USING QFD TO FINE-TUNE THE PROCESS OF TRANSFERRING NEW PRODUCTS FROM CROSS-FUNCTIONAL DEVELOPMENT TEAMS TO MANUFACTURING

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ABSTRACT

This thesis analyzes how cross-functional ("heavyweight") development teams transfer new products into manufacturing. This "hand-off" process can play a major role in the overall level of success of a new product introduction. Organizations that are relatively efficient at transferring new products into manufacturing can deliver their products to market faster, more cheaply, and at higher levels of quality and reliability than their competitors.

The management and academic literature cited herein addresses the implementation of cross-functional development teams. References are also cited that identify general interaction issues between the traditional functions of product development and manufacturing. This thesis attempts to combine those two aspects into recommendations for companies that wish to use cross-functional development teams to more smoothly introduce new products from development into manufacturing.

Quality Function Deployment (QFD) is developed as a tool for understanding internal "customer" needs or problems, and for reengineering internal processes. Specifically, QFD is used to survey and assess the needs of development and manufacturing personnel. This information is then used to modify the process of transferring new products from development teams into manufacturing.

Recommendations are derived that are thought to lead to a smoother product transfer from development teams to manufacturing. The analysis focuses on what the responsibility should be of each party - the development team, the manufacturing "representative" on the team, the recipients from the manufacturing function (including plant management, manufacturing engineers, supervisors, technicians, and production employees). Specifically, the primary topics of discussion include: (1) the level of involvement of non-team members with the development team, (2) the appropriate time to transfer project "ownership" to manufacturing, (3) the role plant management should play in assessing development team members’ performance, and (4) the use of simulation in the early design phases to improve the ramp-up of a new product.

Some of the recommendations are applied on a trial basis. The potential benefits of simulation are demonstrated in a production line modeling and optimization project. It is demonstrated that the use of simulation tools can result in the design of production lines that have faster cycle times, lower inventory levels, fewer people and less equipment.

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CHAPTER 1  INTRODUCTION

The relationship between the business functions of new product development and manufacturing has been a topic of interest to academic scholars and industry managers for years. They have struggled with trying to create the best organizational structure for bringing new products from a concept phase to a point where the new product is mass producible and available to the market.

Some companies have organized by functional specialization. In such organizations, different functional groups within the company are responsible for a development project at different times as it goes from phase to phase in its development. Traditional functions include marketing, research and development, engineering, and manufacturing. By necessity, there is some interaction between all functions. Nevertheless, development projects in traditional functional organizations have sometimes been characterized as being "thrown over the wall" as the project progresses in sequence from one function to the next.

Because of the functional organizational structure, different functional cultures and status levels developed, even within the same company. The nature of product design and development work, for example, is significantly different from the production environment. These differences between the functions seemed to further heighten the "walls," causing companies to search for better ways to improve cross-functional linkages.

At the other end of the organizational spectrum is organization by product. Product-based organizations, or multidivisional organizations, have two or more divisions, each of which is focused on only one of a company's products. Product-based organizations may actually be subdivided into functional groups. However, these "functional" groups specialize in only one product. Organization by product allows the organization to focus on meeting the needs of only one market. Because they focus their energies on only one product, product-organizations are thought to be able to respond to the customer faster and to have richer communications between functions. A disadvantage of organizing by product is that the relationships suffer between same functions serving different product families, sometimes resulting in inferior company-wide functional knowledge (Henderson, 1994).
One way companies have avoided some of the pitfalls of functional or product-structured organizations is through the use of project-based cross-functional teams. Team-based organizations create cross-functional teams that are organized around a particular project or process. A typical application of cross-functional teams is in the development and introduction of a new product. A cross-functional development team has team members representing marketing, development and manufacturing dedicated to a particular new product development effort. In theory, cross-functional teams can bring a new product to market faster than the traditional functional development project. The development process is hastened by having the team members focused on only one project at a time, and by the quick decision making that often results when almost all of the decision-makers are in the same small group. With the increased international competitive pressures facing companies today, development speed-to-market is becoming more and more critical, making teams a popular organizational structure.

Besides the functional, product-based or team-based organizational options, a variety of options exist for improving the effectiveness of the development/manufacturing interface. Companies have experimented with a variety of integrative mechanisms that get manufacturing personnel involved in the development effort for the benefit of the company. Examples range from giving manufacturing "veto" power in design reviews to designing products for ease of manufacturing (DFM) to assigning a liaison "early manufacturing involvement" (EMI) person (Adler, 1992; Susman and Dean, 1992).

The preliminary successes of cross-functional teams observed in industry seem to warrant serious consideration of their usage by companies in the business of developing new products. This thesis will cover two aspects of teams: (1) a review of the "textbook" implementation of cross-functional development teams, and above and beyond that, (2) fine-tuning cross-functional development teams once they are in place. Of particular interest is how such teams interact with the manufacturing functions that will eventually take over responsibility for the new product. Recommendations will be made for improving the relationship between development teams and manufacturing departments. Arguments will relate to the level and nature of manufacturing involvement in development projects, the role manufacturing plays in assessing the performance of the development team members, and the types of things development teams should be expected to do to create a robust, manufacturable product design.
1.1 Motivation for and Objectives of Research

The major goal of this research was to provide helpful insight on the following general topics:

1) **Fine-tuning the Cross-functional Team Structure.** As will be discussed in Section 1.4, most managers are probably aware of the potential benefits of using cross-functional teams. However, because the team-concept has only recently come into wide-spread popularity, the literature is not comprehensive on all aspects of the subject. Many companies are essentially feeling their way along while using cross-functional teams in their business environments. This document is intended to promote the use of teams in appropriate environments, as well as serve as a reference document for specific aspects of team usage that have not been widely documented.

2) **Transfer of a New Product from Development to Manufacturing.** This research includes a derivation of a set of general recommendations for a smoother transfer of new product and process technology from the development organization to the manufacturing organization. Each recommendation's application, advantages, and disadvantages are discussed. It is widely accepted in industry and academia that the ability to rapidly and frequently introduce new products is a strong competitive advantage (Stalk, 1988; Wheelwright and Clark, 1992). By gaining an understanding of some of the problem sources in new product introductions, the reader may apply the lessons in this thesis toward his own organization's ability to rapidly introduce new products.

Of course, a second goal was to improve the specific process of transferring new products from product development teams to manufacturing business units at the company where the research was conducted, Ethicon Endo-Surgery. Ethicon Endo-Surgery, like many companies, recognized that there were weaknesses in their process of "handing-off" a new product from the product development teams to manufacturing. These weaknesses were in the form of poorly designed processes, conflicts between the two functions, and even occasional product redesigns stemming from manufacturability issues. The objective was to find and implement actions that would make for a smoother new product transition into manufacturing. A smoother transition means the development of efficient, reliable processes; attainment of development speed-to-market and cost goals; and fewer disputes between manufacturing and development.
1.2 Scope of Research

The scope of this research covers the process of transferring a new product from development to manufacturing. The manufacturing and development "overlap" period extends from the time the first manufacturing representative becomes involved in the design until the product and process responsibility is completely owned by manufacturing.

During the internship project, a case-study of a cross-functional development team was done. The author's role was to study the process of developing and transferring new products to manufacturing at Ethicon Endo-Surgery, while at the same time building upon the general body of academic research on the subject of cross-functional teams and the interface between development and manufacturing. Beyond researching, the author was to make general recommendations and initiate the application of those recommendations. In particular, the cross-functional team was used as a pilot team for some of the recommendations. The author attended regular team meetings and participated in various team activities on a part-time basis. The intent of this involvement was to thoroughly understand the team environment as well as the trials and tribulations of developing a new product and transferring it to manufacturing.

1.3 Overview of Recommendations

A set of recommendations are presented that apply the conventional management and academic wisdom regarding the development and manufacture of new products to the specific context of cross-functional development teams. Underlying these conventional recommendations is the belief that in today's competitive markets, companies need to take actions that will improve product quality, cost, and development time-to-market (Susman, 1992).

Four recommendations for fine-tuning the process of transferring new products from cross-functional development teams to manufacturing were developed in this study. The recommendations are previewed below.

1) Involve the Long-term Manufacturing Support People Early to Minimize Turnover Effects. The importance of keeping the core contributors with the new
product development effort will be emphasized. In the desired case, the development team members should be transferred through each development phase and into manufacturing along with the new product. A reasonable alternative is to have the long-term manufacturing support individuals (manufacturing engineer, planner, supervisor, etc.) become involved with the development team on a part-time basis as soon as they can, and then remain with the project as it is handed-off to steady-state manufacturing and beyond. Continuity of participants is thought to make for a smoother new product introduction (Westney, 1986; Shapiro and White, 1994).

2) **Hold Development Responsible Until "Steady-State" Production.** It will be explained that development is responsible for much of the new product's ultimate cost because so many product and process characteristics are determined very early in the design phase (Whitney, 1988). Also, product and process development personnel seem to have the highest level of expertise regarding the new product and the associated new production process. The "hand-off" period also can be a time of confusion over responsibilities between development and manufacturing. For these reasons, it will be recommended that the development organization maintain more decision-making responsibility for the new product line until the product is into a "steady-state" production mode, as indicated by specific measurements. Development, not manufacturing, seems most likely in a better position to quickly address product design or new process issues, cost issues, and product availability issues until the product reaches a steady mode. Finally, the use of metrics rather than intuition to define development progress is advised.

3) **Have Manufacturing Partially Evaluate their Development Team Representatives' Performance.** In companies that use some form of cross-functional product development teams, a balance should be maintained between the needs of the development team and the needs of the represented home functions (manufacturing, marketing, etc.). One possible way to do this is to allow the home functions to assess the performance of their team representative and to do a percentage of that individual's performance appraisal, as opposed to giving up all responsibilities to the team leader. True, splitting the performance appraisal between the development team and the home function will involve extra effort and closer ties between the two groups. However, a closer working relationship between manufacturing and development is thought to be beneficial in that it may help to ensure that manufacturability issues are considered.

4) **Use Manufacturing Simulation to Design for CFM.** It will be shown that manufacturing simulation models, of varying levels of sophistication, can provide great benefits in the form of improved process designs, increased line throughput, and
decreased levels of inventory, headcount, and equipment. Simulation is one of the best ways for a development team to ensure that the production process they design is capable and cost-effective.

The reader will have a clearer understanding of the recommendations after reading the remaining chapters. Following the above recommendations should improve product manufacturability, reduce the time it takes to get a reliable product to market, and minimize unnecessary debates over ownership and courses of action. While concentrating on team-based organizations which develop discrete types of products, the recommendations may also be applicable in a general sense in other organizational forms or industries.

1.4 Distinctive Aspects of Research

Here are three distinctive aspects of this research:

1) **Fine-tuning the Cross-functional Team Structure.** Most managers in industry seem convinced of the benefits of using cross-functional teams in certain business applications. Many companies have implemented cross-functional product development teams as described elsewhere by the likes of Wheelwright and Clark (1992) and Clark and Fujimoto (1991). What these companies are discovering is that while many major obstacles are overcome by using teams, new obstacles crop up in unexpected places. This research will attempt to show that simply putting cross-functional development "teams" in place is not enough to guarantee a manufacturable product. There are many details and issues to be resolved beyond the initial reorganization. One such detail examined in this thesis is performance appraisal methods. A delicate balance should be maintained between the manufacturing functional representatives' dedication to the development team's needs versus their home function's needs. The split performance appraisal recommendation mentioned earlier is one way to help maintain this balance.

2) **The Use of QFD to Assess Internal Customer Needs.** Case studies have been done on the use of Quality Function Deployment to develop new products for external customers (Hauser, 1993). However, there is little information in management or academic literature on the use of QFD to gather information and conceptualize the needs of internal customers. It was thought that QFD could provide insights in a way
that traditional anecdotal data collection methods (surveys or interviews) could not. This thesis provides a step-by-step case-study of how this can be done to better understand what development and manufacturing expect from one another, and how the information gathered through the QFD project was used to shape improvement actions and make general recommendations regarding the new product introduction process.

3) A Case-study of the Use of a Manufacturing Simulation Model to Optimize an Assembly Line. A complete production line simulation project is presented to show how development teams can do a better job of production process design.

1.5 Preview of Thesis Contents

Chapter 2 contains a review of current literature on the subject of developing and transferring new products from development to manufacturing. Modern team structures, such as heavyweight teams, are covered. Typical problems, such as missed development targets, poorly designed production processes, and conflicts between the development and manufacturing functions are discussed.

The environment at the company where the research was conducted is described in Chapter 3. It describes how Ethicon Endo-Surgery quickly gained market share by rapid product development efforts and aggressive marketing tactics. A description of their products, organizational structure and strategy follows.

The QFD procedure used to collect data and assess the needs of internal customers of both the development and manufacturing functions at Ethicon Endo-Surgery is described in detail in Chapter 4. The actual results of the QFD exercise are presented as well.

Chapter 5 shows how the information was analyzed and converted into general recommendations for organizations using (or considering the use of) cross-functional teams, or for any organization that develops and transfers new products to manufacturing. Arguments are presented relating to how the development process and supporting organizations and procedures might be structured.

The successes and failures observed (including the results of trying some of the recommendations on a trial basis) during a case-study of one of Ethicon Endo-Surgery's
cross-functional development teams are discussed in Chapter 6. Chapter 6 also includes a presentation of the procedure used and results attained during a manufacturing line modeling project. A detailed study is presented on how a manufacturing simulation model was used to optimize one of Ethicon Endo-Surgery's new production lines. A method for optimizing throughput, cycle and queue times, work-in-process inventory levels, and equipment and personnel usage levels is described.

Chapter 7 concludes the thesis with a review of key findings and suggestions for future research regarding the transfer of new products into manufacturing, the use of QFD as an internal assessment tool, and the fine-tuning of cross-functional team structures.

Lastly, the appendices contain details relating to the QFD and simulation projects.
CHAPTER 2  OVERVIEW OF MANAGEMENT AND ACADEMIC LITERATURE

Introduction

The development and introduction of a new product is one of the most important business processes an enterprise undergoes. There are as many different ways to carry out this process as there are companies that do so. As expected, there are many examples of breakdowns in the process of developing new products and transferring them to manufacturing. What follows is a discussion of some examples that are frequently cited in management and academic literature, after a brief review of the cross-functional product development team structure.

The literature summary in this chapter is intended to draw upon the existing body of knowledge concerning two areas: (1) the implementation of cross-functional new product development teams, and (2) the general relationship issues between development and manufacturing functions in the introduction of new products. This general knowledge of the interactions between development and manufacturing is later applied to organizations that specifically use cross-functional development teams. Thus, this thesis is intended not only to promote the implementation of cross-functional development teams but also to make them more effective.

2.1 Cross-functional Team Structure

2.1.1 Evolution of Cross-functional Teams

All of the major functions of a business (marketing, development, manufacturing, finance, information systems, human resources, etc.) must be involved in bringing a new product to market. Each function must not only coordinate its own tasks but must also interact with the other functions. Of particular interest in this study is the interaction between new product development and manufacturing.

The nature of a new product development effort dictates that the project go through dramatically different phases - each of which requires dramatically different activities. For instance, a new product might move from a concept generation phase to a prototype
development phase to a detailed engineering phase to a production ramp-up phase and finally, to a full-scale production phase.

In the functional organizational structure, a marketing function or a research and development function will typically generate concepts. A product development/engineering function will usually handle the detailed design of the product, and a production function will be responsible for the production process design and the manufacture of the product. Projects tend to be passed from one function to the next in a sequential fashion. Of course, a great deal of interaction is required between the functions to successfully get the development project through to the next phase. However, the idea of "throwing the product over the wall" to manufacturing has often been used to illustrate the sometimes dysfunctional nature of traditional functional organizations.

Of course, functional organizations do have many positive features. In a manner analogous to Henry Ford's mass production system where work is broken into its smallest elements and individual workers specialize in only one task all day long, functions repeated perform the same specialized duties and can become very good at it. In functional structures (including the military), responsibilities, duties, procedures and communication channels are usually clearly defined and very orderly. Because of the tendency of functional organizations to develop specialists, there are fewer redundant jobs or departments.

Nevertheless, much has been written in the past decade about the dangers of relying solely on traditional functional organizations (Dertouzos, Lester, and Solow, 1989; Wheelwright and Clark, 1992). Functional organizations may not see the "big picture" but rather may sub-optimize for the benefit of their function only and not the whole enterprise. Moreover, functions that specialize in narrow areas are often made up of individuals who are also functional specialists. Such individuals may support several new product development efforts without being fully dedicated to any of them. Hence, particular products may not get the attention or turnaround time they need, depending on the priorities of the functional specialist. Similarly, new products may not have any one "owner" who sees that the project successfully gets the resources it needs at each phase of the development cycle. Finally, the cross-functional communication links (through the management hierarchy) can be cumbersome in traditional functional structures.
Of course, limitations of the traditional functional approach have been overcome to some extent in alternative structures for bringing a new product to market. Two of these were mentioned earlier: team-based organizations and product-based organizations. These alternatives are often faster, leaner, more effective and more focused than functional organizations. Of late, the most popular alternative seems to be the use of some sort of cross-functional team dedicated to a particular project. Wheelwright and Clark discuss four forms of development structures that differ in their degree of autonomy and project ownership. They are: (1) the functional team structure, in which traditional functional managers try to coordinate development work as it passes from one function to the next; (2) the lightweight team structure, in which a coordinator tries to organize the work of individuals in different functions while having little real control over them; (3) the heavyweight team structure, in which a powerful team leader is "loaned" empowered cross-functional team members for the duration of the project, and (4) the autonomous team structure, in which members are permanently assigned to the development organization and no longer have any reporting ties to their former home functions, besides their background and past experiences.

Of the four alternatives listed earlier, Wheelwright and Clark recommend the heavyweight team structure, saying it has "tremendous potential for a wide range of organizations." The Wheelwright and Clark text (1992) serves as an excellent reference for implementing heavyweight cross-functional development teams.

This thesis will focus on fine-tuning what they call the heavyweight team structure, particularly as it relates to the interaction between development and manufacturing personnel. For the sake of clarity and because "heavyweight team" means different things to different people, "cross-functional team" will be used in this document. In general, "cross-functional team" will refer to product development teams with an influential team leader and cross-functional team members who are assigned to the team's project full-time until its completion, but retain formal ties to their original home functions. Cross-functional teams will be discussed in more detail next.

2.1.2 Review of Heavyweight Team Implementation

In the past few years, much has been written about the benefits of heavyweight product development teams. This cross-functional, autonomous development team structure and
related forms of organization were cultivated at companies such as Toyota, Honda and Motorola, and were first described by Takahiro Fujimoto. They were introduced to a broad managerial audience in works such as Product Development Performance, by Clark and Fujimoto (1991), and Revolutionizing Product Development, by Wheelwright and Clark (1992). Cross-functional teams can offer many advantages over traditional development approaches.

A heavyweight team is a cross-functional (product development) team with members from the traditionally segregated functions of manufacturing, development engineering, and marketing. According to Smith and Reinertsen in their 1991 book, Developing Products in Half the Time, the ideal team should be physically located in the same area and should have ten or fewer members who are assigned to the team full-time and report solely to a team leader. The heavyweight team leader should have direct access to and responsibility for their work. However, in the heavyweight structure, the longer term career development responsibility of individual contributors remains with their functional managers because individuals are not assigned to the development organization on a permanent basis. The name "heavyweight" refers to the characteristics of an ideal team leader - a senior person within the organization with significant experience and organizational clout.

With cross-functional teams, products can be developed faster because all of the primary contributors are working together on one focused task (generally, getting a high quality product to market quickly, and at a reasonable cost). Much of the traditional bureaucracy - for example, going up and down layers of management to get support for a project - can be overcome. In theory, specialized functional knowledge is not lost because team members maintain some formal ties to their "home" functions. This author supports the use of cross-functional teams in most development applications - particularly where development speed-to-market is a critical success factor. However, cross-functional team structures are not without weaknesses. In the paragraphs that follow, some of the common challenges that result after implementing cross-functional teams are discussed.

2.1.3 Weaknesses of Cross-functional Team Structures

According to Wheelwright and Clark (1992), there are four commonly known problems that may arise when corporations use cross-functional teams.
First, teams sometimes become carried away and expand the definition of their role and the scope of the project. Because a great deal of responsibility and autonomy is given to teams, the issue of teams expanding their boundaries should come as no surprise. This problem may be made worse by insufficient training and insufficient explanation from senior management on expectations, directions, and boundaries for the team.

Second, because of the attention and authority given to newly created cross-functional teams, the remainder of the people in support functions may come to see themselves as "second fiddle." Unfortunately, high levels of visibility and authority are inherent in the successful cross-functional team structure, and status differences are likely to be a source of contention - whether intentional or not.

A third related issue is the need to maintain a balance between the needs of the individual project and the needs of the rest of the organization. On the one hand, the development team is usually very schedule-oriented and may expect fast turn-around from all the support groups it deals with. On the other hand, perhaps the needs of the team are actually less critical to the business than other tasks. The support organization is forced to prioritize its efforts accordingly. The issue is how to prioritize and manage the tasks done by support groups in an optimal way.

Finally, the use of cross-functional teams may lead to team members who are generalists as opposed to specialists in the latest technical knowledge. So that the team does not rapidly develop a product that is merely mediocre in terms of technology or functionality, there needs to be some way to incorporate leading edge concepts into the cross-functional team's design. A balance should be found between functional expertise and cross-functional (general) skills.

Above and beyond the commonly documented cross-functional team issues, other team weaknesses were identified in the course of the research conducted. One such weakness has to do with individual and team performance appraisals and how they should be structured to optimize the balance between the needs of the team and the needs of the home functions. Another issue that surfaced was that functional representatives, after being placed on a cross-functional team, did not necessarily meet their home function's expectations in much the same way that previous development organizations did not always meet the expectations of marketing or manufacturing. Specifically, the issue is
how to find an efficient way to get the manufacturing organization (which will eventually take over responsibility for the product) to contribute and buy-in to decisions made by team members. Finally, the issue of how long a team should be responsible for a product was brought up. These issues will be discussed in later chapters.

