CHAPTER 1

OVERVIEW

1.1 Introduction

Consumer products companies that are considering switching from dedicated high-speed packaging lines to flexible packaging lines are confronted with numerous questions, such as: What is flexibility? How much flexibility is required? What will flexibility cost and how do I justify the investment? What is the impact of changeovers on the efficiency of packaging line flexibility? How is flexibility measured or benchmarked? Industry trade organizations and consultants have attempted to answer these questions with limited success.

The 1980's are known as the decade of quality, and the 1990's are known as the decade of agility which focused on improving responsiveness of the entire supply chain (Hopp and Spearman 2001). The methodology of agile manufacturing was developed in the late 1980s and early 1990s, to ensure that the manufacturing enterprise was agile enough to respond to changing customer requirements, shorter product life-cycles, decreased time to market for new products, greater product diversity and highly fragmented markets. It is characterized by the use of flexible manufacturing systems (FMS), which typically integrate manufacturing equipment and robots to produce highly efficient and flexible work-cells. Integrated design methodologies, such as concurrent engineering and design for assembly (DFA), have focused on activities from product development through manufacturing to meet the same challenges. Agile manufacturing and integrated design methodologies have greatly improved manufacturing operations, but have failed to incorporate packaging and packaging system design (Raper & Sun 1994). Sun (1991) proposed an expanded integrated product and packaging design methodology so that the product and its packaging are equally considered, resulting in greater production and distribution efficiency.

As the diversity and customization of new products continues to expand, the approach to manufacturing and packaging has changed in response to the challenges of improving supply-chain management. Manufacturers can no longer effectively supply customers from dedicated high-speed packaging lines and are responding by switching to machine-paced manual operations, manufacturing in smaller batches with quick-changeover equipment, or using contract specialty packaging companies to accommodate the ever-increasing variety in packaging required. Annual new product introductions, identified as stock keeping units (SKUs), at grocery and drug stores have increased from 2,619 in 1981 to over 16,000 in 1994, and over 25,000 in 1995 (Duncheon 1998a). The majority of these new product introductions were only changes in packaging configurations.

Other manufacturers are adopting a modular flexible packaging strategy, which replaces hard automation and its long changeover times, with flexible automation with minimal changeover times. Servo-motors are replacing mechanical gear and chain motion systems using a central drive system. Some of these systems now utilize robotics, flexible-parts-feeding and machine-vision systems. A combined framework for agile manufacturing and packaging would result in shorter product implementation cycles, minimum life-cycle costs, and improved product quality.

Flexible packaging lines are critical to the success of consumer goods companies. In this praxis, I report on the development of design guidelines for flexible packaging lines, the design and implementation of a flexible packaging line at Alcon Laboratories, and a performance evaluation and financial analysis of this new flexible packaging line based on three years of industrial operation. This chapter presents an overview of the challenges facing the consumer goods packaging industry, critical factors affecting packaging line performance, the application of robots in the packaging industry, and an introduction to packaging and packaging design. The final section of this chapter presents the objectives and contributions of this praxis, and provides and overview of the organization of this praxis.

1.2 Challenges Facing the Consumer Goods Packaging Industry

1.2.1 Overview of the Packaging Industry

In 1996, the U.S. packaging market, (consisting of seven industrial sectors: beverage, food/pharmaceutical, consumer products, paper, chemicals, and automotive / electrical / industrial) exceeded $100 billion in sales, and the world packaging market exceeded $400 billion (Heitzman 1996b). As described in this section, the packaging industry is undergoing massive change and is struggling to remain competitive in an increasingly international marketplace with extreme regulatory, technical and competitive pressures. Packaging costs average 15 to 20 percent of a typical U.S. manufacturing company's sales revenues and represent significant cost savings opportunities, which are increasingly being targeted in the beverage, food, pharmaceutical, and consumer product industries (Katpakjian 1994). These same industries use packaging as a primary marketing strategy and depend on a large variety of packaging styles and configurations for the success of their products (Raper and Sun 1994). Further, these industries invest in automation to improve product quality, eliminate repetitive-motion injuries, and provide greater flexibility to meet decreasing product life-cycles.

In the 1970s and 1980s, large beverage, food, pharmaceutical and consumer goods companies invested heavily in dedicated high-speed packaging lines to reduce their costs and provide a competitive advantage. Most existing state-of-the-art packaging lines utilized the design concepts of mass production and were built for sustained high-speed operations with minimal changeovers. These lines were typically dedicated to a single product. The beverage industry is the most highly automated; for example, many breweries fill and package 12-ounce beer cans at speeds of up to 2000 cans per minute (33 per second). The food and pharmaceutical industries have numerous applications in the range of 200 to 400 units per minute.

In the 1990's these companies have discovered that their dedicated high-speed packaging lines were not flexible enough to respond effectively to shorter product life-cycles, greater product and packaging variety, and highly fragmented markets. In response to these market changes, consumer goods companies are moving away from mass production strategies, adopting flexible manufacturing and mass customization strategies in order to compete (Stalk 1988, Anderson 1997, Gilmore and Pine 1997). This shift requires packaging lines to be significantly more flexible and agile.

The beverage, food and pharmaceutical trade literature (Warner 1990, Swientek 1993a,b,c, Koss 1993 and 1995, Berne 1996, Leary 1995 and 1996, Ferrante 1997, Sleep 1998, Swain 1998, Senti and Parish 1998, Pierce 1998, Morris 1997, 1998, 1999, and 2000, Duncheon 1998b, Wyle 1999, Weber 2000) clearly indicates that flexible manufacturing and mass customization concepts are being implemented in packaging lines and operations. Specifically, these industries are now emphasizing:

- Strategic flexibility (broad product mix, packaging flexibility, fast response, low cost, quick changeovers),
- New product introductions and line extensions (SKUs),
- Short product life for food products (85% of food products remain on the market less than one year),
- Increased automation from raw materials handling through palletized final product,
- A shift from push systems (production and distribution driven) to pull systems (market driven), and
- Increased use of robotics, vision systems, and automation in primary and secondary packaging and material handling.

The consumer products industries have a growing acceptance and understanding of the benefits of robotic packaging.

1.2.2 Regulatory Mandates and Business Challenges

In the United States, the government has a significant impact on packaging through regulatory mandates from the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). These mandates affect the content, appearance, volume of materials, containers and labeling. Regulatory mandates include:

- FDA and EPA regulations on packaging material source reduction and recycled content,
- FDA regulations on packaging materials,
- FDA regulations on the packaging and labeling of pharmaceuticals, considered to be part of the overall system to facilitate proper dispensing and usage, and
- OSHA regulations requiring ergonomic improvements, elimination of repetitive motion injuries, heavy lifting and vibration.

A significant portion of packaging costs are mandated by federal regulations. New FDA regulations going into effect in 2002 for over-the-counter drugs will greatly increase information required on labels and inserts, and this will require innovative new label and carton designs and or replacement of existing literature folding and cartoning equipment (Makely 2000, Barlas 2001, Forciano 2001). Regulatory pressures are just as strong in international markets, particularly those resulting from environmental initiatives in the European Union.

The economic pressures on the packaging industry are severe and there is a critical need to improve the efficiency and agility of packaging systems. According to Noone (1995), the limited supply of traditional raw materials is driving up costs and companies are changing to versatile, lightweight, and cost-effective flexible packaging materials, such as film, paper and foil. These materials also improve oxygen/moisture barrier properties, improve mechanical strength and sealing qualities, and reduce waste. The proliferation of new packaging configurations, such as recloseable bags and pouches, has also required packaging lines to become more flexible.

In the 1980s, many mass merchandisers focused on logistics and supply-chain management to develop a strategic advantage. These programs include "vendor managed inventory," "continuous replenishment," "quick response," "accurate response," just-in-time (JIT), and "efficient consumer response (ECR)."

The emerging technology of ECR was pioneered by Wal-Mart and Kmart to dramatically cut costs in product ordering and distribution by minimizing inventory, paperwork and material handling operations. ECR is an extension of the JIT philosophy in which an item scanned at checkout (point of sale) pulls a replacement product through a manufacturer's order and distribution system electronically. Manufacturers take responsibility for rapid replenishment of a retail stock order management system, which handles order processing, transportation load building (mixed pallets) and sales reporting using electronic data interchange (EDI). Grocery and general merchandise stores are rapidly adopting ECR to reduce costs, but these changes require extreme agility in manufacturing, packaging and distribution from manufacturing companies. Manufacturers are also switching from national brand forecasts to customer SKUs at the distribution center level, and managing the entire integrated supply chain with customer-level SKU data driving manufacturing and distribution. Each SKU represents a unique packaging configuration.

The pharmaceutical industry has fallen behind other consumer products manufacturers in packaging and distribution. The pharmaceutical industry has made major improvements in the packaging and distribution of over-the-counter (OTC) drugs, but has made little progress on prescription drugs. Even in the late 1990's, most prescription drugs are still manufactured to stock (versus to order) and distributed through traditional channels. The industry still keeps about six months of inventory in the supply chain to prevent stock outs and "has done little to modernize its packaging and distribution processes in the last 30 years" (Sleep 1998). But the growth in managed care, the consolidation among wholesales and distributors, and the increase in mail-order prescriptions are driving restructuring of the supply chain (Sleep 1998). As an example, Merck Medco now has two facilities dedicated to the flexible packaging and direct mail-order distribution of prescription drugs.

As examples of the increasing demands placed on manufacturers, consider Miller Brewing, Glaxo Wellcome and Kose. The Miller Brewery in Fort Worth, Texas has transitioned from producing four beers in 100 SKUs in the early 1980s to producing 27 beers in approximately 3000 SKUs in 1996. Glaxo Wellcome's pharmaceutical plant in Zebulon, North Carolina has transitioned from a dedicated solid dosage plant in the early 1980's to producing over 30 products in over 120 SKUs in 1999 (Butchli 1999). Required changeovers have increased from 12 to 70 changeovers per line per year, with a total of over 500 changeovers per year. Kose, a large cosmetics manufacturer in Japan, recently commissioned a new modular quick change bottling line to fill and package over 100 different bottle shapes (30-85 mm diameter, 80-200 mm height) with a variety of different closure systems (Reynolds 2001). The line has servo-motors for automatic changeovers to support the manufacture of up to five different products over two shifts with minimal downtime.

1.2.3 Critical Factors Affecting Packaging Line Performance

As discussed earlier in this chapter, the packaging industry is highly diverse. A literature review and analysis of previous research was conducted to identify potential factors influencing flexible packaging lines and the criteria used to evaluate its performance. Industry trade organizations, such as the Packaging Machinery Manufacturers Institute (PMMI), and trade magazines, such as *Food Engineering*, *Packaging Digest* and *Packaging World*, have sponsored multiple surveys to benchmark packaging productivity trends, to understand the packaging challenges facing the industry, and to establish useful measurements of productivity and flexibility.

PMMI's 1993 Packaging Productivity Benchmarking Survey (Miyares 1993, PMMI 1993) established a Packaging Productivity Index of 72.3 percent (based on hypothetical line configuration) for the food, beverage, pharmaceutical, consumer product and chemical industry sectors. The most commonly identified problems were changeover speed (59%), changeover quality (43%), and worker ergonomics (42%). Manufacturers cited the following as critical needs in automation, ergonomics and machinery:

- totally flexible packaging lines to accommodate continual changes in packaging with tool-less changeovers in minutes, not hours,
- increased productivity through automation to reduce labor, or to maintain headcount while improving throughput,
- elimination / reduction of repetitive motion injuries, and
- upgrading existing packaging lines for productivity / reliability / flexibility improvements.

Bill Haughey of Nabisco clearly summarized the challenges facing the packaging industry today:

> "We want line efficiency and don't care about mechanical uptime, we care about throughput .... we are blessed with a marketing department that continually changes size, shape, and configuration of the products so it is difficult to respond with automated equipment that is able to meet such changing needs. Where we do have hand loading going on, we try to design it as ergonomically as possible by controlling the number of picks, types of motions, sitting vs. standing positions, etc. But it remains a problem in our industry and we are looking at ways of combating it, primarily through robotics as opposed to major pieces of equipment that aren't as flexible" (Miyares 1993).

The Packaging Machinery and Packaging World Expo '94 and '95 Surveys indicated that packagers were focusing on improved ergonomics, productivity and flexibility, and identified tracking packaging line productivity as the most important issue (Orlaski 1994, Orlaski 1995). Increasing automation, decreasing changeover time, increasing equipment flexibility, increasing use of bar codes, and new packaging materials were also identified as areas of primary interest (Orlaski 1995). PMMI's 1995 Packaging Productivity Trends Indicator Survey (PMMI 1995) was conducted with a goal of developing a definitive measurement of productivity, and was focused in three areas: corporate operating philosophy (measurement of cost, line productivity, efficiency, improvement, and efficient consumer response), people (education, training, teams, empowerment, safety, ergonomics, automation influence) and technology (changeover, controls software). The most common packaging productivity measurement methods were output per hour (40%), SKUs shipped per shift (22%), operating equipment effectiveness (15%), hours uptime (12%), and inventory turns (2.5%). The primary factors affecting corporate manufacturing / packaging philosophy were minimizing the time, complexity, and cost required for changeovers since the number of required changeovers is increasing. According to Heitzman (1996a), "there is no question, manufacturers are seeking ways to improve packaging productivity," and "the packaging community is interested in developing some type of model to help assess packaging line productivity."

The Packaging World Expo '96 Survey indicated that over 86% of companies are planning to purchase more flexible packaging equipment even if it means sacrificing line speed, and identified quick changeover, flexibility, and speed as the most important attributes (Orlaski 1996). The 1997 Packaging Productivity Forum was held April 28-30, 1997, and released the results from the 1996 Packaging Productivity Trends Indicator Survey, which again had measurement of packaging line productivity as a major focus (PMMI 1996). The overall trend is an increasing number of changeovers, which are requiring more time to complete. In the 1996 survey, 49% of respondents reported one or more changeovers per shift versus 42% in the 1995 survey. Most manufacturers reported completing two or more changeovers per shift, with two-to-three changeovers per week reported by 20%. In the 1996 survey, 64% reported that changeovers were completed in less than two hours (25% in less than 30 minutes), versus 73% of changeovers completed in less than two hours (32% in less than 30 minutes) in the 1995 survey. 80% of packaging lines returned to acceptable efficiency in less than two hours, 67% in less than one hour. In 1995, an average manufacturer incurs a cost penalty of between one and four hours of lost production for every packaging line changeover! In 1995, 61% of manufacturers reported running five or more products versus 81% running four or more products in 1996. Some companies, such as Anheuser Busch, have adopted a mixed mode operating philosophy utilizing some dedicated lines and some flexible packaging lines in the same plant. Dedicated lines are assigned when a single product utilizes over 75% of the line's capacity, and run high volume products requiring only minor changeovers (cosmetic changeovers). Flexible lines are used for specialty products and to respond to market demand.

The 1997 Packaging Technology & Engineering Survey (Luttenburger 1997) indicated that companies need increased flexibility for their current product mix, are increasing expenditures to purchase equipment with increased flexibility, and are increasingly concerned with their return on investment. The 1997 PMMI Packaging

Machinery Shipments and Outlook Study (PMMI 1997) reported that productivity improvement was the number one driver for the purchase of new equipment, and 32% of all packaging machinery manufacturers were incorporating robotics into their packaging equipment to improve flexibility. Purchasers are seeking machinery with faster speeds, improved changeover flexibility, vision systems and robotics, tool-less changeover, and more systems integration to improve their productivity (Falkman 1998a). The food, beverage, cosmetics and pharmaceutical industries account for 60% of the total expenditures of an estimated \$6.7 billion packaging machinery market, and \$100.8 billion packaging materials and supplies market (PMMI 1997, Falkman 1998). The 1997 PMMI Packaging Productivity Trends Indicator Survey reported that manufacturers faced an increasing number of changeovers, and indicated that changeover inefficiencies were challenging productivity (PMMI 1997). 59.3% reported an increase number of short-run or limited-run products since the previous year thus increasing the number of required changeovers. 53% of packaging lines average more that 5 different product or package-size variations, and 27.2% change product/package sizes more than twice per shift. Packaging equipment is reported as the leading productivity inhibitor because of changeover time (28.5%), downtime (18.8%) and limited flexibility (10.9%). This study (PMMI 1997) suggests nine operations strategies to improve packaging line productivity including; faster more precise changeovers, operations flexibility, simplification and modularization, computerization, robotics, functional integration, remote diagnostics and technical service, training, and improved product and materials handling.

The food and beverage industries struggled with the challenges of shorter runs, more product variety, with minimal downtime for changeovers. The great variety of products and packages required food manufacturers to develop quick changeover capabilities, but they quickly discovered that changeover effectiveness was a critical factor in their success (Ferrante 1997). Morris (1997) described some of the critical tradeoffs to consider when designing for flexibility: capital costs versus labor costs, capital costs versus long term operating costs, and operational efficiency versus changeover downtime. Morris also observed that “people might be the most flexible option, but are also most expensive,” but also recommended that equipment not be designed for flexibility unless absolutely needed because of the changeover issues (Morris 1997).

The 1998 PMMI Packaging Machinery Shipments and Outlook Study (PMMI 1998) reported that increased speed and improved flexibility for changeovers were the primary drivers for the purchase of new equipment. Purchasers are requiring faster more flexible machinery with quick changeover parts to run wider varieties of products and materials and support efficient shorter runs (Yuska 1998). Manufacturers are also seeking reduced labor costs, higher throughput, improved product consistency, and are adding more tamper-evident and anti-counterfeiting devices (Forciano 1999). The 1998 Food Engineering report on the State of Food Manufacturing (Morris 1998) reported that the market was requiring cost reduction, more flexibility and improved changeover efficiency. Most companies were concentrating on improving their packaging line efficiencies and flexibility, but this survey reported that flexibility had declined in 1998 as compared to 1997. Food and beverage manufacturers realized that increased flexibility was required to operate in a JIT mode to achieve Efficient Consumer Response

(ECR) but struggled to do so effectively when 4 or 5 changeovers a day were required (Ferrante 1997).

The 1999 PMMI Packaging Machinery Shipments and Outlook Study reported that expanded robotics, vision systems and flexibility were the top three drivers for investing in new packaging machinery (PMMI 1999). It also reports that packagers are under so much pressure to cost efficiently package a wide variety of new products that they elected to purchase new equipment with quicker changeovers, rather than run these products on existing machinery with the added burden of excessive downtime for the required changeovers. The 1999 PMMI Packaging Productivity Trends Indicator Survey reports large gains in packaging productivity in the food, beverage, and cosmetics industries and some productivity loss in the medical device and pharmaceutical industries (PMMI 1999). Three quarters of all manufacturers reported a gain in packaging productivity in 1998 over 1997, with 45% reporting gains of 10%-20%, and 41% reporting gains of less than 10%. New equipment (73.2%) was the largest factor contributing to increased packaging productivity. More product variations, new packaging materials and new package designs are reported as having both positive and negative effects on productivity, most notably a negative effect in the food and beverage industries. Effective changeovers are identified as the key to packaging productivity, with 90% reporting changeover time as having a significant impact on productivity, and 67% of packagers reporting an increase in the number of short or limited runs over last year (Orlaski 1999). 58% run five or more product size variations per line, 20% run three or less, and only 1% report dedicated lines for a single product or size. The number of product changeovers is also increasing with 27.7% reporting changes more than twice per shift, 23.3% reporting once or twice per shift, and 32.5% reporting one to three times per week. In the pharmaceutical industry, 33% of the lines have one or two changeovers per shift, with 45% requiring more than two hours to complete and only 10% requiring less than 30 minutes.

The 1999 and 2000 Food Engineering reports also describe the trade-off between efficiency and flexibility, and the need for more flexible packaging equipment to support the increasing product variety, and package and product changes (Morris 1999, 2000). These reports stress the need for effective changeovers and quick ramp-up to full production to ensure operational efficiency.

The 2000 and 2001 PMMI Packaging Machinery Shipments and Outlook Studies (PMMI 2000, PMMI 2001, Falkman 2001, Orlaski 2002a) similarly concluded that new product introductions and a sustained focus on increasing packaging productivity were driving investment in new packaging machinery. Packagers were “focusing on increased speeds, improved changeover flexibility, greater accuracy, simpler control, add more versatile handling through robotics” to accommodate the expanding variety in alternative packaging materials and configurations (PMMI 2001). Packagers were also actively retro-fiting and rebuilding equipment to improve speed, increase accuracy, automate and shorten changeovers, and upgrade controls to improve productivity (Orloski 2001, Orlaski 2002a). PMMI’s 4th Annual U.S. Packaging Machinery Purchasing Plans Study provided some additional insight (PMMI 2001), reporting that the “accelerating rate of new product introductions and SKU additions” and the increased output of private labeled products are driving the investment in packaging equipment for food, beverage, personal care, medical device and pharmaceutical companies. The decision to invest in new equipment was driven by the need to improve productivity, speed and flexibility (32%), increase capacity (30%), and support new products (17%) (PMMI 2001). Over 75% of packagers were considering retro-fiting equipment to improve productivity, and 50% of all packagers reported using contract packagers for some or all of their packaging requirements between 1997 and 2000. Some pharmaceutical manufacturers are keeping their routine packaging operations in house but are outsourcing complex and unique packaging challenges to avoid capital investment and leverage the flexibility of contract packaging companies (Lubinsky 2000, Swain 2001). Similarly, pharmaceutical manufacturers are increasingly using contract packaging firms to package drugs in clinical trials to take advantage of their specialized equipment, and postpone capital investment in packaging equipment (Forciano 2000). Packaging World's study on contract packaging (Orlaski 2002 c, d) indicates an increase use of contract packaging to supplement internal capabilities. According to this survey, contract packaging companies are being utilized for new product introductions, promotional packaging, niche and low volume packages "without affecting the operation of in-house high volume packaging lines" (Orlaski 2002d). Primary reasons cited for using contract packagers are technology/capacity not available in house (35.9%), minimize capital investment (31.6%), spedd to market (13.7%), skills not available in-house (12%), and better location for distribution (6.8%). By necessity, contract packagers require much more flexibility to be built into their packaging lines to support their customers needs (Swain 1998).

