | | | | |
|---|---|---|---|---|---|
| Specimen Quality | Evaporation | No evaporation | Equivalent to plugged PS tubes:<br>➢ RT – 12 hrs<br>➢ Refri. – 7 days<br>➢ Frozen: 2 weeks | Equivalent to plugged PP tubes:<br>➢ RT – 12 hours<br>➢ Refri. – 7 days<br>➢ Frozen: 2 weeks | Equivalent to plugged PP tubes:<br>➢ RT – 12 hours<br>➢ Refri. – 7 days<br>Frozen: 2 weeks |
| Robust Design | Leachable and specimen degradation<br>Withstand drop within lab | No change in the specimen due to tube/closure materials<br>Drop from 7 feet:<br>➢ No Specimen loss<br>➢ No tab breakage | No change in the specimen due to tube/closure materials<br>Drop from 5 feet:<br>➢ No Specimen loss<br>➢ No tab breakage | No change in the specimen due to tube/closure materials<br>Drop from 5 feet:<br>➢ No Specimen loss(<10μL)<br>➢ No tab breakage (<1%) | MAPPS reviewed and approved |
| | Multiple cycles of closure | 250 entries with no closure degradation | 10 entries with no closure degradation | 7 entries with no closure degradation | 10 entries with no closure degradation |
| | Operate after freeze and thaw | 2 cycles of freezing<br>➢ No breakage<br>➢ No deformation | 1 cycle of freezing<br>➢ No breakage<br>➢ No deformation | 1 cycle of freezing<br>➢ No breakage<br>➢ No deformation | 1 cycle of freezing<br>➢ No breakage<br>➢ No deformation<br>➢ Less specimen loss than plug closure in secondary tube |
| | Centrifugation | 10,000 g's | 1,500 g's | 1,000 g's | 10,000 g's |
| | Air shipment | | | | |
| | Withstand WW shipping conditions prior to use | ➢ No breakage<br>➢ No deformation<br>➢ No disassembly<br>➢ Opening diameter: No ball movement | ➢ No breakage<br>➢ No deformation<br>➢ No disassembly<br>➢ Opening diameter: <10% half closed | ➢ No breakage<br>➢ No deformation<br>➢ No disassembly<br>➢ Opening diameter: <20% half closed | ➢ No breakage<br>➢ No deformation<br>➢ No disassembly<br>➢ Opening diameter: <18% half closed |
| | Safe biohazard disposable | ➢ No hazard material on incineration of land fill disposal<br>➢ Durable material – no breakage when transported | ➢ No hazard material on incineration of land fill disposal<br>➢ Durable material – no breakage when transported | ➢ No hazard material on incineration of land fill disposal<br>➢ Durable material – no breakage when transported | TBD |

After developing this ADS, it was easy to implement the plan. The communication was good among all parties since all the specifications and requirements were developed by the same team. The ADS was used as good design control, because the revision level was kept, and also the rationale for each change was documented. The Core Team members signed the ADS since they were the one the closet to the project.

The cycle time for the product development was not extensive when compared to others. The work that was done up-front with the ADS made all the difference. All the product requirements and specifications were known early on since the functions in the organization that will dictate the requirements were part of the team, therefore each person knows, which direction the product/process was going and was able to discuss and negotiate on requirements or specifications.

During the product development process the team identified three reference laboratories that were willing to evaluate the product for us. This End User Assessment was one of the most important part of the development process as it validated the ADS. The customers were able to work with the product and tell us their opinion of the product in their own word. In conclusion, not all of the ADS requirements were met, 75% met the goal and the limit, but the customer loved the product and wanted to start purchase it.