2.2 General Problems Relating to the Manufacturing/Development Interface

Besides the weaknesses inherent in cross-functional teams, there are general difficulties that arise in any development effort (team or no team) where a product is developed from a concept to full-scale production. Many problems relating to the interface between manufacturing and development manifest themselves in one of three categories: missed development targets, inefficiently designed production lines, and disputes between development and manufacturing. The following sections are a discussion of some of these problems and how they impact the "hand-off" of a new product from development to manufacturing.

2.2.1 Problem 1: Missed Development Targets

It seems clear that if a development team can keep the project on time and on budget, the transition into manufacturing will be that much smoother. In practice, this is much more difficult than it sounds. Wheelwright and Clark (1992) give a description of an electronics firm (actually a composite of several firms they studied) that continually set - then missed - development schedules. The dates for key development milestones such as design verification and market release often slipped weeks or months due to unexpected incidents such as lack of money or support, the incorporation of new features, and late deliveries from suppliers.

Rather than being the exception, it seems almost the rule in industry that development projects will take longer and use more resources than planned. In many cases, firms should resist the temptation to incorporate new features into a product design midway through the project. In Total Quality Development, Don Clausing (1994) advocates the use of disciplined "freezing" of design decisions as the project progresses. Once a decision has been made, it should be stuck-to, in most cases. Major changes should be postponed until the next product design cycle. If the company is executing properly, it should be able
to develop a series of incrementally better products in rapid succession, as opposed to pushing out indefinitely the development of a product with constantly changing specifications. In many companies, product and process design changes are still occurring when the project is supposed be in a design verification phase. This phenomenon could be due to a desire to continually add new features to the design. It could be due to inadequacies in any of the following areas: design specifications, market research, supplier selection. Many of the changes stem from manufacturability issues that should have been considered much earlier in the design cycle. In such an environment, development budgets and milestones are obviously missed and hand-offs to manufacturing are "fumbled."

2.2.2 Problem 2: Inefficiently Designed Production Lines

The 1990 book produced by MIT's International Motor Vehicle Program, The Machine That Changed the World (Womack, Jones, and Roos), gives ample evidence of inefficient production lines in Western corporations. Poorly designed production lines result in the inability to produce quality, low-cost goods at the quantities desired. Unfortunately, many managers still seem to think of these as manufacturing issues as opposed to company-wide issues. As we will discuss in section 2.3.1, the majority of manufacturing process specifications and costs are determined during the design phase.

In general, "inefficiently designed production lines" refers to production systems with one or more significant wasteful characteristics. They may have poorly planned inventory systems with relatively high levels of inventory in the process. They may have inexplicably long operation times or overall process cycle times. Such manufacturing lines may be unable to meet the specified delivery quantities - often due to unexpected line shut-downs required to fix production problems that should have been discovered and corrected during the process design and verification phases. As a result, customer orders may not be filled on time and may go into a backorder situation. Moreover, quality specifications may not be satisfied by inefficient production systems, both at suppliers and in-house operations. Costs, scrap, and rework levels are typically higher than expected or planned in poorly designed production systems. Finally, inefficiently designed production lines are often highly inflexible - meaning long setup or change-over times and large batch sizes.

The ability of the (process) development organization to design an efficient production line often determines how successful the production ramp-up will be - whether it will be
"smooth" or "rough." If the manufacturing organization has to redesign the process or the development team has to redesign the product to accommodate the production process, major delays could occur.

These problems are surely evident to varying degrees in almost all manufacturing companies. Some waste is inherent in any production system, but many of the types of problems cited earlier could be drastically reduced by designing a more lean production system.

2.2.3 Problem 3: Disputes Between Development and Manufacturing

In most U.S. industrial companies, development has a higher status than manufacturing (Susman and Dean, 1992). This status difference often contributes to poor working relationships between the two functions. Lack of mutual knowledge, vague definitions of responsibilities, role dissatisfaction and work overload are other factors that commonly contribute to disputes between development and manufacturing (Walton and Dutton, 1969). Naturally occurring differences in business practices, incentives and missions between the two groups can also cause disputes. It is believed that such differences have led companies to focus on product attributes at the expense of manufacturing process design in the past. Henderson and others (1994) argue that barriers to effective process improvements are deeply rooted in the organizational structures, information systems, and incentive structures that evolved to support companies' emphasis on product design.

Although it could be argued that disputes are a natural and healthy result of cross-functional interaction, too many disputes can be harmful (Walton and Dutton, 1969). If a company is to become adept at introducing new products, it should strive to avoid disputes that serve no purpose other than delaying the release of a new product and further polarizing development and manufacturing personnel.

Cross-functional product development teams may mitigate cross-functional disputes to a large extent. However, a cross-functional development team could certainly find itself in similar "functional" disagreements with external functional groups such as manufacturing or marketing, or with other development teams.
2.3 Suggestions from Management and Academia

Suggestions are plentiful on what manufacturing enterprises should do to prevent the above types of development/manufacturing problems. Utilization of some form of cross-functional team structure is on top of the list. This section contains an overview of some of the other suggestions and best industry-wide practices found in current management and academic literature. Fundamental to this discussion is the widely held belief that companies must improve quality, costs and cycle times simultaneously to remain competitive in today's increasingly competitive global markets.

2.3.1 Impact of Development on Manufacturing

First, organizations need to recognize that the development organization is ultimately responsible for much of the manufacturing process. Studies have shown that between sixty and ninety percent of the total long-term manufacturing costs are determined during development. (For an example, see Whitney, 1988.) Type of materials, number of components and production methods are implicitly determined to a large extent before the first prototype is even made. Wolff (1985) argues that because of the tremendous impact designers have on the long-term production, the responsibility for transferring the product to manufacturing and ensuring that the process is operating reliably and at a profit rests firmly with development.

2.3.2 Early Manufacturing Involvement

Much has been written in the past decade about the advantages of early manufacturing involvement (EMI) in development. The point is simple: EMI can make for a more manufacturable design. Early involvement of manufacturing personnel in design (in any of several forms) can save money by resulting in more manufacturable products as well as fewer late changes, according to Coughlan (1992). Dean and Susman (1989) have suggested that design for manufacturing (DFM) barriers can be overcome to some extent simply by giving manufacturing sign-off power in design reviews. In any case, few would argue against the idea that considering manufacturing capabilities and ease of manufacturing issues early in the development cycle is advantageous.
2.3.3 Simulation

Similarly, the use of manufacturing simulation software has increased dramatically with the personal computer revolution of the past decade. Simulation is one of the best ways to understand manufacturing issues before they become issues. Nwoke (1993) and others have written about the advantages of simulation. Simulation allows the user to analyze production characteristics such as process cycle times and flow, inventory levels, and resource usage (people and machines) to come up with a better production line design. In addition to production line modeling, software packages exist for a variety of manufacturing applications, such as analyzing injection molded plastic flow or assessing a product's level of manufacturability.

2.3.4 Design Changes

Product design changes are a normal, yet costly and time-consuming part of the design process. Changes in product or process designs can have a rippling effect through the organization and supply chain, as one small change often requires a "mountain" of paperwork and costly modifications in tooling. Multiply this by the hundreds of changes that can occur in a development project, and you will see why it is advantageous to maintain control over the design changes. Barkan (1992) states that design or process changes are especially costly if late in the development cycle - thus arguing that the earlier changes are implemented, the better. He also shows that in comparable development projects, U.S. companies have a much higher total number of changes and that these changes occur much later in the development cycle than they do in Japanese companies.

2.3.5 People Rotation

One of the best practices in industry (primarily in Japanese companies) involves keeping the original research and development people with the new project as it advances through the development and manufacturing phases. Westneyt and Sakakibara made this point in their 1986 article, "Designing the Designers." This practice not only reduces confusion over responsibilities and reduces the need for training new people, but it also gives the design engineers first-hand knowledge of manufacturing that they may apply during their
next design project According to Susman and Dean (1992), it is best to minimize people
turnover on any particular design project Shapiro and White (1994) estimate that every
time a critical product development team member has to be replaced, development time
increases by at least two months.

2.3.6 Value of Communication

Clear communications, clear incentives and clear milestones can contribute to the success
of a project. This seemingly obvious idea of good communication is something that all
companies probably agree on in principle, but often fail to perform adequately in practice.
However, good communications and transfer of knowledge between groups are essential
in developing and manufacturing products (Griffin and Hauser, 1992). Furthermore, clear
milestones with no ambiguity lead to better relations between manufacturing and
development (Langowitz, 1989). On a similar note, Susman and Dean (1992) contend
that shared, common incentives between manufacturing and development keep the two
functions working together. The point is clear - in order for a project to be successful, all
parties involved should be kept abreast of what is going on and what the expectations are.
Failure to do so may be an invitation for last minute surprises.

2.3.7 Tension Between Functions

The management and academic articles show that tensions do exist between business
functions and that they should be reduced where possible. In 1969, Walton and Dutton
demonstrated that there are many corporate practices and cultural aspects of a business
that tend to exacerbate tensions between development and manufacturing. They went on
to demonstrate that conflict between functional units can and does result in negative
consequences to the performance of the business. As mentioned earlier, Susman and Dean
(1992) have continually stated that in most U.S. companies, development has a higher
status than manufacturing, and that this contributes to poor working relationships and
poorly executed new product ramp-ups.
Summary

The ideas presented thus far lay the groundwork for the recommendations to come. The literature cited seems to have been primarily written with the functional organizational context in mind. This thesis will extract that general knowledge regarding the manufacturing/development interface and apply it in the context of cross-functional development teams.

While seeming straight-forward, the suggestions from management and academia can be difficult to implement in real life. Companies may be faced by a multitude of problems of higher priority. With limited resources, a company must pick and choose its "battles" carefully, meaning that the most fundamental business survival challenges are often addressed before the company can work on fine-tuning other aspects of the business - such as the use of cross-functional teams.

In general, the consensus seems to indicate that more partnering is needed between development and manufacturing personnel. Many of the problems discussed in this chapter stem from the nature of the new product introduction process. By studying this process at Ethicon Endo-Surgery as well as looking at best practices industry-wide, recommendations can be derived and implemented to create more of a "seamless" transition of a new product from development teams to manufacturing. A smoother transfer means faster time-to-market, better product quality and lower costs - desirable goals for any competitive company.
CHAPTER 3 ETHICON ENDO-SURGERY BACKGROUND INFORMATION

Introduction

The previous chapter introduced some of the issues that surround the "hand-off" of a new product from development to manufacturing. Ethicon Endo-Surgery, like many companies, converted to a development organization made up of cross-functional teams, with the intent of developing products in a faster and more effective manner. Thus far, Ethicon Endo-Surgery and its parent company, Johnson & Johnson, have been thought to have a successful strategy, based on revenue and market share growth, as well as rapid product development practices. Rightly or wrongly, success in these areas may have come at the expense of such things as manufacturability and product cost. Ethicon Endo-Surgery's development team structure has occasionally had problems relating to designing for manufacturability and early manufacturing involvement.

The success or failure of a company's strategy will largely depend on the business context in which it operates. An overview of Ethicon Endo-Surgery's environment is presented in this chapter.

3.1 History of Company and Division

In 1992, Johnson and Johnson executives announced the formation of a new medical products subsidiary - Ethicon Endo-Surgery. Ethicon Endo-Surgery would be responsible for marketing, developing and manufacturing mechanical tissue staplers, clip applicers and cutting devices for surgeons. Ethicon, Incorporated (the original subsidiary) would remain in the traditional suture (tissue stitching) business. Johnson and Johnson felt that the great potential of a modern type of minimally invasive surgery - endoscopic surgery - merited the establishment of a new subsidiary that would concentrate on that market and act quickly to develop new endoscopic surgical instruments. Furthermore, the mechanical staplers were a substitute for sutures in many surgical applications, and it was thought that efforts to penetrate this rapidly growing new market might be stifled by internal debates of product "cannibalism" if under the management of Ethicon's traditional suture business. By 1994, the number of employees at Ethicon Endo-Surgery had grown to over 2000.
3.2 Products and Technology

Ethicon Endo-Surgery's products can be categorized as either endoscopic (minimally invasive) or conventional (open) surgical tools. While the conventional surgical tools have enjoyed a slow steady growth, the endoscopic segment has experienced rapid growth through revolutionary technology and health-care cost savings. With minimally invasive surgical tools, surgery recovery times are significantly reduced, as are hospital stays and the associated costs.

The majority of Ethicon Endo-Surgery's instruments are simple mechanical devices, consisting primarily of injection molded plastic and stamped/machined metal components. In total, Ethicon Endo-Surgery has over ten distinct product families, with over three-hundred unique products. A very significant portion of Ethicon Endo-Surgery's revenue each year comes from new products.

3.3 Market Analysis

A summary of the market in which Ethicon Endo-Surgery competes is presented next. The format is based on Michael Porter's "forces" that determine industry competitiveness (Porter, 1985).

**Rivalry Among Competitors:** For the past decade, U.S. Surgical Corporation was the dominant producer of endoscopic instruments. Since the early 1990s, Ethicon Endo-Surgery has used Johnson and Johnson's financial resources and market strengths to rapidly penetrate this market. Products were quickly developed that offered incremental improvements over U.S. Surgical in almost all endoscopic product niches. Ethicon Endo-Surgery typically priced their products below U.S. Surgical.

Aggressive marketing along with Ethicon Endo-Surgery's expansions in capacity and development over the past three years have paid off for Ethicon Endo-Surgery. Ethicon Endo-Surgery's endoscopic market share went from the single digits to the point where it is slightly ahead of one-time market leader, U.S. Surgical.
**Barriers to Entering the Market:** There are at least three major obstacles to overcome when entering the endoscopic surgical instrument market: FDA regulations, brand loyalty, and sales/distribution economies of scale.

The FDA approval time for medical devices can take a year for "me-too" products (Nissen, 1993) and up to three years for breakthrough products. This may be too long to wait for many companies, especially smaller companies who do not have product line breadth. The approval process requires a series of pre-clinical (animal) and clinical (human) trials before a new product can be released for sale in the U.S. In addition, FDA requires very stringent record-keeping and manufacturing practices. Many companies may not have the ability to adhere to such standards.

Although Ethicon Endo-Surgery has taken over a large share of U.S. Surgical's customer base, it has not always been a simple matter of having a better product at a lower price. Ethicon Endo-Surgery salespersons often found a fierce customer loyalty to their competitor's products, especially from the surgeons. Ethicon Endo-Surgery has overcome this obstacle to a large extent, but it has been through the arduous process of convincing one customer at a time.

Finally, to competitively sell to hospitals, it is beneficial to have a national/international sales and distribution network. Through their large Hospital Services Division, Johnson and Johnson has such a network. J&JHS, as it is known, does a variety of things for the hospitals it serves, such as placing orders and stocking hospital shelves. Again, smaller companies that do not have economies of scale in a distribution network (or even in a large sales force) are at a distinct disadvantage.

**Customers:** The "health-care crisis" was brought to the forefront of American politics during the 1992 presidential campaign, and it seems that attention will remain on health-care costs for years to come. One trend resulting from this is the greater impact that health maintenance organizations (HMOs) and hospital purchasing groups have on purchasing decisions. Ethicon Endo-Surgery recognized this trend early and marketed their products to hospital purchasing organizations in addition to surgeons. Of course, the surgeon is still the ultimate end-user and the ultimate decision maker in most hospitals.

An interesting aspect of the endoscopic instrument market is that it actually benefits from the move toward lower health-care costs. As mentioned earlier, hospital stays and patient
recovery times are greatly reduced with endo-surgery. However, this also results in lower revenues to the customers who are buying endoscopic instruments - the hospitals.

**Conclusion of Market Analysis:** The effect of suppliers and substitute products on the endoscopic surgical tool market is not remarkable. Like many of the medical device companies they serve, suppliers of metal and plastic components to the medical device industry seem to be small to medium-sized and fragmented, but not overly dependent on any one customer. Endoscopic surgery is itself a growing substitute for traditional surgery, and speculation as to which technology will replace endoscopic surgery would be premature.

The market can be summarized as a near-duopoly, with growing demand and significant barriers to entry. However, Ethicon Endo-Surgery has at least one aggressive competitor to contend with, U.S. Surgical. From the market analysis, it appears that development speed-to-market will continue to be important. While there are only two primary competitors, the one that gets to market first with a new product application will likely win significant market share and revenues at the expense of the other (Smith and Reinertsen, 1991).

3.4 Organizational Structure and the Development Process

Ethicon Endo-Surgery built an organizational structure around its strategy of getting competitive products to market quickly. As mentioned in the introduction, the backbone of this structure is a number of cross-functional product development teams. They were put in place during a reengineering project done eighteen months after Ethicon Endo-Surgery was split from Ethicon, Incorporated. As described by Wheelwright and Clark (1992), a heavyweight team project leader has direct access to and responsibility for the work of all those cross-functional members involved in the project. However, in the heavyweight structure, the longer term career development responsibility of individual contributors remains with their functional managers because individuals are not assigned to development on a permanent basis. At Ethicon Endo-Surgery, modified heavyweight teams, usually about 10-12 people strong, are responsible for all phases of development of particular products. It is a modified heavyweight team structure because functional team members have differing levels of allegiance with their home functions. As an example, functional team members had anywhere between zero and seventy-five percent of their
performance appraised by their home functional manager, even though they all were fully
dedicated to the team and its one project

Prior to the reengineering, the development organization was a hierarchical, management-
oriented organization with abundant managerial career paths. Development efforts
typically involved two champions - one from development and one (at the distant Ethicon
headquarters site) from marketing. Although it was typical to have a manufacturing
representative assigned to a development project, most support individuals supported
multiple projects simultaneously and officially reported 100% to their home functions.
Some of these support individuals were located in remote sites, making the development
process even more difficult. There were only informal performance objectives -
emphasizing speed-to-market. Development was commonly over budget and occasionally
late. The development group essentially told the manufacturing organization how the
process was going to be run after the product design had been finalized.

There are many advantages of the reengineered organization put in place in 1993. A
single heavyweight team leader was put in place as opposed to two managers (one from
marketing and one from development). Goals and objectives of the new development
teams were made clearer. The team members from the functions of marketing,
design/development, manufacturing, purchasing, finance and quality are now collocated
and report to the team leader. This reduced the dilemma of support individuals choosing
between multiple projects. The team members were free to focus on one thing -
developing and introducing their new product.

Ethicon Endo-Surgery also created a pilot manufacturing department to act as liaisons
between development and manufacturing during the production ramp-up phase. This
group reports to the manufacturing plant manager. The pilot manufacturing department
provides the early manufacturing line supervisors, technicians, and operators to assist the
product development team during the ramp-up of a new product. Later, they assist in the
transfer to the long-term manufacturing departments by training workers and documenting
procedures. Besides the groups described earlier, Ethicon Endo-Surgery has more
traditional functional organizations for sales and marketing, manufacturing, finance,
quality, and human resources.

The role of the manufacturing representatives (synonymous with "manufacturing
integrators" in this document) on the development teams is to coordinate all the
manufacturing-related issues that pertain to the new product development effort. In theory, this means they are responsible for ensuring that manufacturing capabilities are known by development team members, that products and processes are designed with manufacturability in mind, and that production processes and equipment are fully capable of producing a high quality, low cost product on a reliable, repeatable basis. Of note at Ethicon Endo-Surgery is the fact that when the cross-functional development teams were put in place, it was agreed that the team leader would be responsible for 100% of the manufacturing integrator's performance appraisal. Thus, the plant management had no formal say in whether the manufacturing integrator was doing the right things to meet manufacturing's needs. Incidentally, manufacturing was the only discipline that waived its right to assess the performance of their "representatives" on the teams, because they felt the manufacturing representatives could be empowered to make the right decisions regarding tradeoffs between rapid product development and design for manufacturing issues. The development procedures allowed no other method of formal input from the manufacturing function such as design sign-off privileges or manufacturability reviews. As will be discussed later, this lack of involvement from the manufacturing function turned out to be a source of tension.

There are six defined phases in Ethicon Endo-Surgery's product development cycle: concept selection, feasibility phase, design phase, engineering pilot (design verification) phase, process verification phase and manufacturing ramp-up phase. Please refer to Figure 3.1 for an overview of deliverables of each phase of the product development cycle.

Typically, the Ethicon Endo-Surgery manufacturing integrator on the development team handles all manufacturing issues until the start of the engineering pilot phase. Then someone from the pilot manufacturing department becomes involved. The pilot manufacturing person acts as a liaison between development and the long-term manufacturing business unit. The pilot manufacturing person and the manufacturing integrator on the team work jointly to ramp-up the manufacturing line, train production employees, and create all necessary production documentation.

Later, the manufacturing business unit's level of involvement begins to increase. When the product and process are deemed ready and FDA grants approval, the product is released for sale. At this point, a sign-off occurs signifying that the product is ready to be marketed and that the processes have been declared capable. At Ethicon Endo-Surgery,
Figure 3.1

Product Development Phases
this sign-off also marks the start of joint ownership between development and the manufacturing business unit. Many of the design engineers on the team begin new work assignments after this sign-off, but the manufacturing-related members of the team remain. At some theoretical point in the future, the product line is declared to be in "steady-state" and it is completely signed over to the manufacturing business unit to support for the remainder of the product's life. The remaining pilot manufacturing and development team representatives are then assigned to successive projects.

3.5 Mission/Strategy of the Organization

So far, Ethicon Endo-Surgery's strategy has been to catch-up with U.S. Surgical. Because of the emphasis to gain a large portion of the endoscopic market, Ethicon Endo-Surgery's primary strategy was to get reliable and safe products to market fast, in all the main endoscopic niches. Now that stage one has been completed successfully, the focus is shifting toward expanding technical innovation and product line breadth. Rather than remain a follower, Ethicon Endo-Surgery intends to be a financially secure and innovative leader in the endoscopic field. However, before this transition can be completed, it may be necessary for Ethicon Endo-Surgery to change some of its ways of thinking.