The 2001 PMMI Packaging Productivity Trends Indicator Survey reports that U.S. packaging productivity (packaging output per unit of labor) was up 7.8% largely due to the installation of new equipment (PMMI 2001, Orlaski 2002b). The survey reported that 78% of manufacturers had an increase in productivity, 14.8% had no change, and 5.7% reported a decrease in productivity. The most significant market trend continues to be the "continued emergence and adoption of new and alternative packaging materials, sizes, configurations, and concepts." 47.8% report that packages were redesigned specifically to improve productivity. New packaging materials were reported to have both positive and negative impacts (57.3%), positive impacts (25.1%), no effect (12%) and negative effects (5.6%) on packaging productivity. 72.3% report improving their packaging efficiency by redesigning the layout of their lines, 61% reported installing faster equipment, and 39.9% reported installing more flexible equipment.

There are two additional trends to review. Manufacturers are increasingly seeking to add network based line control and data acquisition capability to their packaging lines to facilitate automatic changeovers, monitor critical performance indicators and identify performance bottlenecks (Zepf and Rumi 1999, Newcorn 2000, Lubinsky 2000, Newcorn 2001). In order to support these integrated packaging lines, manufacturers are also seeking to develop standards for packaging machinery (Forciano 1995) and motion controls (Newcorn 2000, Newcorn 2001).

What do the results of these studies mean? Consumer products companies have focused efforts to improve the flexibility, productivity and efficiency of their packaging operations, but the constant introduction of new packaging materials and configurations required to compete in today's market have prevented them from completely solving these challenges.

1.2.4 Applications of Robotics in Packaging

Robots were introduced to the United States automotive industry in the 1960s and robotic work cells use became widespread in the 1970s. Vision systems were introduced during the 1980's but the flexibility of robotic work cells were still limited by dedicated parts feeders, tooling and fixtures (Carlisle 1998). Better vision-based part flexible part feeders were introduced during the 1990's, which reduced changeovers and increased the efficiency and flexibility of robotic work cells (Manji and Forciano 2000). The cycle time for a typical robotic work cell has been reduced from 5-6 seconds in the late 1970's to around 2 seconds in 1990, and the operating cost has reduced from over $20 per hour to less than $10 per hour during the same period (Carlisle 1998). Robotic and vision systems technology has matured and they are now easier to use, have reduced operating costs and improved performance.

Today, robots are utilized in many applications in all industrial sectors, but the largest user of robots in the U.S. remains the automotive industry, with well over 50 percent of the market. The Robotic Industries Association (RIA 1997, RIA 2000) estimates that 110,000 industrial robots are currently in use in the U.S., and that as many as 14 times as many robots are in use in Japan. According to RIA, the U.S. robotics industry has recently posted their two best years in history, with sales of $1.22 billion in 1999 and $1.1 billion in 2000 (RIA 2000). A summary of industrial robot applications in the U.S. in 1995 (Hill 1995, RIA 1995) is presented in Table 1.1.

Table 1.1 Robot Applications in the U.S. (Hill 1995, RIA 1995)

Application	% of Total

Welding	53%
Material Handling	24%
Assembly	10%
Dispensing / Painting	8.5%
Other	3.5%
Measuring / Inspection	1.0%

In Table 1.1, the material handling applications includes machine loading and unloading, grinding, deburring, palletizing, depalletizing, and packaging applications. Packaging applications account for approximately one-third of the material handling applications, or eight percent of the total robot applications in the U.S.. Robots are widely used in packaging applications because of their flexibility, and are displacing custom high-speed packaging equipment. In the food and beverage industry, the most common use of robots is in secondary packaging operations such as case packing and palletizing. They are also widely used for loading, kit assembly and variety packaging applications. Some current robot packaging applications are listed below:

Horizontal Form/Fill/Seal Load and Unload
Wrapper Load and Unload
Vertical Form/Fill/Seal Unload
Carton Erection and Load
Case and Shipper Packing
Kitting
Literature Insertion
Flexible Feeding
Palletizing / Depalletizing mixed SKUs
Robotic Vertical Cartoning
Vision-Controlled Packaging
Flexible Feeding
Synchronous / Asynchronous Machine Interface
Single / Multiple Array Product Configurations
Single / Multiple Pick-and-Place Applications

Manufacturers in the U.S. have found that robotics can play a significant role in improving productivity, flexibility and time to market (Manji 1994, Benassi 1995, Manji 1996, Teresko 1996, Sprovieri 1997, Mangle, Richard and Desrude 1997, Senti and Parish 1998, Carlisle 1998, Sleep 1998, Duncheon 1998a, Sprovieri 1999, Herman 2000, Forciano and Manji 2000, Baird and Campbell 2001). Robots are particularly well-suited for handling multiple product sizes, product customization, fast changeovers, and for pick-and-place operations used to fill cartons, kits, trays, clamshell, and pouch packages (the latter type of activity is known as kitting). An explosive growth area for robotic packaging is kitting in the food, beverage, and pharmaceutical industries to improve product quality, and reduce labor costs, repetitive motion injuries, handling damage, and human contamination (bioburden). Pepperidge Farms uses 10 vision guided robots to package 20 different types of cookies into two different trays at a rate of 1100 cookies per minute (Newcom 1999). Procedure packs for hospital and home use are becoming widespread. National Healthcare produces a wide range of single-use medical procedure kits at its new factory in Winnepeg, Canada using robots to load standard components. The new factory required four years to design and build and was completed in July 1995 (Freiherr 1995). Other examples include, Miles Laboratories' Glucometer Elite Diabetes Home Test Kits (Larson 1995) are constructed from two thermoformed trays and contain nine components; and Alcon Laboratories' Lens Care Kits consist of a carton with up to seven vision-care products.

Robots continue to improve packaging-line productivity and quality but play an even more important role in improving flexibility. Manufacturers are increasingly sensitive to the rising cost of labor and are seeking to either reduce costs or to increase capacity without increasing their workforce size. The installed cost of robots and vision systems has dropped significantly in recent years and the improved price-to-performance ratio of flexible robotic automation has made this technology more attractive (Storjohann 1986, Jerney 1992). The time required for the installation of an integrated robotic/vision system work cell has dropped from years to months, and the return on investment averages between six months and two years (Carlisle 1998, Sprovieri 1998, Duncheon 1998a, Manji 1999). Integrated robot and vision systems are becoming widely used in the food and beverage industries for product inspection, product orientation, conveyor tracking, and primary and secondary packaging (Manji 1999). The primary drivers for this increased utilization of robots in packaging are increased labor costs and liabilities, reduced robot operating costs, integrated robot/vision system solutions for flexible feeding, and standardized work cells built from standard components (Duncheon 1998a). Manufacturers are also realizing that up to 90% of the equipment used in these robotic work cells can be reused for new products.

1.2.5 Overview of Packaging

In general, packaging serves four primary functions: containment, protection, performance, and communication (Twede 1988, Sun and Raper 1994). As indicated in Table 1.2, three different levels of packaging are utilized to fulfill the primary functions of containment and protection.

Table 1.2 Examples of Primary, Secondary and Tertiary Packaging

Product	Primary Packaging	Secondary Packaging	Tertiary Packaging
Beer	Bottle or Can	6/12/18/24 Pack	Shipper
Contact Lens Care Solution	Bottle	Carton	Shipper

Primary packaging is in direct contact with the product and is used for product containment, protection and identification. The shape of the packaging is used to reinforce product positioning and enhances product presentation. Primary packaging of a pharmaceutical product includes the bottle, plug, cap, tamper band, and label. Secondary packaging is used for protection (preservation) and communication, and may consist of a single product carton, an insert, or a paperboard multi-pack. Primary and secondary packaging is becoming increasingly important for pharmaceutical manufacturers because of the expanded labeling and insert requirements to meet FDA's new over-the-counter labeling regulation taking affect in 2002 (Swain 2000, Barlas 2001). Pharmaceutical manufacturers are having to "balance the tradeoffs between meeting these new regulations while maintaining their brand identity, shelf presence and cost effective production" (Makely 2001). Primary and secondary packaging also play critical roles in making the product tamper-evident, which is critical to ensuring consumer confidence ever since the Johnson & Johnson Tylenol product tampering cases and resulting deaths in the 1980s. Tertiary packaging, such as corrugated shippers, is used to protect the product during storage and shipping.

Tertiary packaging must be cost effective, strong enough to prevent damage, and also light enough for people to handle.

The third primary function of packaging is performance. Packaging is often part of a product delivery system (nozzle, neck design, etc.) and can be integral to the successful use of many products. Its design should add value and convenience (easy-to-open, single-use/dose, resealable, etc.) to the consumer. If the packaging fails, then the product may not be usable or may be more difficult to use. For example, if the packaging fails to keep a drug or food product sterile it will be unusable.

The fourth primary function of packaging is communication, which includes product identification, required product information and instructions for use. As discussed previously, many consumer goods companies use packaging as a primary marketing strategy and depend on a large variety of packaging styles and package configurations (different shapes, sizes, singles, multipacks, etc.) for the success of their products (Raper and Sun 1994, Swain 1998a and 1998b). A recent study indicated that customers are frustrated by current packaging options and confirmed that 70% make their purchasing decision based on the packaging (Consumer Network 2000, Forciano 2000). Packaging is used to position the brand (name, color, logo, shape, etc.), to reinforce brand recognition, maximize shelf impact and product appeal, and for promotional messages. Complimentary reinforcing messages are used on secondary and tertiary packaging to make the packages easily identifiable throughout the distribution chain.

Packaging design is often subjected to conflicting requirements from marketing and manufacturing. The use of packaging as a marketing tool requires a large variety of packaging configurations to differentiate a product. The simplification and/or standardization of packaging configurations is required for efficient production on existing packaging lines, which typically lack flexibility. Recognition of the importance of both the product and its packaging led Sun (1991) to develop an integrated product and packaging design methodology (see Figure 1.1), which integrates both manufacturing and marketing design requirements, optimizes product and packaging design, and reduces costs. This design methodology has improved the ability of companies to deliver efficient packaging designs, however most companies are still limited because their packaging lines are not flexible.

But packaging design is not a one-time design effort. It is a continuos improvement process or changing packaging to satisfy consumer needs, manufacturing and logistics needs, and responding to competitors packaging innovations. It requires continuous feedback from customers, retailers and distributors. The design process should focus on reducing the total cost of packaging and consider the packaging material, packaging efficiency and scrap, capital investment requirements, labor costs, distribution costs, and product damage during distribution. Secondary and tertiary packaging design should consider the requirements of the entire distribution chain, and specifically consider handling in

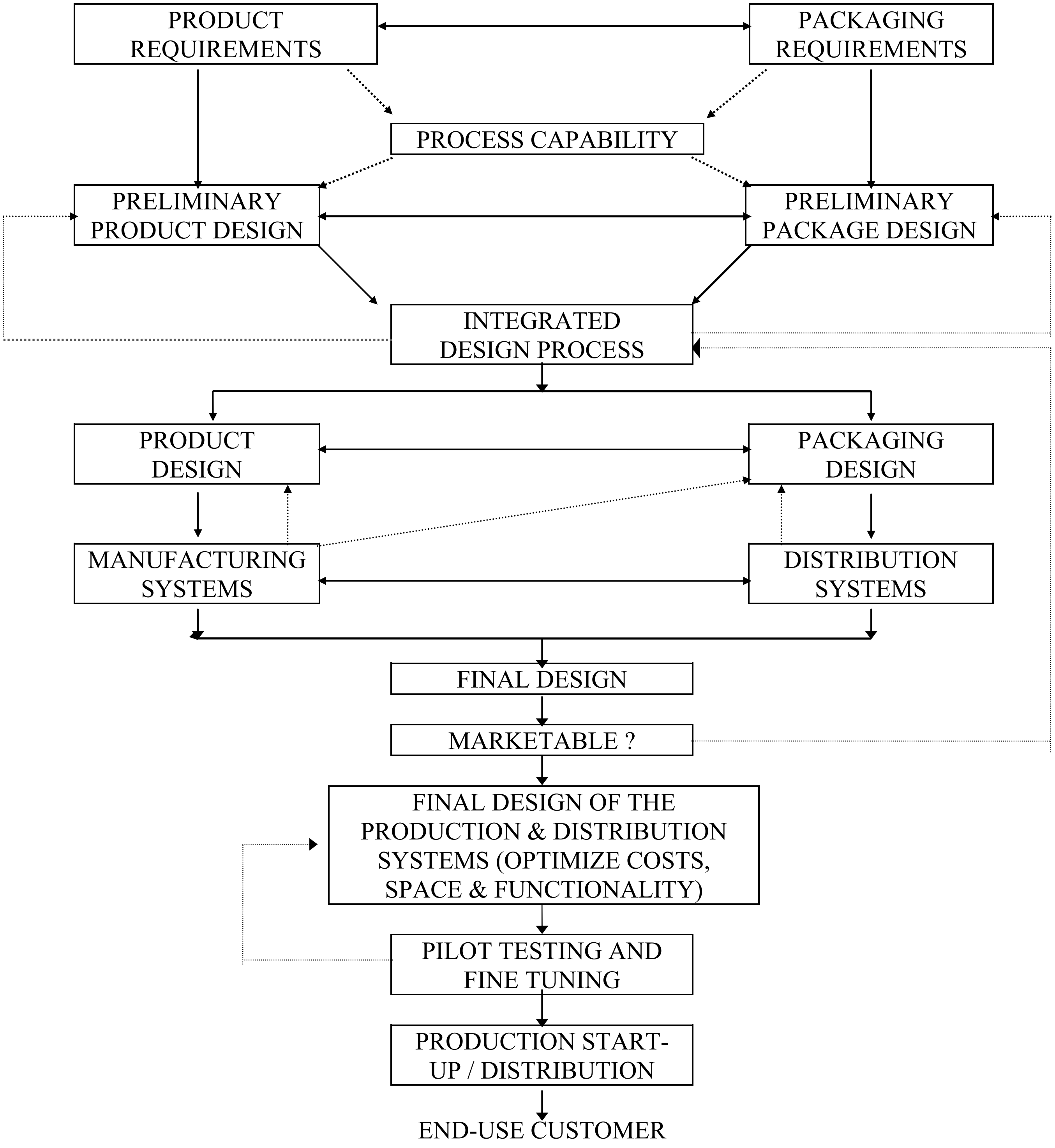


Figure 1.1: Integrated Product and Packaging Design Method (Sun 1991)

distribution centers and stores. Distributors and retailers should be consulted during the design process to understand their requirements and incorporate them into the packaging concept development. Typically, these requirements include package size, weight, easy to handle/grip, easy opening, standard material handling equipment, and clear identification of product. Distribution constraints such as transport methods and storage conditions need to be identified.

Research efforts in the 1980s and 1990s focused on manufacturing and distribution but failed to adequately address packaging. Manufacturing research developed the concepts of: concurrent engineering, lean manufacturing, flexible manufacturing and agile manufacturing. As discussed previously, the importance of concurrent engineering incorporating both product and package development has been recognized by Sun and Raper (1994). Some of these concepts are being commercialized in new software packages to facilitate online concurrent design of packaging with visibility throughout the supply chain (Canabe 2000). Other research focused on product distribution, logistics, integrated supply chain management, vendor-managed inventory, continuous replenishment, quick response, and accurate response, efficient consumer response. There is extensive literature defining flexibility, flexible manufacturing, design for assembly, design for manufacturing, concurrent engineering, performance assessment, and investment justification of manufacturing systems, but little, if any, of this previous research has been extended into packaging. No definitions or models of flexible packaging lines exist, and no assessment tools have been developed. A unified research framework for integrated manufacturing and packaging operations is required.

1.3 Objectives and Contribution of this Praxis

The purpose of this praxis is to define packaging line flexibility and agility and extend the concepts of agile manufacturing into packaging applications leading to cost reduction and efficiency increases throughout the distribution chain. This praxis consists of completion of the following tasks:

1) develop definitions of flexibility and agility for packaging lines,
2) development of design guidelines for flexible packaging lines,
3) development of a performance measurement framework for flexible packaging lines. Identify critical factors influencing packaging line flexibility, define input / output metrics that could be used to benchmark industry performance and identify best observed practices, provide metrics of inefficiency for packaging lines not exhibiting best practices,
4) the design and implementation of a new flexible packaging line at Alcon Laboratories for the production of 10 different contact lens care kits
5) operational analysis and performance evaluation of the flexible packaging line based on three years of operational data,
6) the financial justification of the flexible packaging line based on three years of operational data.

The remainder of this praxis is presented in two parts. Part I consists of the design and implementation of flexible packaging systems, and focuses on the development of design guidelines and the practical implementation of a flexible packaging line at Alcon Laboratories. Part II consists of a financial analysis and project justification, and a performance evaluation of the Alcon's new flexible packaging line based on three years of operational data (4/1998-4/2001).

PART I: DESIGN AND IMPLEMENTATION OF FLEXIBLE PACKAGING LINES

CHAPTER 2

FLEXIBLE MANUFACTURING AND PACKAGING

Part I of this Praxis discusses the requirements for the successful design and implementation of flexible packaging systems. Chapter 2 focuses on developing definitions of flexibility and agility, discusses flexibility's role as a manufacturing objective and in financial justification, and provides an overview of design for manufacturability, reliability and assembly. Chapter 3 discusses the development of design guidelines for flexible packaging systems. Chapter 4 discusses the practical design, implementation and justification of a flexible package line at Alcon Laboratories.

2.1 Definition of Flexibility and Agility

There are many similarities between flexible assembly lines and flexible packaging lines. Both systems must contend with the same component feeding, orienting, inspection and testing problems to be successful. As part of this praxis, an extensive literature review was conducted on manufacturing flexibility and agility. Attempts to define flexibility, develop a strategic framework for flexibility, define the relationship between flexibility and performance, develop performance measures of flexibility, and previous literature reviews are represented in the work of Mandelbaum (1978), Buzacott (1982, 1986), Gerwin (1982, 1987), Zelanovic (1982), Slack (1983, 1988), Browne, et. al. (1984), Chattejee (1984), Harrigan (1984), Kaplan (1984), Piore and Sabel (1984), Yao and Buzacott (1984), Adler (1985), Kapur (1985), Carter (1986a,b), Falkner (1986), Jaikumar (1986), Kumar and Kapur (1986), Storper and Christopherson (1986), Kumar and Kumar (1987), Meredith and Hill (1987), Yao (1987), Tombak and deMayer (1988), Clubb (1990), National Center for Manufacturing Sciences (1990, 1997), Womack, Jones and Roos (1990), Sethi and Sethi (1990), Surarez, Cusumano and Fine (1991), Fiegenbaum and Karnani (1991), Maskel (1991), Gerwin (1991), Hyun and Ahn (1992), Agile Manufacturring Enterprise Forum (1992), Bititici (1993), Dove (1993), Upton (1994), Zald (1994), Fine (1995), and Thomas (1995). Modeling methods such as discrete event simulation (Gibson and Winterberger 1992, Bulgak 1994) have been used to evaluate the performance of pharmaceutical packaging lines but have not addressed flexibility.

The results of this review indicate that flexibility is difficult to define and measure. Table 2.1 includes a partial listing of the types of flexibility discussed. Sethi and Sethi (1990) report that over 50 different types of flexibility (mix flexibility, quality flexibility, routing flexibility, etc.) have been defined by researchers.

Machine	Operator	Labeling
Process	Delivery	Cost
Product	Parts	Customer requirement
Routing	Design change	Layout
Volume	New product	Job
Expansion	Product mix	Machine
Operation	Quality	Production
Functionality	Strategic planning	Adoptation
Loading	Material handling	Information
Set-up	State	Action

Table 2.1 Types of Flexibility

Fine, Cusumano, and Suarez (1995) and others contend that many of these definitions are really variants of four basic types of flexibility: product mix (product range), new product (ability to add/delete products), volume (profitable at different production levels) and delivery time (ability to meet customer expectations). Further, their research concluded that: there are significant relationships between the different types of flexibility, increased flexibility has no adverse affect on either quality or cost, and flexibility is affected equally by both technical and nontechnical factors.