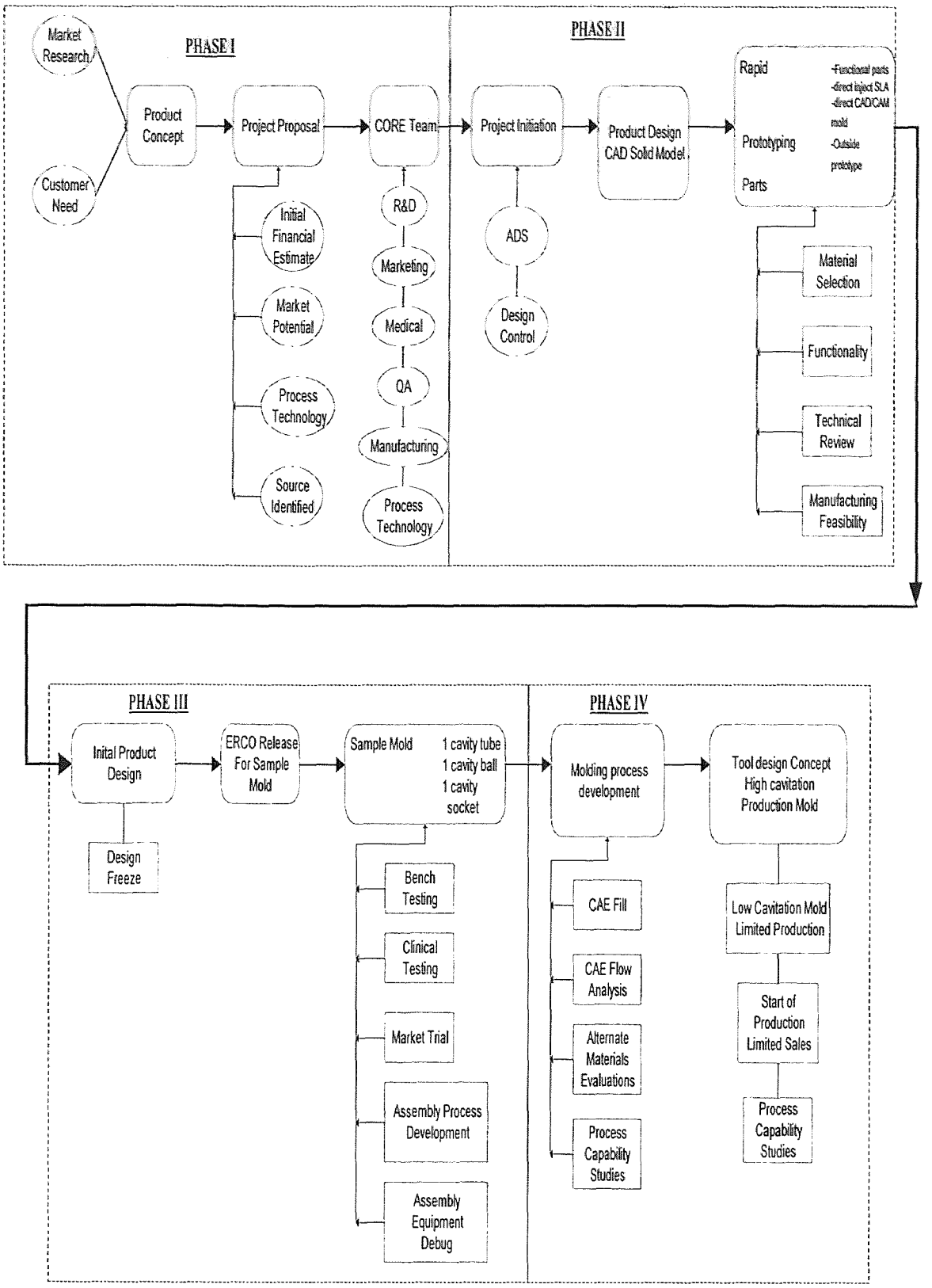



**Figure 16** Phase Approach

## 5.4 The Phase Approach

The diagram in **figure 16** shows another way of looking at the new approach by dividing it into four phases. Phase I is the conceptual phase: market research, project proposal, selection of the Core Team and product registration. Phase II is the design phase: the creation of the ADS, rapid prototyping, and initiation of the design control. Phase III is the development phase: design freeze, one-cavity mold validation, documentation release through ECO process, clinical testing, physical performance and market trial. Phase IV is the release phase: product launch, high cavitation production mold, process capability and high-speed assembly.

# CHAPTER 6

# CONCLUSION

Developing a new product is unique every time. Even if the product is the same the project would have been different, the team would have been different, the learning curve would have been different. The development cycle time is generally considered to be the elapsed time from initial product concept until new product is commercially available. The period of interest to us in this thesis is shown in **figure 8**. Getting a new product to market in advance of the competition has the obvious advantage of capturing additional sales and higher profit margins, assuming the product meets a need not otherwise met by existing products. Competitive and market concerns increasingly force companies to set more aggressive development cycle times.

The value of the Attribute Driven Specifications approach in the development of medical devices is significant. The example provides in Chapter 5 shows how efficient and quick the development process for a new medical device is by using the approach.

The term effective means doing the right things; in this case, designing a medical device that, once manufactured and delivered, will exceed customer expectations while meeting company objectives with respect to revenues, profits or market shares.

Continuous Improvement seems destined to dominate the world of business for years to come. In an environment of dynamic global competition, manufacturing companies that are today's industry leaders do not retain their industry position unless they get increasingly better at all value-added activities and are increasingly productive by paring down other overhead activities. Those who are not aggressive leaders must

embrace this philosophy if they are to survive, and they must do so with vigor if they are to have a chance of attaining and sustaining a viable position in their chosen markets.

Improving the design and development processes of new medical device products has moved upward on the agenda of most manufacturers. Improvement efforts are widespread and have gone on long enough for many companies to see real differences in their process and their results.

Managing across organizational boundaries becomes especially challenging in a global context. This is as true for widely dispersed plants or engineering groups in a single company as for external suppliers from another country. Agreeing in advance on the purpose and desirable extent of this interaction is a good place to start.
There is no reason to believe that the pressure for speed to market coupled with increased quality and customer satisfaction and reduced product cost will subside in the foreseeable future.

In summary, cutting lead-time and increasing customer satisfaction for medical devices require strengthening a company's capability for horizontal integration, so that a cross-functional team can work effectively and productively toward a common end.
The capability to develop new products rapidly and efficiently is a powerful source of competitive advantage. The Attribute Driven Specifications approach explained in this thesis gives some guidelines to be more efficient in the product development process of medical devices. Various business strategies call for a different emphasis in the design and development of products, and a company's business strategy ought to be compatible with its distinctive competence in the introduction of new products.

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