Development team members within Ethicon Endo-Surgery have reached a level of fairly high status within the company due to both their success and the high level of experience of many team members. With the emphasis on rapid product development, other functions, such as manufacturing, have received less management attention. Thus far, development has had a tendency to give directives to manufacturing rather than soliciting input. With the overwhelming priority of getting the product to the market fast, few teams have made the extra effort to really focus on product manufacturability and process design. It appears that the team members either do not always know how to design a robust process and manufacturable product or choose not to because they think it will save time. Unfortunately, this strategy has occasionally hindered Ethicon Endo-Surgery in the form of delays late in the development cycle (during process verification), large backorders, product redesigns, and inefficient manufacturing lines. According to Susman and Dean (1992), it is typical for development to have a higher status than manufacturing because of such things as education level and compensation differences. However, if a company intends to become proficient at developing and transferring new products to manufacturing, it should learn to address manufacturing issues. Even in companies such
as Ethicon Endo-Surgery that have been very successful in other areas such as marketing, there is always potential to improve manufacturing effectiveness and increase profits. As an added incentive, the FDA will likely continue to press for higher quality and process improvements in the medical equipment industry.

When several high level individuals are put together and labeled a team without receiving any formal team training, they tend to work as a group of individuals (Katzenbach and Smith, 1993). This was evident early-on in some Ethicon Endo-Surgery "teams". Although the team members were to be measured on overall team success, many still compartmentalized the work into individual tasks. Thus, the mindset that "it's his job and I don't have to worry about it" has been observed within some teams. An example of this is the (mistaken) belief that all supplier interactions are to be handled by the procurement representative only and that the other team members are not responsible for it. To succeed in the future, Ethicon Endo-Surgery may need to change their behavior and mindset from that of "working groups" to true teams. The expectation that the whole team needs to be responsible for "individual" tasks should be ingrained in the minds of employees. This is one of the basics of teamwork, and Ethicon Endo-Surgery does seem to be learning this lesson as their team structure matures.

Although most of Ethicon Endo-Surgery products were generally priced lower than the competitor's, manufacturing costs seemed to be of secondary importance during this period of rapid growth. Because U.S. Surgical had dominated the market for so long, their profit margins were high and product costs were only a small fraction of price. This allowed Ethicon Endo-Surgery significant gross profit margins as well. Costs may have to be addressed for Ethicon Endo-Surgery to compete successfully over the long term. Although costs have been less important in the past, increased competition and health-care cost pressures could draw much more attention to them.

How companies like Ethicon Endo-Surgery might design their cross-functional team structure to address the above issues is discussed in Chapter 5 (Recommendations).

Summary

The importance of understanding the company's business environment prior to choosing a strategy cannot be overemphasized. Obviously, no one strategy can be universally applied
to all companies in all situations. There are many factors that affect the choice of business strategy, ranging from external market conditions to internal company cultures. The level of industry competition, the level of industry and company growth, and the company's position as either a market leader or follower will strongly influence a company's product development strategy.

The market analysis in this chapter showed that Ethicon Endo-Surgery is in a fairly competitive market despite the barriers to entry and the fact that there are only two main competitors (like Coke and Pepsi in the soft drink market). The customers are focusing more and more on health-care costs (as is the government). Timing will likely play a major role in winning in the medical equipment industry: development time-to-market, FDA approval cycle time, and production cycle time. Moreover, the FDA will likely expect better quality and process improvements from medical equipment manufacturers.

As Ethicon Endo-Surgery now makes its transition from market follower to market co-leader, it needs to understand these issues. Some new strategies seem to be in order. Fast product development will continue to be important - indicating that cross-functional product development teams will remain in place. If Ethicon Endo-Surgery wishes to become very adept at transferring new products from development to manufacturing, it should treat manufacturing as more of a partner in the development process - by designing manufacturable products and robust processes. The competition in this market with two co-leaders is expected to be fairly intense, thus pointing to the need for price (and cost) flexibility. Compounding the cost pressures is the belief that Johnson & Johnson will expect Ethicon Endo-Surgery to return a larger profit as market leader.

In this thesis, an attempt will be made to show companies how they might improve the relationship between development and manufacturing in the new product "hand-off." As a consequence, the benefits sought by Ethicon Endo-Surgery - faster development time, lower costs, and better quality products and processes - can result.

There is more to a product development strategy than the textbook implementation of cross-functional development teams. Many details relating to the dynamics of cross-functional teams and the corporate "climate" must be understood so that the team structure can be further improved. While cross-functional teams can be beneficial, they may also create unanticipated new problems. The following chapter is a step by step illustration of how a company might determine whether its specific problems have more to
do with the proper implementation of cross-functional teams or the fine-tuning of such teams above and beyond the basic implementation.
CHAPTER 4 APPRAOCH TO COLLECT INFORMATION

Introduction

In this study, the primary on-site research approach used to conceptualize and address the problems surrounding the new product transfer process at Ethicon Endo-Surgery was quality function deployment (QFD). This chapter describes how QFD was used within Ethicon Endo-Surgery to assess the needs of the development and manufacturing functions. Typically, QFD is used to design a product to meet the needs of an external customer. In this case, QFD was used to design the internal process of introducing a new product to manufacturing, as well as to design the supporting organization structure.

4.1 How the QFD was Done

Two QFD processes were conducted between the mutually dependent manufacturing and development organizations. In the first QFD, internal customers (i.e., development teams) of the manufacturing plant were interviewed on what they needed from the manufacturing plant. Their input was summarized and narrowed down to a few key things the manufacturing plant needs to improve upon. The second QFD was done in the opposite direction. That is, internal customers (i.e., the manufacturing plant) of the development teams were interviewed and their needs were summarized. The needs of both groups were put into House of Quality matrices. Analysis was done to characterize the needs.

It should be noted that the internal needs or wants of employees are not always completely correlated with the needs of the external customers or the profit needs of the company. Thus, the needs identified in this internal QFD process had to be considered in the context in which they were attained - asking employees what they wanted from the other business functions. In the sense that most of the needs and recommendations contribute to a faster and more efficient new product introduction process, they do contribute to the needs of the overall business. Nevertheless, throughout this process at Ethicon Endo-Surgery the external business and customer needs were always kept in mind. Pros and cons were thoroughly analyzed before any action plans were implemented.
What follows is a step by step description of how to do such a QFD project. This case-
study can serve as a how-to manual for using QFD internally, or more generally, for any
QFD process. For more detailed information on how to use QFD, the House of Quality,
and Kano characterization, the following are excellent references: Clausing (1994),
Hauser and Clausing (1988), and Shiba (1993).

4.1.1 Internal "Customer" Requirements

The first step in any QFD process is to define who you are (which specific group you
represent) and who your customers are. Although two QFD exercises were done at
Ethicon Endo-Surgery, in this chapter we will use the example where the manufacturing
plant used QFD to assess the needs of its internal customers. (In the second QFD, the
development teams assessed the needs of one of their customers, the manufacturing plant.)
The customers of the manufacturing plant are the primary groups that depend on the plant
to do certain tasks. The primary internal customers are the cross-functional product
development teams, the sales representatives, and the regulatory affairs/compliance
department.

The next step is to come up with a way to attain the "voice of the customer" - to find out
what their needs are. Two common methods are contextual observations and customer
interviews. A combination of contextual observations (working closely with one cross-
functional team) and formal interviewing was used by the author at Ethicon Endo-Surgery.
It is inadvisable (and probably not feasible) to interview 100% of the customers. Rather, a
representative cross-section of the customers - perhaps fifteen individuals of varying
demographics - should be targeted for interviewing. In this case, those interviewed
included at least one person from every discipline (marketing, manufacturing, design, etc.)
on the cross-functional teams, and two to three individuals each from the sales and
regulatory affairs organizations. One must be careful not to include every group as a
customer in the interviewing process - the pool of interviewees should be representative of
only the significant customers. If every possible "customer" is included, the QFD project
quickly becomes excessively cumbersome.

The interviews done at Ethicon Endo-Surgery were typically one-on-one, lasting
approximately one half-hour each. Four open-ended, non leading questions were used as
the basis of each interview (from Shiba, 1993):
1) What images or pictures come to mind when you visualize the manufacturing plant
serving your organization? (This is a warm-up question that provides to the
interviewer a sense of the context of the interactions between the individual and the
plant. Examples of images might include, "dollars flying out the window because the
plant continues to use Federal Express to ship parts to us," or "smiling manufacturing
supervisor presenting information to us each week ")
2) From your experience, what complaints, problems, or weaknesses would you like
to mention about the manufacturing plant's service to your organization? (This
question identifies what the customers currently expect.)
3) What factors do you look for when selecting an individual from the plant to
interface with (or serve) your group? (This question helps determine factors that
shape current perceptions.)
4) What new things could the plant do that might address your future needs? (This
question helps identify future needs that can lead to increased customer satisfaction.)

Of course, the above questions are just a starting point and the interviewer should follow-
up with related questions where appropriate. Some interviewers find that asking, "why?"
several times leads to more useful information. The idea is to get the customer to state
specific needs, not solutions. Tape recording the interview, if acceptable to the customer,
ensures that nothing the customer says will be lost or forgotten.

Once the interview is complete, the next step is to review what the customer said. Two
types of things should be recorded on Post-it notes or index cards and placed on separate
flip-charts or poster-boards: images and needs. Examples of images were given earlier.
A need statement might read, "the manufacturing plant should look at all their overtime
charges each week," or "we want the manufacturing engineers to come to our meetings." If
possible, the exact words the customer used should be duplicated on the cards. At
Ethicon Endo-Surgery, the typical half-hour interview yielded approximately three to four
image cards and ten to twelve need cards.

The next step is to create an "image KJ diagram," named after Japanese anthropologist
Jiro Kawakita. KJ's are also known as affinity diagrams. The image KJ diagram is made
up of the image cards collected in the previous step. The cards should be grouped and
arranged to show relationships between groups of images. An image KJ is displayed in
Figure 4.1. The purpose of the image KJ is to provide the "designer" with images of the
FIGURE 4.1

WHAT IMAGES COME TO MIND WHEN YOU VISUALIZE THE MANUFACTURING PLANT SERVING YOUR ORGANIZATION?

Manufacturing's focus has been primarily on getting products to the market on time.

Manufacturing is concerned with getting volumes of existing products out the door, making it difficult to focus on other tasks.

The "handoff" of a new product into manufacturing has been rough in the past due to inadequate mfg. involvement.

There hasn't been a lot of manufacturing involvement in early development, making for a "rocky" transition into manufacturing.

The communications within manufacturing and other groups has been deficient.

Manufacturing gets an incapeable process "dumped" on them and they have to make do as best they can.

The manufacturing plant overall has had good working relationships with the other functions.

The mfg plant has done a good job of working on product related issues with the development teams, once they get involved.

The mfg personnel have displayed a good attitude while meeting other functions' needs.

The manufacturing plant has done a good job in working with the development teams, overall.

Manufacturing has been an effective source of product improvement ideas to the product development teams.

Manufacturing has known the instrument best - they're closest to it, and the best source of improvement ideas.

Having manufacturing on the same site as development is great - quick feedback on manufacturability.

Overall, manufacturing does a good job in working with the teams.

Manufacturing associates have a cooperative, enthusiastic attitude.

Manufacturing associates are very cooperative and eager to do the right thing and provide help if asked.

Surgeons have been impressed with the people on the line during their tours.

Manufacturing related product inquiries are handled promptly and with good service.

Manufacturing does not yet have world-class ability.

Manufacturing associates do not yet have the same skills as engineers (quality competence, problem analysis & solving skills).

The simple assembly lines here do not seem like world class manufacturing.

It's just a simple "assembly house." It doesn't "feel" like a high quality, world class manufacturing facility.

The manufacturing plant has made "quantum leaps" in the last four years toward world-class manufacturing in the medical device industry.

Team members (Quality and Design Engineers) have stumbled onto a crisis on the line that manufacturing knew about for a while.

There is little or no interaction between my organization and manufacturing (far removed).

The manufacturing plant has done a good job in working with the development teams, overall.

The plant group has done a good job of supporting the teams and bridging the gap between development and manufacturing.

Manufacturing is becoming a full partner with development.

Overall, manufacturing does a good job in working with the teams.

Manufacturing associates have a cooperative, enthusiastic attitude.

Manufacturing associates are very cooperative and eager to do the right thing and provide help if asked.

Surgeons have been impressed with the people on the line during their tours.

Manufacturing related product inquiries are handled promptly and with good service.

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Surgeons have been impressed with the people on the line during their tours.

Manufacturing related product inquiries are handled promptly and with good service.
context in which her product or service is used - contexts that the designer may not have been aware of. This step seems less important in QFD projects where the input will be used to improve internal practices than in QFD projects used to design actual products for external customers. For further details on KJ diagram construction, see Shiba (1993).

With the images clearly in mind, the customer need cards must now be "scrubbed," or reworded, (if necessary) from the original exact words of the customer into specific requirements. When converting the voice of the customer into requirements, it is important to avoid abstract or intangible concepts. Solutions or judgments should be avoided at this stage. The intent is to get all the cards into comparable format and comparable levels of abstraction. Examples of scrubbed requirements might include, "manufacturing overtime is avoided where possible," or "manufacturing engineers are made aware of information covered in meetings."

The next step - and perhaps the most difficult step - is to select the most significant customer requirements from the many requirements collected. If fifteen interviews were conducted and each yielded ten to twelve needs, a total of 150 to 180 needs could be attained. It is recommended that the needs be narrowed down to the ten or twenty vital few needs that can be further analyzed and targeted for corrective action. The number of needs can be reduced simply by grouping similar needs and eliminating duplicates. After that, the most significant needs can be selected based on any of several criteria - frequency of mention, judgment of relevance, or ability of the particular group to address the need. At Ethicon Endo-Surgery, a total of 151 needs was narrowed down to eighteen. Frequency of mention and the ability of the manufacturing plant to address the needs were the criteria used to get to the final eighteen needs.

The next step is to categorize the needs into five or fewer groups. Again, the tool to do this should be the KJ diagram. The KJ diagram, if properly done, will display the ten to twenty customer requirement cards in groups. Arrows should be used on the diagram to show relationships between the need groups. The KJ diagram is a very useful tool for understanding problems and the relationships between them. Figure 4.2 contains the KJ of things the internal customers need from Ethicon Endo-Surgery's manufacturing plant.

To characterize and prioritize the remaining needs in an objective, quantitative manner, questionnaires should be sent to a representative sampling of the customers. The
questionnaire at Ethicon Endo-Surgery contained the following questions for each of the ten to twenty customer requirements.

1) On a scale of one to five, rank the importance of this customer requirement.

2) How would you feel if the manufacturing plant offered this customer requirement?
   a) I like it that way.
   b) It is a basic necessity -- I expect it that way.
   c) I am neutral.
   d) I dislike it, but I can live with it that way.
   e) I dislike it, and I can't accept it.

3) How would you feel if the manufacturing plant DID NOT offer this customer requirement?
   a) I like it that way.
   b) I expect it that way.
   c) I am neutral.
   d) I dislike it, but I can live with it that way.
   e) I dislike it, and I can't accept it.

4) How is the manufacturing plant doing in meeting your needs on this customer requirement? (Scale of one to five)

5) From your experience, how are the other manufacturing plants (internal "competitors") doing on this customer requirement? (Scale of one to five)

The actual survey used at Ethicon Endo-Surgery is included in Appendix A. The survey questions above will not only tell the relative importance of each need (from Question 1), but also the nature of the need (Questions 2-3) and an assessment of "how we're doing" in meeting that need (Questions 4-5). The nature of the need refers to the characterization scheme first proposed by Kano (1984). Under the Kano characterization scheme, needs are characterized as "must-bes, delighters, linear satisfiers, indifferenters or reverses", depending on how the customer answers Questions 2 and 3 above (Shiba, 1993). These types are described below:

1) Must-be: These are things that the customer feels he must have. An example would be headlights on an automobile. They are expected to be there. If headlights are not on an automobile, the customer is dissatisfied. If headlights are present, the customer is only neutral because it is a basic expectation.
2) Delighter, or Nicety: These are things that go above and beyond the customers' basic expectations, to their delight. An example would be a side-door air-bag in an automobile. If this feature is not there, the customer is neutral because they do not expect it. If this feature is there, the customer is delighted — assuming she doesn't have to pay an arm and a leg for it.

3) Linear Satisfier, or One-Dimensional: The more you have of these things, the more the customer is satisfied. An example would be miles-per-gallon in an automobile. All other factors held constant, the higher the miles-per-gallon, the higher the customer's satisfaction.

4) Indifferent: On these items, the customers either did not lump the "need" into one of the above categories, or the majority of customers did not feel strongly about the need. An example might be whether the automobile salesperson has a college degree or not. As the name "indifferent" indicates, most of the customers are indifferent about the "need" being satisfied or not.

5) Reverses: With reverses, the item you thought was needed by your customers actually turned out to be not needed. That is, the majority of customers indicated on the survey that they preferred the opposite case (in Question 3) over the one originally proposed (in Question 2).

At this point in the QFD process, the customer requirement/data collection phase is complete. By understanding the nature of the internal customer's needs, Ethicon Endo-Surgery's manufacturing management had a tool to help them decide which needs should be addressed first. However, additional analysis on the needs and their interrelationships was done to further help the management choose a course of action. The following section describes how the House of Quality tool was used to help Ethicon Endo-Surgery's manufacturing plant figure out what it should do to meet the needs of its internal customers.

4.1.2 Completing the House of Quality

The tool used in QFD to display all the information collected on customer requirements is called the House of Quality. The House of Quality diagram created by Ethicon Endo-Surgery's manufacturing plant is displayed in Figure 4.3. In this section, the procedure to create each section of that House of Quality is described. For a thorough introduction to creating a House of Quality, refer to Hauser and Clausing (1988).
Ethicon Endo-Surgery's House of Quality started with the eighteen customer needs derived in the previous section. These are grouped and listed along the left side of the House of Quality in Figure 4.3. Those needs were then "built" upon to complete the House of Quality. When done, the House will contain most of the essential information on each need and on the interrelationships between the needs.

The data collected in the QFD questionnaire can immediately be added to the House. Each need's relative importance, Kano characterization, and competitive assessment scores are listed in the columns on the far right side of the House of Quality. Ethicon Endo-Surgery included two optional columns as well: importance of the need to the plant (not just to the customer) and level of implementation difficulty. Additional columns containing other related information on the needs may be included if so desired.

The next thing Ethicon Endo-Surgery did was list metrics that would be good indicators of how well they are doing in meeting each need. A group of the manufacturing plant's managers brain-stormed on metrics indicative of each customer need. The metrics included existing measurements that were already being tracked as well as new ones. For each need, one or two of the most relevant metrics were selected that directly affect the perception of that need - either positively or negatively. These are listed across the top of the House shown in Figure 4.3. For example, one of the needs identified at Ethicon Endo-Surgery was for the production employees to have better problem-solving abilities. A metric that would strongly correlate to that need would be the number of production employees that have completed Ethicon Endo-Surgery's problem-solving class.

How strongly the metrics correlate to the needs is the essence of the center portion of the House of Quality - the needs versus metrics matrix. The matrix maps each need against each metric. If there is a relationship between the two, a symbol is placed at their intersection indicating a strong, moderate or weak relationship (or blank if no relation at all). A good way to complete this matrix is to ask, for each metric and need combination, "if this metric goes up, will it impact customer satisfaction on this need?" The purpose of completing this matrix of correlation is to understand which metrics are most important and provide for the most leverage in satisfying customer needs.
The next step should be to fill out the bottom portion of the House of Quality. In this section, actual numeric values for each of the metrics are input. If available, target measurements and competitive benchmarks also prove very useful in understanding relative performance. Of course, other optional information on costs or difficulty in improving the metrics can be listed in this section as well.

The final step to complete the basic House of Quality is to fill in the "roof" matrix. In this section, the relationships between the metric's are listed. The purpose of the roof is to assess the tradeoffs involved if one metric impacts another. For example, at Ethicon Endo-Surgery, two of the metrics identified were (1) manufacturing costs and (2) number of manufacturing engineers. If the number of manufacturing engineers is increased, their additional salaries negatively impact costs. This is an example of a tradeoff. (However, it could be argued that the manufacturing engineers will pay for themselves via process improvement savings!) Management should carefully analyze the impacts of such a tradeoff in order to make the best decision. Similar to the needs versus metrics matrix, the metrics versus metrics matrix contains symbols that indicate whether the two metrics have negative tradeoffs, a weak relationship, or positive complementary relationships.

Once the House of Quality diagram is complete, users have almost all the valuable information they need to make a decision. Armed with this knowledge, management can select areas for concentrated efforts. For example, they may choose to first address those customer needs that were considered very important to the customers and in which they scored poorly, yet whose implementation involves few negative tradeoffs. At Ethicon Endo-Surgery, the House of Quality diagram has been used to make improvements and shape strategy for the manufacturing plant.

Remember, a second QFD exercise was completed at Ethicon Endo-Surgery when the development teams assessed the needs of the manufacturing plant. That procedure mirrored the one described earlier. By formally analyzing what development and manufacturing expect of one another, Ethicon Endo-Surgery took the first step toward improving the transfer of a new product from development to manufacturing. In the following section, the actual results of both QFDs are presented.
4.2 Results: Internal Customer Needs Identified

The preceding pages of this chapter have described how to carry out a QFD project. What follows is a description of what information was collected and how that will benefit Ethicon Endo-Surgery.

At the conclusion of the QFD data collection project, there were few surprises in terms of the qualitative content of the QFD results. People had been talking about many of the identified problems for years. What the QFD project offered that was new and different was the formal mechanism for managers to characterize and prioritize the problems, and then decide how to best address those problems. The QFD provides quantitative information on how important the problems are to the customers, how well the groups are doing in meeting their customer needs relative to competitors, and how difficult the problems will be to address. QFD provides the managers a way to understand the problems they face and their interrelationships. The KJ diagrams provide a mechanism for understanding the causes and effects surrounding a particular issue. The House of Quality diagram formalizes the tradeoffs between customer needs and the actions the group can take to address them. Without QFD, the managers at best only have a vague idea about how and why they should address each issue. A final benefit of QFD is the fact that it is customer-driven. That is, when you do a QFD project you take it upon yourself to improve what you can control. This approach seems to make more sense than trying to tell some other group what they need to do to satisfy you.