Buzacott (1982) defined flexibility as the ability of a system to be reconfigured over a range of states, and Lubben (1988) defined flexibility in terms of the cost and time required to reconfigure a system. Leary (1995) defines two aspects of flexibility for pharmaceutical packaging lines. The first is the ability to be changed over quickly between alternate products and packages that are presently planned to be run on the line," and the second as the ability to be "readily adapted to run unknown future packaging configurations" (Leary 1995). Hopp and Spearman (2001) define flexibility for a manufacturing plant as "its ability to respond to short-term changes in product mix and volume," and define agility as " its ability to rapidly reconfigure a manufacturing system for efficient production of new products as they are introduced." Slack (1983) and Carter (1986b) proposed a three-dimensional definition of flexibility, which included the range of states (or scope) of the system, and the cost and time required to perform a changeover. Dove (1994) contends that this is still an insufficient definition of flexibility because it excludes robustness, which is the ability of the system to operate reliably in its new configuration. Thomas (1995) has proposed a definition of flexibility that includes these four dimensions: scope, cost-effectiveness, responsiveness and robustness. The flexibility of a system is given by the polygon formed by points A, B, C and D (Thomas 1995). He states that "for a manufacturing system to be flexible it must have a balanced response to change across all four dimensions." Further, Thomas (1995) defines flexibility "as the capability of a resource, process or system to be rapidly and cost-effectively transformed over a range of stable and robust states."

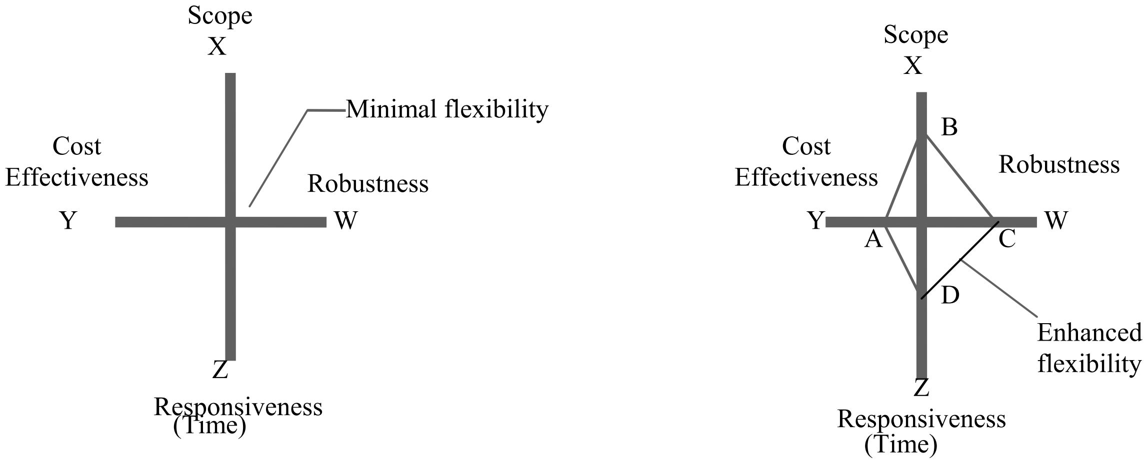


Figure 2.1: The Four Dimensions of Flexibility (Thomas 1995)

Thus, packaging line flexibility can be defined as the capability of a packaging line to be rapidly and cost-effectively transformed over a planned range of stable and robust configurations. Flexibility is the ability to smoothly and effectively change planned products, whereas agility is the ability to rapidly reconfigure for unplanned or unexpected products outside the established product range.

Thomas' four dimensions of flexibility (range of states, cost effectiveness, responsiveness, and robustness) can be restated in terms of a flexible packaging line. The range of states is simply the range of packaging configurations that can be produced on the packaging line using either adjustments or change parts. Cost effectiveness is a measure of the cost to reconfigure a packaging line, including the cost of labor and packaging components consumed in the changeover. Responsiveness is a measure of the time required for the changeover, defined by McLaughlin and White (1996) as the “elapsed time from the last good unit of product *x* produced until the first unit of product *y* is produced at the target run rate.” Robustness is a measure of the “quality of the changeover,” and may be defined as the ability of the packaging line to operate efficiently in its new state following changeover. Efficiency may be affected by either higher level of rejects or by not achieving the specified production rate. Ideally, the line immediately returns to the specified production rate and quality level. Robustness is a major concern because of increased product variety and shorter product runs. According to Leary (1995), changeover efficiency affects operations and the efficiency loss following changeovers can be very costly.

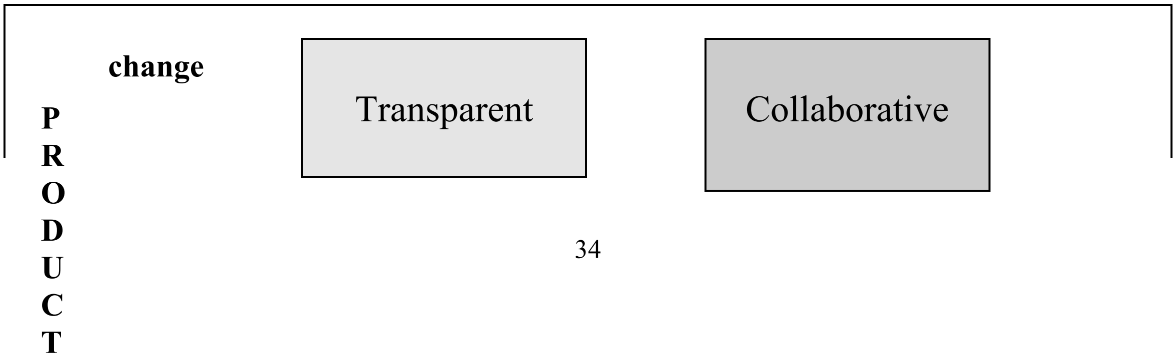
2.2 Flexibility and Agility as a Manufacturing Objective

Section 2.1 provided a working definition of flexibility and agility. This section discusses the importance of flexibility as a manufacturing objective and how flexibility can be used to justify capital investments.

2.2.1 Incentives and Benefits

Recent research (Swamidass and Newell 1987, Stalk 1988, Stalk and Hout 1990, Youssef 1992, Gerwin 1993; Paratharthy and Sethi 1993; Honeycutt, Siguaw and Harper 1993; Zald 1994, Lei and Goldhar 1994; Lei, Goldhar, and Prabhaker 1995; Thomas 1995, Lei, Hitt and Goldhar 1996, National Center for Manufacturing Science 1997) indicates that manufacturing flexibility facilitates the development of a company’s marketing strategy to produce sustainable competitive advantage through product customization and time-to-market for new products. According to Zald (1994), flexible manufacturing is a critical component of competitive strategy, and robotics and automation are the keys for achieving manufacturing flexibility. Hayes and Pisano (1994) contend that focused factories are outdated and that specific competitive advantage can be obtained by improving an organization's strategic manufacturing capability and flexibility. Pine, Victor and Boynton (1993) report that flexible manufacturing systems are the enabling technology for mass customization of products at the speed and cost of standardized, mass produced products. Established firms have a "zone of strategic flexibility" which provides a barrier to market entry by potential new competitors (Chang 1993), and manufacturing flexibility provides a hedge against market uncertainties (Swamidass and Newell 1987, Newman 1993). However, mass customization is a manufacturing strategy that has allowed companies to prevent entry of new competitors, exploit niche markets and break market barriers. Flexible manufacturing systems support product variation in product families but should avoid unfocused product proliferation, which leads to loss of strategic focus. Only specific customization that adds market value, such as differentiating features, should be allowed.

Gilmore and Pine (1997) have defined four basic approaches to mass customization - collaborative, adaptive, cosmetic, and transparent -as illustrated in Figure 2.2.



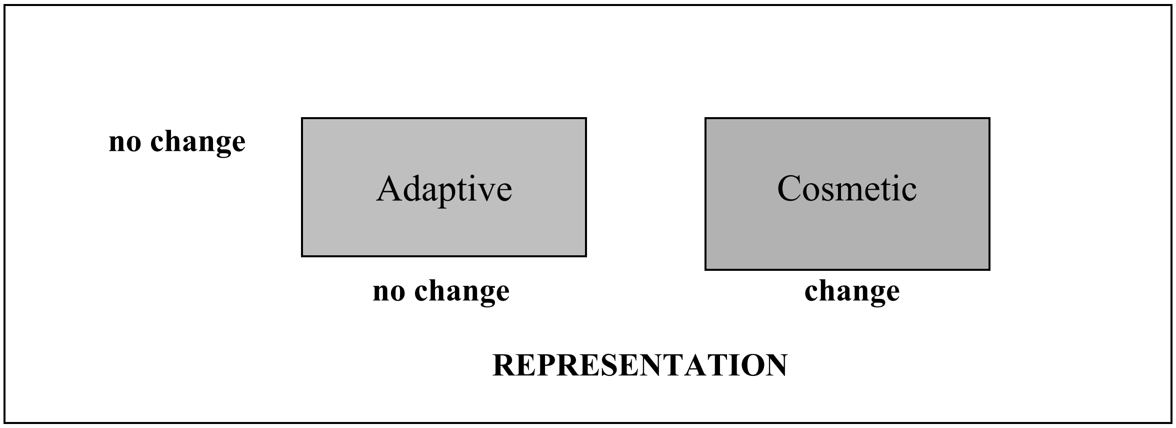


Figure 2.2 Four Approaches to Customization (Gilmore and Pine 1997)

Collaborative customization is a joint effort by the manufacturer and customer to define specific additional requirements and then produce a customized product. In adaptive customization, a manufacturer offers a standard product that is customizable by the customer. Transparent customizers manufacture unique products for customers without informing the customer that those products have been customized specifically for them. Cosmetic customizers manufacture a standard product that is marketed differently to different customers.

Cosmetic customization is of primary interest in this praxis because consumer goods companies often label and package the same product in different sizes, configurations, brand names, etc. specifically for different customers. This requires their packaging lines to have the flexibility to produce the required product range and respond quickly to changes in the market.

HP has developed a unique strategy of delayed mass customization which has been called postponement (Feitzinger and Lee (1997)). Instead of producing country specific printers for countries in Europe and maintaining specific inventory for each country, HP produces a flexible inventory of generic printers, and then customizes them with country specific power connections upon receipt of order (Hopp and Spearman (2001)). This gives HP the dual benefit of lower inventories and faster customer response.

2.2.2 Investment Justification

According to the work of Hayes and Garwin (1982), Skinner (1984), Meridith and Mantel (1985), Huber (1985), Kaplan (1986), Meredith (1986), Sullivan (1986), Canada (1986), Meridith and Hill (1987), Klammer (1993), Parsaei, Wilhelm and Kolli (1993), Newman and Hanna (1994), Sarkis (1994), Zald (1994), de Ron (1995), and Shang and Sueyoshi (1995), investment in advanced manufacturing systems and flexibility is difficult to justify because the benefits are difficult to define and measure. These researchers have concluded that traditional economic justification measures (such as internal rate of return and payback period, return-on-investment, net present value, and cash flow analysis) are still the most widely used financial justification methodologies, but they are inadequate and present a barrier to the use of advanced manufacturing systems. Thus, financial justification for advanced manufacturing systems must be more sophisticated and include non-financial measures such as quality, customer service, flexibility, and strategic capabilities. The development of these more advanced justification methodologies does not render obsolete the use of traditional economic justification techniques. As suggested by Meredith and Hill (1987), manufacturers should consider selecting the most appropriate justification methodology (or combination, based on the level of integration and complexity of the system being evaluated.

Several portfolio approaches, based on scoring and optimization models have been proposed to evaluate projects. In an attempt to overcome the limitations of traditional financial analyses, multiple evaluation criteria are used. These criteria often include traditional financial metrics as one element in the portfolio analysis. The most commonly used portfolio analysis techniques are compared in Table 2.2.

Table 2.2: Portfolio Analysis Techniques

Type	Portfolio Model	Objective
Scoring Models	• Unweighted 0-1 factor model • Weighted and unweighted factor models • Constrained factor model	Highest project score
Optimization Models	• Linear programming • Integer programming • Goal programming	Maximize profits Maximize utilization

Value analysis and risk analysis have been introduced (Hertz 1964, Saaty 1980, Keen 1981) to further refine the portfolio approach by eliminating the evaluator's bias. Meredith and Mantel (1985) and others have also utilized expert systems as analytical financial justification tools.

Strategic considerations and regulatory requirements may justify a project regardless of expense if they are required for the firm to remain in regulatory compliance or in business. According to Meredith and Hill (1987), such strategic factors include: technical importance, business objectives, competitive advantage, quality and research and development.

As discussed in section 2.2, flexibility and agility are becoming a key strategic initiative for sustainable competitive advantage. According to Zald (1994), the cost justification of flexible manufacturing systems must include on evaluation of additional capacity and flexibility, improved responsiveness (total cycle time to customer), and high salvage value of flexible/reusable automation systems.

The National Center for Manufacturing Services (1997) recently published a report on the economic evaluation of flexible manufacturing systems, which advocates using both traditional justification techniques with extensions that include non-financial factors to provide a single rating factor for each project based on both financial and non-financial measures. Traditional methods (NPV, IRR, etc.) should include consider multiple product cycles until the useful life of the equipment is exhausted. The NCMS team identified a total of 27 specific benefits of flexibility that should be considered to justify investment in flexible manufacturing systems.

2.3 Design for Manufacturing, Reliability, and Assembly

U.S. manufacturing companies have closed the quality gap with world-class competitors but must now close the time-to-market gap by focusing on logistics and the supply chain to remain competitive. Concurrent engineering is a systematic approach to integrated product design, manufacturing and logistics processes which promises faster product introduction, lower product cost, higher quality, and improved reliability by changing the sequence of product conceptualization, design, development, and manufacturing from a sequential to a concurrent process. This requires a clear understanding of the current manufacturing process and the customer's requirements, plus excellent communication and cooperation between the design, development, marketing and manufacturing departments. Design for manufacturability, reliability and assembly are three of the most quantifiable and widely utilized concurrent engineering tools.

2.3.1 Design for Manufacturability

Manufacturability is defined as the ease of fabrication and/or assembly and is important for cost, productivity and quality. Design for manufacturability (DFM) is a structured approach to design from a set of functional requirements, which are mapped into the design parameters using a design matrix and then into the manufacturing process variables. DFM utilizes several techniques and methodologies such as design guidelines, competitive benchmarking, reverse engineering, design efficiency rating, and group technology to improve product design and quantify manufacturability. One goal of DFM is to use 90 percent of existing and standard parts in the design of new products to reduce or simplify assembly operations, reduce part count and defects, lower costs, and increase quality and reliability. To achieve this goal, DFM uses group technology (GT) to promote the use of standard, symmetrical, and interchangeable parts to produce modular designs. GT is a classification and coding system, which uses common attributes of parts to define part families, store manufacturing tolerance data, and group similar part manufacturing and assembly operations into cells for manufacturing. Introduction of GT into manufacturing results in reduced production lead time, work-in-process, labor, tooling, rework and scrap materials, and set-up and delivery time. Specialized databases are used to maintain standard parts inventory for designers. Rule-based manufacturability analysis tools, when linked to group technology, provide the design team the ability to evaluate designs, reduce the part count and simplify part manufacturing and assembly operations.

DFM utilizes knowledge of the manufacturing process to complete extensive tolerance analysis to ensure that parts will fit at assembly, and employs self-locating features to facilitate error free assembly. Extreme-case tolerance analysis and statistical analysis are used to evaluate standard (purchased) parts and non-standard (manufactured) parts. The design team can only change the tolerances of non-standard parts. Extreme-case analysis (best/worst scenarios) is widely used and ensures that parts will assemble, but it has a built-in waste mechanism leading to overly conservative designs. Statistical analysis uses statistical probability distributions to analyze tolerances for assembly and prevents over design. With statistical analysis, tolerances can be widened and, if process capabilities are known, even wider tolerances can be assigned.

2.3.2 Design for Reliability

Reliability can be defined as the probability that a part, product, or system will perform its intended function under a prescribed set of conditions. The three aspects of reliability analysis are: 1) reliability as a probability, 2) definition of failure and 3) the prescribed operating conditions. A failure is an occurrence in which a product, part or system does not perform as intended. Note that a part failure may or may not result in a system failure depending on the configuration of the system. Reliability can be enhanced by improving component design, system design, production and assembly techniques, testing, preventative maintenance, user education, and redundancy.

Design analysis tools have decreased the reliance on exhaustive testing to determine the quality and reliability. Reliability measures and goals must be consistently set and reliability objectives must be the highest priority for the design team. Measures such as mean time between failures (MTBF), mean time to repair (MTTR), and warranty costs should be used to determine reliability. Reduction of manufacturing variability and design complexity have a positive impact on reliability. Reliable components, processes and technologies should be selected. Part counts should be minimized to reduce assembly time and increase reliability. Every failure should be analyzed to determine the cause and then design it out of the product. Design reviews for reliability are used to eliminate poor design practices and to review the progress on meeting reliability goals. Further, design reviews can determine whether the product has the proper application of component types and the desired margin between component parameter specifications and design requirements. Potential problems are analyzed using either fault tree analysis (FTA) or failure mode and effect analysis (FMEA), or both.

The reliability of individual machines is critical to the reliability and efficiency of the entire line. Consider a line consisting of 12 pieces of equipment, the reliability of the line is a multiple of the efficiency of the reliability of the individual machines. As shown in Table 2.3, the reliability of the overall line decreases rapidly with small reductions in the reliability of the individual pieces of equipment. A similar effect occurs when one piece of equipment has very poor reliability even when the rest of the equipment has very high reliability. The piece of equipment with the lowest reliability is often the bottleneck for the entire line.

Reliability of Machines	Reliability of Packaging Line

	(n=12)
1.000	1.000
0.999	0.988
0.995	0.942
0.990	0.886
0.980	0.785
0.970	0.694
0.960	0.613
0.950	0.540
0.940	0.476
0.930	0.419
0.920	0.368
0.910	0.322
0.900	0.282
0.850	0.142

Table 2.3 Effect of Machine Reliability on Reliability of Entire Packaging Line

Some pharmaceutical manufacturers have analyzed the reliability of their packaging operations using functional failures and effects analysis (FFEA), which is a hybrid methodology based on traditional FMEA and other risk assessment techniques (Mitchell and Williams 2000).

2.3.3 Design for Assembly

Design for assembly (DFA) is widely used in industry to simplify product design by reducing the number of parts required, and simplify automated assembly operations. According to Boothroyd (1999), “automated assembly operations are usually credited with substantial product quality improvements”….”the challenge is separating the effect of design simplification, which is often necessary to make automation possible from the effect of the automation itself.” Design for manual, automated and robotic assembly is increasingly important and each considers the symmetry and geometry of parts, part transportation and presentation, robot gripper design and material handling (Boothroyd and Dewhurst 1984, Mortimer 1986, Eade 1989, Tomovic, Zelenovic and Seslija 1990, Koelsch 1992, Koshiba, Tanaka, and Miura 1993, Mosier, Ruben and Talluru 1993). Katpakjian (1994) has recently produced summary guidelines for manual assembly, high speed automated assembly and robotic assembly (see Table 2.3).

Table 2.3: Guidelines for Manual, High-Speed Automated, and Robotic Assembly
(adapted from Katpakjian 1994)

	Guidelines for Manual Assembly
1)	Minimize number of different parts in a product so that fewer steps and fixtures are required, thus lowering assembly costs.
2)	Parts to be assembled should have a high degree of symmetry, or they should be highly asymmetrical to avoid errors by the worker.
3)	Parts should be designed so that they cannot be installed incorrectly, and do not require locating, aligning or adjusting.
4)	Parts should be assembled without obstructions or lack of direct line of sight.
	Guidelines for High-Speed Automated Assembly
1)	Part designs should consider factors such as size, shape, weight, flexibility, tangling with other parts, etc. to allow automated orientation and presentation
2)	Parts should be designed to be inserted from a single direction, preferably vertically. Avoid assembly from two or more directions.
3)	Products should be designed, or existing parts redesigned, so that there are no physical obstructions to the free movement of parts during assembly, sharp external and internal corners should be replaced with chamfers, tapers or radii.

	Guidelines for Robotic Assembly
1)	Parts should be designed so they can be gripped/manipulated by common grippers.
2)	Parts should be delivered to the gripper in the proper orientation
3)	Avoid threaded fasteners (bolts, nuts, screws). Robots can handle snap fits, rivets, welds, adhesive fasteners.

Design rating methods developed for manual assembly have expanded to include automatic and flexible assembly. The two primary approaches to DFM (see Table 2.4) currently used in industry are the Boothroyd/Dewhurst method and the Hitachi GE method.

Table 2.4: A Comparison of Design for Manufacturability Techniques (adapted from Shina, 1991)

Broothroyd/Dewhurst Technique	Hitachi/GE Technique
Emphasis on part design	Emphasis on assembly process
Includes equipment costs for automation/robotic assembly	Focuses on Manual assembly
Compares to ideal design	Compares alternatives
Focuses on reducing part numbers	Does not penalize too many parts
Measures assembly time from given tables	Normalizes assembly time to standard downward motion

The Boothroyd/Dewhurst method emphasizes parts design but has been criticized as being biased towards snap fit and methods. The Hitachi method emphasizes the assembly process, but has been criticized as being biased towards assembly and joining motions.

The current research and trade literature on automated assembly is filled with articles promoting the unique benefits of “synchronous” and “asynchronous” assembly systems (Williams and Anderson 1998, Sprovieri 1998, Herman 2000). Synchronous assembly systems are characterized by an indexing transfer system (rotary or linear) of 12 or fewer stations. The transfer systems (rotary fixtures or pallets) move in lockstep and are paced by the slowest assembly operation at an individual station. Parts are supplied to each station and assembled at a constant rate, and the effectiveness of these systems falls off quickly with increased number of stations. Synchronous assembly systems have been widely used for high-speed traditional assembly operations and criticized due to lack of flexibility, but synchronous assembly and flexibility are not-mutually exclusive.