4.2.1 What Development Needs From Manufacturing

The primary needs the manufacturing plant's internal customers (primarily development teams) identified are covered in this section. The main categories are roughly listed in order of importance. It is important to note that some of these needs may already be satisfied. However, they are still listed as things the internal customers expect. The needs fall into five categories:

1) Manufacturing needs to have a high level of skill and empowerment.
2) Manufacturing needs to get involved in the design of the product and process.
3) Manufacturing processes need to be cost effective and on time.
4) Manufacturing needs to do a better job of communicating and using information.
5) Manufacturing needs to understand and explain its roles and responsibilities

Please refer to Table 4.1 for details on the actual needs under each category, as well as the scores from the QFD survey. Figure 4.2 (the KJ diagram of the needs, presented earlier) serves as a supplement to Table 4.1. The KJ diagram was beneficial in that it helped to show the relationship among the five categories of needs. For example, listed item number three ("cost effective and on-time"), will undoubtedly be a positive side effect if manufacturing can meet the other four needs. Conversely, addressing item three by itself will likely be ineffectual unless the other needs are addressed simultaneously.

One of the surprising things that manufacturing found out by doing this QFD was the important role their attitudes play in satisfying their customers in development. The internal customers ranked "world-class attitude" a 4.8 out of 5.0 on the importance scale. Surprisingly, this was deemed more important than on-time delivery, technical problem solving ability and cost-effectiveness. The QFD also showed manufacturing that they are not meeting some of the needs that the customers considered "must-bes." This told manufacturing that they should improve in the areas of cost reduction, early manufacturing involvement, and understanding the technical "intent" of the product design (why the design was designed the way it was). Finally, the local manufacturing plant scored higher than the remote plants in communications, but unexpectedly worse in providing technical support, participating in early manufacturing involvement, and understanding design technicalities. These issues will be directly addressed in the recommendations.

The QFD diagram provided insight into the things manufacturing management can do to impact customer satisfaction. For example, by training operators and implementing SPC, manufacturing can likely improve it's rating in the "quality system" need expressed by their internal customers. Similarly, the QFD interrelationships show that quality can be indirectly improved by solving other problems, such as training in problem solving, keeping track of production data, and hiring additional technical support people.

4.2.2 What Manufacturing Needs From Development

The primary things manufacturing needs from its representatives on the product development teams are summarized next.
<table>
<thead>
<tr>
<th>NEED OPERATIONS TO BE EMPOWERED</th>
<th>Importance to Customers</th>
<th>Difficult to Implement</th>
<th>Nature of This Need (Kano)</th>
<th>COMPETITIVE ASSESSMENT</th>
<th>Cincinnati Plant</th>
<th>Other ESS Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>WORLD CLASS ATTITUDE: Manufacturing should have a &quot;World Class&quot; attitude. (Enthusiastic, cooperative, proactive, see big-picture, take ownership, challenge others, etc.)</td>
<td>4.8</td>
<td>3</td>
<td>Nice</td>
<td>2.7</td>
<td>2.4</td>
<td></td>
</tr>
<tr>
<td>UNDERSTAND GMP/COMPLIANCE: Manufacturing Associates should understand the importance to the business of complying with GMP and quality</td>
<td>4.5</td>
<td>3</td>
<td>Nice</td>
<td>3.2</td>
<td>3.6</td>
<td></td>
</tr>
<tr>
<td>TECHNICAL SUPPORT PEOPLE: Need more technical support people in operations to take over and maintain all responsibilities for ongoing product or process design issues.</td>
<td>3.9</td>
<td>5</td>
<td>Nice</td>
<td>1.5</td>
<td>2.6</td>
<td></td>
</tr>
<tr>
<td>PROBLEM SOLVING ABILITY: Manufacturing associates should be able to analyze and solve problems themselves.</td>
<td>4.5</td>
<td>3</td>
<td>Nice</td>
<td>2.0</td>
<td>2.3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEED MANUFACTURING TO BE INVOLVED IN DESIGN</th>
<th>Importance to Customers</th>
<th>Difficult to Implement</th>
<th>Nature of This Need (Kano)</th>
<th>COMPETITIVE ASSESSMENT</th>
<th>Cincinnati Plant</th>
<th>Other ESS Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNDERSTAND DESIGN INTENT: Manufacturing Business Units should understand the technical intent of the product's design.</td>
<td>4.8</td>
<td>4</td>
<td>Must</td>
<td>1.9</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>EARLY MANUFACTURING INVOLVEMENT: Manufacturing Business Units need to be aware of and involved in significant development issues when the</td>
<td>4.0</td>
<td>5</td>
<td>Must</td>
<td>2.1</td>
<td>3.0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEED OPERATIONS TO BE COST EFFECTIVE AND ON TIME</th>
<th>Importance to Customers</th>
<th>Difficult to Implement</th>
<th>Nature of This Need (Kano)</th>
<th>COMPETITIVE ASSESSMENT</th>
<th>Cincinnati Plant</th>
<th>Other ESS Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>ON TIME DELIVERY: Manufacturing needs to deliver (products or services) to requesting groups on time.</td>
<td>4.5</td>
<td>3</td>
<td>?</td>
<td>3.4</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>CFM IN OPERATIONS: Operations needs to practice Continuous Flow Manufacturing (CFM) along entire chain. (Minimal inventory and cycle times;</td>
<td>4.5</td>
<td>4</td>
<td>?</td>
<td>2.5</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>REDUCE COSTS: Manufacturing costs (labor, material and overhead) need to be reduced.</td>
<td>4.7</td>
<td>4</td>
<td>?</td>
<td>2.7</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>STANDARD PROCESS VALIDATION: A standardized process validation procedure should be used across all product lines to ensure stable, capable</td>
<td>3.7</td>
<td>5</td>
<td>?</td>
<td>2.2</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>CONSISTENT MFG/TEST PROCESSES: Consistent production and test processes should be used across different product lines. (Examples: leak tests, quality systems.)</td>
<td>2.7</td>
<td>3</td>
<td>?</td>
<td>3.2</td>
<td>2.7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEED OPERATIONS TO SHARE AND USE INFORMATION</th>
<th>Importance to Customers</th>
<th>Difficult to Implement</th>
<th>Nature of This Need (Kano)</th>
<th>COMPETITIVE ASSESSMENT</th>
<th>Cincinnati Plant</th>
<th>Other ESS Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGULAR INFO EXCHANGE: Manufacturing needs to regularly exchange knowledge with my team/group on issues, production information, and strategy.</td>
<td>4.3</td>
<td>1</td>
<td>Nice</td>
<td>2.7</td>
<td>2.6</td>
<td></td>
</tr>
<tr>
<td>COMMUNICATION INTERFACE: An individual from manufacturing should be designated as the communications interface to my group.</td>
<td>3.7</td>
<td>1</td>
<td>Nice</td>
<td>3.2</td>
<td>2.6</td>
<td></td>
</tr>
<tr>
<td>BETTER QUALITY SYSTEM: A more sophisticated quality system should be used to monitor and improve quality levels.</td>
<td>3.5</td>
<td>3</td>
<td>Nice</td>
<td>3.2</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>EARLY PRODUCTION TRACKING: Production batch information should be tracked and made available as per GMP guidelines from the pilots onward.</td>
<td>3.7</td>
<td>1</td>
<td>Nice</td>
<td>3.2</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>INVENTORY MGMT SYSTEM: There should be an inventory management system in use with at least 99% accuracy, cycle-counting, and inventory visibility.</td>
<td>2.8</td>
<td>3</td>
<td>Nice</td>
<td>2.6</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>BETTER BACKORDER ANALYSIS: More thorough analysis should be done during backorders to determine which course of action is best for the company.</td>
<td>3.4</td>
<td>5</td>
<td>Nice</td>
<td>2.6</td>
<td>2.6</td>
<td></td>
</tr>
<tr>
<td>UNDERSTAND RESPONSABILITIES: Responsibilities of the Pilot Group and the Manufacturing Business Units should be explained to and understood by the development teams.</td>
<td>3.9</td>
<td>3</td>
<td>Nice</td>
<td>2.0</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>
1) Manufacturing should be allowed to be a partner in development.
2) Development needs to provide clear and thorough development information.
3) Need development to be responsible for a "good" product and process.
4) Need development team representatives to have good business skills (particularly manufacturing know-how).
5) Need development to minimize late design changes.

Table 4.2 provides details on the actual needs under each category, as well as the scores from the QFD survey. Figure 4.4 contains the KJ diagram of the needs. Similar to the earlier KJ diagram, this KJ showed the relationships between the needs. For instance, in order for development to design a good product and process (number three above), they should try to meet the other four needs (partner with manufacturing, communicate information well, upgrade their business skills, and minimize late design changes).

The House of Quality diagram helped development to see the tradeoffs involved in addressing the various needs brought to their attention from manufacturing. In general, there seemed to be a negative relationship between serving some of manufacturing's needs and meeting project timelines. Example: while it may prove beneficial in the long-run, visiting and understanding remote manufacturing facilities takes away from the time designers could be designing their new product.

The QFD project served as a bit of a "wake-up call" to the development organization at Ethicon Endo-Surgery. For instance, they learned that on a scale of one (not very satisfied) to five (very satisfied), manufacturing only gave development an average score of 1.9 on all of the needs listed in the survey. This low score may be partially explained by feelings of dissension on the part of manufacturing personnel not selected to be on the higher status cross-functional teams. However, the low scores are also a clear indication that development could do a better job of meeting the manufacturability needs of their partners in manufacturing.

The three most important needs, according to manufacturing, are that development listens to and respects them as a partner; that the development schedule should be realistic and thorough; and that development does a better job of designing for manufacturability. These needs were rated as much more important than development's "people skills," development cost reduction activities, and reducing the number of late design changes.
### Table 4.2

<table>
<thead>
<tr>
<th>What do the Manufacturing Plants need from the Product Development Teams?</th>
<th>Nature of This Need (Kano)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPERATIONS SHOULD BE A PARTNER IN DEVELOPMENT</strong></td>
<td></td>
</tr>
<tr>
<td>The Product Development (P.D.) teams should listen to, respect and recognize Operations as a partner.</td>
<td>5.0 Must</td>
</tr>
<tr>
<td>There needs to be regular communications on relevant issues between Development and Operations throughout the development cycle.</td>
<td>4.9 Must</td>
</tr>
<tr>
<td>The P.D. team needs to solicit involvement from Operations early in the development cycle to address manufacturing/packaging issues.</td>
<td>4.7 Must</td>
</tr>
<tr>
<td>Operations should have formal representation in the development process (i.e., appraisal of Mfg. Integrator's performance and sign-off privileges).</td>
<td>4.4 Must</td>
</tr>
<tr>
<td>The P.D. teams' performance incentives should be consistent with Operations' performance incentives.</td>
<td>4.3 Must</td>
</tr>
<tr>
<td><strong>NEED CLEAR AND THOROUGH DEVELOPMENT INFORMATION</strong></td>
<td></td>
</tr>
<tr>
<td>The development schedule/plan should be realistic and thorough.</td>
<td>5.0 ?</td>
</tr>
<tr>
<td>Knowledge of the product and process should be transferred to operations by way of clear and complete documents, videos, design meeting minutes, user-friendly training and FMEAs/fault tree analysis, etc.</td>
<td>4.6 Must</td>
</tr>
<tr>
<td>Release and steady-state signoffs should be clearly defined with metrics such as quality, scrap, costs, cycle times and market penetration.</td>
<td>4.3 Nice</td>
</tr>
<tr>
<td>The Mfg. Integrator's duties should be clearly defined relative to other team members and Operations personnel involved.</td>
<td>3.9 Nice</td>
</tr>
<tr>
<td><strong>NEED DEVELOPMENT TO BE RESPONSIBLE FOR GOOD PRODUCT &amp; PROCESS</strong></td>
<td></td>
</tr>
<tr>
<td>The P.D. teams need to design products for manufacturability (DFM: = fewer parts, minimal equipment, simple assembly).</td>
<td>5.0 Linear</td>
</tr>
<tr>
<td>The P.D. team needs to ensure that suppliers have capable processes and are</td>
<td>4.6 Must</td>
</tr>
<tr>
<td>The Product Development (P.D.) team should provide support and resolve issues after the product transfers to Operations.</td>
<td>4.5 Must</td>
</tr>
<tr>
<td>The P.D. team should test a wide variety of product end-uses and process conditions to validate robustness and capability.</td>
<td>4.2 Must</td>
</tr>
<tr>
<td>The P.D. team should have sole responsibility for COGS until steady-state.</td>
<td>4.0 Must</td>
</tr>
<tr>
<td><strong>NEED TEAM REPS TO HAVE GOOD BUSINESS SKILLS</strong></td>
<td></td>
</tr>
<tr>
<td>Manufacturing (Mfg.) Integrators on the P.D. teams need to visit and understand all the processes their product goes through (like sterilization, packaging, and</td>
<td>4.6 Must</td>
</tr>
<tr>
<td>Representatives on the P.D. teams should have a strong knowledge of quality systems and validation methods.</td>
<td>4.6 Must</td>
</tr>
<tr>
<td>The Mfg. Integrators need to be strong influencers who stand up for Operations' needs during development activity.</td>
<td>4.6 Must</td>
</tr>
<tr>
<td>The P.D. teams need to understand the objectives, goals and strategies of the three</td>
<td>4.1 Linear</td>
</tr>
<tr>
<td>The Mfg. Integrator should be a &quot;people person&quot; with good communication skills and should get along with all levels and disciplines.</td>
<td>3.1 Indif.</td>
</tr>
<tr>
<td><strong>NEED DEVELOPMENT TO MINIMIZE LATE CAFs</strong></td>
<td></td>
</tr>
<tr>
<td>From the manufacturing pilot onward, the P.D. team should minimize changes (temporary or permanent).</td>
<td>3.1 Nice</td>
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</tbody>
</table>
WHAT DO THE MANUFACTURING PLANTS NEED FROM THE PRODUCT DEVELOPMENT TEAM?
In general development did the poorest in representing and involving manufacturing in the whole development effort. They were doing a better job of meeting manufacturing's needs in the areas of people skills and in testing product and process conditions. Considering the Kano analysis within the QFD, manufacturing strongly felt that development *must* do several things in order for the hand-off to manufacturing to be smooth: communicate with manufacturing, partner with manufacturing, and validate production process capabilities. In Chapter 5, some of these needs are addressed in the recommendations.

Summary

The QFD project served as a good way for the author to gather information relating to the hand-off of new products from development to manufacturing. As opposed to interviews or questionnaires alone which generate bits of anecdotal data about a managerial problem, QFD seems preferable in many situations where more thorough, objective, quantitative information is needed. It is clear that QFD is not just for designing new products. QFD appears to be especially promising for reengineering-type projects where business processes (such as the new product hand-off to manufacturing) are being thoroughly analyzed and then redesigned to be faster, cheaper, and more effective.

The strongest general theme that emerged from the study was that manufacturing felt that their "representatives" on the development teams were not meeting their expectations. As is evident above, most of the needs that surfaced in the QFD process were found to both manufacturing and development. Figure 4.5 demonstrates this, by combining all the specific needs on one chart. Although they vary in magnitude, these needs are common in development and manufacturing divisions of other companies in other industries. The lessons learned from this QFD project can be transferred to many companies that engage in both development and manufacturing functions. The needs identified here, along with external business needs and information gathered from management and academic literature, will now be used to shape general recommendations regarding the transfer of new products from cross-functional development teams to manufacturing.
- Understanding of "secondary" operations.
- Better backorder analysis.
- Clear, synchronized plans/schedules.
- Consistency across teams/lines.
- Better process/supplier validation.
- Technical support after Fact-Book.
- Understand and use CPM.
- Definition of responsibilities.
- Use DFM/A in product design.
- Reduce costs.
- Involvement in ds:development.
- Knowledge of quality systems and GMP.
- Good attitude and "people" skills.
- Problem-solving skills/abilities.
- Regular & better communications.
- Formal appraisals and sign-off privileges.
- Dev to listen/respect Mg as a partner.
- CQCs/backorders) until Steady-State.
- PD teams should "own" the product.
- Stand up for Mg.
- Strong, influential Mg. Integrators who manage.
- Minimal CQPs from Mg. Pilot on.
- More consistent incentives with Dev.
- New Product Transition Into Manufacturing.
CHAPTER 5. RECOMMENDATIONS

Introduction

In this chapter, the information collected thus far is used to shape general recommendations regarding the transfer of new products from the development teams to the manufacturing function. Using the internal customer needs identified through the QFD process (Chapter 4) as a starting point, a set of alternative solutions is proposed to address those needs. Four recommendations are then analyzed in detail or are applied on a trial basis, to determine their validity. Benefits and trade-offs involved in implementing these recommendations are presented. (A trial-basis experiment with one cross-functional product development team is presented in Chapter 6 to shed further light on some of the proposed solutions.) Of course, in setting any corporate strategy, it is necessary to consider the company's business environment (Chapter 3) as well as important management and academic concepts (Chapter 2).

5.1 Approach for Generation and Analysis of Alternative Solutions

The internal QFD process provided an understanding of the needs, or problem areas, identified by employees in development and manufacturing functions. The identified problem areas served as a starting point in determining possible courses of corrective action. For review, the primary objective of this study was to find ways to improve the process of transferring a new product from development to manufacturing, primarily in the context of cross-functional product development teams.

A critical success factor in any company is to meet the needs of real customers. During the course of generating alternative solutions to this project, the external customers' needs were carefully considered. Besides customer needs relating to product featurization, there are four other categories of external customer needs (source: Ethicon Endo-Surgery market research). They are: (1) product quality (i.e. consistent performance; no defective or missing components), (2) good value for the money, (3) a good ordering process (i.e., ease of ordering; reliability accuracy and timeliness of the order fulfillment process; and availability), and (4) fast development speed-to-market. The recommendations to follow - while focused on the internal process of developing and transferring new products to
production - contribute to the external customer needs simultaneously. What follows is a description of how alternative solutions were generated and analyzed.

The first step was to take the needs identified through both QFDs and sort them into two categories: (1) those that were "obvious" (meaning well documented in the management and academic literature), inexpensive, or easy to address, and (2) those that needed further research relating to the topic of handing-off a new product from a cross-functional development team to manufacturing. The House of Quality served as an invaluable reference at this time. First, the numerical survey scores and the "implementation difficulty" scores showed which needs were straight-forward and which were more controversial. Second, the tradeoffs and interrelationships between and among the needs and metrics indicated which items would be easy to address and which would be more difficult.

Table 5.1 provides a conceptual map of the solutions proposed to meet the needs identified. The alternative solutions were generated from a combination of sources including literature from management and academia, and brainstorming with Ethicon Endo-Surgery employees. The first column of Table 5.1 contains the list of relevant needs identified through the development and manufacturing QFD projects. The second and third columns sort the needs into those that were obvious, inexpensive, or easy to address, or those that needed further research. The solutions requiring further research are analyzed in detail in this chapter. Alternative solutions are listed in the last column.

Those issues that were termed "obvious, inexpensive, or easy to address" are not discussed further here. However, detailed recommendations relating to those issues can be found in numerous management and academic publications. They directly relate to the process of transferring a new product from cross-functional development teams into manufacturing. In short, those recommendations revolve around the importance of training, communicating and partnering between development and manufacturing, and the importance of testing a variety of product and process conditions before handing a new product to the manufacturing organization.

Those "hand-off needs" from Table 5.1 that required further research make up the essence of this thesis. They have been sorted into four main proposals and are previewed next.
<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve process efficiency.</td>
<td>Reduce waste and improve flow.</td>
</tr>
<tr>
<td>Focus on customer needs.</td>
<td>Understand customer requirements.</td>
</tr>
<tr>
<td>Develop new products.</td>
<td>Increase product innovation.</td>
</tr>
<tr>
<td>Support organization goals.</td>
<td>Align with organizational objectives.</td>
</tr>
<tr>
<td>Ensure employee engagement.</td>
<td>Boost employee morale and motivation.</td>
</tr>
</tbody>
</table>

### Proposed Solutions

- **Hand-off Needs**: Identify areas where hand-offs are frequent and improve communication.
- **Additional Alternate Solutions**: Implement cross-functional training.

### Obvious, Easy, or Obsolete

- **Design**: Focus on customer feedback.
- **Development**: Use agile methodologies.
- **Manufacturing**: Implement just-in-time manufacturing.

### Needs

- **Development**: Conduct regular reviews and updates.
- **Manufacturing**:推行持续改进措施。
1) Early Manufacturing Involvement Needs
- "Partnering" early in the development process is needed between manufacturing and development teams on manufacturability issues. How can manufacturing be even more involved in important development decisions?
- An effective method of transferring technical design knowledge from development teams to manufacturing is needed. How can this knowledge about the product design be transferred to the proper people in manufacturing?

2) Needs Relating to Development's Responsibilities
- Formal milestones in the development and product transfer process should perhaps be defined with metrics such as quality levels, scrap, costs, cycle times and market penetration, as opposed to merely using consensus and signatures. What is the best way for formal milestones to be defined?
- Development may need to have more responsibility for the product (costs, design changes, backorders, etc.) until the product reaches specified "steady-state" levels. Which group, manufacturing or development, is in a better position to "own" the project?

3) Manufacturing's Need for Representation
Manufacturing may need some form of formal representation in the development process, perhaps even beyond the manufacturing representatives on development teams. What form should this formal representation take?

4) Need for Simulation and CFM
Production and distribution networks need to be designed for continuous flow manufacturing (CFM). How?

It is interesting to note that the above issues seem fairly generic. That is, they seem applicable at almost any company that develops and manufactures discrete products. After the above needs were selected for further research, the next step was to determine possible courses of action that would address each need. What follows is the analysis of each of the four recommendations. For each of the four recommendations, alternatives are first discussed, then one alternative is selected by the author and analyzed in detail.
5.2 Recommendation 1: Involve the Long-term Manufacturing Support People Early

5.2.1-a Manufacturing/Development Partnering Alternatives

How can manufacturing be more involved in important development issues and decisions? The primary alternatives that were considered by the author are described below.

1) Use a cross-functional development team structure and allow team representatives to speak for manufacturing.
2) Assign the long-term manufacturing personnel to the development project part time from the project's inception (in addition to the manufacturing representatives already on the development teams).
3) Organize the manufacturing plant into two groups: one dedicated to supporting emerging products (under development) and one for the existing products.

At Ethicon Endo-Surgery, the first approach was not working as well as they thought it would. A person with a manufacturing background was placed on each team, but poor design-for-manufacturability had still resulted on occasion and had even led to product redesigns. A combination of factors probably led to this: lack of training and experience in team roles, lack of early manufacturing influence on design, or no formal ties between the manufacturing representatives and the manufacturing function. In alternative three, the emerging products department - or pilot manufacturing department - would act as a coordinator between the development teams and the long-term manufacturing group in ramping-up new products. The trouble with this option is that it adds a "middleman" between development and the long-term manufacturing group. That means more "hand-offs" between groups, and the associated training, overlapping responsibilities, and other difficulties associated in hand-offs.

Some form of early-manufacturing-involvement (EMI) is recommended by the experts. They generally say that the more and the earlier the involvement, the better (Coughlan, 1992). Dean and Susman (1989) go so far as to propose four different levels of manufacturing involvement, depending on how advanced the company is in its EMI efforts. Because of the downsides of the alternatives, option two was chosen by the author for further study. It proposed that the long-term manufacturing support should be involved with the product development team members on a part time basis from the project's start.
5.2.1-b Knowledge Transfer Alternatives

How can knowledge about the product's design intent (why the design was designed the way it was) be transferred to the proper people in manufacturing? The primary alternatives that were considered are described below.

1) Train manufacturing well on design intent/reasoning after design is done.
2) Transfer the development team members into manufacturing along with the project.
3) Assign the long-term manufacturing personnel to the development project part time from the project's inception (in addition to the manufacturing representatives already on the development teams).

The first option occurs too late for manufacturing to have much of an impact on the design. While it is necessary to train manufacturing personnel who have not been involved in the development effort, it is more desirable to get them involved early enough so they do not require training. While the second option sounds good in theory and has been implemented successfully in many Japanese companies (Westney and Sakakibara, 1986), it seems unlikely to be warmly received by Western companies because of the status differences between development and manufacturing functions. It also may take developers away from their chosen occupation. The alternative selected for further study was number three. By involving the people who will ultimately run the manufacturing line, the need for training additional people is reduced and simplified. Note that this alternative can be combined with the alternative chosen in Section 5.2.1-a to create the recommendation that is analyzed in detail next.

5.2.2 Analysis of Recommendation 1: Involve the Long-term Manufacturing Support People Early

Above and beyond the manufacturing representative(s) already on a cross-functional product development team, how should the long-term manufacturing support staff be structured to best develop and introduce the new product? When should the manufacturing engineers, supervisors, production employees, and planners start becoming involved in the product development effort?
In one of the Japanese industry's best practices, the cross-functional team members remain with the product throughout the product's life as it goes through all the development and manufacturing phases (Westney and Sakakibara, 1986). Who else knows the product and process better than the team that nurtured it from a concept to full-scale production? This option eliminates costly and time-consuming product "hand-offs." It reduces the need to train or transfer responsibilities to people outside the team. However, this seems unrealistic in most Western companies because of the length of time it ties up the individual design team members and keeps them from their chosen career paths. Going from a development setting into a production setting may also be thought of as a step down for many employees.

Until the above option is proven to work in many American companies, the question remains: when should the long-term manufacturing engineers, supervisors, production employees, and planners start becoming involved in the product development effort? The proposed answer is that the long-term manufacturing support (in addition to the manufacturing representatives already on the development team) should become involved with the product development team on a part-time basis from the project's inception.

The reader may be wondering why the manufacturing representative on the cross-functional development team cannot fill this role without needing additional headcount from manufacturing. The fact remains that the project (and the associated responsibility) will eventually have to be handed-off from one group of people (the team) to another (the manufacturing department). Thus, the primary benefit of involving the manufacturing function early is not for them to do the job of the manufacturing representative on the team but rather to gain valuable technical knowledge they will need when they eventually accept responsibility for the new product.

As a related observation, large "middleman" groups such as pilot manufacturing groups may prevent the development teams from talking to their long-term "customers" in manufacturing. While supporting the development team in producing early batches of products, they may inadvertently serve as a screen that prevents the long-term manufacturing group from learning the necessary product and process information uncovered during the development and production ramp-up phases. Because of the training and overlapping responsibilities involved, pilot departments may actually increase the overall headcount involved in transferring a new product to manufacturing. Why not
bypass the middleman and have the long-term manufacturing support fill the same role? The effort required to keep the ultimate manufacturing engineers, planners, supervisors and other manufacturing employees up to speed on the development project in its early phases is estimated to be less than a-tenth of the effort they put into supporting existing product lines. Please refer to Figure 5.1, which graphically shows the development and manufacturing headcount involved throughout the various development phases, a) for a typical Ethicon Endo-Surgery product development effort, and b) for the proposed development effort.

The payoff of getting the long-term manufacturing personnel involved early can be enormous. The development team can be immediately informed of manufacturing capabilities, the product's level of manufacturability, and procedural aspects of ramping-up a new product. It has been shown that the number of manufacturing related people involved in a product development effort has an inverse relationship to the number of late, time consuming, costly design changes (Coughlan, 1992). Better manufacturing processes and a higher quality product design can result.

The communication between manufacturing and development that results from such early manufacturing involvement is invaluable. As the QFD processes have shown, communication (or the lack thereof) is one of the top concerns of both development and manufacturing personnel. What better way is there to promote communication than to assign manufacturing personnel as contact points for the development project?

On the other hand, manufacturing can also benefit greatly, not only from the improved manufacturability but also from having a very knowledgeable manufacturing staff at the end of the development effort. No after-the-fact training can match the level of knowledge acquired by the long-term manufacturing involvement in the evolution of the product and process design. The manufacturing staff will know the intent of the design (why the product was designed the way it was). They will know the strengths and weaknesses of the design and the potential causes of defects. They will know the capabilities of the production process. Such information should prove to be very valuable in the future when production issues arise or design changes become necessary.

There are some downsides to such early manufacturing involvement. When individuals from manufacturing are assigned to work with development, it may detract from existing production line support. For instance, a manufacturing engineer assigned to work part-
time with the development effort may find herself in a constant tug-of-war between supporting existing product lines and supporting the development effort. There must be enough discipline in place to prevent the manufacturing engineer from dropping her development responsibilities to respond to the often urgent "fire-fighting" in manufacturing. Similarly, the early manufacturing involvement will likely involve a higher labor expense from manufacturing at first. However, this initial investment will likely pay for itself through process and product manufacturability efficiencies. Another potential downside might be confusion over roles between the manufacturing personnel on the team and those merely supporting the team. To avoid confusion, management may wish to make clear which manufacturing representatives are under the direction of the team leader and which are merely supporting the team on a part-time basis while learning about the new product and process. It should also be clear that the development team is calling the shots.

A disadvantage of not having some sort of pilot manufacturing group is that the development effort may not always get the undivided support of the long-term manufacturing group. Without the pilot manufacturing department, there will be few experts dedicated to ramping up a new product. Rather than do away with the ramp-up experts altogether, it may be advisable to keep a handful of such experts in the development organization to advise the development teams and supervise the early production employees.

Obviously, variations of the early manufacturing involvement theme will occur, depending on the nature of the product and process technology and the company. At Ethicon Endo-Surgery, for example, several of the long-term production floor employees were under the direction of the team leader while the long-term manufacturing engineer, planner and equipment technician were only needed to support the team on a part-time basis; they continued to report only to their manufacturing functional managers. A good rule of thumb seems to be: if the long-term manufacturing person's support for the team will be full-time or nearly full-time, assign that individual to the team leader. If only part-time support is needed from the manufacturing function, the individual involved should continue to be under the direction of their manufacturing manager. Another consideration is that many products are developed in one site and manufactured in another. In such circumstances, it may be inadvisable to have too many long-term production support people collocated on the development site during development. However, it is still
probably advisable to have one or two key individuals - perhaps the manufacturing engineer or production technician - spend significant time with the development team

By having the ability to address manufacturing concerns early, development teams should have a smoother production ramp-up which equates to a shorter development cycle and fewer budgetary surprises. The early manufacturing involvement may also result in a knowledgeable manufacturing organization that is competent to assume complete ownership of a new product line. In conclusion, early manufacturing involvement, particularly the involvement of the manufacturing persons who will ultimately support the product line, seems an excellent way to design more manufacturable, competitive products and more robust production process.

5 3  Recommendation 2  Hold Development Responsible Until "Steady-State" Production

5 3 1-a  Milestone Definition Alternatives

How should formal milestones in the development and product transfer process be defined? The primary alternatives that were considered are described below.

1) Use metrics such as cost levels, quality levels, profitability, or rate of design changes to determine when milestones are reached.
2) Allow development and manufacturing to declare that milestones are attained based on negotiated "soft" rules that are convenient.

Wolff (1985) suggests that the development team is responsible for the product line until it is running reliably, to specification, and at a profit. Others have suggested that the level and frequency of design changes are good indicators of whether the design is complete. It is hard to argue with fact-based measurements when trying to determine whether a product design is ready to be transferred from development to manufacturing. While waiving the formal requirements (as in option 2) and passing a product through to manufacturing and the market can speed things up considerably, it may hurt the product family in the long run if defective or costly designs are continuously passed along. The use of gut feel and intuition to advance a product to the next development phase may come back to hurt the organization in the form of late re-designs or major process overhauls. The alternative chosen for further study was number one - that specific
predetermined metrics should be reached indicating the product has passed a milestone or is producible in a "steady-state" mode. Of course, for strategic reasons, managers always reserve the right to overrule measurement plans, but a focus on meeting specific metrics seems desirable in a new product development.

5.3.1-b "Ownership" Alternatives

Who should have the primary responsibility for the product (costs and expenditures, design changes, backorders, etc.) during the production ramp-up phase until the product has reached a specified steady-state mode? The primary alternatives that were considered are described below.

1) The development team owns it until "steady-state."
2) Manufacturing assumes full ownership from the time the first units-for-sale are produced.
3) Joint ownership during the period in question.

The alternative chosen for further study was number one - that the product development team should "own" the product until specific predetermined metrics have reached a level indicating the product is producible in a "steady-state" mode. This alternative relates closely to the one described in earlier - that specific metrics should be used to indicate when development has met its expectations. Option one seems to make the most sense and is backed up by other writers on the subject (Wolff, 1985; Clausing, 1994). Since the development team is in the business of developing products and processes to a specified level, they seem to be in a better position to address design issues than manufacturing is. Depending on the level of product and process expertise in the manufacturing organization, some companies assign the responsibility to manufacturing. However, if a problem in the design arises, design engineers may be in a better position to make changes than manufacturing engineers, because the design engineers know the intricacies of the product's design and are usually familiar with the procedure for making a design change.

While joint ownership might promote teamwork and interaction between development and manufacturing, it has not worked ideally at Ethicon Endo-Surgery. This is due in part to the inherent differences in missions and performance measurements of the two groups. Disputes frequently arise over what should be done during this phase - get products out
the door or fine-tune the product design. On a related note, having two "owners" often results in confusion over responsibilities. The alternative selected in Sections 5.3.1-a and 5.3.1-b have been combined into one recommendation, the analysis of which is next.

5.3.2 Analysis of Recommendation 2: Hold Development Responsible Until "Steady-State" Production Metrics are Reached

How long should the product development team be responsible for supporting a new product, before turning that responsibility over to the manufacturing organization? This question has plagued companies for years. All too often, products are hurriedly passed on to manufacturing in the interests of getting the product out to the customers before the competitor does. In such cases, "gut-feel," or intuition, becomes a substitute for rigorous metrics or fact-based analyses on product readiness. Defective products can be released for sale without adequate testing of the conditions in which the product will be used or manufactured. As a result, products may later be recalled or redesigned. By the time a product of acceptable quality is again available to the market, it may be far later than it would have been had the design been done right in the first place.

Because of their background in the intricacies of the product and process design, the product development team seems to be in a better position to address design problems or take corrective actions than is the manufacturing organization. The design team knows why the product was designed a certain way and why the process was laid out in a particular manner. They know who to ask for support and expertise. They know the paperwork that has to be done to get a design change implemented. Manufacturing organizations, particularly those which have little involvement in the development effort, may have limited visibility to such information. Furthermore, the ramp-up of production is an important test for a new product design. It typically is a time when numerous unexpected design issues are discovered because of the high volume of products being run through the process for the first time. In short, this period can make or break a project. Some products advance to full-scale production. For others, it's "back to the drawing board." Still others meet product quality expectations but fail to live up to process capability expectations. These are valid reasons for keeping the design engineers around.

A product that has been hand-carried this far along in the development cycle does not deserve to be "fumbled" so close to the "end-zone". The "hand-off" period when a
product goes from development to full-scale production is crucial. To ensure a smooth transition into manufacturing, it is recommended that the product development team maintain ownership of the development project through the manufacturing process design period, through the manufacturing ramp-up, until the product is into full-scale production and has "leveled-off" for a period of time. Metrics relating to product quality, finance, product availability, and design readiness could be used to determine whether the product has indeed leveled-off, or reached a point where it is producible in reliable, steady-state mode. After steady-state is reached, the ownership should transfer to manufacturing. If a product and process have been robustly designed and the manufacturing staff has been involved in the effort, there should be no challenges the manufacturing personnel cannot handle after this point. If the manufacturing personnel have been properly involved in supporting the development effort all along, they should know enough about the product and process to address almost any future design issues. Of course, manufacturing should be closely involved in the development effort all along. The idea of having development "own" the project is not intended to exclude manufacturing but to ensure that no important tasks fall through the cracks for lack of knowledge or ownership. This way, it is clear that development is responsible for seeing to it that all facets of the product development and ramp-up effort are done.

"Ownership" simply refers to decision making authority regarding development issues. Of course, the development organizations should not be expected to take over every aspect of the traditional production/operations function. Rather, those operational groups such as purchasing, capital equipment procurement and support, manufacturing, facilities engineering, finance, and information systems should recognize that the development is responsible for the timeliness, costs, and quality/reliability of the product and process under development. Depending on the company and industry, those support groups should work closely with the product development team to ensure that the best decisions are made. The development team must therefore have an understanding of the overall strategies of the support groups to ensure that equipment, information systems, or other systems are consistent and compatible with the overall business plans. At Ethicon Endo-Surgery, for example, all manufacturing capital equipment was procured by the product development team representatives, but they generally bought equipment that was compatible and consistent with existing production equipment.

The main issues that require ownership and decision making have to do with product cost responsibility, product availability during the ramp-up phase, and product and process
design improvements. By maintaining only one "owner" of the product, there should be no questions or disputes over responsibilities. The metrics recommended for determining whether a product is in steady-state fall into four categories (taken in part from Susman and Dean, 1992). They are product quality, finance, availability, and design readiness. Of course, the specifics of such a transfer and the value of these measurements will vary widely, depending on the type of product, process and organization involved. One method might be to measure an existing product that has been around for some time, and use that as a baseline for comparisons to the new product's metrics. What follows are some general guidelines for the use of metrics in determining a product's readiness to be transferred to steady-state manufacturing.

1) Product quality is often measured in either of the following two ways: yield percentage or defect levels. "Yield" is the number of "good" products divided by the total number of products that start the production process. Defect levels indicate the actual count of the number of "defects" that are found in production and subsequent testing. Yield or defect levels should be tracked from the earliest batches of products onward. If the company's typical product has a yield of X% when in steady-state, and the new product is not significantly different, then it may be reasonable to declare the new product to be in steady-state after it has been shown to consistently yield around X%, all other factors being equal.

2) Financial metrics could include parts costs, in-house manufacturing costs, or cost-of-goods-sold as a percentage of sale price (gross profit). Frequently, early production parts are produced in low volumes and therefore at a higher cost per part. For a product to be declared to be in steady-state, parts costs should have leveled-off and neared their long-term targets. The same is true for in-house manufacturing costs. By steady-state, labor and other costs should be well along the learning curve. Profitability measures (and even market penetration measures) are sometimes used to determine when a product is ready to be transferred to manufacturing, but they are not as strongly recommended because of the frequent inability of development or manufacturing organizations to impact the product's selling price or volume.

3) The development organization should have the obvious expectation of meeting preliminary customer demand by making sufficient quantities of product available to them. Like the yield measurement, some sort of measurement should be used to show what percentage of the expected production volumes is being attained as the product is ramped-up. If there is insufficient production capacity to meet demand, something must be done before the product reaches steady-state.
4) Design readiness refers to the frequency and magnitude of product or process design changes. Most manufacturing companies have a procedure for making design changes, or engineering changes (ECs) as they are known in some places. It is recommended that the number of ECs per month be tracked for specific products. In many cases, by the time the product is in a steady-state, the level of design changes per month probably will have "died-down." At Ethicon Endo-Surgery, it is common for a wave of design changes to occur late in the development cycle, as the production process is starting to be ramped-up and production-related design issues are first observed. Figure 5.2 shows a graph of design changes per month for some typical products at Ethicon Endo-Surgery. Note that design changes are initially high, but level off considerably after the first few months in production. From this chart, design changes seem to be one of the best indicators of whether the design is ready or not.

It is important to keep in mind that while metrics can and should be used to determine product readiness, management should reserve the right to go around the metrics under special strategic circumstances.

In addition to the steady-state milestone, there may be other metric-based milestones earlier in the development cycle for such events as product design reviews, process reviews, or first salable unit. The concept of using metrics as opposed to intuition or consensus holds for these milestones equally well.

It should be noted that at some point the costs incurred in developing and introducing a new product switch from being called research and development costs to being called manufacturing costs. It needs to be emphasized that this switch in accounting "buckets" does not have to coincide with the actual product transfer from development to manufacturing. It is acceptable to treat the development team as a manufacturing cost for a while after the first units are released for sale, but before the responsibility has transferred to the manufacturing organization. There is no need to coordinate the accounting transfer with the actual product transfer.

Having development own the development project until certain steady-state measurements are attained has its advantages. It can avoid some of the confusion and disputes over ownership and milestones that can occur. Also, if development is responsible for costs during the production ramp-up, they may be less inclined to spend money than they would if someone else were responsible for costs. The use of specific cost, quality, availability,
and design change metrics helps to ensure that manufacturing capability issues are addressed before they transfer to manufacturing - at which point it is often too late to make significant improvements. Because development seems more knowledgeable about the product, the overall labor involved might be less if done by development instead of manufacturing.

One disadvantage of development owning the product longer is the confusion over accounting practices and the need to come up with a rule that says when the accounting books switch from development to manufacturing. A downside to the use of strict metrics is that more effort is required up-front making sure that targets are met. In some cases, the targets may be so optimistic that they would never be met and the development project would never advance to the next phase. Finally, stating that development owns the product and process during the early phases of production may encourage manufacturing to "mind their own business" and not become involved in supporting the production ramp-up.

Although it may require a paradigm shift in many companies, it seems best for development to maintain decision making control of the new product until it is in a steady-state. During the production ramp-up time, knowledge of the product, process, and the design change procedure is crucial to moving the product along. And, it is no time to stop and debate who should do what. Given a choice between the cross-functional development team and the manufacturing function, the development team seems in a better position to do what is necessary to quickly get a high quality, low cost product to a steady-state production mode.

5.4 Recommendation 3: Have Manufacturing Partially Evaluate their Development Team Representatives' Performance

5.4.1 Alternatives

How should manufacturing have formal representation in the development process? The primary alternatives that were considered are described below.

1) Grant manufacturing sign-off privileges for design reviews.
2) Allow the manufacturing plant to do a percentage of the development team manufacturing representative's performance appraisal.

3) Allow the development team representative to speak for manufacturing.

Sign-off privileges are probably more of a token gesture than a true indication of manufacturing having representation in the development process. The one main downside to this alternative is the potential for a time-consuming veto from manufacturing. Allowing manufacturing to review the status of the design as it passes through major milestones may at least prevent some manufacturing-related problems from slipping through the cracks. It also boosts the status of manufacturing, making them feel as if they are an equal partner with development. Dean and Susman (1989) have recommended this alternative as a first step in getting manufacturing involved in design.

Taken directly from the heavyweight team concept, where the team members' career management remains with their home functions, option two encourages close ties between the individual and his or her home function. A downside is that the plant management may have limited visibility to what development team members do on a daily basis. Neither of the first two options are used in Ethicon Endo-Surgery's team structure. As mentioned earlier, the manufacturing organization strongly feels that it is not getting adequate representation through the cross-functional team members. To keep the manufacturing-related team members from "caving-in" to the often conflicting needs of the team, perhaps some formal ties to the home function should be in place. The alternative chosen for further study was number two - that a percentage of the manufacturing representative performance appraisals should be done by the home functions they represent, as opposed to 100% by the team leader.

5.4.2 Analysis of Recommendation 3: Have Manufacturing Partially Evaluate their Development Team Representatives' Performance

Without any formal ties to their home function, representatives on cross-functional development teams may have no incentive to meet the needs of their home functions. In the case of a team representative from manufacturing, not meeting the manufacturing function's needs means products are designed with little thought given to how those products will be manufactured. This is probably unacceptable for most companies. Therefore, it is recommended that to provide such incentives for team representatives on
cross-functional teams, fifty percent of their periodic performance appraisals should be done by the home functions they represent and fifty percent by the team leader. In other words, the appropriate manager in manufacturing would play a role in assessing the performance of the team's designated manufacturing representative (or the team as a whole if the performance appraisal system is sophisticated enough). The manufacturing representative could be assessed in terms of process design, product manufacturability, and other manufacturing-related items. That assessment could then be evenly weighted with the team leader's assessment of the individual to determine merit pay and promotions in the manner that traditional performance incentives do.

It should be noted that the development team members should still be considered full team members despite having half of their appraisals done by their home function. For example, the manufacturing representative should be collocated with the team representatives from design, marketing, quality, etc., and should take orders or receive direction only from the team leader (or team as a whole). The role of the manufacturing functional manager would be to make clear what things he expects from the manufacturing representative on a long-term basis and how the manufacturing representative will be measured at appraisal time.