Asynchronous, or “non-synchronous”, assembly systems are characterized by linear transfer system (pallets), an unlimited number of independent assembly stations with buffers between each station. Multiple path configurations are possible, and typically include a loop to return pallets from final assembly unload to the first assembly station. Asynchronous assembly systems are reportedly more flexible, accommodate larger product variation, and can utilize multiple stations to achieve the required output, but have been criticized because they are typically slower than synchronous systems and require more frequent changeovers.

But, despite these arguments, both synchronous and asynchronous systems have many similarities. The speed of both systems is determined by the speed of the slowest assembly or inspection station in the system. Both systems have to solve the same part feeding, singulation, orientation, presentation, and fixturing challenges. Both systems use vibratory bowls, belt feeders and magazines to handle parts. The layouts of both systems have to be optimized by minimizing the time and distance that parts and assemblies are moved. Both types of systems are confronted with problems of inconsistent and non-conforming parts, and subassembly inspection and testing issues. Current industrial practice has many hybrid systems which utilize synchronous transfer systems with asynchronous assembly or packaging operations (Sprovieri 2001).

Major (1995), Aronson (1995), Bensassi (1995), and Benson (1995) have identified the current trends for automated assembly systems, which are summarized in Table 2.5. Rampersad (1995) completed a study identifying current bottlenecks in robotic assembly systems (see Table 2.6). Rampersad (1995) concluded that the reliability of an assembly systems decreases as the number of unique parts per robot increases, and recommended that the number of unique product parts per robot be limited to two-five, with an average of four unique parts per robot.

Table 2.5 Trends in Automated Assembly Systems

Hybrid asynchronous and synchronous assembly systems for maximum benefit.
More modular, expandable, reconfigurable flexible assembly lines.
Flexible part feeding systems with integrated vision systems are replacing part-dedicated feeders and minimizing changeovers.
Increased automation, improved diagnostic capabilities. RF or other ID systems used for tracking/history.
Increased use of integral test / inspection systems.
Increased use of mistake proofing, fault diagnosis, and auto-recovery
Increased focus on financial justification and use of nontraditional evaluation methods
Increase use of DFA / DFM and simulation tools in design.

Table 2.6 Current Bottlenecks in Automated Assembly Systems (Rampersad 1995)

Highly complex products
Poor/inconsistent part quality
Limited flexibility/part dependence of peripheral equipment / robots grippers
Limited acceleration / deceleration of robots (cycle time)
Insufficient reliability and integration of sensors
Limited flexibility of grippers and other assembly tools

The successful application of design for manufacturability, reliability, and assembly concepts have improved quality, responsiveness and reliability of flexible manufacturing systems, and reduced product costs. Chapter 3 focuses on the extension of these concepts to develop design guidelines for flexible packaging lines.

CHAPTER 3

DESIGN OF FLEXIBLE PACKAGING LINES

3.1 Introduction

The purpose of this chapter is to develop Design for Flexible Packaging Line (DFPL) concepts and guidelines to facilitate the design of flexible packaging lines. Most of the DFPL heuristics developed here are an extension of the Design for Assembly (DFA), Design for Reliability (DFR) and Design for Manufacturability (DFM) concepts discussed in the previous chapter and have been expanded to provide a recommended design process for flexible packaging lines.

It is difficult to clearly differentiate between efficiency, flexibility and agility when developing DFPL guidelines. In general, efficiency guidelines can be classified as those concerned with the operating rate of the line and are thus concerned with reliability, maintainability, online inspection, vision systems and auto-recovery systems. Similarly, we can classify flexibility guidelines as those concerning changeover, which includes flexible parts feeding, material handling, robotics, and servo-based equipment selection. Agility guidelines are focused on the ability of the system to be reconfigured, which includes the elements of modular design and automation. The DFPL guidelines developed below include elements enhancing efficiency, flexibility and agility.

3.2 Project Phases

A typical packaging line design project in the pharmaceutical industry can be described by the phases listed in Table 3.1.

Table 3.1 Project Phases for Design of Flexible Packaging Line

I. Project Planning
    Scope, Schedule, Budget
II. Preliminary Design
III. Detailed Design
    Prototyping, System Architecture, Concept and
    Layout Development
IV. Manufacturing / Integration
    Equipment Build/Debug
    Factory Acceptance Testing (FAT)
V. Commissioning / Validation
    Package, Shipment and Installation
    Site Acceptance Testing (SAT)
VI. Start-up

As shown in Figure 3.1, Phases II-IV (preliminary design, detailed design, and manufacturing and integration phases) can be represented by a waterfall project lifecycle model with subprojects for each subsystem. In this model, the design progresses through a sequence of iterative steps from the initial system concept through final testing.

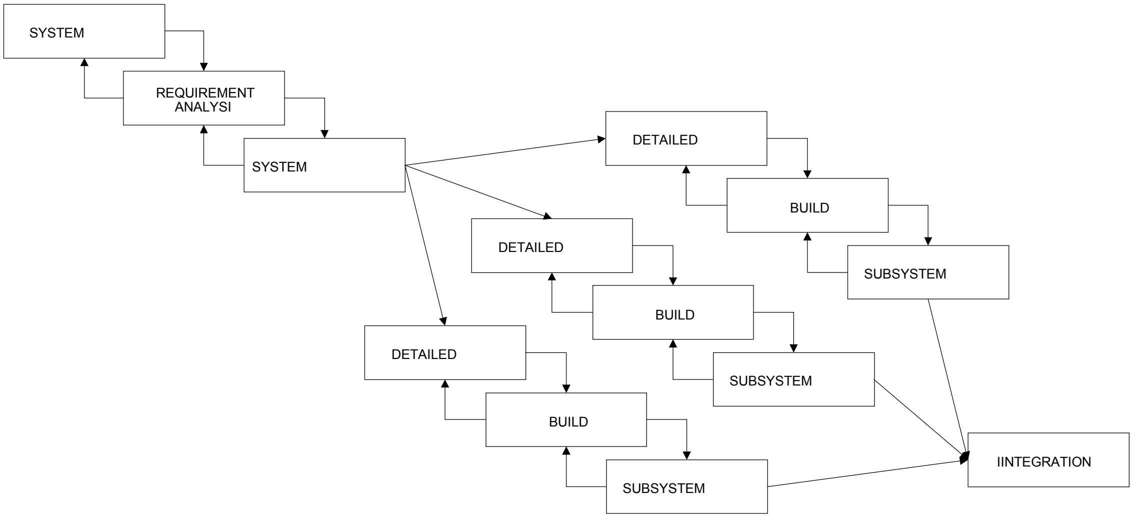


Figure 3.1 - Generic Waterfall with Subprojects Lifecycle Model

Before starting on the development of the design guidelines it is important to consider the type of packaging design problem under consideration. First, is the problem structured or unstructured? Specifically, is there a fixed or variable sequence of packaging operations? Second, is a high or low level of precision required in the packaging operations being designed? Third, is the design process and packaging operations constrained or unconstrained by regulatory requirements (FDA, ISO, OSHA)? If regulatory approvals are required it is critical that a highly efficient packaging process be developed concurrent with the product to prevent delays. Fourth, future needs such as increased speed or capacity requirements should be evaluated. How much flexibility is required? Potential changes in product or packaging need to be considered to determine the project's scope. Flexibility maybe more important than packaging line speed but efficiency is also critical. Fifth, it is also important to remember that there is typically a tradeoff between three elements: high part mix, high speed and low cost. Finally, it is important to remember that every flexible packaging line design is unique. Systems integrators recognize that successful projects contain "as much art as engineering" (Rowland 1998), and that "there are often many solutions that are equally good as they are different" (Bodine 2001).

Definitions of packaging line flexibility and agility were developed in Chapter 2. Packaging line flexibility was defined as the capability of a packaging line to be rapidly and cost-effectively transformed over a planned range of stable and robust configurations.

As discussed, this definition reflects Thomas's four dimensions of flexibility: scope (range of packaging configurations), cost effectiveness (low cost, quick changeovers), responsiveness (rapid return to nominal speed and quality), and robustness (efficient operation following a changeover). Flexibility is the ability to smoothly and effectively change over for planned products, whereas agility is the ability to rapidly reconfigure for unplanned or unexpected products outside the established product range. Thus, the design guidelines for flexible packaging lines must include elements that focus on designing flexibility in the range of packaging dimensions, minimal time for changeovers, reliable and efficient operation at nominal rate, quick recovery following changeovers and start-up, minimal downtime, auto-recovery features, and minimal time required for line clearances.

3.3 Preliminary Design Guidelines

The preliminary design phase for a flexible packaging line consists of analyzing the projects functional requirements specification (FRS), completing a packaging engineering study, developing material handling and layout concepts, and completing feasibility studies and prototypes of critical areas. These elements make up the conceptual design package that will be utilized for the detailed design phase. This conceptual design process is critical to assuring that the new packaging line will be flexible and will perform as desired.

3.3.1 Define Line Capacity and Performance Requirements

The capacity of the packaging line, its operational plan and the performance requirements need to be defined. Typically, this defines the annual capacity of the line in units per year based on a stated number of shifts, days per week, etc. The nominal speed of the line, its expected efficiency and downtime must also be defined so that the proper instantaneous operating rate for each machine can be designed high enough to ensure that the performance rate of the overall line exceeds the desired nominal rate. The most economic speed and level of automation should be selected based on the project's specific requirements, recognizing that there is a tradeoff between capital cost, flexibility and line speed. Low speed, high flexibility options include manual packaging lines, machine-paced manual (semi-automated packaging with components manually loaded), and fully automatic packaging. These lines typically operate in the 30-100 units per minute range. For moderate flexibility and speeds in the 100-600 units per minute range, a fully integrated line consisting of a series of modular interconnected machines are typically used. Fully integrated, high speed, low flexibility lines are used for speeds over 600 units per minute, and are usually dedicated to a very limited range of package configurations.

The capacity of any packaging line can be defined as the expected output of the packaging line operating at its nominal speed, per time period, for a given product mix and operating plan. The nominal speed (NS) is defined as the highest sustainable throughput at 100% efficiency on the bottleneck machine allowing for safe production of quality product. The slowest machine (or system) in the packaging line, or the machine with the most downtime, is the bottleneck or critical machine. The critical machine (CM) concept was developed in the beverage industry to determine the capacity and scheduling constraints for a given packaging line. The CM is simply the machine (filler, pasteurizer, etc.) which is the speed constraint for the entire packaging line. Typically, a packaging line has at least one, but no more than two, critical machines. For a packaging line with a single critical machine, the goal is to minimize the effect of the speed constraint by ensuring that the machine runs at its maximum nominal speed at all times. In order to achieve this, a machine speed curve is developed which is shaped like a "V". Machines upstream of the critical machine are designed to run 4-6% (additive not multiplicitive) faster than the previous machine to compensate for downtime, scrap and other losses. Machines downstream of the critical machine are designed to run 2-4% faster than the previous machine to pull product from the critical machine. A major focus has been on increasing machine reliability, which has the effect of flattening the required speed curve (Zepf 1996). The effective nominal speed and capacity of the line is determined once the critical machine has been identified.

Figure 3.2 Speed Curve

There is a complication in determining the nominal speed and capacity for flexible packaging lines. The most obvious complication comes from the addition of multiple products to the scheduling mix, and the problems of determining lot size, number of changeovers, etc., which have been studied previously. The less obvious complication comes from the product mix. With multiple products being packaged on a flexible packaging line the critical machine could be different based on the product selected, and some of the machines (e.g. robotic loading station) may not be used at all for a particular product. Thus, the aggregate product mix is also important in identifying the critical machine, nominal speed and packaging line capacity. Also, since some equipment may not be utilized for all products, equipment utilization may not be a realistic measure of packaging line efficiency.

The target hours (TH) is the theoretical minimum line hours required to produce a desired amount of product meeting all quality specifications on a packaging line operating at nominal speed (NS) with no efficiency losses. Thus, TH is equal to the desired production quantity divided by the nominal speed, or TH = Production Quantity/NS. There will be time lost when the bottleneck machine has efficiency losses (E) and is either running below its nominal speed, has poor quality, rework, material jams, or has stopped completely while operators are on the line.

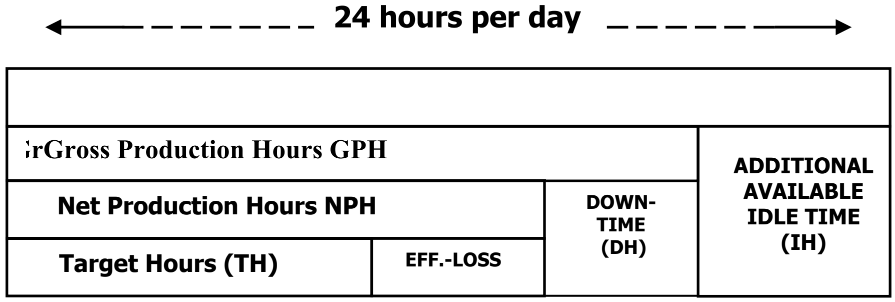


Figure 3.3: Packaging Line Capacity Terminology

As a result of efficiency losses it takes more hours to produce the desired amount of product. The net production hours (NPH) is the target hours plus the efficiency losses, or NPH = TH + E. Efficiency loss describes how well the packaging line operates when operators are on the line. There is also time lost when the line is not operational which is called downtime (D). Downtime categories include personnel (breaks, meetings, lunch, etc.), maintenance, set-up (check, adjust settings, etc.), start-up (time between start of line until first product off end of line), cleaning, changeover, and operational (load packaging material, sampling, etc.). The gross production hours (GPH) required is thus the net production hours plus downtime, or GPH = NPH + D. The gross production hours are the total hours that the line is either operational or is not physically capable of production. There may be addition idle time (I) that the line is physically capable of production but is not in use or down. An example of these calculations is given in Chapter 4.

DFPL 1.0 Define Line Capacity and Performance Requirements

DFPL 1.1 Define annual capacity and operational plan

DFPL 1.2 Specify required nominal speed (NS) of the line based on the annual capacity and operational plan. Specify estimated maximum production hours, gross production hours (GPH), net production hours (NPH), and estimate efficiency loss (E) and downtime (D).

DFPL 1.3 Define changeover requirements in terms of number of operators and maximum time, and quick change over tools, or tool-less changeover.

3.3.2 Package Engineering Study

The next step in the design of a flexible packaging line is a package engineering study. The purpose of this study is to identify the potential product mix that will be packaged on this line, and identify the required minimum and maximum capabilities in each dimension (length, width, height) for each packaging component. The study consists of developing a process flowchart for each product to identify the required sequence of operations, and reviewing the bill of materials for each product to identify the common components and potential component families. If there is an existing manual or automated operation it should be studied in detail to understand the current operation, its purpose and constraints. Current engineering specifications for all components, and primary, secondary and tertiary packaging should be obtained and reviewed. The package engineering specifications should be reviewed with suppliers to determine which components can be improved, and or standardized, for automated material handling. A packaging line is only as reliable as the parts presented to it, so more consistent components will result in a more reliable automated process. Non-conforming components will not run reliably and are therefore quickly identified on an automated packaging line.

DFPL 2.0 Package Engineering Study

DFPL 2.1 Evaluate current specifications for all product components, and primary, secondary and tertiary packaging. Determine which components can be improved for automated material handling.

DFPL 2.2 Determine if packaging operations sequence is constrained or unconstrained (fixed or variable sequence)?

DFPL 2.3 Group similar packaging and product components into parts families, and review for automated handling possibilities.

DFPL 2.4 Environmental conditions defined (temperature, pressure, humidity) which affects packaging components

3.3.3 Material Handling Concepts and Layout

Material handling concepts and potential layouts are developed following the completion of the package engineering study. The material handling concepts and packaging engineering specifications are reviewed concurrently to identify opportunities for further packaging component improvements and to optimize the final material handling systems. The material handling concepts and system layout are the biggest challenges in the design of a flexible packaging line. According to Hood (1999), “the excitement and creative challenge is in the infinite variations and approaches to parts handling applications.” This includes planning the movement (both manual and automatic) of all required components and packaging materials to the line and removal of finished products and rejected materials from the line. Components are delivered to the line in a variety of configurations (random, vertical, horizontal, organized layers, etc), must be singulated, oriented, and conveyed to the correct position on the packaging line for use. The primary packaging must also be consistently transported to each required station so that the required components can be loaded. Automated packaging operations are only possible with very reliable components and component handling systems. The packaging component itself is the most critical factor (shape, size, weight, etc.) in the selection of appropriate material handling equipment. Physical and material characteristics of the component will determine what material handling methods are feasible because of bridging, tangling, nesting, etc. of components. For components that do not tangle, flexible feeder systems are becoming widely used and minimize the changeover required compared to dedicated components feeders. The challenge is to reliably provide the components at the required location, in the proper orientation, and at the desired rate. Table 3.2 includes a partial listing of the wide variety of both standard and custom equipment available for material handling applications.

Table 3.2: Commonly Available Material Handling Equipment

- Belt feeders and conveyors
- Hoppers
- Centrifugal bowl feeders
- Vibratory bowl feeders
- Magazines
- Gravity Storage Feeder
- Conical Belt Hopper
- Part Qualifier / Presorter
- Rotary drum feeders
- Rocker arm mechanical feeders
- Dual opposing belt feeders
- Floor elevator feeders
- Linear Feeder
- Linear Track
- Vibratory Bulk Hopper
- Feed Screw
- Flexible Feeder (robot, vision system, belt conveyor and vibratory bin)
- Synchronous Transfer Systems (rotary carousels, walking beams, etc.)
- Asynchronous Transfer Systems (pallet conveyors, etc.)
- Pick-and-Place
- Robot
- Custom

As discussed in Chapter 2, synchronous, asynchronous and combination material transfer systems are widely used in assembly and packaging applications. The most typical combination applications use an asynchronous material transfer system with synchronous assembly (or loading) stations. Synchronous material transfer systems are based on a rotary (carousel) or inline (walking beam) indexing system driven by a central camshaft rotating at a constant speed, with up to 16 assembly or loading stations. These systems operate continuous at a constant speed of up to 200 indexes per minute. Asynchronous material transfer systems (pallet transfer systems) use a belt conveyor system to transfer pallets between designated assembly or loading systems. Assembly or loading operation is triggered when pallets enter a station and cycles rates are controlled by the conveyor transfer speed and station cycle speeds. The rate of pallet based systems can be increased by loading multiple (1-4) cartons per cycle. Pallet transfer systems are totally modular and they are very easy to install, maintain, and reconfigure. A wide variety of linear or closed loop customized routings can be developed including ovals, rectangular and over-under configurations. Unique pallet routings may be customized using pallet identification devices (mechanical code blocks, RF, etc) and supervisory control systems to allow individual pallet routings to support small order quantities. Loading stations are also interchangeable and may be customized for specific products.

Servomotors are continuing to replace multi-axis motor driven (mechanical line shafts, CAMS, gears/sprockets, clutches, arms, indexes, stepping motors, etc.) positioning systems to increase the flexibility of assembly and packaging equipment. Speed control is easily changeable with servomotors, but requires significant mechanical modifications in traditional systems. With servomotors, adjustments are programmable; systems can have soft starts/stops, and gradual acceleration/deceleration. Mechanical drive trains are limited in speed, are labor intensive to maintain, and complex to design. Servomotor systems provide more repeatability with high resolution (4 million counts per revolution, accuracy ± 0.0001") positioning and feedback. Electronic camming provides synchronization of multiple packaging machines and the related material handling equipment. Electronic line shafting (electronic gearing) increases speed and machine flexibility, and reduces the cost to design, develop, operate and maintain the equipment. Electronic multi-axis controls also support modular machine design concepts and makes equipment reconfiguration easier. Servo motor controls have fewer parts, higher reliability, and allow quicker line changeovers. Finally, recovery from machine faults is quicker with servomotor based systems because the need to clear the machine of product is eliminated since the axes do not need to be re-homed. This also minimizes the costly scrapping of product and packaging components that cannot be effectively reintroduced into the packaging line.

All material handling equipment must be selected with a clear understanding of the required production speeds and ranges. It is also important to reduce or minimize all material handling time and distances while providing appropriate accumulation to allow the system to continue operation during automated recovery. Rate calculations should be performed for all material handling equipment to ensure that the main packaging line is never waiting for components. Timing diagrams, critical path method, queuing models and discrete event simulation can be used to perform these rate calculations. The desired nominal speed (or throughput rate) of the equipment will be lower than the instantaneous machine rate because of expected inefficiencies and downtime. Typically, the nominal speed is 75-85% of the maximum instantaneous machine rate. The desired nominal speed is equal to the instantaneous machine rate multiplied by an estimated efficiency factor, which is less than one. The line's operation will be constrained by the total process time, which is the total transfer time between loading stations and the load time in each station. As the operating rate of the line increases, it is less likely that robots can be successfully integrated into the line. Increased operating rate may also affect labeling (online printing), vision inspection, bar code inspection, part presentation consistency and overall line reliability.

The layout of the system (linear, closed loop, etc.) is dictated by the required order of packaging operations, the selected equipment, and the available floor space. The layout and cycle-time can be optimized by minimizing the time and distance that components and finished kits are moved. The layout also needs to be reviewed for accessibility by operators, for any ergonomic concerns, and for product and packaging staging requirements.