To maintain a balance between the needs of the home function and the needs of the product development team, the percentage selected was fifty percent. Anything other than fifty percent might indicate that one function was more important than the other. This, in turn, could have the effect of swaying one hundred percent of the disputable decisions in the favor of the function with the higher percentage.

Modifications of this proposed structure can be acceptable, as long as development and the other functions (manufacturing, marketing, etc.) are given equal weight in the process. For example, instead of the team leader assessing performance, some teams allow the members to assess their teammates. Another modification might be that the team leader and the home functional manager work on one joint performance appraisal of an individual. Taking the team concept to the extreme, an organization could give each team member an identical appraisal based solely on the overall team performance. Such a team performance could be measured by obtaining fifty percent of the appraisal from development management and the remaining fifty percent from the combined appraisals of the other company functions. By assessing the team as a whole, the idea of teamwork is stressed. It reemphasizes what true teams already know - that the team as a whole, and
not an individual team member, is responsible for the task at hand. For example, designing for manufacturing is not just the manufacturing representative's job but rather the responsibility of all team members.

The benefits of having fifty percent of the team representatives' performance appraised by their home function appear straightforward. As mentioned earlier, it promotes a balance between development and the home function (in this case, manufacturing) and puts the individual in a position to make decisions that are the best for the company, rather than simply favoring the stronger function. At Ethicon Endo-Surgery, it was strongly felt that manufacturing integrators had "gone native" after being placed on development teams with no formal ties back to manufacturing. The manufacturing team representatives apparently had more incentives - formal and informal - to appease their new teammates than to strongly stand up for manufacturing-related needs. The split performance appraisal helps to negate the "gone native" phenomena. As a result, important manufacturability issues will more likely be addressed.

There are some negative aspects of splitting the performance appraisals of team members between the team and their home functions. For example, it would add to the already high levels of red tape and bureaucracy existent in many companies. It means complicating the performance appraisal process. Another disadvantage is that the home functional manager may not be closely involved in the day-to-day work of the individual or the development team and thus may not be in a good position to assess her performance. So, giving a portion of the performance appraisal responsibility to the manufacturing manager would probably require frequent and detailed interactions between the individual and the manager. Finally, there are some schools of thought that believe performance appraisals are ineffective and a waste of time altogether (Deming, 1986).

At Ethicon Endo-Surgery, some of the disciplines on the development teams already use some form of split performance appraisal where the home functions assess between 25 and 75 percent of the individual's performance. (This was not the case for the manufacturing integrators, who were assessed 100% by the team leader.) Based on interviews at Ethicon Endo-Surgery, the home functional managers liked having the ability to rate their representatives. They mentioned that they felt better represented and that it forced communication on important issues. They verified that it was extra work to keep tabs on the individuals and to do the paperwork but that it was well worth the effort.
On the other hand, the individual team members with split performance appraisals had mixed emotions about having two "bosses." In some cases, they felt as if the home functional manager had no idea what kind of work they were doing. Some felt insulted by the idea that a "lower level" manufacturing manager could appraise a "higher level" cross-functional team member. Some claimed that the appraisal system didn't affect their behavior - they knew what the right things to do were and would have done them the same way regardless of the measurement system. Others pointed out that they did not feel as much a part of the team when someone else assessed half of their performance. Despite some of the negative implications of such an appraisal system, the individuals did agree that they needed to pay attention to the needs of their home functions and do a better job of communicating with them and meeting their needs. They felt the communication of needs and expectations that resulted was a positive thing.

Overall, the benefits appear to outweigh the costs of a split team/home function performance appraisal system. By taking an action that promotes product manufacturability, the company should have a greater chance of catching manufacturability issues much earlier in the development cycle (when they are cheaper, quicker and easier to address). As a result, higher quality, lower costing products may be brought to market earlier than they otherwise would have. The system may not have much of an impact on the actions of some team members. It will require more effort on behalf of the team members and their home functional managers. However, forcing them to keep each other informed of what they are doing is not a bad thing. In fact, it may prove more of an advantage than a disadvantage, as communication between development and manufacturing is important for the success of a product introduction. In short, companies seem to have much to gain by implementing a split performance appraisal system, and little to lose.

5.5 Recommendation 4. Use Manufacturing Simulation to Design for CFM

5.5.1 Alternatives

How can continuous flow manufacturing (CFM) be implemented along the entire manufacturing and distribution chain? There has been a plethora of books and articles in recent years (e.g., Womack, Jones, and Roos, 1990; Ohno, 1978) on the benefits of CFM and the use of just-in-time, pull or kanban systems, etc. Most companies do not doubt the
benefits of CFM. The questions have to do with how, when and where to start CFM efforts. The primary alternatives that were considered are described below:

1) Modify existing production lines to use more CFM.
2) Design future production lines to use more CFM through the use of modeling/simulation.

In general, many companies could reap benefits with conscious efforts toward streamlining existing production lines. However, the majority of product costs are determined during design. For this reason, it is advantageous to focus on products costs early. One way to do so is by designing efficient production lines by using simulation during the early design phases, so that potential problem areas can be corrected before they ever become real problems. The alternative chosen by the author for further study was number two - that the product development team should use manufacturing simulation models throughout the process design phase (when the production line is still a concept and not a reality), to design for efficient, continuous flow manufacturing.

5.5.2 Analysis of Recommendation 4: Use Manufacturing Simulation to Design for CFM

Continuous flow manufacturing (CFM) has been highly touted in the media in recent years. CFM primarily refers to manufacturing lines with low inventory buffers. As a consequence, defects and scrap rates are low because problems are caught before inventory is built up. CFM lines also have low cycle times because work-in-process inventory does not sit in queue for long. In general, the term CFM has also come to mean simple, efficient, consistent processes with rapid setup/changeover times and high quality levels. (Ohno, 1978.)

It is strongly recommended that simulation, or modeling, be used to design for efficient, continuous-flow manufacturing - particularly by development teams in the process of designing a new product or process. In terms of improving the process of developing a product and handing it off to manufacturing, there seem to be few options that result in more "bang for the buck" than manufacturing simulation.

The advantages of using manufacturing simulation software during the design phase are many. It presents the opportunity to see how the manufacturing line will run before it is
actually set up. As a result, major capacity or other issues can be detected and addressed before they become catastrophes. Work-in-process (WIP) inventory levels, cycle times, and line balancing can be determined and improved. Capable, efficient, continuous-flow production lines can be developed by using simulation to go through several line design iterations that might take years to develop in actuality. Similar to the early involvement of manufacturing personnel, the use of simulation can prevent late process design changes and can promote communications between development and manufacturing. By using continuous flow manufacturing, orders can be filled more quickly, to the delight of the customer.

The disadvantages of simulation are few. Some training efforts and software expenses are incurred up front. However, such expenses are low compared to the benefits of simulation. Many adequate simulation software packages can be purchased and learned relatively cheaply and easily. Of course, the best simulation model is only as good as the information fed into it. For this reason, care must be taken to make a valid model of the production line with reasonable estimates of operation times, yields, inventory levels and staffing levels.

As will be demonstrated in Chapter 6, modeling the production line can lead to significant cost avoidances and process efficiencies. Models can range from simple, "back of the envelope" calculations to homemade spreadsheet models to sophisticated simulation software packages complete with animation. The models require varying levels of up-front information-gathering on such data as operation times, process yields, unit sales volumes, staffing and capital equipment levels. Modeling options exist that will meet just about every company's budget and level of manufacturing knowledge.

The simplest "back of envelope" calculations often provide the most important, basic information. Assuming the cycle times and other general information is known (or estimated), simple equations can tell how much equipment is needed, the daily capacity of the line, or the number of people required to staff the line at different levels of production volumes.

Spread-sheets or simulation software packages can be used for models of increasing complexity. The combination of several work-stations, people and products can be modeled as a whole to see how the individual components contribute to the system. The variables in the model can be "run" under a variety of conditions and interrelationship
assumptions  The objective is to simultaneously increase the line's throughput while
decreasing costs of the line under development  The advantage of the simulation software
is that it lets the operator quickly change the conditions and fine-tune the production line
design through a series of iterations

Because the benefits of using simulation are clear, many companies have taken advantage
of simulation software in recent years  Compared to the results they achieve, the costs of
simulation are small in these companies (Nwoke, 1993)  However some companies have
not yet taken advantage of the simulation revolution  They may have been scared away by
the exorbitant prices on some of the sophisticated, fully animated simulation programs and
the associated hardware, especially in the early years of simulation  Others may have been
intimidated by the programming or mathematical sophistication involved in some
packages  Nevertheless, very inexpensive and simple models are available that can meet
the majority of production line simulation needs

Summary

By following the above recommendations, companies should see marked improvements in
the working relationships between manufacturing and development teams  The
manufacturing work force should be more knowledgeable, involved, and empowered  The
development teams can be expected to produce more manufacturable designs in the long
run - although it will probably require extra effort in the early phases of the development
process  For further evidence of the validity of the recommendations, please read the
following chapter that documents the application of several of the recommendations
CHAPTER 6  APPLICATIONS

Introduction

This chapter presents the results of applying some of the recommendations at Ethicon Endo-Surgery. Some of the recommendations were tried on a pilot basis on the "Omega" product development team. One of the best ways to improve the transfer of a new product from development into manufacturing is to simulate the production line early in the development phases. A description of how a manufacturing line was optimized using computer simulation is presented in the latter half of this chapter.

6.1 Case Study of Product Development Team

6.1.1 Introduction to the "Omega" Cross-functional Team

A case study of one of the cross-functional product development teams at Ethicon Endo-Surgery was done to better understand some of the problems involved in transferring new products from development to manufacturing. The case study began when the "Omega" team was nearing the end of its product design phase and about to enter its design verification phase. The study ended at the close of this internship project, when the product was in the manufacturing process verification phase. It had yet to fully transfer to manufacturing, but during the course of the study there was significant involvement from the manufacturing business unit that would eventually take over the product line.

The Omega team was a cross-functional team of about ten individuals. It had representatives from the disciplines of design engineering, procurement, manufacturing (process and equipment) engineering, marketing, and quality. It also had part-time members for finance and documentation activities. The full-time members were all located together and all reported to the team leader.

The surgical instrument under development within the Omega team was made up of approximately 20 metal and plastic components. Compared to other Ethicon Endo-Surgery products, it was of medium complexity. However, it was a new design as opposed to a follow-on or incremental improvement to a previous design.
Throughout the study, the author attended regular team meetings and manufacturing meetings and participated in various team activities on a part-time basis. The intent of this involvement was to thoroughly understand two things: (1) the team environment, and (2) the trials and tribulations of developing a new product and transferring it to manufacturing.

The case study also served as a pilot experiment in which some of the proposed recommendations could be implemented on a trial basis. During the study, new ideas were tried, ranging from the use of manufacturing simulation in designing the assembly line to involving the long-term manufacturing personnel much earlier than usual.

6.1.2 Observations and Experimentation on the Omega Team

As a supplement to the QFD information attained through interviews and surveys, this case study would serve as a first-hand look at how development issues actually manifest themselves. As it turns out, most of the problems observed were common problems like those described in Chapter 2. In particular, unanticipated design changes proved costly and time consuming. As a consequence, suppliers were unable to deliver components on time which caused the development schedule to slip. However, the assembly line ran smoothly during the early stages and no disputes were observed between the team and plant, in part due to the simulation project and the early involvement of the manufacturing plant personnel.

Other problems occurred relating to marketing, design, production and management issues. These are summarized below:

The Omega cross-functional team was originally created in mid-1993. However, patent issues delayed the official "kick-off" of the design work for several months. After some time the issues were resolved, meaning the Omega project could officially be launched. Besides this early delay, the product suffered another three month delay later in the design verification phase, due primarily to the inability of design changes to be made quickly enough. Minor glitches in quality and functionality were discovered during the fairly rigorous product design verification testing, prompting the changes in product and processes. Other causes of this second delay included the inability of new precision metal
forming technologies to meet the design specifications at first, and the general inability of suppliers (internal and external) to meet commitments.

A significant amount of paperwork is required in the manufacture of medical devices as per FDA specifications. Complete tracking must be done for all components and finished goods. Detailed procedures must be recorded and justified. Clinical trials must be held before a product can ever be sold to the public. The Omega Team members appeared to have been caught off-guard by the magnitude of paperwork they were expected to complete. While the paperwork has not caused explicit delays, it has kept the team members from concentrating on other important issues such as production process design.

During this study, the line layout came to fruition, the "process" transferred from a design engineer's workbench to the actual assembly line, and the number of production employees went from zero to a full staff. Besides the production line simulation project described later in this chapter, another remarkable aspect of ramping-up the production line was the nature in which the production employees were selected. For the first time at Ethicon Endo-Surgery, competitive interviewing was done to select employees (from other Ethicon Endo-Surgery product lines as opposed to new hires) with the highest levels of training and experience in quality, problem solving, documentation and other skills. These were the same skills identified as important in the QFD process.

6.1.3 Results of Applications

Beyond pure observation, this study also served as a proving ground for some of the recommendations made in this thesis. The most significant of these is the simulation of the assembly line, to be presented later in this chapter. Other applications of the recommendations are described below.

As another example of a recommendation being piloted, a manufacturing engineer (M.E.) who was to be the eventual "owner" of the line was pulled in to work part time with the team's manufacturing and development engineers. The M.E. attended the team's weekly meetings and assisted in early manufacturing tasks such as line layout, preparation of manuals, and training of production employees. This proved to be a success. The M.E. involvement was welcomed by the overworked development team, and it was needed by the manufacturing organization to get up to speed on the new project. Unfortunately, this
M.E. was later pulled off the project to support an existing product line, due to an unexpected shortage of manufacturing engineers. After a delay of a month or more, another M.E. was assigned - this time it turned out to be the one who would stay with the product for the long term. Besides the loss of the first engineer, the concept of having an M.E. from manufacturing was enthusiastically accepted by the development team and manufacturing management. Just knowing who to consult (beyond the development team) on manufacturing issues was a great benefit. The part-time help the M.E. was able to offer the team was an added benefit that enabled the development team to get more work done in a shorter period of time. One unresolved dilemma of early M.E. involvement is the constant tradeoff the individual faces between spending time supporting the development effort and spending time supporting existing manufacturing lines. Because of the more immediate nature of existing manufacturing problems, it can be difficult for an M.E. to break away to work on a new product that may not be released for several months.

In addition to the M.E. involvement, individuals from the pilot manufacturing department partnered closely with the Omega product development team. The pilot participants included one coordinator and three lead production operators who were dedicated to the team for early production runs, training and documentation efforts, and line layout. While the outcome was unclear at the time of this writing, the author was informed that the intent was for the pilot manufacturing participants to remain with the Omega product line for at least a year, to minimize additional training and hand-offs of responsibility. The pilot manufacturing department, while perhaps being an unnecessary third party between development and manufacturing, seemed to play a very influential role by influencing manufacturability issues in the development effort. The same function could have been performed by the long-term manufacturing support, but it was clear that someone representing manufacturing's interests was needed to "keep the development team honest."

In following another recommendation (although it has not yet occurred at the time of this writing), the development team has agreed to maintain "ownership" of the product line until a steady-state has been reached. Most Ethicon Endo-Surgery products have had joint ownership between manufacturing and development from the earliest production runs onward. In this case, it was made clear that the development team has ultimate responsibility for resolving technical issues that arise in the manufacture of the new product until the day the ownership transfers to steady-state manufacturing. However, no formal measurements have been established that will indicate when "steady-state" is
Manufacturing did create a template of things it expects development to do prior to the transfer, but it is more a checklist of "to-dos" than a set of scientifically derived measurements. The template was useful in that it mapped out the responsibilities of both the development team and the manufacturing employees and that both groups agreed on who was responsible for specific tasks. It is believed that "steady-state" will be jointly declared by the team leader and the manufacturing manager after a specified volume of products have gone through the line.

Two recommendations that were not able to be piloted on the Omega team included the transfer of development team members into manufacturing along with the new product and splitting the performance appraisals of manufacturing integrators between the team and their home function.

Manufacturing did extend an invitation for the development team members to take a temporary (approximately one year) assignment in manufacturing. However, it was a voluntary measure because not many development engineers expressed an interest in working in manufacturing. Besides the improved development work that can be expected when development engineers have manufacturing experience, this idea is expected to bring more product design expertise to the manufacturing departments.

Although the split performance appraisal recommendation was not piloted on the Omega team, it was later announced that starting in the next year, a significant percentage of all the manufacturing integrators' performance appraisals would be done by the plant manager. Thus far, the closest manufacturing came to being able to assess the performance of the Omega team's manufacturing integrator was through the QFD process and an informal "360-degree feedback" forum where both groups were allowed to give feedback and constructive criticism to the other. Neither the QFD nor the 360-degree feedback had any impact on the manufacturing integrator's official performance appraisal.

Of the other (more "obvious") recommendations covered in Table 5.1, several were done by the Omega team. These are touched upon next.

The Omega design was considered a good design for manufacturability. While it was a new product, it had significantly fewer parts than similarly functioning products created by previous design groups. It also had a relatively simple production process with a low assembly time. An early emphasis on DFM concepts is the main reason. It is interesting
that the usage of DFM concepts varied widely from team to team at Ethicon Endo-Surgery. The successful DFM projects, like Omega, seemed to have one thing in common - strong DFM advocates such as skilled design engineers or an experienced manufacturing integrator. For more information on DFM, refer to Boothroyd and Dewhurst.

Communications between the Omega team and the designated manufacturing department were good. In addition to the M.E. and pilot department involvement in the development work, a regular meeting was held between the development team leader, the manufacturing integrator, the M.E., and the manufacturing manager. This was not done in all Ethicon Endo-Surgery development projects. The participants indicated that the meeting was a positive thing and that it largely eliminated the disputes that typically result from poor communications, surprise problems, and assumptions over responsibilities.

To avoid disputes between development and manufacturing over the use of existing manufacturing resources, the Omega team set up a dedicated production line prior to the production of the first batches. In a related move, the Omega team selected the long-term production operators fairly early in the development process. In doing the personnel selection, the Omega team used an unprecedented, rigorous selection process. Several current Ethicon Endo-Surgery employees were interviewed and tested to determine their level of technical skill and leadership competency. Positive attitudes, people skills, and technical skills in such things as problem solving, statistical process control, computers, and communications were considered prerequisites to working on the Omega line. When the production department was selected, the Omega team thought they had the most qualified production department in the company.

In an attempt to transfer technical knowledge about the product design from the development team to manufacturing, the Omega team planned to use new training materials that most other development teams had not used. These included an assembly training videotape so that everyone would be trained consistently and a fault tree document that would allow the production assembler to trace an assembly problem back to its possible causes (as experienced and documented during the development and ramp-up phases).

The Omega team members made an effort to visit all links in the entire supply and distribution chain. The intent was to understand all processes the Omega product would go through and ensure those processes were capable of meeting the Omega team's
expectations. With help from their quality engineer, the Omega team went to great lengths to test a variety of process conditions and product dimensional extremes. The Omega team made use of a recent standard validation procedure that was being implemented throughout the company to do just that. While the assembly operations were on-site, an important sterilization and packaging site was located in another state. The manufacturing integrator as well as some of the other team members visited this site in an effort to understand their processes and capabilities. The procurement representative, quality representative, and design engineering team members also made several trips to suppliers in an effort to ensure suppliers' processes were capable of meeting specifications and demand levels.

As mentioned earlier, the Omega schedule slipped a few times. However, the initial schedule was intentionally aggressive. They felt that due to the tendency to procrastinate, deadlines are likely to be missed whether a schedule is aggressive or lax - so why not strive for the aggressive schedule? The Omega schedule and plan were very detailed, with each step of the development cycle mapped out on the wall of the team meeting room. Within each step, expectations were clearly laid out in terms of the product's physical characteristics, product and process design verification criteria, and early production volumes.

The schedule slippage was due in part to design changes. Although the Omega team members agreed in principle that late design changes should be limited, in reality design changes were absolutely necessary to maintain product functionality. The general feeling seemed to be that freezing the design was a desirable goal, but not likely to be possible in the fast-paced development team environment.

Costs, while talked about from time to time, did not appear to be of great concern to the Omega team. Increases in expenditures - either due to a material change, additional direct labor, or an extended development budget - were considered sacrifices necessary to get a functional product out to the market-place in a short period of time.
6.4 Summary of the Omega Team

In addition to being a pilot for some of the recommendations, this case study also verified some of the common problems and interdependencies (QFD needs) involved in developing and transferring to manufacturing a new product. It is interesting that almost every one of the internal manufacturing and development needs identified through the QFD process was observed throughout the course of this particular case-study. For example, it was evident that development needed manufacturing employees with the proper skills and level of involvement. They also needed the manufacturing employees to be cost effective and on time so that the team's development effort could proceed on time and on budget. On the other hand, manufacturing obviously needed clear and thorough communications from the development team. Manufacturing also pushed the development team to listen to them and treat them as a partner in making important decisions. It should be noted that the Omega product development team showed a marked improvement in performance over some of the earlier cross-functional development team efforts, indicating that the company has learned a fair amount since the introduction of the team-based structure two years ago.

In conclusion, the case study of the Omega cross-functional team indicated that at least two of the main recommendations are worthy of further implementation and study. Again, these are the early deployment of long-term manufacturing personnel in the development effort and the use of simulation software for designing efficient production lines.

6.2 Simulation

A manufacturing simulation project was done on the Omega team's proposed assembly line. Manufacturing line design is an important part of the hand-off from development to manufacturing. Significant costs may be avoided by modeling the line prior to making final decisions on such things as staffing levels, amount of equipment needed, and line flow.
6.2.1 Introduction to Simulation

A manufacturing simulation software package was used to create a model of the proposed Omega assembly process at Ethicon Endo-Surgery. The program, called XCELL+ Factory Modeling System (Conway, 1990), allows the user to input and link together multiple workstations, inventory buffers, receiving areas, shipping areas, and operators. Other parameters that must be input are operation cycle time, size of inventory buffers and specific line conditions such as maintenance or line down-time. Once the model is set up, the program "runs" the line for a period of time under conditions specified by the user. A wide range of conditions was tested under different assumptions for forecasted volumes, headcount levels, and the line's physical layout. The general objective of simulation projects is to simultaneously increase line throughput while decreasing cost drivers such as cycle and queue times, work-in-process inventory, number of operators and amount of capital equipment.

The intent of the simulation project was to demonstrate that expenditures can be avoided and lines can be designed and run more efficiently by using some form of modeling. In short, simulation can make for a smoother new product transition into manufacturing. Ethicon Endo-Surgery rarely used any formal production line modeling prior to this experiment. By starting with a successful demonstration on the Omega project, the simulation concept could then be introduced to other product/process development teams as well as existing manufacturing lines. Although the scope of this simulation project was contained within the walls of the factory, greater benefits may be attained by modeling the finished goods and raw materials distribution processes.

Simulation packages have been developed in recent years that are more user-friendly and cheaper yet more powerful than their costly predecessors. The simulation package chosen for this application was very simple, cheap, and easy to use. Preliminary demonstrations of the program have been met with enthusiasm and have led to additional copies of the program being purchased.

6.2.2 Simulation Objectives

At Ethicon Endo-Surgery, there was strong evidence that an improvement in assembly line design was needed. Cycle times for simple assembly processes were measured in days, not
hours. Capacities were not known with accuracy. One production department struggled for weeks to meet the scheduled production volumes, only to find out through basic modeling that their line was actually only capable of producing 50% of the daily volumes, at best. Elsewhere, high levels of inventory were held in raw materials and finished goods.

The advantages of creating some sort of model to better understand the production line are obvious. Simple models or more sophisticated ones (e.g., simulation) can be used to improve existing lines or to develop new ones. In either case, simulation allows the user to understand how the line will run in terms of throughput, cycle times, bottlenecks, inventory levels, and staffing levels. By trying different scenarios of line layout, staffing, and inventory buffering, more efficient methods of production can be discovered. In the case of the production line that was only meeting 50% of their quota, not knowing their capacity resulted in backorders and lost sales. Other general benefits of simulation are that it may reduce late process changes by allowing an understanding of process issues early; it can speed up the process design time (and hence the whole development cycle); and, it can result in lower manufacturing costs.

For the Omega assembly line that will be modeled here, there were some specific objectives. At the start of this project, the line did not yet exist. It needed to be laid out and staffed. Because it was a new product, demand was not known with great accuracy, so the flexibility to increase capacity was needed. The plan in this case was to design a line that was capable of meeting the forecasted daily volumes (plus a safety factor for unpredictability) working one shift per day. Given that, the objective was to minimize the number of people, work-in-process (WIP) inventory, equipment and cycle times while still being able to meet the daily quota. Because of the FDA requirement that batches of products be fully traceable, it was decided that the entire line would be cleaned of all WIP at the end of each day. Thus, very small WIP buffers were another specific objective.

6.2.3 Information Gathering

The most important step in any simulation project is the gathering of information prior to modeling. As computer users say, "garbage-in, garbage out." The same idea holds true for simulation - fairly accurate numerical values are essential if the model is to be at all representative of the real world. It should be noted that the numbers presented here have been changed to protect confidentiality.
A manufacturing simulation software package was used to create a model of the proposed Omega assembly process at Ethicon Endo-Surgery. The program, called XCELL + Factory Modeling System (Conway, 1990), allows the user to input and link together multiple workstations, inventory buffers, receiving areas, shipping areas, and operators. Other parameters that must be input are operation cycle time, size of inventory buffers and specific line conditions such as maintenance or line down-time. Once the model is set up, the program "runs" the line for a period of time under conditions specified by the user. A wide range of conditions was tested under different assumptions for forecasted volumes, headcount levels, and the line's physical layout. The general objective of simulation projects is to simultaneously increase line throughput while decreasing cost drivers such as cycle and queue times, work-in-process inventory, number of operators and amount of capital equipment.

The intent of the simulation project was to demonstrate that expenditures can be avoided and lines can be designed and run more efficiently by using some form of modeling. In short, simulation can make for a smoother new product transition into manufacturing. Ethicon Endo-Surgery rarely used any formal production line modeling prior to this experiment. By starting with a successful demonstration on the Omega project, the simulation concept could then be introduced to other product/process development teams as well as existing manufacturing lines. Although the scope of this simulation project was contained within the walls of the factory, greater benefits may be attained by modeling the finished goods and raw materials distribution processes.

Simulation packages have been developed in recent years that are more user-friendly and cheaper yet more powerful than their costly predecessors. The simulation package chosen for this application was very simple, cheap, and easy to use. Preliminary demonstrations of the program have been met with enthusiasm and have led to additional copies of the program being purchased.

6.2.2 Simulation Objectives

At Ethicon Endo-Surgery, there was strong evidence that an improvement in assembly line design was needed. Cycle times for simple assembly processes were measured in days, not
At the start of the simulation project, the Omega product's components were designed for the most part, the forecasted volumes were published (although not known with certainty); production equipment had been ordered; and, a production staff had been interviewed and selected to start at a later date. As a result, the Omega assembly process was largely predetermined. At this point, the equipment purchased can be considered a sunk cost whereas the production staff (transferred from within the company) can be considered a variable cost (at least to this product's costs). The manufacturing representatives on the team had a preliminary plan for how the line would be laid out and how the assembly tasks would be distributed among the various workstations. A key missing ingredient was an estimate of the assembly cycle times.

Therefore, a time and motion study was done for each of the initial steps, or operations, in the Omega assembly process. This study was backed up by actually timing each operation several times with a stop-watch, using actual assembly parts, operators, and assembly line equipment. Additionally, the level of variability in the assembly times of each step was determined. Figure 6.1 shows the preliminary Omega process flow diagram along with the associated assembly times for each of the discrete steps.

Other information was gathered. Estimates of process yields were made for each operation by the team's engineers. Sales forecasts were scrutinized by the marketing representative on the team and reasonable daily production volumes were estimated. Other assembly lines at Ethicon Endo-Surgery were analyzed to determine typical line down-time due to factors such as lack of parts, equipment repair or maintenance, quality problems, and unavailability of personnel. Because Omega was a totally new product, a capacity safety factor of approximately 40% was considered necessary to buffer for volume fluctuations due to line downtime, as well as demand uncertainty. That is, the maximum daily production capacity was designed to be 40% higher than the average forecasted daily demand.

6.2.4 Simulation Models

Models of three levels of sophistication were used in this study. They were, in increasing order of complexity, "back-of-envelope" calculations, a spreadsheet model, and the
Figure 6.1
Final Process Flow

Incoming Parts

Sub-assembly
1.0 Minute Avg.
0.7-1.3 Range

Assembly

Assembly

Buffer

Weld
1.15 Minutes
No Variation

Check
2.40 Minutes
2.05-2.75 Range

Load
2.45 Minutes
2.1-2.8 Range

Attach
1.55 Minutes
1.2-1.9 Range

Couple
1.45 Minutes
1.25-1.65 Range

Handle
2.45 Minutes
2.1-2.8 Range

Cycle
1.8 Minutes
1.55-2.05

Compare
1.75 Minutes
1.5-2.0 Range

Test
1.05 Minutes
No Variation

Inspect & Pack
2.25 Minutes
1.65-2.85 Range

Outgoing goods

Final Configuration: 12 Operations, 6.5 Operators, 9 Buffers, Output 105 per day, 23.55 Total Minutes Labor Per Unit
manufacturing simulation program. Again, the success of using any of these types of models is determined by the quality of the information gathered beforehand.

6.2.4.1 Back-of-Envelope Models

Back-of-envelope calculations can be used to get rough estimates of such things as the number of people needed to staff a line, the number of workstations needed, or the maximum daily capacity. Despite their crudeness, such calculations typically provide most of the information needed in planning a production line. A disadvantage of these simple formulas is that they cannot model a manufacturing system as a whole but only the individual components. The impact of variability cannot feasibly be analyzed by hand; typically only averages are used in such formulas. Furthermore, the calculations can become very tedious if the manufacturing line consists of more than a few steps. However, the use of back-of-envelope formulas is far better than doing nothing at all. A sample calculation is presented below.

\[
\text{No. of People Needed} = \frac{(\text{Monthly Volume}) \times (\text{Total Labor Hours Per Unit})}{(170 \text{ Hours/Month/Person}) \times (85\% \text{ Utilization})}
\]

\[
= \frac{(1150 \text{ Units/Month}) \times (0.42 \text{ Hours/Unit})}{(170) \times (0.85)}
\]

\[
= 3.3 \text{ People Needed to Staff Line}
\]

The figure of 170 hours per month per person is simply forty hours per week times the average of 4.3 weeks per month. The 85\% work force utilization factor is common in industrial engineering studies. At Ethicon Endo-Surgery, the number of people calculated was multiplied by the capacity safety factor of 1.4. This indicated that a total of five people (3.3 x 1.4, rounded up) were needed to do the direct production work. As an example of the savings that "back-of-the-envelope" modeling provides, the Ethicon Endo-Surgery line had originally slated 6.5 people (1.5 too many) to directly support the line (not counting the pilot manufacturing support, documentation support, and all other indirect support).
A similar formula exists for calculating the number of workstations needed to support a particular operation at a given volume of production units.

\[
\text{No. of Stations Needed} = \frac{(\text{Max. Daily Output Needed})(\text{Cycle Hours Per Unit})}{(\text{Number of Shifts Per Day}) \times (8 \text{ Hours x 85\%})}
\]

A third useful formula is used to calculate the maximum daily capacity for each particular operation, given the number of workstations and workers is already known.

\[
\text{Max. Daily Capacity} = \frac{(\text{No. of Stations Staffed})(\text{No. of Shifts})(8 \text{ Hrs x 85\%})}{(\text{Cycle Hours Per Unit at This Operation})}
\]

The latter two formulas, because they apply to each of several operations in the process as a whole, are more efficiently applied in a spreadsheet model.

6.2.4.2 Spreadsheet Models

Spreadsheet models are capable of applying the above formulas (or similar ones) in larger quantities - each step of the process, for example. Spreadsheet models show the next level of detail that simple formulas are not capable of showing. Once set up, spreadsheets have the added advantage of doing sensitivity, or "what-if," analysis. For example, if production volumes are not forecast with much accuracy, the spreadsheet enables one to insert different numbers for production volumes to see how the uncertainty affects staffing or equipment levels. Similarly, if a step in the process is highly variable, tests can be done using spreadsheets to determine some impacts of the variability. Spreadsheets also allow all the various steps of a process to be efficiently compared side-by-side. Bottleneck analysis and workstation utilization studies are feasible with spreadsheets. Please refer to Figure 6.2 for an example of the information contained in one of Omega's spreadsheet models.

Through the use of a spreadsheet model of the Omega line, it became clear that the purchase of capital equipment could have been avoided had the assembly times been known and modeled earlier. To meet the daily production volume, no more than one of each workstation was needed. As shown in the process flow diagram, three assembly stations had already been put in place along with two handle stations. To be fair, the sales
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<td>4.6 0.4 0.3 0.2 0.1 0.1 0.05 0.02 0.02 0.03 0.03 0.04</td>
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</table>
volumes of the Omega product are still largely uncertain at the time of this writing, and the
equipment may be used eventually, either by the Omega line itself if volumes grow, or by
another line with similar product attributes.

Unless significant effort is spent creating "macros" and doing fairly complex programming,
spreadsheets cannot model a manufacturing system as a whole. Interrelationships between
different steps in the overall process are more difficult to understand. The impact of
operation time variation or random down-times cannot be modeled well. The impact of
kanbans, or buffers of inventory, on overall process flow cannot be easily determined with
spreadsheets. These are all advantages that simulation programs, the subject of the next
section, offer.

6.2.4.3 Simulation Programs

As mentioned previously, simulation programs allow all the parts of a manufacturing
process to be modeled together, as one interrelated system. Variability, random
interruptions, yield data, and inventory buffers are just some of the features that can be
modeled in simulation programs.

The information presented in the sections on back-of-envelope and spreadsheet
calculations is the same information fed into the simulation program. The flowchart
presented earlier (Figure 6.1) can serve as a conceptual model of the simulation program.
(In fact, the simulation program made use of graphics very similar to the flowchart
shown.) In setting up the model, workstations are defined. Cycle times and the nature of
the variation are input for the operations performed at each workstation. Inputs (sources
of WIP or raw materials) and Outputs (where the WIP flows next) are defined for each
operation, to show the interrelationships between the workstations. Inventory buffers, or
kanban squares, are defined between the appropriate workstations to indicate all points
where WIP inventory is stored. When defining buffers, buffer size and the nature of the
buffer (first-in-first-out or last-in-first-out, etc.) is specified. Workers are assigned to
various workstations. Yield data is input for each step of the process (if less than 100%
yield). In this case, the sequence of workstations was already fixed, but in some cases it is
possible to rearrange the sequence to improve the flow. Although it was not done in this
case, some simulation programs have the ability to track costs of various production lines.
When all the defining information is entered, the simulation model is ready to be "run." At this point, the computer will essentially start a production run with the first operation, assigning random numbers for operation times (within the user's specification) for each step in the process. WIP will be built up at each buffer in turn, or processed at the following workstation, depending on the conditions specified. The user must specify whether he wants the run period to represent one day's worth of production, a month's worth, or any other period of time so desired. Depending on the hardware and software used, the time actually taken to simulate a day of production can range anywhere from a few seconds to several minutes. At the end of the run, the program reports the following valuable information:

1) Output, or Throughput - this is the number of units that were produced by the fictitious factory in the specified period of time.
2) Flow Time - this tells how long the average unit took from the start of the first operation until the completion of the last operation. Flow time is broken into two components - processing (value-added) time and queue (waiting in buffer) time.
3) Equipment Utilization - this indicates the percentage of the time each workstation, or piece of equipment/machinery, was busy during the run.
4) Operator Utilization - this indicates the percentage of the time each person was busy during the run. It often differs from equipment utilization because operators may be assigned to more than one workstation.
5) Bottleneck - this refers to the one workstation with the highest utilization. That is, the bottleneck is the one operation that slows the others down and prevents throughput from being higher.
6) Inventory Levels (WIF) - this indicates the average number of units that were sitting in each inventory buffer during the course of the run.

Aside from providing the information above, whose benefits are obvious, many simulation programs provide some level of animated graphics that enable the user to "see" the process flow as the line is running. In the XCELL+ program used at Ethicon Endo-Surgery, primitive but adequate animation indicated whether workstations and operators were busy at the time and how many units were in a buffer. Often, viewing the animated production line in a step-by-step fashion provides much more insight about the workings of the manufacturing system than just looking at the final results.
Perhaps the greatest advantage of simulation programs is their ability to do sensitivity analysis. Once the model has been set up, it can be altered (numerous times) to come up with an improved production line design. Parameters that can be varied include buffer sizes (for the reduction or fine-tuning of inventory levels), staffing levels, and number of workstations. Excluding the event of a major design change, the overall operation times will not likely change. (Simulating a manufacturing line will not reduce the number of parts to assemble.) However, operations may be split or combined to better balance the line flow. For example, say one operation requires ten minutes of assembly and the next one takes five minutes. It may be possible to take 2.5 minutes of work from the first person and assign it to the second person, so the two stations are balanced at 7.5 minutes apiece. Similarly, the sequence of operations may be changed in some cases to improve the process flow. Another analysis option is to increase the production volumes until the existing production equipment is no longer capable of meeting them. This determines how high the volumes can increase before more capital equipment must be purchased. Naturally, the type of sensitivity analysis will depend on the nature of the process being simulated. Of course, any results obtained in a simulation exercise should be carefully checked for validity before drastic action is taken.

Summary

The execution and results of the actual simulation project are presented in Appendix B. By using the varying levels of modeling, from back-of-envelope calculations to a sophisticated simulation model, the costs avoided on the Omega line were significant. The number of inventory buffer locations (opportunities for waste) was reduced from ten to four. Headcount was reduced from 6.5 to 5. The number of workstations and pieces of equipment was reduced considerably, although after they had been purchased. Finally, the flow time was reduced to a very desirable level.

In summary, the usefulness of simple formulas and complex simulation models has been demonstrated. As it turns out, simulation is primarily the gathering of information and the repeated use of simple formulas. The more sophisticated simulation software packages are useful for fine-tuning a production line's design after the basics are known. Beyond what was discussed in this paper, manufacturing simulation programs are also capable of modeling more complex manufacturing systems with multiple WIP inputs and outputs, multiple operations per workstation, maintenance and other random down-times, material
handling systems, yield drift phenomena, random deliveries and pickups, and batch processing.

Simulation is a particularly useful tool during product and process development, for that is when most of the ultimate product costs are determined. By trying alternative line layouts on a trial-and-error basis, world-class continuous flow manufacturing lines can result. Simultaneously, transitions between development and manufacturing will likely be much smoother when simulation has been used to develop the production process.
CHAPTER 7. CONCLUSION

7.1 Review of Thesis

In this thesis, cross-functional "heavyweight" product development teams, if implemented intelligently, are the recommended structural mode for companies that require rapid development and introduction of new products. The recommendations presented here are intended to fine-tune the cross-functional team structure and, in general, create opportunities for smoother transfers of new products from development organizations into manufacturing organizations.

A summary of current literature on the subject of developing new products and transferring them to manufacturing was presented. In general, industry experts stress the importance of manufacturing's involvement in development in any of several forms such as cross-functional development teams or formal manufacturing design reviews. They explain how early manufacturing involvement can lead to higher quality products, lower costs, fewer late design changes and quicker development time. They also stressed the importance of thorough communications, minimal turnover of project personnel, and DFM and simulation concepts during the design cycle.

The importance of modifying strategies so that they fit the company's business environment has also been mentioned. Ethicon Endo-Surgery's background was described in conjunction with their strategies to demonstrate that different strategies, cultures, and practices are appropriate at different times in the life of a company or product line. Why did Ethicon Endo-Surgery seem to be very successful in some areas (marketing and rapid product development) and less successful in others (manufacturing)? The answer lies not only in the traditional marketing and development cultural focus that typifies the Johnson & Johnson family of companies, but also in the implementation of cross-functional teams. The switch from a functional organization to a team-based organization was a "shock to the system" and was not accompanied by immediate training and detailed analysis of how the new organization should be run. The lesson to be learned is that trying to change a traditional individualistic, functional culture to one that rewards teamwork and the integration of manufacturing, development and marketing is a slow and arduous process. However, it is a process that cannot be completed without taking dramatic steps.
QFD has been established as a valuable tool for the collection and assessment of customer needs when developing a new product. This paper has expanded the use of QFD to include the assessment of "internal customer" needs. In any situation where the needs of a particular group must be understood, QFD seems an excellent choice. In this case, QFD interviews and surveys were used to assess the needs of manufacturing and development personnel, in hopes of improving their working relationships and streamlining the new product introduction process. Both groups then have an in-depth, quantitative understanding of what is expected of them and what they have to do to address the needs of their internal customers.

The data collected through the use of QFD and literature searches led to the analysis of several recommendations for improving the process of transferring new products from development teams into manufacturing. The primary recommendations are reviewed below.

1) **Involve the Long-term Manufacturing Support People Early:** The importance of keeping the core team of contributors with the new product development effort was emphasized. In the extreme case, the development team members should be transferred to manufacturing to support the new product line they developed. An alternative is to ensure that the long-term manufacturing support individuals (manufacturing engineer, planner, supervisor, etc.) get involved with the development team (in addition to the manufacturing representatives already on the team) on a part-time basis from the project's start. They should remain with the project as it transfers to steady-state manufacturing and beyond, thus eliminating the knowledge lost when projects are shuffled from one group to another.

2) **Hold Development Responsible Until "Steady-State" Production:** It was explained that development is responsible for much of the new product's ultimate cost because so many product and process characteristics are determined very early in the design phase. Also, development personnel seem to have the highest level of expertise regarding the new product and the associated production process. For these reasons, it was recommended that the development organization maintain decision-making ownership of the new product line until the product is well into a "steady-state" mode, as indicated by specific measurements. Development, not manufacturing, seemed most likely in a better position to quickly address product design or process issues, cost issues, and product availability issues until the product reached a steady mode.
3) Have Manufacturing Partially Evaluate their Development Team Representatives' Performance: In companies with product development teams, a balance needs to be maintained between the needs of the team and the needs of the home functions represented. It was shown that one way to do this is to allow the home functions to assess the performance of their team representative and contribute 50% of that individual's performance appraisal, as opposed to giving up all responsibilities to the team leader. True, splitting the performance appraisal between the development team and the home function may involve extra effort and closer ties between the two groups. However, a closer working relationship would likely be beneficial in that it would help to ensure that manufacturability issues are considered.

4) Use Manufacturing Simulation to Design for CFM: It was shown that manufacturing simulation models, of varying levels of sophistication, could provide great benefits in the form of improved process designs, increased line throughput and decreased levels of inventory, headcount, and equipment. It is especially important that the product development team use manufacturing simulation models early (throughout the process design phase), to design for efficient, continuous flow manufacturing.

In conclusion, the actions recommended in this thesis should contribute to a smoother new product transition into manufacturing. The end result may be products with faster development time, higher quality, and lower costs - necessary ingredients in today's highly competitive markets.

7.2 Recommendations for Future Research

During the course of the research, gaps were discovered in the current body of academic or management literature, prompting the recommendations for future research that follow. The areas recommended for further study involve the practical implementation of concepts touted in literature such as heavyweight development teams, TQM/QFD, and design for manufacturability.

Academic references have been cited herein regarding the benefits of temporarily transferring development personnel into manufacturing, along with the new product. The benefits of transferring people who have traditionally been labeled as "design" people into manufacturing are clear - the product expertise remains with the product line, and the
development personnel gain valuable manufacturing knowledge that they can apply toward future product development efforts. What is not so clear is how to institutionalize such a concept in American companies, where several forces seem to be working against it.