The flexible packaging line should be designed based on a modular, expandable and re-configurable concept to simplify the design, and to ensure that modules can be added or removed as required for specific current and future packaging configurations. A standard process module interface (supplying air, power, I/O communications, etc.) for connecting and reconnecting the various component feeder/assembly mechanisms to the packaging line should be utilized (Mills, Criswell, Huff and Liles 1992). Flexible, re-programmable, re-configurable automation and robotic systems should be used. The system should be developed such that the operation of the cells are independent and configurable to specific product codes (i.e., if a particular zone is not required, it should not be necessary to initialize and start the zone as part of the system startup procedure).

The entire packaging line should be designed with future requirements and flexibility in mind. The system should contain at least one manual station to provide additional flexibility. Manual stations can accommodate a large variety of special components for custom packing marketing specials and promotions without requiring additional hardware, software or validation. This is critical for responsiveness and flexibility of the line.

DFPL 3.0 Material Handling Concepts and Layout

DFPL 3.1 Develop a conceptual flow diagram based on packaging operations sequence, showing all product and packaging material flows to and from the packaging line including finished product, reject handling, scrap and waste.

DFPL 3.2 Determine the number of modules required based on parts families.

DFPL 3.3 Determine the method of component delivery and loading into feeding systems. Determine method of final product removal from end of line.

DFPL 3.4 Determine the method of packaging materials delivery and loading into feeding systems.

DFPL 3.5 Determine the method of component singulation, orientation, and presentation to the packaging line.

DFPL 3.6 Determine component handling method and how it will be inserted into packaging. (EOAT pickup, vacuum, mechanical, feed screw, bucket)

DFPL 3.7 Determine required nominal rate of feeding and transfer equipment. Speed should be high enough that the main line is never waiting for presentation of components.

DFPL 3.8 Evaluate alternative methods (synchronous, asynchronous) for conveying primary packaging.

DFPL 3.8.1 Mass convey using low backpressure. Add zones if necessary to prevent miss-orientation and component damage.

DFPL 3.8.2 Select correct speed to avoid uncontrolled acceleration and deceleration.

DFPL 3.8.3 Avoid change of orientation of product transportation whenever possible.

DFPL 3.8.4 Maintain positive control whenever possible.

DFPL 3.8.5 Avoid dead plates at transfer points between equipment that requires backpressure of product for transfer. Manual line clearances will be required if product does not completely clear line on its own.

DFPL 3.9 Identify preliminary accumulation requirements for product and packaging material in feed station and on main line.

DFPL 3.10 Identify materials of construction with emphasis on product contact parts to ensure equipment durability, and to ensure there is proper friction to move product without causing damage or defects.

DFPL 3.11 Identify required online inspection systems and automatic recovery methods.

DFPL 3.12 Develop preliminary layout concepts.

DFPL 3.13 Develop preliminary layout of subsystems including system boundaries, interfaces, material transfer points, product orientation, throughput and machine rates.

DFPL 3.14 Preliminary layout concepts are functionally decomposed into logically independent modules (subsystems) which can be independently designed, tested and integrated to form a complete packaging line.

DFPL 3.15 Review conceptual layout for the need for manual stations, and for future expansion. Reserve space for additional modules.

DFPL 3.16 Review subsystems and vendors for preliminary design/build evaluation. Select commercially available equipment if it meets FRS requirements. Select custom equipment if commercially available equipment is not available or if a unique competitive advantage is required.

DFPL 3.17 Evaluate the use of servomotor based motion control systems for all packaging equipment motion control and changeover adjustments.

3.3.4 Feasibility Studies and Systems Engineering

In the design of any new packaging line there will be portions that are very familiar and can be handled with existing or proven technologies. There will be other portions that will be new or very challenging. Typically, 80% of the operations will be familiar and 20% will be unfamiliar. In order to minimize the project risk, it is recommended that feasibility studies be conducted to determine if the desired operation can be performed on a highly reliable basis. This proof-of-principle assessment typically includes the development and testing of key engineering design concepts using prototypes. If the prototypes work as required, then the design of the packaging line can proceed with a higher level of confidence in both the estimated cost of the project and in meeting the proposed schedule. If the prototypes do not function as required then the design process is continued to develop suitable alternatives before proceeding with the rest of the design. Robot end-of-arm-tooling, automatic inspection systems (IR, RF, vision, bar code, etc.), error checking, automatic recovery systems, and critical material handling systems are candidates for feasibility studies. These technologies are often very reliable but become more challenging when integrated into a packaging line.

Prototype end-of-arm-tooling (EOAT) should be designed for each product family to verify operation, reliability, and cycle time, and to validate the automation concepts for feeding and orienting parts. For each product family, the EOAT and product nest should be designed to require minimal adjustable features or no changeover. As discussed previously, the reliability of the packaging line will decrease as the number of unique parts per robot increases. The number of unique parts handled per robot should be between 2 and 5, with an average of 4 per robot, because of the design impact on the feeding, escapement, presentation and EOAT systems. Typically, the EOAT is designed to grasp the components using gripper fingers, vacuum, or a combination of both. EOAT design must consider the size, shape, weight, and material of the packaging components. Appropriate sensors in the product nest and EOAT should ensure positive handling of all components. A flexible component feeding system with an integrated vision system should be evaluated for possible replacement of part-dedicated peripheral part orientation equipment. The reduction in changeover improves line flexibility, but speed and product specific requirements may prevent its use.

Automatic inspection and recovery systems should be identified and prototyped. The system should include mistake proofing, fault diagnosis and auto-recovery features to minimize or eliminate manual operator intervention for system recovery. System recovery from a fault condition should be automatic and include the clearance of components and resumption of operations. Failure to incorporate automatic recovery systems may result in significant downtime. The system should also include integrated inspection and verification systems for automatic component confirmation, identification of defects and rejection of non-conforming packages. These may include barcodes readers, RF sensors, vision systems (with optical character recognition (OCR) and optical character verification (OCV) capabilities) code blocks, and check-weighers. These systems are used to verify packaging component identification, component presence, lot code, manufacturing and expiration date, etc. Packaging components should include registration marks or features to facilitate these inspections.

The control system for the packaging line should be designed to provide the level of control required for line control and integration, but be modular and flexible enough to allow reconfiguration. A common PLC and SCADA equipment vendor should be selected for all equipment, and all critical monitoring and control points need to be identified. The SCADA system is used to collect data to measure line efficiency, equipment utilization, and to monitor key performance criteria. The SCADA system may also be used to store and download changeover set points to servomotors for automatic changeover for each packaging configuration. The control system is also used for line speed control through the use of accumulation buffers, proximity switches, photo-eyes and other sensors.

DFPL 4.0 Feasibility Studies and Systems Engineering

DFPL 4.1 Conduct Engineering Feasibility Studies of Critical Subsystems

DFPL 4.1.1 Identify high-risk areas which require assessment.

DFPL 4.1.2 Build and test prototypes of EOAT, escapements and feed track

DFPL 4.1.3 Identify preliminary auto-recovery and inspection requirements

DFPL 4.1.4 Build and test prototypes of critical subsystems

DFPL 4.2 Develop an Overall Systems Architecture (PLC/SCADA/Robots/Vision Systems)

DFPL 4.3 Determine modular automation and line control concepts

DFPL 4.3.1 Identify control input/output points

DFPL 4.3.2 Identify data acquisition input points

DFPL 4.3.3 Identify control zones based on subsystems

DFPL 4.3.4 Identify required sensors and photo-eyes

DFPL 4.3.5 Define operation modes (start-up, run, line run out, shutdown)

3.3 Detailed Design of Subsystems

Sub-system Concept Development is the design process phase that develops concept alternatives and selection criteria, and selects an optimal concept for development, and develops this concept into a realized engineering design. The description of operation is a text-based description of the functions of the system and the components involved. The description of operation should present both a process flow description of the product moving through the system and a component based description.

DFPL 5.0 Develop Sub-system Design Concepts and Layouts

DFPL 5.1 Develop process flow diagram (PFD)

DFPL 5.2 Develop Description of Operations

DFPL 5.2.1 Describe movement of the product and packaging components through sub-system.

DFPL 5.2.2 Develop descriptions of each operation and a description of components involved and their functions

DFPL 5.3 Develop Subsystem Layout

DFPL 5.4 Define Concepts for Sub-systems and Evaluate Alternatives

DFPL 5.4.1 Develop subsystem design concepts and alternatives based on functional requirements specifications

DFPL 5.4.2 Conduct feasibility study of alternate design concepts.

DFPL 5.4.3 Identify sub-system boundaries and material transfer interfaces using overall systems architecture and layout.

DFPL 5.4.4 Identify product throughput requirements, and calculate required rate/speed requirements for sub-system operations.

DFPL 5.4.5 Performance Requirements (Rate, reliability, maintainability, availability)

DFPL 5.4.6 Safety Requirements

DFPL 5.4.7 Ergonomic and Accessibility Requirements

DFPL 5.5 Select final design for subsystem/equipment

DFPL 5.5.1 Develop selection criteria based on system requirements, performance, cost, make versus buy evaluation, and prior experience with vendors.

DFPL 5.5.2 Compare alternatives based on prioritized selection criteria

DFPL 5.5.3 Select final design for subsystem

DFPL 5.6 Detailed Design of Subsystems

DFPL 5.6.1 Decompose final subsystem design into component elements (process, mechanism, structure, controls components)

DFPL 5.6.2 Determine test requirements

DFPL 5.6.3 Determine which parts will be fabricated and which will be purchased

DFPL 5.6.4 Select materials and specify component parts

DFPL 5.6.4 Select and purchase parts

DFPL 5.6.5 Fabricated non-purchased parts

DFPL 5.6.6 Wear and failure analysis of parts. Complete expected life analysis of wear components using vendor information and load analysis. Identify single-point-of-failure parts and analyze failure probability using FMEA, etc.

DFPL 5.6.7 Develop recommended spare parts list for single point of failure parts and wear parts

The design for flexible packaging line guidelines outlined in this chapter are a compilation of concepts known before beginning the Kit Automation project and lessons learned during the course of the actual project. In Chapter 4, these DFPL guidelines will be used for the design of a new flexible packaging line.

CHAPTER 4

KIT AUTOMATION PROJECT

4.1 Alcon Laboratories

Alcon Laboratories, Inc. (a wholly owned subsidiary of Nestle, S.A., based in Fort Worth, Texas) is a $2.7 billion global leader in the research, development, manufacture, and marketing of pharmaceutical and medical devices in the otic, ophthalmic and vision-care industry. Alcon's Ft. Worth manufacturing plant produces over 10 million contact lens care kits per year. In the early 1990's these were assembled using three machine-paced manual kitting lines, and the repetitive motions required were causing significant ergonomic issues and medical expenses.

A contact lens care kit consists of a carton containing between three and seven components. Contact lens care kits are manufactured to budget, not to demand, unless new promotional kits are required. Typically ten to fifteen kits account for over 90% of the total volume, but in 1996 over 100 different kits were produced. The main drivers for this diversity in kits were new product introductions, marketing promotions, intense cost pressure, shorter product life cycles, and reduced inventory.

This chapter provides an overview of Alcon's Kit Automation Project to replace the manual kitting operations with a automated flexible packaging line, and includes an overview of the new line's design, construction, start-up, and validation.

4.2 Project Overview

4.2.1 Objectives

The objective of this project was to develop and implement a flexible robotic packaging line to replace two of the three existing manual kitting lines. It was designed for the flexible packaging of Alcon's current contact lens care kits, and for the future strategic capability to produce kits containing 20 ml., 25 ml., 30 ml. droptainers and 16 oz. bottles. The new line was designed to produce kits at a rate of 60 to 65 kits per minute, and has the capacity to produce over one million kits per month (running two shifts, five days per week). In order to maximize the project's savings, all kits are scheduled to run on the new automated kitting line and any overflow (above 1 million per month) is run on the manual kitting line. The new automated kitting line was located in Alcon Laboratories' Fort Worth manufacturing facility, and is called "kitting line six."

4.2.2 Budget and Financial Justification

The funding for the Kit Automation project was authorized from two primary sources. In 1993, the Automation and Robotics Research Institute (ARRI) at the University of Texas at Arlington was contracted to perform an initial engineering study and assist in the development of the project's functional requirements specification (FRS) with Alcon's project team which had no prior experience with robotics. The cost for this initial study and FRS development was expensed. A greatly abbreviated version of the FRS is included as Appendix I.

Funding for the project was obtained by submitting two capital authorization requests (CAR). Each CAR contains an executive summary of the project, financial justification, and an approval section. Capital is required for any equipment purchase over $5,000, and any required components, direct labor and validation services are budgeted and expensed. Both CARs were approved in 1994, and the project had a net present worth of $2.89 million and an expected payback of 2.68 years. A detailed review of the kit automation project budget and financial justification is provided in Chapter 5.

4.2.3 Project Risks

There were several areas of risk for this project. The first area of risk was the transition from manual to automated operations. People are naturally resistant to change, especially if there is a fear of job elimination or having to acquire additional skills. This fear was mitigated by having operators and mechanics participate on the project team and by management's commitment that employees would have jobs either in the existing manufacturing plant or in the a new manufacturing plant that was being constructed onsite. The second area of risk was that this project represented the first use of industrial robots anywhere in Alcon. There were concerns about whether the line was going to be flexible enough to meet marketing demands and robust and reliable enough to meet quality and capacity demands. The third area of risk was financial. There were concerns about whether the project would be successful and provide the estimated savings.

4.2.4 Project Organization

The project team was organized using a cross-functional team approach and included representatives from all functional areas within Alcon including operators and mechanics. The team consisted of a project manager, a core team, and an expanded project team. The Core Project Team consisted of John Via (Project Manager, Automation Engineering), Greg Hamlin (Package Engineering), and Richard Stout (Plant Engineering). The expanded cross-functional project team consisted of over 20 people from Automation Engineering, Production (including operators), Materials Management, Quality Assurance, Plant Engineering, Safety, Package Engineering and Purchasing.

4.2.5 Project Schedule

The original project schedule was developed by the systems integrator as part of their bid documentation. The base schedule projected a June 24, 1994 start date and estimated seven months for completion of the bulk-pack cell, and one year for completion of kitting line six. A high-level project schedule, with actual start and completion dates is included in Appendix II to assist in the understanding of the major events in this project. Unfortunately, the actual schedule was much longer because of repeated failures of the system to meet the required design speed, efficiency and reject rate. These numerous delays required significant redesign focusing on reliability, speed and auto-recovery improvement of many subsystems to successfully complete the project. The bulk pack cell site acceptance test was not completed until September 1995, which was eight months late. Validation of the bulk pack cell was completed in December 1995. The kitting line site acceptance test was not completed until September 1997, which was over two years late. The validation schedule for the kitting line was forecast to require five months and was completed in seven months due to additional changes implemented during validation. Validation of the new kitting line was completed in two parts using a boundary approach to test the capabilities of the system. Part I included the validation of the base equipment and control systems, and the performance qualification of the four active kits (which included the smallest kit). Part II completed the validation for kitting lines upper boundary and operational range for the largest kit. Validation is a structured testing and documentation methodology to ensure that the equipment is functioning properly, and is required by the U.S. Food and Drug Administration for all pharmaceutical manufacturers. According to Wagner (1997), validation can cost pharmaceutical companies 10-20% of the cost of a new packaging line. The new packaging line can not be put into production until validation has been successfully completed.

4.3 Project Design and Implementation

4.3.1 Line Capacity

The function requirements specification for this project required that the new line produce 10 different kits at a rate of 60 to 65 kits per minute, with an efficiency of 95%, and a reject rate of 0.1%. These requirements were based on the current demand for 12 million contact lens care kits per year.

The daily capacity can be used to calculate the annual capacity for this line. The maximum hours available per year is 365 days x 24 hours/day = 8760 hours. The planned idle time is based on the selected shift plan (1,2, or 3), the number of workdays per week, the number of holidays, and the duration of any planned plant shutdowns. If there is no third shift, no weekend work, 11 holidays, and a two-week planned shutdown, the total days available in one year is 365-104-11-10=240 days. In order to produce 12 million kits per year in a plant operating 240 days per year, the line would have to produce 50,000 kits per day. In Table 4.1, the annual capacity of the new kitting line is calculated based on 7.5 hours per shift and 240 operating days per year, with operating efficiency ranging from 0.85 to 0.95, and operating rate from 55 to 65 kits per minute.

Table 4. 1: Annual Capacity in Millions (MM) for the New Kitting Line for Various Operating Scenarios

	Rate (kits/min)	Efficiency 0.95	0.90	0.85
2 shifts (3600 hours)	55	11.3 MM	10.7 MM	10.1 MM
	60	12.3 MM	11.7 MM	11.0 MM
	65	13.3 MM	12.6 MM	11.9 MM
3 shifts (5400 hours)	55	16.9 MM	16 MM	15.1 MM
	60	18.5 MM	17.5 MM	16.5 MM
	65	20.0 MM	19.0 MM	17.9 MM

With a nominal speed of 60 kits per minute, the line requires 13.89 target hours (TH) for production. If the efficiency of the line is 95%, then the effective production rate is 57 kits per minute, and the line will require 14 hours 37 minutes of net production hours (NPH) to produce the same quantity of kits. If the expected operational downtime rate is 5% then the total expected downtime is 45 minutes. The gross production hours (GPH) required is 15 hours and 21 minutes. Thus, the operating plan should thus be two eight-hour shifts (16 hours) to produce 50,000 kits per day.

On an annual basis, the gross production hours required are 240 days x 16 hours/day = 3,840 hours, and the net production hours required are 240 days x 15 hours/day = 3,600 hours. The annual production capacity for the stated operating plan is 3,600 hours x 60 min/hour x 55.25 kits/minute, or approximately 12 million kits per year.

4.3.2 Package Engineering Study

The existing kit packaging process consisted of three machine-paced manual lines and was labor intensive, requiring between 12 and 18 operators and material handlers per shift depending on the kit being produced. The part number of the cartons is verified using a barcode reader, then the cartons are erected and conveyed on a Langen B-1 cartoning machine while operators manually load the components into the cartons. The cartons are sealed, embossed with the lot code and expiration date, and manually loaded into shippers which are taped closed in a taping machine. The closed shippers are manually stacked on a pallet at the end of the line. Table 4.2 summarizes the contents of the ten standard kits being manually produced at the beginning of the Kit Automation project and identifies the components required for each kit.

Table 4.2 Alcon Kit Product Matrix

KIT	5ml btl	10ml btl	15ml btl	Lens Case	45ml btl	4oz btl	12oz btl	8oz btl	Tablet Box 1	Tablet Box 2/3	Tablet Box 4	Literature
1		1		1				1				1
2	2			1		1			1			1
3	1		1	1			2			1		1
4	1		1	1			1			1		1
5	1		1	1			1					1
6			1	1		1					1	1
7				1			2					1
8	2			1	1							1
9	2			1	1							1
10	2			1		1						1

The smallest kit has three components in a carton and the largest kit contains seven components. Each kit consists of:

- One carton, with dimensions between 2-1/2” (L) x 1-25/32” (W) x 5-3/4”(H) and 5-1/8” (L) x 4-7/16” (W) x 7-5/16” (H),
- One lens case (4 possible types)
- One literature insert (of two possible sizes),

and a mix of additional of components depending on the specific kit being produced:

- Bottle(s) of lens care solution (45 ml., 4 oz., 8 oz., 12 oz., or (2) 12 oz.),
- One or two droptainers (5 ml., 10 ml., 15 ml.),
- One enzymatic tablet kits (4 possible types).

The completed kits are packed in corrugated shipper in-groups of 12 or 24, depending on the product. The shippers dimensions are between 10-1/8” (L) x 5-9/16” (W) x 5-7/8” (H) and 20-13/16” (L) x 12-7/16” (W) x 7-7/16” (H).

After reviewing the process flow diagrams, bill of materials and packaging engineering specifications for each product, it was determined that the appropriate grouping (similar characteristics in size and shape) of component families and the required range for each component was:

4 tablet box sizes
10 cartons [min / max range]
10 shippers [min / max range]
2 literature sizes
4 bottle sizes (45 ml., 4 oz., 8 oz., 12 oz.)
3 droptainer sizes (5 ml., 10 ml., 15 ml.)
4 lens cases

Evaluation of the existing manual packaging operations indicated that the appropriate sequence of packaging operations was carton erection, literature load, bottle load, tablet box load, droptainer load, lens case load, carton sealing, shipper erection, carton load into shippers, shipper sealing, and shipper palletize. This sequence of operations also largely determines material flows and the layout of the line.

4.3.3 Material Handling Concepts and Layout

A summary of the current material handling and automation methods for handling these components used on other Alcon manufacturing lines is presented in Table 4.3.

Table 4.3 Automation Methods and Current Bulk Packaging Orientation for Kit Components

Component	Automation Methods		Current Packaging
	Singulation	Escapement	
5 ml., 10 ml., 15 ml. droptainers	Bowl Feed	Blow Feed	Random
45 ml., 4oz., 8oz., 12 oz. bottles	Magazine/ Rotation Table	Mechanical	Organized Layers
Literature	Magazine	Vacuum Cups	Organized Layers
Lens cases	Bowl Feed	Blow Feed	Random
Tablet Boxes	Stackable Magazine	Mechanical Pusher, Adjustable Rails	Organized Layers

A material handling analysis of the existing manual kitting operations was conducted to understand how bulk bottles and bulk enzymatic tablet boxes are created, stored, and brought to the kitting line. The existing material handling concept was to pack bulk bottles (or enzymatic tablet boxes) into corrugated boxes, which were sealed and palletized for warehouse storage. One material handling challenge was to develop a way to get the four different bottle sizes (4oz, 45ml, 8oz, 12oz) and four different enzymatic tablet boxes into a repeatable configuration that could be automatically depalletized and fed to the packaging line. Several different concepts were evaluated before finally selecting reusable corrugated trays (about half bottle height) for storage of bulk bottles. The four different bottle sizes required the development of four different trays (45 ml., 4 oz., 8 oz., 12 oz.) to hold the matrix of bulk bottles. The system was also designed to handle 16 oz. bottles if required in the future. The trayed bulk product was palletized, with eight trays per layer, and stored in the warehouse. The number of layers was determined by the existing rack height in the warehouse. The same material handling design concepts developed for the bulk bottles were utilized for the enzymatic tablet boxes. The tablet boxes were manually loaded into bulk trays and palletized for storage in the warehouse. Three different trays were developed for the four different tablet box sizes. This analysis also led to the addition of the bulk pack cell to the scope of this project.

Some standard equipment was selected based on Alcon's previous experience with it in the existing manufacturing plant. A Langen carton erector, carton sealer, and case erector/sealer with quick changeover options were selected to handle the cartons and corrugate shippers. Hoppman bowl feeders were selected to handle the singulation of droptainers and lens cases.

The FRS was issued to three systems integrators for budgetary quotations and to further evaluate potential design concepts. The three proposals received from systems integrators are summarized in Table 4.4.

Table 4.4: Kit Automation Project Proposal Evaluation

	Proposal #1	Proposal #2	Proposal #3
Rate (kits/min)	60	60-65	60
Efficiency	90%	95%	92%
Required Minimum	66.67	63.16-68.42	65.22

Engineering Rate (kits/min)			
Cycle Time (seconds)	4	4	2
Changeover Time	40-60 minutes	30 minutes	30-60 minutes, 4-6 people
Design Concept	Dual flighted conveyor, 2 cartons per flight, synchronous	Bosch Pallet Conveyor, kit carrier with 4 cartons, asynchronous	Jones CMV Coninuous Motion Vertical Cartoner
Kits loaded per cycle and format	4 (2x2) vertical	4 (1x4) vertical	2 vertical
Robots	7	7	5
Carton Coding	Embossing	Embossing	Embossing
Validation Documentation	FAT, SAT, IQ, OQ Included	FAT, SAT, IQ, OQ Included	Not included
Bottle and Tablet Depalletizing	No	Yes	Yes
Bulk Pack Cell	No	Yes	No
Safety Guarding	Yes	Yes	Yes
Installation	Yes	Yes	Yes
Training	Yes	Yes	Yes
Schedule	10-11 months	8-9 months	10 months
Kitting Line Cost (without bulk pack cell)	\$2.185 million	\$1.64 million	\$1.82 million
Bulk Pack Cell		\$0.375 million	

Designs for both a synchronous conveying system and an asynchronous pallet conveying system were evaluated for the main transfer line. The first proposal's design was based on the cartons being loaded with the required components while being transported on a synchronous (indexing) flighted-conveyor, with adjustable flight spacing and conveyor width to accommodate the range of required carton sizes. The second proposal's design was based on an asynchronous pallet conveyor system conveying the cartons through the loading stations, where the required components are loaded into the cartons. Proposal number three was based on a continuous motion vertical cartoner from Jones. The design concept in proposal number two was selected because it satisfied the largest number of requirements in the FRS, had a higher throughput rate and provided greater flexibility. A standard Bosch pallet conveying system was selected as the asynchronous conveying system, and custom kit carriers were developed to hold the cartons on top of the standard Bosch pallets. A rectangle-shaped conveyor system layout was selected so that the pallets could be recycled efficiently to the beginning of the line once the cartons were unloaded from the kit carrier.

A gantry-style pick-and-place was selected to pick the erected cartons from the carton erector and load them into the kit carriers, and unload the fully loaded cartons (finished kits) and place them onto either a belt conveyor (good product) or a reject table (bad product). The initial end-of-arm-tooling (EOAT) design was to mechanically grip the cartons by two of the top flaps. Five FANUC A510 robots were selected to pick and load the literature, bottles, tablet boxes, droptainers, and lens cases. Two FANUC M400 robots were selected to depalletize the bulk tablet boxes and bottles, and for palletizing the final shippers.

4.3.4 Systems Engineering and Feasibility Studies

The control system was designed using commercially available hardware and software. The control system consists of seven GE FANUC Series Six PLCs, nine FANUC robots, three pick-and-places, and three operator interface terminals using Wonderware software as the operator interface. The system is designed on a modular concept and is separated into four major zones. Each operator interface provides all information regarding the operational status of the individual zones, and product counts - rejects, total, product average counts per minutes.

The feasibility studies for this project focused on two primary areas: design of the kit carriers, and design of the end-of-arm-tooling (EOAT) for the nine robots and three pick-and-place units. A “kit carrier” was designed during prototype testing and attached the pallet to hold the required range of cartons in the proper orientation for component loading. No changeover was required. A rate analysis concluded that four kits had to be loaded concurrently to achieve the desired cycle time. The kit carrier was designed to hold four kits at an angled position to facilitate loading of components.

The initial design of the carton load and unload operations was based on a gantry-style pick-and-place. This pick-and-place was used to pick four cartons from the Langen carton erector and place them into each kit carrier. The same pick-and-place picked up the loaded cartons from the kit carrier and placed them onto either a belt conveyor (good product) or a reject table (bad product). The initial EOAT design mechanically gripped the cartons by the two of the top flaps, and no changeover is required.

The depalletizing zone consisted of one M400 robot and two pick-and-place tray unloaders. The M400 was equiped with a single EOAT to handle the empty pallets, tier sheets, and loaded bulk trays. The tray unload pick-and-place required four separate EOATs, one for each bottle size (4 oz., 45 ml., 8 oz., and 12 oz.). Three EOATs using vacuum cups were designed to handle the four tablet box sizes. The tray unload EOATs have to be changed depending on the kit being run.

The bottle load EOAT consisted of four mechanical grippers that picked up the bottles by the neck. No changeover is required because this is a common feature on all bottles. A single EOAT was also designed using vacuum cups to handle the four tablet boxes.

A single EOAT was designed to load either one or two droptainers into the kits. Vacuum cups are used to pick-up the droptainers from top of their caps, and the design requires no changeover. A single EOAT was also designed using vacuum cups to handle all four lens case designs and requires no changeover. Each EOAT design was tested to confirm capability and the required performance rate.

4.4 Detailed Design

4.4.1 Bulk Pack Cell Design

The bulk pack cell was designed to replace the current manual packaging of bulk bottles directly from the manufacturing line. A bottle conveying system was designed using Laughlin conveyors and Simplimatic elevators to transport the bottles from the production line to the bulk pack cell. A custom bottle matrix-forming unit was designed to take the singulated bottles and form the appropriate matrix of bottles so they could be loaded into trays. A Hytrol tray conveyor was designed to transport empty trays into a bottle load station, where the bottles are loaded into the trays, and then transported to the pick position for palletizing. An A510 robot was selected to load the bottles into the trays. After extensive attempts to design a single reliable EOAT for all four of the bottle matrices, 4 EOATs were designed and constructed. A M400 robot was selected for the palletizing operations, and a single EOAT was designed to handle the empty pallets, tier sheets, and bulk product trays. A Hytrol chain conveyor transported the completed pallets out of the bulk pack cell to a forklift pick-up position. The completed pallet was taken to the warehouse for storage.

4.4.2 Conveyor and Kit Carrier Design

A standard Bosch pallet conveyor system was selected with a constant speed belt to move the pallets between loading stations and lift pins to hold pallets in position at the designated station. The conveyor speed, number of kit carriers, and the location of queue and load positions on the conveyor were determined to achieve the required transit speed between load positions. The eight load positions were carton load, literature load, bottle load, tablet box load, droptainer load, lens case load, manual load, and kit unload. A queue position was also positioned prior to each load station. The Bosch ID-10 code block system was selected to identify the current status (process / no process / reject) of each pallet. The height of the conveyor was selected to be 30 inches for ergonomic reasons, and the height of all other equipment was selected in relationship to the conveyor.

4.4.3 Langen Carton Erector, Carton Load Pick-and-Place

A Langen B-1 horizontal carton erector was selected to erect the cartons, and seal the bottom flaps. An extended carton magazine was selected to minimize the frequency of carton replenishment, and a quick changeover option package was selected to facilitate quick and repeatable changeover of the cartoner. A Datalogic barcode reader was selected to verify the carton identification, and a Lincoln coder was selected to emboss the lot code and expiration date on the bottom of the carton. The Langen, Datalogic and

Lincoln equipment was all standard and were currently being used by Alcon on the existing manual kitting lines. Rejected cartons (wrong barcode, open bottom flap, etc) are rejected from the end of the conveyor into a bin. A gantry style pick-and-place and its EOAT was designed to pick four cartons at a time from the Langen carton erector and place them into the kit carriers.

4.4.4: Literature Magazine and Load Robot

A literature feeder magazine with adjustable rails was designed to singulate the literature. Bulk literature is loaded into the magazine and gravity fed to the four pick locations. An A510 robot was selected to load the literature into the cartons. The EOAT design uses vacuum cups to pick four pieces of the literature at a time from the literature magazine. Although a simpler pick-and-place mechanism could have been used for the literature load, the robot was selected for its future flexibility.

4.4.5: Depalletizing Area: Bottle and Tablet Box Singulation and Load

In order to feed singulated bottles to the bottle loading robot, the palletized bulk bottles in trays have to be depalletized, and the bottles have to be removed from the trays. The design concept developed was basically the bulk pack cell in reverse. A M400 robot was selected to depalletize bulk product and place the tier sheets and empty pallets into stacks for manual removal from the cell, and a single EOAT was designed to handle the empty pallets, tier sheets, and bulk product trays. The M400 placed the full trays onto a roller conveyor that transported the trays to a pick-and-place for unloading. A tray unload pick-and-place and EOAT was designed to remove bottles from the bulk trays.

The EOAT designs are the same as those used in the bulk pack cell. The empty bottle trays were released onto a roller conveyor for removal from the depalletizing cell. Bottles are then singulated using a Garvey accumulation table, a conveyor and mechanical stops at the bottle load positions. An A510 robot was selected to pick the bottles and place then into the cartons on the kit carriers. A single EOAT with mechanical grippers was designed to handle all four bottle sizes.

The same M400 robot and EOAT designed to depalletize the bulk bottles was also selected to depalletize the bulk tablet boxes using the same sequence of operations. The M400 placed the full tablet box trays onto a roller conveyor that transported the trays to a pick-and-place for unloading. A tray unload pick-and-place was designed using an EOAT which used vacuum cups and side supports to hold the tablet boxes. The empty tablet box trays were released onto a roller conveyor for removal from the depalletizing cell. Tablet boxes are then singulated using a conveyor and fed to the pick positions. An A510 robot was selected to pick the tablet boxes and place then into the cartons on the kit carriers.

4.4.6 Droptainer Load

Zero, one or two droptainers are packaged in each kit as required by the specific kit. The normal combinations for droptainers required by kits are 5ml., two 5ml., one 5ml. and one 10ml., one 5ml. and one 15ml. Two Hoppmann bowl feeders were selected for the escapement and singulation of droptainers because it was standard equipment currently being used by Alcon on other manufacturing lines. Bulk droptainers are dumped into the bin of the Hoppmann bowl feeder, and transported by an elevating conveyor from the bulk bin to the rotating bowl feeder. The bowl feeder singulates the droptainers and places them onto a belt conveyor which transports the droptainers to the robot pick location (nest). Change parts for the Hoppmanns and the robot pick nest were purchased for 5 ml., 10 ml., 15 ml. products, and the design incorporated the requirements for the 20 ml. and 30 ml. droptainers to accommodate future flexibility.

4.4.7 Lens Case Load

The initial project requirements specification required three different type of lens cases, and a fourth design was added to the project scope during implementation. Only one lens case is packaged in each kit. A Hoppmann bowl feeder (same model as the units selected for the droptainers) was selected for the escapement and singulation of lens cases. The bulk lens cases are dumped into the bin of the Hoppmann bowl feeder and transported by an elevating conveyor to the rotating bowl feeder. The bowl feeder singulates the lens cases and places them onto a belt conveyor, which transports the lens cases to the robot, pick location (nest). Change parts for the Hoppmann and the robot pick nest were purchased for each of the four lens case designs.

4.4.8 Carton Unload Pick-and-Place, Shipper Pack and Palletize Cell

The same pick-and-place used to load the empty cartons into the kit carriers was used to unload the filled cartons. Good cartons are loaded onto a conveyor that feeds the checkweigher. Reject kits are placed on the reject table for inspection and rework.

A HiSpeed checkweigher was selected to weigh each kit online as a secondary verification that all kit components were correctly loaded. A standard Langen carton sealer was selected to seal the cartons, and a standard Langen shipper erector/sealer was selected to handle the shippers. A custom carton matrix forming unit was designed to form the correct number of kits (12 or 24) into the required matrix, and a pick-and-place was designed to pick up the kits and load them into the shippers. A M400 robot was selected to palletize the shippers to maximize palletizing flexibility. A single EOAT was designed to handle empty pallets, tier sheets, and the shippers. The palletizing robots EOAT requires no changeover.

4.5 Performance Issues and Redesign Efforts

Between June and August 1996, testing of the integrated kitting line indicated it was not achieving the required performance specifications. This was confirmed when the system repeatedly failed the factory acceptance test (FAT) in August. The kitting line had substantial downtime (24%), was not meeting design rate (46-48 completed kits per minute), and had excessive rejected kits and kits missing components (1-5%). A detailed recovery plan consisting of three phases was developed jointly with the systems integrator. Phase I consisted of a technical review and capability analysis to clearly establish the current capabilities of the kitting line and identify and implement the required changes to improve its performance. Once these changes were implemented, the factory acceptance test would be repeated at a reduced performance level and the system would be shipped to Alcon for installation. In Phase II, additional improvements were implemented concurrent with installation and tested as part of the site acceptance test (SAT). Phase III consisted of further improvements implemented concurrent with production until the line met the performance requirements in the original FRS. This section describes the design and performance issues that were encountered during this project and how they were resolved.

4.5.1: Phase I: Technical Review, Capability Analysis and Corrections

The technical review and capability analysis was completed in August and September 1996. These activities identified the issues preventing the kitting line from reaching the specified speed, efficiency and reject rate, and identified the cause of missing components. The initial goals of the project team was to reduce downtime to less than 10%, increase the maximum rate to 54-60 kits per minute, increase the rate of completed kits to 48-56 kits per minute, ensure there were no kits missing components, and reduce rejects to 1%.

Analysis of the kitting line FAT results indicated that the line was not achieving the specified throughput because of excessive downtime, insufficient speed of the Bosch conveyor, insufficient speed of several load stations, and the time required to manually intervene and recover from jams or fault conditions. Measured downtime was 24%, which was substantially higher than the specified maximum of 5%. Performance of the kitting line was constrained by critical equipment faults or component jams in nine stations, which required manual intervention to clear so that packaging operations could continue. The droptainer load station had over 9% of the total downtime due to numerous robot gripper faults, and component jams on the escapement conveyor and in the robot pick nest. The lens case zone had 3% of the total downtime due to component jams in the escapement conveyor and in the robot pick nest, and missing lens case caps. The carton erector and load pick-and-place had 3% downtime and the carton unload pick-and-place had 2% downtime due to the inability of the EOAT to reliably pick the smallest and four largest cartons, and failure to load cartons into the kit carrier. The tablet box feeder and bottle feeder stations each had 2% downtime because of product jams at the discharge from the matrix, during singulation, or from product falling over in the matrix itself. The depalletizing robot's search routine was also too slow to keep up with the kitting line. An additional 3% downtime was caused by "no kit carrier in station penalty" caused by stations waiting on kit carriers to enter the loading stations. Further analysis indicated that the time penalty for manual intervention was substantial, and that the downtime could be reduced to 10-12.5% overall by implementing auto-recovery features.

The kitting line was also not meeting its specified throughput because the Bosch conveyor transfer speed and the load cycle time in four of the loading stations was too slow. An engineering design rate of 63.2 kits per minute, or 3.79 seconds per station cycle, is required to achieve a throughput rate of 60 completed kits per minute at 95% efficiency. The kit carrier transfer time plus the individual station load cycle time must be less than 3.79 seconds to achieve the desired rate. The Bosch kit carrier transfer rate was measured as 2.2 seconds between stations, so the individual station load cycle time was limited to 1.59 seconds. Additional throughput analysis and timing studies of the kitting line indicated that six stations were preventing the line from achieving its performance. The cycle time for the bottle load robot, tablet load robot, carton load pick-and-place, and droptainer load stations were too slow. Two stations had cycle times that were fast enough, but had to wait on the Bosch pallet conveyor. As summarized in Table 4.5, the constrained stations had station cycle times greater than 3.79 seconds.

Table 4.5: Engineering Analysis of Kitting Line Rate

Station	Station Rate (seconds/cycle)	Station Rate (kits/min)
Lens Case Load Robot	3.66	65.6
Carton Unload Pick and Place	3.75	63.3
Required Design Rate	3.79	63.2
Bottle Load Robot	3.90	61.5
Tablet Load Robot	4.00	60.0
Carton Load Pick and Place	4.15	57.8
Droptainer Load	4.2	57.1

The Bosch conveyor speed issue was quickly resolved by upgrading the belt drive units to the next highest speed, and by adding more stops for improved pallet queuing management. Increased conveyor speed removed the constraints on the lens case load robot and carton unload pick-and-place. Escapements on all load stations were redesigned to allow auto-recovery, which greatly reduced the downtime penalty incurred by having to manually clear and reset following a jam or fault. The EOAT at each load station was also significantly redesigned and improved on all stations to improve the reliability of the system.

The reliability of the lens case loading zone was improved by adding loose and missing cap detection and removal systems, and auto recovery features to clear the robotic pick locations. Sensors were added to the EOAT grippers to confirm presence of the lens cases to prevent missing components.

The droptainer load zone was significantly improved through layout and equipment changes to improve the reliability and efficiency of operations. The EOAT was redesigned to overcome its failures to pick droptainers from the nest or release the droptainers into the cartons. Better vacuum cup seals were installed, blow off capability was added, and sensors were added to the grippers to ensure placement into the carton to prevent missing components. Auto-recovery features were added on the escapements and pick nest, and down-bottle detection systems were also added.

The bottle load zone was improved by changing conveyor speed to prevent bottles tipping during transfer into escapement and to reduce bottle jamming at the singulation at matrix discharge. The feeder escapements were also improved for the bottle and tablet box load stations to improve operational reliability and to add auto-recovery capability. The mechanical bottle stops were replaced with Ernst feed screws to get more reliable and repeatable bottle positioning at the load positions. Five Ernst timing screws were puchased, one for each bottle size (4 oz., 45 ml., 8 oz., 12 oz., and twin 12 oz.). The speed of the depalletizing robot search routine was also improved by optimizing the search routine.

The carton load and unload pick-and-place was completely replaced with two new robots and EOAT. The original EOAT that picked the cartons by two of the top flaps worked reliably for only six of the ten kits, and there were additional problems encountered with cycle time in order to meet the required kit production speed for the entire system. The pick-and-place for carton loading was replaced with a S12 robot and the EOAT was redesigned to pick the cartons using vacuum on the inside of the carton. The robot and its EOAT picks four cartons at a time from the Langen carton erector, rotates the cartons from a horizontal to a vertical orientation while reducing the spacing between cartons, tilts the cartons 30 degrees and loads the cartons into the kit carrier. The final EOAT design works with all cartons within the specified design range and requires no changeover. The carton unload used a new A520i robot, and the EOAT was redesigned to pick the cartons using clamps on the outside of the carton. The final EOAT design picks four cartons at a time, works with all cartons within the specified design range and requires no changeover. The S12 and A520i robots were selected for these applications because they are faster than the A510 robots.

Redesign, modification, and re-testing of the kitting line required eight months to complete. The abbreviated FAT consisted of running four kits at a throughput rate of 52 completed kits per minute for one hour, and running the six remaining kits for 15 minute capability runs. The systems integrator retained responsibility for achieving compliance with original FRS in Phases II and III. The FAT was successfully completed in August 1997, and the system was shipped to Alcon in Ft. Worth, Texas.