First of all, a move to manufacturing is often seen as a demotion or step down for development engineers. Compared to designing a new product, the "fire-fighting" nature of manufacturing work often involves unglamorous tasks, uncomfortable labor relations issues, and unclean conditions. It is hard enough to get development to listen to and respect the needs of manufacturing; how can they be persuaded to take a job in manufacturing? Second, it is common in American companies for employees to spend two years or less in a position before moving on to their next position. This makes it harder to persuade someone to stay with the same new product development project for the several years it often takes to develop and introduce a product. Another force preventing the movement of development personnel into manufacturing is the fear development managers have of letting their best designers go. It seems that more research on implementing the movement of developers into manufacturing is needed before American companies can greatly benefit.

The topic of cross-functional product development teams has received much positive press recently. However, the body of knowledge relating to the experiences of American companies who have implemented such teams is incomplete. More research may be needed on how companies have made the cultural and operational transition from individual-focused, hierarchical corporate systems to the flatter team structures. One such detail is performance appraisals. What is the best way to assess the individual, while still emphasizing the performance of the team as a whole? Similarly, what if the functional representatives on the cross-functional team are not enough to get the job done? How much involvement should the home functions have in a development project? Such questions need to be answered in practice. More guidelines are needed from academia on these and other cross-functional team issues.

Finally, how can total quality management (TQM) tools such as QFD gain widespread acceptance in American companies? It has been observed during this project that House of Quality diagrams may end up being little more than window-dressing, being enthusiastically talked about initially but rarely used during the course of day-to-day decision making thereafter. It appears that the majority of development employees at Ethicon Endo-Surgery have not yet internalized QFD. They regard it as more of a design
review check-off item than a useful tool. More needs to be written about how successful companies have institutionalized TQM concepts and "won over" their doubtful employees.

Summary

The use of cross-functional product development teams seems to be a step in the right direction for most companies. Such development teams have often proven to be faster and more cost effective than traditional development efforts. While it may be possible (in theory) to rely too much on teams at the expense of functional capabilities, most Western companies observed have not yet neared the danger threshold of relying too heavily on teams. It is expected by this author that there will be a continual migration toward the use of cross-functional teams by Western industry for several years to come.
MANUFACTURING PLANT Internal Customer Survey; Page 1 of 2

Please complete both sides of the survey and mail to Steve Obay at Mail Location #3 by the end of the day, Wednesday, August 3. If you have questions or comments, call 8199.

<table>
<thead>
<tr>
<th>Future need/wish for the mfg. plant</th>
<th>Check one</th>
<th>Check one</th>
<th>Check one</th>
<th>Check one</th>
<th>Check one</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A) A standard process validation procedure is used across all product lines.</td>
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<tr>
<td>1B) Each team is free to &quot;validate&quot; their production process as they see fit.</td>
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<tr>
<td>2A) There is an inventory management system in use with at least 99% accuracy, cycle-counting, and inventory visibility.</td>
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<td>2B) The current inventory management system is used.</td>
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<td>3A) More thorough analysis is done during backorders to determine which actions are best</td>
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<td>3B) The level of analysis done during backorders is the same as it is today.</td>
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<tr>
<td>4A) Manufacturing Business Units are involved in significant development issues WHEN THEY</td>
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<tr>
<td>4B) Manufacturing Business Units are NOT informed of significant development issues until they &quot;own&quot; the product. Prior to that, the team's manufacturing integrator represents them.</td>
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<tr>
<td>5A) Manufacturing has a &quot;World Class&quot; attitude. (Enthusiastic, cooperative, proactive, see big-picture, take ownership, challenge others)</td>
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<tr>
<td>5B) Manufacturing does NOT have a &quot;World Class&quot; attitude.</td>
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<tr>
<td>6A) Manufacturing Associates understand the importance of complying with quality practices and GMP.</td>
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<tr>
<td>6B) Manufacturing Associates learn about GMP and quality practices ONLY as needed.</td>
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<tr>
<td>7A) Manufacturing Business Units understand the technical intent of the product's design.</td>
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<tr>
<td>7B) Manufacturing Business Units are NOT aware of the technical intent of the product's</td>
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<tr>
<td>8A) Manufacturing delivers products or services to requesting groups ON TIME.</td>
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<tr>
<td>8B) Manufacturing occasionally delivers products or services after the deadline.</td>
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</tbody>
</table>
### Appendix A

**SURVEY, Page 2 of 2**

<table>
<thead>
<tr>
<th>Future need/wish for the mfg. plant</th>
<th>Rank Importance</th>
<th>If this were the case, how would you feel?</th>
<th>Satisfaction w/ Cincinnati?</th>
<th>with other manufacturers?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 3 5</td>
<td>1 2 3 4 5</td>
<td>1 3 5</td>
<td>1 3 5 0</td>
</tr>
<tr>
<td><strong>9A</strong> Operations practices Continuous Flow Manufacturing (CFM). (Minimal inventory and cycle times; simple operations, ...</td>
<td>Check one</td>
<td>Check one</td>
<td>Check one</td>
<td>Check one</td>
</tr>
<tr>
<td><strong>9B</strong> The mfg. processes are the same as today.</td>
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<tr>
<td><strong>10A</strong> An individual from manufacturing is designated to be the communications interface to</td>
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<tr>
<td><strong>10B</strong> There is no one from manufacturing specifically designated to be the interface to my</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td><strong>11A</strong> Consistent production and test processes are used across different product lines.</td>
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</tr>
<tr>
<td><strong>11B</strong> Each project team and product line are free to design their process as they see fit.</td>
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<tr>
<td><strong>12A</strong> A more sophisticated quality system is used to monitor and improve quality levels.</td>
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<tr>
<td><strong>12B</strong> The existing quality systems are in use.</td>
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</tr>
<tr>
<td><strong>13A</strong> Technical support people in operations can take over and maintain all responsibilities for ongoing product or process design issues.</td>
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<tr>
<td><strong>13B</strong> Development teams keep some responsibility for ongoing product/process design</td>
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</tr>
<tr>
<td><strong>14A</strong> Manufacturing costs are minimized.</td>
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</tr>
<tr>
<td><strong>14B</strong> Manufacturing costs are NOT a concern.</td>
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</tr>
<tr>
<td><strong>15A</strong> Production batch information is tracked and made available as per GMP guidelines FROM THE PILOTS ONWARD.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>15B</strong> Batch information is tracked ONLY DURING ACTUAL PRODUCTION, after the pilots.</td>
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</tr>
<tr>
<td><strong>16A</strong> Mfg. regularly exchanges knowledge with my group on issues, production info, and strategy.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>16B</strong> Manufacturing ONLY exchanges knowledge with my team/group on an informal, &quot;as needed&quot; basis.</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>17A</strong> Manufacturing associates can analyze and solve problems themselves.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>17B</strong> Manufacturing associates call the technical experts to solve problems.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>18A</strong> Responsibilities of the Pilot Group and the Manufacturing Business Units are understood by the development teams.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>18B</strong> The development teams do NOT understand responsibilities of the Pilot Group and the Manufacturing Business Units.</td>
<td></td>
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</tr>
</tbody>
</table>

OTE * Specify who you were referring to (Other EES Plant or Contract Manufacturer Name):
Appendix B - Results of Simulation

At Ethicon Endo-Surgery the first simulation model matched the conditions shown in the Figure 6.1 flowchart. This was an approximation of the line at the start of the project. Several iterations, or production line scenarios, were simulated before a final line design was settled upon. In this section, the optimization method is described in the simulation of Ethicon Endo-Surgery's Omega production line. For review, a table of the original process steps is given below.

<table>
<thead>
<tr>
<th>Op#</th>
<th>Description</th>
<th>Avg Time</th>
<th>Range</th>
<th>No. Stations</th>
<th>Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Subassembly</td>
<td>1.00 minute</td>
<td>0.70-1.30</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>Assembly</td>
<td>4.25 minutes</td>
<td>2.15-6.35</td>
<td>3</td>
<td>98%</td>
</tr>
<tr>
<td>3</td>
<td>Weld</td>
<td>1.15 minutes</td>
<td>---</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>4</td>
<td>Check</td>
<td>2.40 minutes</td>
<td>2.05-2.75</td>
<td>1</td>
<td>99%</td>
</tr>
<tr>
<td>5</td>
<td>Load</td>
<td>2.45 minutes</td>
<td>2.10-2.80</td>
<td>1</td>
<td>98%</td>
</tr>
<tr>
<td>6</td>
<td>Attach</td>
<td>1.55 minutes</td>
<td>1.20-1.90</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>7</td>
<td>Couple</td>
<td>1.45 minutes</td>
<td>1.25-1.65</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>8</td>
<td>Handle</td>
<td>2.45 minutes</td>
<td>2.10-2.80</td>
<td>2</td>
<td>100%</td>
</tr>
<tr>
<td>9</td>
<td>Cycle</td>
<td>1.80 minutes</td>
<td>1.55-2.05</td>
<td>1</td>
<td>97%</td>
</tr>
<tr>
<td>10</td>
<td>Compare</td>
<td>1.75 minutes</td>
<td>1.50-2.00</td>
<td>1</td>
<td>99%</td>
</tr>
<tr>
<td>11</td>
<td>Test</td>
<td>1.05 minutes</td>
<td>---</td>
<td>1</td>
<td>99%</td>
</tr>
<tr>
<td>12</td>
<td>Inspect/Pack</td>
<td>2.25 minutes</td>
<td>1.65-2.85</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>23.55 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Given the initial conditions (Figure 6.1) and an existing production staff of 6.5 to work with, the first step was to divide the 12 operations among the 6.5 people. For perfect balance, each individual would have 3.6 minutes worth of work (23.55/6.5). However, there were a few constraints to consider. First, it was decided that the twelve operations would not be further subdivided at this time to balance the line, making 3.6 minutes apiece unattainable. Second, because of the nature of the process, the Cycle and Compare operations had to be done together by the same person. Finally, because of the travel distance between stations, it was decided that operations would only be combined with the operation immediately before or after. Given these constraints, the only way to assign operations to the 6.5 people was as follows:
<table>
<thead>
<tr>
<th>Person #</th>
<th>Op#</th>
<th>Description</th>
<th>Avg Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (half-time)</td>
<td>1</td>
<td>Sub assembly</td>
<td>1.00 minute</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Assembly</td>
<td>4.25 minutes</td>
</tr>
<tr>
<td>3</td>
<td>3,4</td>
<td>Weld &amp; Check</td>
<td>3.55 minutes</td>
</tr>
<tr>
<td>4</td>
<td>5,6</td>
<td>Load &amp; Attach</td>
<td>4.00 minutes</td>
</tr>
<tr>
<td>5</td>
<td>7,8</td>
<td>Couple &amp; Handle</td>
<td>3.90 minutes</td>
</tr>
<tr>
<td>6</td>
<td>9,10</td>
<td>Cycle &amp; Compare</td>
<td>3.55 minutes</td>
</tr>
<tr>
<td>7</td>
<td>11,12</td>
<td>Test &amp; Inspect/Pack</td>
<td>3.30 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>23.55 minutes</td>
</tr>
</tbody>
</table>

It should be noted that the rotation of people from station to station is encouraged but is independent of this analysis. For example, person 2 in this study refers to whoever is staffing the assembly workstation, whether it is a different person every hour or the same person all day.

The next step was to determine the line's capacity with 6.5 people staffed as described earlier. The simulation model was loaded and run. Initial parameters included the operation times, yields, and variations. At this point, buffers were defined to have arbitrary sizes of ten units with first-in-first-out methodology. The highlights of the simulation run are shown in Figure B.1, under the "Original" column.

There are a few highlights of this first simulation run worthy of mention. The throughput rate of 105 units is far higher than the amount needed to satisfy the demand forecast (even after adding the 40% capacity safety factor). The excess capacity is also evident in looking at the low levels of workstation utilization. In other words, the model has shown that the line has more equipment than they need with only 6.5 people. The employee utilization is about what one would expect in a realistic line - 100% utilization of every individual is never realized.
### Figure B.1

<table>
<thead>
<tr>
<th>Simulation</th>
<th>Original</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day's throughput</td>
<td>105</td>
<td>82</td>
</tr>
</tbody>
</table>

**Average WIP Units**

<table>
<thead>
<tr>
<th>Buffer</th>
<th>Original</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer 1</td>
<td>10</td>
<td>0.196</td>
</tr>
<tr>
<td>Buffer 2</td>
<td>0.17</td>
<td>0.054</td>
</tr>
<tr>
<td>Buffer 3</td>
<td>0.58</td>
<td>0.032</td>
</tr>
<tr>
<td>Buffer 4</td>
<td>0</td>
<td>0.019</td>
</tr>
<tr>
<td>Buffer 5</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Buffer 6</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Buffer 7</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Buffer 8</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Buffer 9</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Buffer 10</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>10.75</strong></td>
<td><strong>0.301</strong></td>
</tr>
</tbody>
</table>

**Workcenter Utilization**

<table>
<thead>
<tr>
<th>Workstation</th>
<th>Original</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workstation 1</td>
<td>24%</td>
<td>100%</td>
</tr>
<tr>
<td>Workstation 2</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>Workstation 3</td>
<td>28%</td>
<td>89%</td>
</tr>
<tr>
<td>Workstation 4</td>
<td>58%</td>
<td>86%</td>
</tr>
<tr>
<td>Workstation 5</td>
<td>59%</td>
<td>81%</td>
</tr>
<tr>
<td>Workstation 6</td>
<td>37%</td>
<td>N/A</td>
</tr>
<tr>
<td>Workstation 7</td>
<td>35%</td>
<td>N/A</td>
</tr>
<tr>
<td>Workstation 8</td>
<td>59%</td>
<td>N/A</td>
</tr>
<tr>
<td>Workstation 9</td>
<td>44%</td>
<td>N/A</td>
</tr>
<tr>
<td>Workstation 10</td>
<td>42%</td>
<td>N/A</td>
</tr>
<tr>
<td>Workstation 11</td>
<td>26%</td>
<td>N/A</td>
</tr>
<tr>
<td>Workstation 12</td>
<td>54%</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>AVERAGE</strong></td>
<td><strong>47%</strong></td>
<td><strong>89%</strong></td>
</tr>
</tbody>
</table>

**Employee Utilization**

<table>
<thead>
<tr>
<th>Employee</th>
<th>Original</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee 1*</td>
<td>24%</td>
<td>100%</td>
</tr>
<tr>
<td>Employee 2</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>Employee 3</td>
<td>86%</td>
<td>89%</td>
</tr>
<tr>
<td>Employee 4</td>
<td>97%</td>
<td>86%</td>
</tr>
<tr>
<td>Employee 5</td>
<td>94%</td>
<td>81%</td>
</tr>
<tr>
<td>Employee 6</td>
<td>86%</td>
<td>N/A</td>
</tr>
<tr>
<td>Employee 7</td>
<td>80%</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>AVERAGE</strong></td>
<td><strong>81%</strong></td>
<td><strong>89%</strong></td>
</tr>
</tbody>
</table>

* Employee 1 in 1st Column is half-time

**Flowtime (minutes)**

<table>
<thead>
<tr>
<th>Flowtime</th>
<th>Original</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>110.1</td>
<td>24.9</td>
</tr>
<tr>
<td>Processing time</td>
<td>23.6</td>
<td>23.6</td>
</tr>
<tr>
<td>Waiting Time</td>
<td>86.5</td>
<td>1.3</td>
</tr>
</tbody>
</table>
A nice feature of the line as it was arranged in this simulation is the low levels of WIP inventory, and consequently, the low total cycle time from start to finish. When the work was assigned to the 6.5 people, it (coincidentally) was arranged with the most time consuming operations near the beginning and the shorter operations near the end of the process. As a result, a "starved" line condition resulted where "downstream" operations were often waiting for WIP from the lengthier operations "upstream." Contrary to what the name implies, a starved line can be preferable to the opposite case where vast stockpiles of WIP inventory can build up if not managed carefully. Starved lines, as long as they are fairly well balanced (no operation takes more than 15-20% more or less than the others), are actually continuous flow lines, or "pull" systems. Such conditions are especially desirable in companies such as Ethicon Endo-Surgery where the lines have to be purged of material at the end of each work day, to facilitate better batch-tracing for the FDA. This type of line flow where the operations are "stacked" with the longest operations first and the shortest operation last would be kept as a goal for future iterations of the Omega simulation project.

In actuality, several simulation iterations occurred before and after the "original" scenario described earlier. Minor process changes were made and minor tweaking was done on such things as buffer sizes or line balancing. For the purposes of illustration, only two simulation models are described, the "original" and the "final." The methodology for getting to the "final" line design is described next.

Because the capacity of 105 units per day was too high, it was decided to try to redesign a manufacturing line that could operate with only five people. Five individuals was the number identified by the headcount formula earlier. If 6.5 individuals could produce 105 units per day, five individuals could reasonably be expected to produce around 80 units per day, all other factors being equal. Eighty per day allowed a reasonable buffer (1.4X) above the forecasted average daily volume.

Thus, the objective of this second simulation exercise was to design a line with five people and 80 per day capacity, with minimizing costs, WIP levels, cycle time and equipment. Remember, spreadsheet analysis indicated that no more than one of each of the original twelve workstations was needed to produce 80 per day.
The next step was to divide the work among the five employees, similar to how it was done in the previous example. In this experiment, a more sophisticated method, linear programming, was used to balance the line. As in the first simulation example, the original 12 operations (with operation times average ranging from 1.00 to 4.25 minutes) were used as building blocks in dividing the work. For perfect balance, each individual would have approximately 4.7 minutes worth of work (23.55/5). The objective of the linear program was to get each person's operation time as close to 4.7 minutes as possible. In other words, minimize the standard deviation, or range, of the five person's operation times. Two of the original constraints were kept - that the original 12 operation times could not be subdivided, and that the Cycle and Compare operations had to be together. Because a good balance could not be found by combining only adjacent operations, that constraint was thrown out.

When run, the linear program assigned the 12 operations to the five individuals so that their respective operation times were 4.7, 5.0, 5.0, 4.6, and 4.25, for a total of 23.55 minutes. Although very well balanced (with a standard deviation of only 0.31 and a range from highest to lowest of 45 seconds), the "optimal" solution was not really optimal. In some cases, individuals were assigned workstations that were on opposite ends of the line and would require much travel back and forth. The members of the Omega team did not want to have operators running back and forth every time, and they also did not want to build up large buffers of inventory to permit traveling less frequently, say ever hour.

To further improve the line balancing without requiring a lot of walking from workstation to workstation, the original 12 operations were eventually re-examined at to see if any operations could be subdivided and then recombined with other operations. The original time and motion study was used to study each sub-step within each of the 12 operations. As it turned out, some of the operations involved tasks that could be moved from one operation and combined with another. Through several iterations, potential solutions were manually generated, analyzed and ruled out. Eventually, a solution emerged that was almost as well balanced among the five workers as the solution generated by the linear program (standard deviation of 0.35 and a range from highest to lowest of 57 seconds). It had the added advantage that operations were combined only with the steps immediately before or after it, which eliminated the need for employees to travel back and forth between distant workstations. To make it even better, the operations were arranged from most time consuming to least, which would allow for a "starved" line condition and very
low levels of WIP. Figure B.2 shows the new and improved (simplified) process flow.

The table below shows how the work was divided:

<table>
<thead>
<tr>
<th>Person #</th>
<th>Op#</th>
<th>Description</th>
<th>Avg Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2, 3</td>
<td>Assembly &amp; Weld</td>
<td>5.25 minutes</td>
</tr>
<tr>
<td>2</td>
<td>4, 5</td>
<td>Check &amp; Load</td>
<td>4.75 minutes</td>
</tr>
<tr>
<td>3</td>
<td>6, 7, 8a</td>
<td>Attach, Couple &amp; Handle-1</td>
<td>4.70 minutes</td>
</tr>
<tr>
<td>4</td>
<td>8b, 9 10</td>
<td>Handle-2, Cycle &amp; Compare</td>
<td>4.55 minutes</td>
</tr>
<tr>
<td>5</td>
<td>11,12</td>
<td>Test, &amp; Inspect/ Pack, &amp; Subasm</td>
<td>4.30 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>23.55 minutes</td>
</tr>
</tbody>
</table>

The second simulation model was created and run with the above specifications. The results of this exercise are also summarized in Figure B.1, under the "Final" column. The final simulation results outdo the original case in all efficiency measures. In fact, if implemented and managed as indicated in the simulation model, the final line may have a truly world-class flow time with almost no WIP or non-value-added (queue) time. Other highlights worthy of mention are that the throughput (82 per day) is near the desired number, and that the five workers will be busy from 81% to 100% of the time - enviable numbers for assembly processes of this sort.

By using the varying levels of modeling, from back-of-envelope calculations to a sophisticated simulation model, the costs avoided on the Omega line are significant. The number of inventory buffer locations (opportunities for waste) was reduced from ten to four. Headcount was reduced from 6.5 to 5. The number of workstations and pieces of equipment was reduced considerably, although after the fact. Finally, the flow time was reduced to a very desirable level.

The assumptions underlying this final simulation model have evolved and have been revalidated as the actual production line begins to take shape. Because human beings are involved in the process, the operation times, availability times, and consequently, the levels
of inventory will vary considerably. Actual performance of the line may be better or worse than the model has indicated. In fact, the WIP levels are so close to zero in the model that they can probably only increase in actuality. Regardless of future changes in process or product design, or in operator variability, the simulation project provides an excellent starting point for laying out the Omega assembly line.
Figure B.2
Final Process Flow

Incoming Parts

Assembly & Weld
5.25 Minutes Avg.
3.10-7.35 Range

Buffer
4.75 Minutes Avg.
4.05-5.40 Range

Check & Load

Attach, Couple, & Handle-1
4.70 Minutes Avg.
4.1-5.3 Range

Buffer

Handle-2, Cycle, & Compare
4.55 Minutes Avg.
3.90-5.25 Range

Buffer

Test, Insp/Pack & Subassay.
4.30 Minutes Avg.
3.45-5.15 Range

Outgoing goods

Final Configuration: 5 Operations, 5 Operators, 4 Buffers, Output 82 per day, 23.55 Total Minutes Labor Per Unit
BIBLIOGRAPHY