4.5.2: Phase II: Site Acceptance Testing and Validation

In Phase II, the kitting line was installed and successfully completed its site acceptance test (SAT). The SAT required one hour runs for four kits and 15 minute capability runs for four others. The demonstrated maximum rate had to exceed 60 kits per minute, the net throughput of completed kits had to exceed 55 kits per minute, downtime had to be less than 10%, the scrap rate had to be less than 1%, and no kits could have missing parts. Additionally, changeover had to be completed in 30 minutes per zone, and the kitting line had to be operating at the normal throughput rate within 30 minutes of completing the changeover. The definition of reject rate was changed to scrap rate. Scrap rate was defined as parts that could not be re-introduced into the system following automatic or manual rejection from a station. Scrap rates also include kits that were rejected from the system – automatically or manually – due to missing components. All scrap was based on scrap caused by the equipment and excluded incoming component defects and other non-equipment-related causes. The SAT was successfully completed in October 1997. The four one-hour runs averaged 56.7 completed kits per minute, 6.4% downtime, and less than 1% scrap. The four 15-minutes averaged 58.3 kits per minute, 1.3 % downtime, and less than 1% scrap. Changeover of all five zones required one hour and twenty-four minutes with two mechanics, and within 15 minutes the line was operating at 55.2 kits per minute and 8.5% downtime. The installation qualification (IQ) and operational qualification (OQ) for the kitting line, and the first four kits, was completed between September and December 1997. A summary of the two-part validation approach is given in Table 4.6. Part I covered the validation of the four active kits so that the kitting line could be put into commercial production, but did not test the full operating range of the kitting line. Part II covered the validation of the boundary conditions and full operating range of the kitting line. The process qualification for the four active kits was completed in March 1998, and the line was put into commercial production in April 1998. Part II of the validation was completed in early June 1998.

Table 4.6 Validation Plan for Kitting Line

	Part I	Part II
Langen Area (PLC A/B)		
Carton Erector	3 cartons	Smallest/largest carton
Barcode scanner	4 cartons	N/A
Carton Loader S12 Robot	3 cartons	Smallest/largest carton
Literature Load A510 Robot	2 sizes	N/A
Bottle Load A510 Robot	45 ml., 4 oz., 12 oz.	8 oz.

Tablet Load A510 Robot	N/A	N/A
Checkweigher	3 kits	Smallest/largest kit
Carton Sealer	3 cartons	Smallest/largest carton
Kit Unload A520 Robot	3 cartons	Smallest/largest carton
PLC Area A/B	4 kits	Smallest/largest kit
Depalletize Area (PLC C)		
Depalletize M400 Robot	45 ml., 4 oz., 12 oz.	8 oz.
Bottle Tray Unloader	45 ml., 4 oz., 12 oz.	8 oz.
Tablet Tray Unloader	N/A	3 sizes
PLC Area C	4 kits	Smallest/largest kit
Hoppmann Area/ Bosch Conveyor (PLC D)		
Hoppman Droptainer Feeder #1	5 ml.	N/A
Hoppman Droptainer Feeder #2	5 ml., 10 ml., 15 ml.	N/A
Hoppman Lens Case Feeder	1 lens case	2 lens cases
Droptainer Load A520 Robot	5 ml., 5 ml./5 ml.	5 ml./10 ml., 5 ml./15 ml., 10ml., 15 ml.
Lens Case Load A510 Robot	1 case	2 cases
Kit Carrier Conveyor	3 kits	Smallest/largest kit
PLC Area D	4 kits	Smallest/largest kit
Shipper Pack & Palletize (PLC E)		
Shipper Erector	3 shippers	Smallest/largest shipper
Carton Matrix Pick-and-Place	3 kits	3 matrices
Shipper Palletizer M400 Robot	3 shippers	Smallest/largest shipper
PLC Area E	4 shippers	Smallest/largest shipper

4.5.3: Phase III: Final Acceptance

In Phase III, the final acceptance of the kitting line was achieved by demonstrating that the kitting line was able to meet the specified net throughput rate, downtime, and scrap levels in the original functional requirements specifications. Normal production runs for the four active kits documented that the line had a maximum rate of

63 kits per minute, a net throughput of 60 completed kits per minute, a scrap rate less than 0.1%, and no kits with missing components. Downtime was slightly higher than 5% during these trial runs but was deemed acceptable.

4.6 Operational Description of Completed Project

Alcon Laboratories' kit automation project consists of two flexible manufacturing systems: the Bulk Pack Cell and Kitting Line Six.

4.6.1 Bulk Pack Cell

The Bulk Pack Cell packs the labeled bottles (45mL, 4oz, 8oz, and 12oz) into trays at a rate of 135 to 150 bottles per minute, and palletizes the trays for transport to the kitting line. The Bulk Pack Cell consists of an elevator, overhead conveyor, infeed and tray transport conveyors, pallet conveyor, pallet and tier sheet stands, an A510 robot and a M400 robot. Bottles are conveyed into the bulk pack cell using a Simplimatic elevator, Laughlin conveyor, a Simplimatic elevator ("lowerator") from one of two production lines. The bottles are formed into a matrix in preparation for loading into trays. A bulk tray is conveyed into the loading station, and an A510 robot picks up the matrix of bottles and loads them into the tray. The filled tray is released from the loading position and conveyed to the palletizing position, and another empty tray is conveyed into the loading position and the above sequence is repeated. Filled bulk trays are automatically palletized by a M400 robot, and the robot also handles the empty pallets and tier sheets. Completed pallets are removed from the cell using a Hytrol chain conveyor, picked up by fork trucks, and stored in the warehouse until needed to feed the kitting line.

4.5.2 Kitting Line Six

The Automated Kitting Line assembles kits, packages the kits into the appropriate shipper, and palletizes the shippers. Once a specific kit is scheduled to be produced on the kitting line, a material handler brings the appropriate components (cartons, literature, bottles, enzymatic kits, droptainers, lens cases and shippers) to the line. The operator selects desired kit product to be packaged on the automated kitting line from a menu on the master operator interface and initiates the line. The kitting line's control system is subdivided into four manufacturing zones and supports three modes of operation: start-up, production, and shutdown.

The cartons are erected by the carton erector, a bar code reader verifies that it is the proper carton, the bottom flaps are glued shut, and the carton is embossed with the lot code and expiration date. Cartons are then removed from the carton erector by a S12 robot and loaded in groups of four into the kit carrier on the asynchronous pallet conveyor.

The required components (literature, bottles, enzyme tablet kits, droptainers, and lens cases) are automatically singulated (presented to the robot loading stations) by feeding mechanisms that are restocked by a material handler. As the kit carrier traverses the pallet conveyor, A510 robots automatically load the required components for the specified kit into the cartons. Space for two manual loading stations is provided at the end of the robotic loading stations (prior to carton closure) to allow for manual addition of components for additional flexibility if required. The loaded cartons are removed from the kit carrier by an A520i robot and placed on either a product or reject conveyor.

The product kits then travel over a checkweigher for a weight check prior to being sealed by a carton sealer. Completed cartons that are below minimum weight, or that have been identified as rejects by the code-block verification system are rejected. Sealed cartons are transported by a conveyor to the Shipper, Pack and Palletize Cell, which consists of a shipper erector / sealer, a carton matrix forming unit, pick and place, and a M400 palletizing robot. The Shipper, Pack and Palletize Cell operates as follows. A shipper is erected and transported into the carton loading position. The sealed cartons are fed by a conveyor to the matrix forming unit, formed into a matrix, and loaded by a pick-and-place into the erected shipper. The loaded shipper is released from the loading station and taped shut. The shippers are palletized by a M400 robot into a pre-specified pallet configuration and sent to the warehouse for distribution.

4.6 Post Project Evaluation and Conclusions

As stated in section 4.2.1, the objective of this project was to develop and implement a flexible robotic packaging line to replace the manual kitting operations, and to provide both the capability to produce existing lens care kits, and the strategic capability and flexibility to produce future products. The line was designed for the flexible assembly of lens care kits at a rate of 60 to 65 kits per minute requiring minimal changeover, and for the future possible expansion for kits containing 20 ml., 25 ml., 30 ml. and 16 oz. products. Because of product innovation, product standardization, and product changes by marketing only two of the original ten kits specified in the FRS remained active at the end of the project, and five other kits were introduced during the project. As summarized in Table 4.7, the kitting line’s demonstrated performance met the project's original functional requirements specification except for downtime. The actual downtime was approximately 6.9% which is greater than the 5% specified.

Table 4.4 Comparison of Required and Demonstrated Capabilities for the Kitting Line

Performance Measure	Original Specification (Rev 1)	Demonstrated capability at SAT	Demonstrated capability in production
kits/min	60-65	55-60	58-63
Uptime	95%	91%	93.1%
reject rate	0.1%	<1%	<0.1%

The project also provided proof of the concept of a flexible packaging line by successfully demonstrating its flexibility by accommodating significant product changes during implementation and validation. Many of these changes were driven by changing product mix, and the transition from multiple products (separate contact lens care solutions, cleaners, etc.) to multipurpose products. Several significant changes were accommodated by the flexibility of the system, including:

- Product mix change – new liquid enzymatic cleaner in a 5ml. droptainer was introduced which resulted in the obsolescence of the enzymatic tablet products. The liquid enzymatic cleaners are packaged in the droptainer load station.
- The initial project requirements specification included three different type of lens cases. A fourth design was introduced by marketing during the project. Following factory acceptance testing, the pick nest and inspection station for loose and missing lens cases was modified to accommodate the new design, and is capable of packaging all four

lens cases. A cost reduction initiative resulted in the standardization on a single new lens case design.

- Marketing required the addition of 1 ml., 20 ml., 25 ml., and 30 ml. droptainer (increase from 3 to 7 sizes) and 2 oz. bottle (increase from 4 to 5 sizes) capability, which were added with minimal changes. One new EOAT was required to unload trayed 2 oz. bottles and a new 2 oz. Ernst feed screw were required. The 1 ml. and 2 oz. components were outside the anticipated future requirements for the line. New change parts for the Hoppmann bowl feeder for component presentation, and the robot pick nest was replaced.

- The capability to package kits in either 12 or 24 per shipper was also added following the site acceptance test, adding additional flexibility to the kitting line.

- Five new kits were added by marketing during the project. Four were within the planned product range and were incorporated into the project, implemented and validated. One new kit was added that was outside of planned product range (the carton size was too small), was produced on one of the manual kitting lines, and was later eliminated.

Several valuable lessons were learned as a result of the kit automation project including:

- Auto-recovery systems – The time penalty incurred to clear component jams and machine faults can be very significant. Auto-recovery systems should be designed into the flexible packaging line’s feeder systems to minimize the need for manual intervention.

- Machine Design - Machine design is critical. The machine must work well mechanically or it cannot be automated. A poor mechanical design can also not be corrected with software or automation.
- High Speed Video – High Speed video analysis is very valuable to identify and isolate the condition causing the problem.
- Packaging Materials – Packaging components must be very consistent to be effectively automated. When problems are encountered, evaluate both the packaging components and the equipment to identify the cause of the problem and the best corrective action.
- Speed – Fastest speed is not necessarily the best. The packaging components must operate consistently at the desired speed. A packaging line operating at its most reliable speed may have minimal downtime and a faster payback when compared to a packaging line operating unreliably at its maximum speed.
- Operator/Mechanic Involvement – The operators and mechanics should be trained and involved in the design, FAT/SAT and start-up of the packaging line to create a sense of ownership. Ultimately people will make a the difference in the success of the new packaging line regardless of the level of automation or flexibility designed into the line.
- Servomotor-based Equipment – This project took the conservative approach to utilizing some standard packaging equipment that was current utilized in the plant, and while this equipment worked as designed it also resulted in some limitations. Specifically, if servomotor based equipment (even from the same vendors) had been utilized then the changeovers could have been more automatic, the required footprint of

the equipment could have been smaller, and the integration of the system would have been much easier to design and maintain.

- Simulation – New software tools were commercialized during the course of this project that would have greatly aided in the design of the flexible packaging line, and for the evaluation of the problems encountered during system integration and testing.
- Flexibility – The flexibility realized may be less than the potential flexibility designed into the system due to regulatory restrictions. Required line clearances, which may take 15-45 minutes, may offset the potential advantages of automatic changeovers. Sterility testing of the product requires 14 days to complete and may offset the potential benefits of quick response. Validation testing requirements may prevent the rapid introduction of new products, and/or new loading stations, or the rapid reconfiguration of a modular packaging line. For products requiring regulatory approval prior to manufacture, new product introduction (packaging and label changes included) may be delayed significantly, or not approved at all.

A detailed review of the kit automation project budget and financial justification is presented in Chapter 5. An analysis of three years of operational data is presented in Chapter 6.

Chapter 5

FINANCIAL ANALYSIS AND RESULTS OF THE KITTING LINE PROJECT

5.1 Project Funding and Assumptions

This chapter consists of a financial analysis of the kit automation project. The original project justification and sensitivity analysis are reviewed first, followed by an analysis of the actual project through April 2001, to compare the expected versus actual payback. Funding for the project was obtained by submitting two capital authorization requests (CAR) for a total of $2,398,500. The Bulk Pack CAR was for $462,500 and had a projected savings of $124,000 per year in reduced labor costs, and an additional $100,000 (in 1993) in cost avoidance of repetitive motion injury medical expenses. The kitting line CAR was for $1,936,000 and had a projected cost savings of $966,000 per year in reduced labor costs, and an additional $500,000 (in 1993) in cost avoidance of repetitive motion injury medical expenses. Both CARs were approved in 1994, and the project had a net present worth of $2.89 million and an expected payback of 11 quarters (or 2.7 years). The project was expected to begin in 1994 and be completed in 1996.

The following assumptions were made for completing these financial calculations. All cash flows were assumed to be at the end of the period, except for the initial down payment. Discrete compounding was used assuming a 10% annual interest rate. The project proposal calculations were based on 1994 values for the labor rate and cost avoidance and were considered fixed. The effects of inflation were ignored, and the tax rate was assumed to be a fixed 40%. Depreciation costs were $199,875 per year, based on the 12-year straight-line method ($2,398,500/12). Finally, the capital payment schedule was based on 20% payment on placement of order, 40% at design review and approval, 20% upon successful completion of the factory acceptance test (FAT), and 20% upon successful completion of the site acceptance test (SAT). Reduced labor costs for the bulk pack cell were $124,000 per year, based on a savings of four-and-one-half packaging operators at $27,600 per year. Reduced labor costs for the kitting line were $966,000 per year, based on a reduction of 35 packaging operators at $27,600 per year. A summary of the CARs and expected savings is presented in Table 5.1.

Table 5.1 Capital Authorization Requests and Expected Savings for the Project

	Bulk Pack Cell	Kitting Line	Total
Capital	$375,000	$1,640,000	$2,015,000
Contingency	37,500	176,000	213,500
Facility Modifications/ Installation	50,000	120,000	170,000
Total Investment	462,500	1,936,000	2,398,500
Labor Savings	124,000	966,000	1,090,000
Cost Avoidance	100,000	500,000	600,000

The total annual savings and payback for the project were calculated twice, both including and excluding the reduction in medical expenses related to repetitive motion injury, which was approximately $600,000 per year. A summary of the total annual savings calculations is presented in Table 5.2.

Table 5.2 Total Annual Savings Calculations

Total Annual Savings	Not including cost avoidance	Including cost avoidance
Savings	$1,090,000	$1,690,000
Depreciation	–199,875	–199,875
Taxable Profit	890,125	1,490,125
40% Tax	–356,050	–596,050
Total After-Tax Savings	534,075	894,075

Payback for the two cases is calculated as follows:

Payback (with no cost avoidance) = ($2,398,500)/($534,075) = 4.5 years, or 18 quarters.

Payback (with cost avoidance) = ($2,398,500)/($894,075) = 2.7 years, or 11 quarters.

Cost avoidance is included in the calculations and analysis that follows. The cash flow diagram for the proposed project is illustrated in Figure 5.1. It is based on an initial investment of $2,398,500 (20% initial payment of $479,700 in 1994, 40% payment of $959,400 in 1995, and a 40% payment of $959,400 in 1996) and an annual savings of $894,075 per year for 1997-2008.

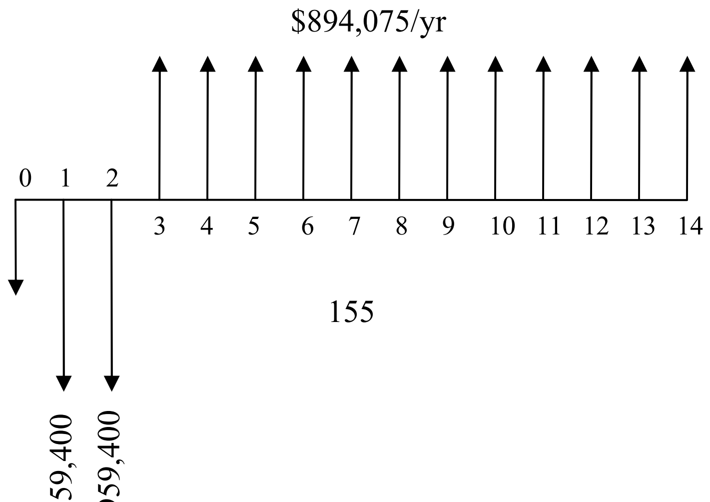


Figure 5.1 Cash Flow Diagram for Proposed Project

The net present value (NPV) of the project is (-$479,700) + (-$959,400) (P/A, 10%, 2) + ($894,075)(P/F, 10%, 2) (P/A, 10%, 12), where (P/F, 10%, 2)=0.8265, (P/A, 10%, 2)=1.7355, and (P/A, 10%, 12)=6.8137. Thus, NPV = $2.89 million.

5.2 Sensitivity Analysis

A sensitivity analysis was completed on the initial project proposal to evaluate the sensitivity of the project's net present value based on variation of the initial $2,398,500 capital investment (from –20% to +30%) and of the $894,075 annual savings (from –40% to +20%). The results of this analysis are shown in Table 5.3.

Table 5.3 Sensitivity of NPV to Variations in Capital Investment and Savings

Capital Sensitivity	Capital Investment	Net Present Value
-20%	$1,918,800	$3,318,851
-10%	2,158,650	3,104,374
Base Case	2,398,500	2,889,896
+10%	2,638,350	2,675,419
+20%	2,878,200	2,460,941
+30%	3,118,050	2,246,464

Savings Sensitivity	Annual Savings	Net Present Value
-40%	$536,445	$876,028
-30%	625,853	1,379,495
-20%	715,260	1,882,962
-10%	804,668	2,386,429
Base Case	894,075	2,889,896
+10%	983,483	3,393,363
+20%	1,072,890	3,896,830

5.3 Project Results

The project's execution deviated from the original project plan and the assumptions used in the justification financial analysis had to be modified as a result. The actual project took longer than planned and was delivered in two parts instead of one. The bulk pack cell was completed in 1.5 years (Purchase Order 6/94, Design Approval 10/94, FAT 4/95, SAT 9/95, Startup 12/95). But the kitting line incurred significant delays and was completed two years later than planned (Purchase Order 6/94, Design Approval 9/96, FAT 7/97, SAT 9/97, Startup 4/98). Due to changes in project scope, the capital cost for the kitting line was increased by $140,870. The anticipated savings were reduced because a total of six operators were required to operate the new line instead of the five operators used in the justification calculations. The total number of packaging operators reduced was 32.5, instead of 35 in the original proposal, and this resulted in the reduction of the anticipated savings from $966,000 per year to $897,000 per year.

The actual cash flows for this project were captured for January 1994 through April 2001 and are shown in Table 5.4, and the actual project's net present value is calculated in Table 5.5.

Table 5.4 Actual Cash Flows

Year	Actual Bulk Pack Cash Flow	Actual Kitting Line Cash Flow	Total Actual Cash Flow
1994	–$297,500	–$387,200	–684,700
1995	–165,000	0	–165,000
1996	126,635	–915,270	–788,635
1997	132,460	–774,400	–641,940
1998	140,217	691,528	831,745
1999	148,390	972,979	1,121,369
2000	156,966	1,026,468	1,183,435
2001 (4/01)	55,324	360,877	416,201

Table 5.5 Net Present Value (1994) Calculations for Actual Cash Flows

Year	(P/F, 10%, n)	Total Actual Cash Flow	NPV
1994		–$684,700	–$684,700
1995	0.9091	–165,000	–150,002
1996	0.8265	–788,635	–651,807
1997	0.7513	–641,940	–482,290
1998	0.6830	831,745	568,082
1999	0.6209	1,121,369	696,258
2000	0.5645	1,183,435	668,049
2001 (4/01)	0.5132	416,201	213,594
			177,185

The NPV (1994) for the actual project is $177,185 based on the actual cash flows for the kit automation project for the period January 1994 through April 2001. The NPV (1994) was $350,320 for the proposed project cash flows for the same period. From this analysis we can conclude that the project had a positive financial return despite the delayed implementation schedule, but it was significantly less profitable than if the project had been completed according to the original schedule.

5.4 Additional Considerations

The kitting line project was justified using the financial justification and analysis shown above. This analysis was somewhat traditional because it was limited to labor savings, which are often only a small part of the savings realized in flexible automation projects. Additional potential benefits should be evaluated for flexible automation systems. As discussed in Chapter 2, a study completed by NCMS (1997) identified a total of 27 specific benefits of flexibility that should be considered to justify investment in flexible manufacturing systems (see Appendix III). These potential benefits include non-financial benefits, and financial benefits categorized by reusability, multiple-products and scalability. However, to date, none of these potential savings have been realized for the kitting line.

One additional potential cost savings is in the reduction of inventory in the supply chain. In the old manual process, raw materials were issued to the fill line, the product was filled and labeled, and then returned to the warehouse as work-in-progress (WIP). After passing the sterility test (14 days), the WIP was released by the Quality Assurance (QA) department, kitted manually, and then sent to the finished goods warehouse. QA then performed a final release (one day) on the product and it was shipped to customers.

When the new flexible packaging line was put into operation, the supply chain stayed the same, except that the kitting operation was now automatic instead of manual. WIP was reduced and the supply chain was simplified by allowing the product to be packaged under risk (prior to completion of the sterility test), but the total inventory was not significantly reduced. Subsequently, WIP was eliminated by kitting the product immediately after it was labeled. But inventory was still not reduced because the supply chain was still constrained by the 14-day sterility test for product release. This 14-day sterility test cannot be reduced and it remains the largest obstacle to further reducing the supply chain. There was some cost reduction in material handling of the WIP and in damaged inventory, but these were negligible compared to the labor savings.

From a scalability standpoint, one potential strategic benefit was that the new kitting line provided additional reactive (safety) capacity that could be used for faster response or new product introductions. This reactive capacity could be utilized instead of maintaining higher levels of safety stock inventory. The kitting line's capacity could easily be expanded from 50,000 to 75,000 kits per day (or 12 to 18 million kits per year) simply by adding six operators and a third shift, versus adding 17 operators and possibly an additional capital investment for an additional manual line. However, we have not utilized this reactive capacity due to our product demand and thus have not realized any additional savings.

While this project has not yielded additional savings beyond the labor savings discussed in this section, each project should be evaluated against the potential benefits identified in the NCMS study and justified on its own merits.

Chapter 6

KITTING LINE OPERATIONAL ANALYSIS AND RESULTS

6.1 Introduction

In this chapter, three years (4/1998-4/2001) of operational data are reported and analyzed to evaluate the performance of Alcon's kitting line. Mean time between failures (MTBF), mean time to repair (MTTR), and inherent availability calculations are used to evaluate the kitting line's performance. The performance index (Zepf 1996) and other current industrial performance measures are calculated to benchmark performance of the kitting line against other packaging lines.

6.2 Production Data

The new kitting line was put into service in April 1998. Three years (4/1998-4/2001) of operational data were collected to evaluate the performance of the flexible packaging line. Downtime was reported by major pieces of equipment and by zone. During this three-year period the line averaged a rate of 55 completed kits per minute, had a scrap rate of less than 0.1%, and downtime of 6.4% due to equipment failure and 6.88% for all reasons. As shown in Table 6.1, the new kit line produced over 24.8 million kits.

Table 6.1 Kitting Line Production Data

Year	Kits Produced
1998 (4/98-12/98)	5,779,599
1999	6,519,761
2000	9,209,880
2001 (1/01-4/01)	3,322,856
TOTAL	24,832,096

6.3 MTBF, MTTR, and Inherent Availability

Reliability, maintainability and inherent availability are performance measures concerned with the frequency of system failures and system performance (in terms of downtime) over time. Reliability can be defined as the probability that a machine (or system) will perform its intended function under stated conditions for either a specified period of time or over its useful life. For repairable systems this can be restated as the probability that the system will perform its intended function for a specified period of time without a breakdown. The reliability of a repairable system can be characterized by the MTBF, which is the expected time between failures. Maintainability can be defined as the probability that a machine (or system) will be restored to a state in which it can perform its specified function. The maintainability of a repairable system is characterized by the MTTR.

Availability is a function of uptime and downtime, and in its simplest form is calculated as A = Uptime/(Uptime + Downtime). Inherent availability (A_i) is a function of both reliability and maintainability, and can be defined as the percentage of time that a machine (or system) operates correctly. Inherent availability is calculated using the equation A_i = MTBF/(MTBF+MTTR). This section includes calculations of total downtime, evaluation of cumulative failure, development of physical and reliability models, and Pareto analysis to identify major failure modes of the line and of each zone. The scope of this reliability, maintainability, and availability analysis is limited to calculations of MTBF, MTTR, and inherent availability.

6.3.1 Maintenance Philosophy

Maintenance philosophy has changed significantly over the past half century as the complexity of equipment and systems has increased, and because of the overall adverse impact of downtime. Research and experience has revealed that six failure patterns occur in practice, and conclude it is apparent that there is far less of a connection between the operating age of a piece of equipment and how likely it is to fail (Moubray 1997). Figure 6.1 is the reliability life characteristic curve (conditional probability of failure versus operating age) which includes periods of decreasing, constant, and increasing failure rate.

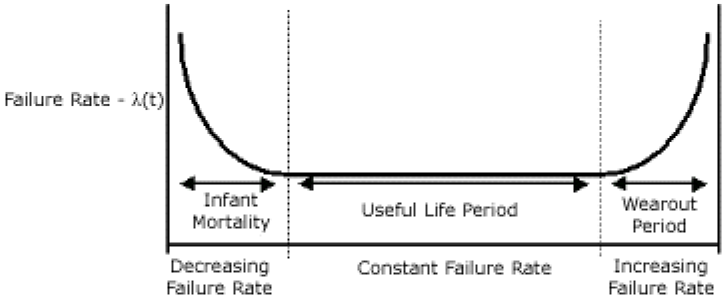


Figure 6.1 Reliability Life Characteristic Curve (“Bathtub Curve”)

The curve in Figure 6.1 is called the “bathtub curve” because of its characteristic shape. The six failure patterns (conditional probability of failure versus operating age) are shown in figure 6.2, and the patterns are described in Table 6.2.

Figure 6.2 Six Patterns of Failure (Moubray 1997)

Table 6.2 Description of the Six Failure Patterns
(adapted from Moubray 1997)

Pattern	Description
A	High initial failure rate, followed by a constant or slowly increasing conditional probability of failure, and ends with a wear-out zone.
B	Constant (or slowly increasing) conditional probability of failure, followed by a wear-out zone.
C	Slowly increasing conditional probability of failure, but no identifiable wear-out age.
D	Low initial conditional probability of failure (when new or just repaired) followed by a rapid increase to a constant level.
E	Constant conditional probability of failure at all ages (random failure).
F	High initial failure rate, which decreases to a constant or very slowly increasing conditional probability of failure.

For repairable complex equipment or systems, a constant failure rate is typical when different parts have different failure rates, and an increasing failure rate is typical when wear-out failure modes of parts predominate (O'Connor 1991). The result of this new research (Moubray 1997) has also concluded that complex systems exhibit constant (or very gradually increasing) conditional probability of failure exhibited by failure patterns E and F.

Table 6.3 provides an overview of the significant changes in maintenance philosophy and the understanding of equipment failure between the 1930s and today.

Table 6.3 Changes of Maintenance Philosophy (adapted from Moubray 1997)

	View of Equipment Failure	Maintenance Philosophy
1930s – 1940s	As things get older, they are more likely to fail. Failure pattern B.	• Equipment fairly simple, downtime not that important. • Run until failure and fix it when it breaks. Corrective maintenance
1950s – 1970s	A growing awareness of 'infant mortality' led to widespread belief in the "bathtub" reliability curve. Failure pattern A.	• Increased mechanization. More numerous and complex equipment. Downtime becoming more important. • Concept of preventative maintenance to prevent/reduce failures. • Development of maintenance planning and control systems.
1970s - 2000	New research indicates there are six failure patterns (A,B,C,D,E,F). Complex systems exhibit patterns E and F.	• More mechanized/automated equipment. Increased focus on cost effectiveness, quality, reliability, and availability. Move to JIT systems increases focus on minimizing downtime. • Design for Reliability, Design for Maintainability, and Failure Modes Effects Analysis tools developed. Condition monitoring equipment utilized to detect failures. • Maintenance has become significant percentage of manufacturing costs. • Introduction of Reliability Centered Maintenance.

As a result, some companies have elected to stop performing scheduled maintenance because they recognize that scheduled maintenance "can actually increase failure rates by introducing infant mortality into otherwise stable systems" (Moubray

1997). According to a recent food industry study (see Table 6.4), 23% of companies currently have a reactive maintenance (run it until it breaks) philosophy.

Table 6.4 Food Plant's Approach to Maintenance (Gregerson 2002)

Approach to Maintenance	%
Routine / Preventative Maintenance Schedules	55.6%
Reactive Maintenance (run it until it breaks)	23.1%
Line Operators Troubleshoot Equipment	10.3%
Proactive Maintenance Being Developed	8.5%
Condition Monitoring Tools	2.6%

Reliability centered maintenance (RCM) focuses on analyzing failure conditions and their consequences to determine which maintenance activities should be performed proactively.

6.3.2 Systems and Reliability Models

Two models were developed in order to complete the reliability analysis of the packaging line. The kitting line can be represented by five primary zones:

- Zone A (Carton Erector/Carrier Load/Unload/Main Conveyor)
- Zone B (Literature/Bottle/Tablet Load)
- Zone C (Bottle Tray Unload/Tablet Depalitizating)
- Zone D (Droptainer/Lens case/Kit Unload)
- Zone E (Shipper Pack/Palletize)

The physical model is a representation of the physical associations between the packaging equipment and is shown in Figures 4.2 and 4.3. The reliability model represents the functional relationships between equipment. A series reliability model (see Figure 6.2) is valid when a failure of any machine will result in failure of the line. Thus, the system reliability is simply the product of the individual machine reliabilities.

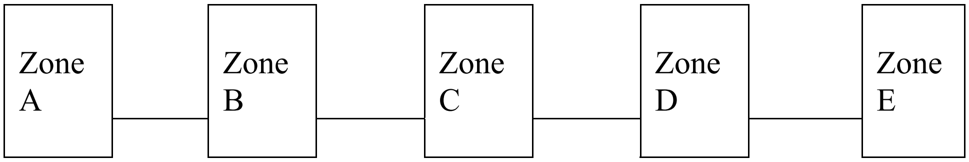


Figure 6.2 Reliability Model of Kitting Line

6.3.3 Data Collection and Analysis of Results

Each piece of equipment in the packaging line is prone to failure. Each failure causes one or more machines to be stopped and reduces the performance of the packaging line. Three years (4/1998-4/2001) of operational data for the kitting line were collected and analyzed. The cause for each failure was identified and classified by zone and the three major failure modes: Equipment Breakage, Equipment Adjustment, or Operator Error/Component (shippers, cartons, literature, lens cases, bottles, etc.). A Pareto analysis was completed on the overall system to determine which zone and failure modes were responsible for the largest percentage of system failure. Table 6.5 indicates that zones B (Literature/Bottle/Tablet Load) at 28.2%, E (Shipper Pack/Palletize) at 27.5%, and A (Carton Erector/Carrier Load/Unload/Main Conveyor) at 23.7% were the three largest causes of system failure.

Table 6.5 Downtime and Number of Failures by Zone (4/1998-4/2001)

ZONE	Downtime (minutes)	Downtime %	# of failures	% of failures
A	9,910	21.94%	297	23.74%
B	11,659	25.81%	353	28.22%
C	2,103	4.66%	55	4.30%
D	7,103	15.72%	202	16.15%
E	14,398	31.87%	344	27.50%
Total	45,173	100.00%	1,251	100%

As shown in Table 6.6, equipment adjustment (43.66%) and equipment breakage (42.94%) were the predominant failure modes for this line.

Table 6.6 Downtime by Primary Failure Mode (4/1998-4/2001)

Year	Equipment Breakage	Equipment Adjustment	Components/ Operator Error/ Other	Total
1998	2,378	4,201	1,165	7,744
1999	7,143	4,692	1,779	13,614
2000	7,374	8,788	2,599	18,761
2001	3,945	3,508	960	8,413
Total (mins)	20,840	21,189	6,503	48,532
Total (hours)	347.33	353.15	108.38	808.87
Percent	42.94%	43.66%	13.4%	100%

Table 6.7 presents the number of failures classified by zone and by year.

Table 6.7 Number of Failures Classified by Zone and Year (4/1998-4/2001)

Year	Zone A	Zone B	Zone C	Zone D	Zone E	Total
1998	45	72	6	40	49	212
1999	74	75	10	46	95	300
2000	146	147	35	61	175	564
2001	32	59	4	55	25	175
Total	297	353	55	202	344	1,251
Percent	23.74%	28.22%	4.3%	16.15%	27.5%	100%

The time basis used for the downtime calculations was 11,760 hours, based on an analysis period of three years, running 49 weeks per year, five days per week, two shifts per day, eight hours per shift. Total downtime was (808.87 hr)/(11,760 hr) = 6.88%, and downtime due solely to equipment is (700.48 hr)/(11,760 hr) = 6.40%. The second calculation excludes 3,359 minutes of downtime due to components and operator error.

The historical data was also used to construct a graph of cumulative failure. Table 6.8 presents the cumulative failure data for the kitting line for the period 4/1998- 4/2001.

Table 6.8 Failure Rate and Cumulative Downtime for Kitting Line

Date	Number of Failures	Hours per Month	Failure Rate (1/hr)	Downtime Minutes	Cumulative Total Downtime
04/98	11	320	0.0344	343	343
05/98	10	320	0.0313	356	699
06/98	68	400	0.1700	2071	2770
07/98	32	320	0.1000	603	3373
08/98	22	400	0.0550	828	4201
09/98	23	320	0.0719	1840	6041
10/98	22	320	0.0688	767	6808
11/98	16	400	0.0400	659	7467
12/98	8	160	0.0500	277	7744
01/99	38	320	0.1188	1835	9579
02/99	59	320	0.1844	2351	11930
03/99	24	400	0.0600	1128	13058
04/99	17	320	0.0531	649	13707
05/99	28	320	0.0875	1686	15393
06/99	5	240	0.0208	502	15895
07/99	39	320	0.1219	1395	17290
08/99	40	400	0.1000	1309	18599
09/99	20	320	0.0625	988	19587
10/99	13	320	0.0406	266	19853
11/99	12	400	0.0300	1203	21056
12/99	5	160	0.0313	302	21358
01/00	21	320	0.0656	507	21865
02/00	43	320	0.1344	1033	22898
03/00	49	400	0.1225	2043	24941
04/00	47	320	0.1469	1464	26405
05/00	51	320	0.1594	1869	28274
06/00	44	240	0.1833	1515	29789
07/00	68	320	0.2125	2288	32077
08/00	85	400	0.2125	2900	34977
09/00	38	320	0.1188	1236	36213
10/00	58	320	0.1813	1470	37683
11/00	39	400	0.0975	1397	39080
12/00	21	160	0.1313	1039	40119
01/01	56	320	0.1750	3468	43587
02/01	41	320	0.1281	2312	45899
03/01	44	400	0.1100	1256	47115
04/01	34	320	0.1063	1377	48532

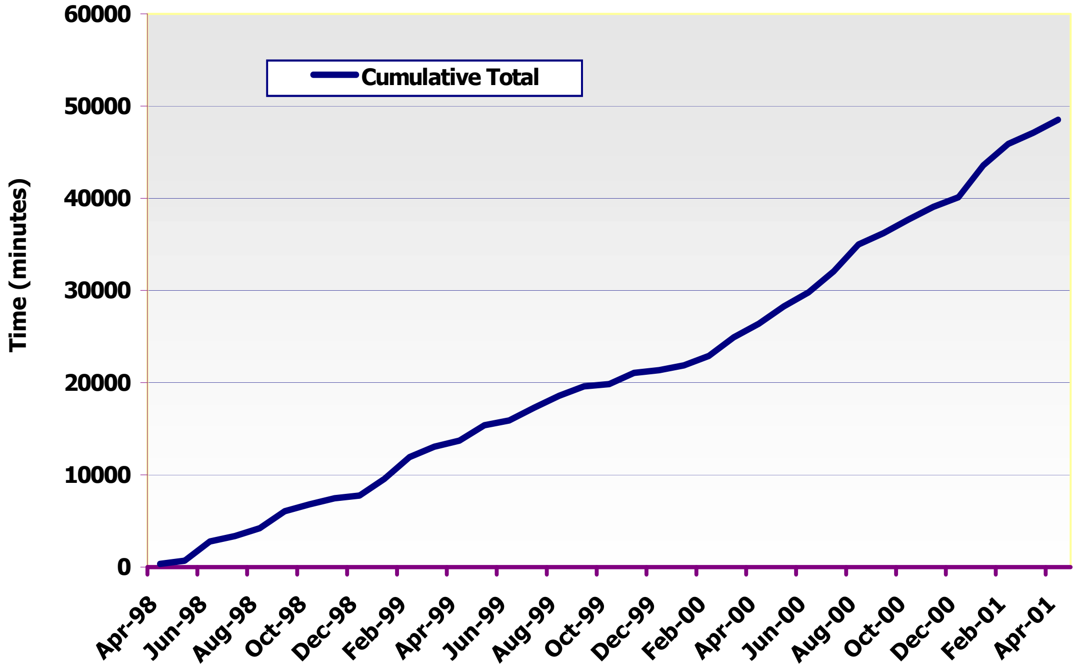


Figure 6.3 Cumulative Failure for Kitting Line, 4/1998 – 4/2001

Figure 6.3 indicates that the cumulative failure time appears to increase at a constant rate, and is roughly linear. Figure 6.4 shows the number of failures recorded each month. The average number of failures was 33.8 per month. There appears to be no overall trend to the data (failures appear random) although there is a detectable increase in the total number of failures with time. For the calculations which follow, it is assumed that the failure rate was approximately constant and that an exponential probability function could be used for the reliability calculations.

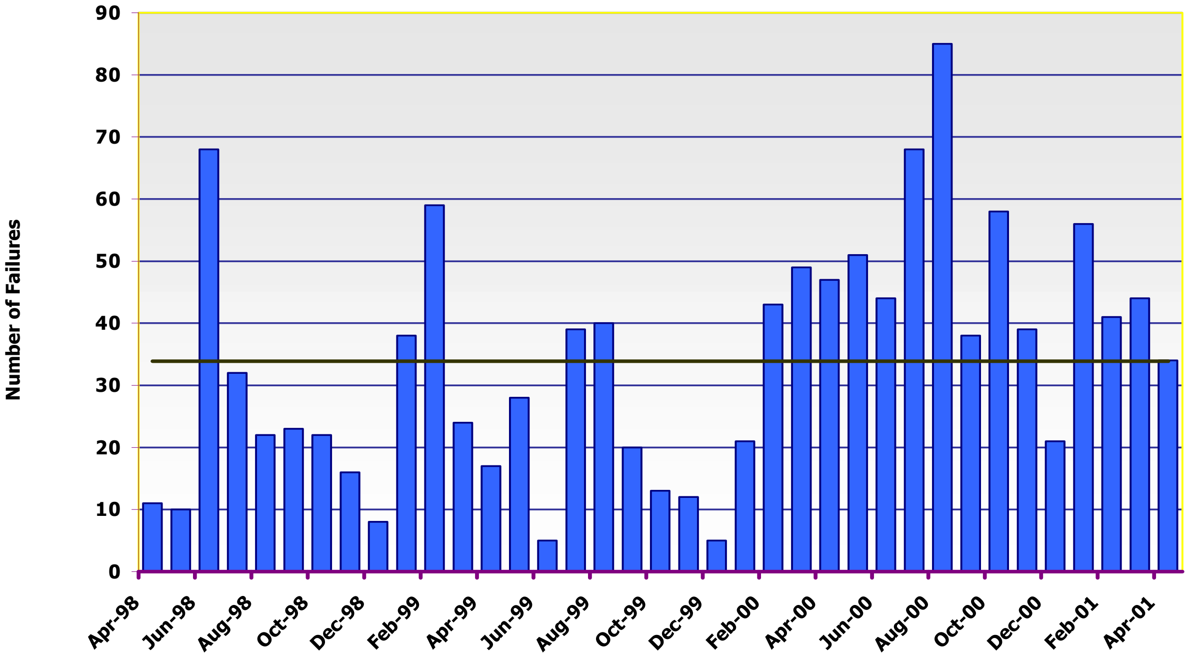


Figure 6.4 Number of Failures for Kitting Line, 4/1998 – 4/2001

The total number of failures, total downtime, MTBF, failure rate, MTTR and inherent availability for the line were calculated using three years (11,760 hours) of production data and the reliability model. MTBF is equal to the time basis divided by the number of failures in each zone, or (11,760 hours/# of failures). The failure rate is equal to one divided by the MTBF. Reliability (R) is calculated using the equation R = exp (-failure rate)(time). In the table below, one day (16 hours) was used as the time to determine the probability that the line would run for two complete shifts without a failure. The MTTR is equal to the zone downtime (from Table 6.5) divided by the number of failures. The inherent availability of the line is calculated using the equation, Ai = MTBF/(MTBF+MTTR). The results of these calculations are summarized in Table 6.9.

Table 6.9 Reliability and Inherent Availability Results for Kitting Line (4/1998-4/2001)

ZONE	# of failures	MTBF (hrs)	Failure Rate (1/hr)	Reliability (1 day or 16 hours)	MTTR (hrs)	Inherent Availability
A	297	39.60	0.0253	0.6671	0.5562	0.9861
B	353	33.31	0.0300	0.6188	0.5505	0.9837
C	55	213.82	0.0047	0.9276	0.6373	0.9970
D	202	58.22	0.0172	0.7594	0.5860	0.9900
E	344	34.14	0.0293	0.6258	0.6975	0.9800
Total	1,251	9.40	0.1064	0.1823	0.6018	0.9398

The kitting line's system failure rate was 0.1064 (1/hr), the MTBF was 9.4 hours, and the MTTR was 0.6018 hours or 36.65 minutes. There was only an 18.23% probability that the packaging line would operate over two shifts (16 hours) without a failure, but the system was expected to be running 93.12% (6.88% downtime) of the time.

6.4 Performance Measures and Measurement Methods

An overview of current performance measures and methods is provided in this section. The calculation of specific performance indicators for Alcon's new kitting line is included.

6.4.1 Performance Measures of Packaging Lines

This section includes the calculation of the performance index and other performance measures for the new kitting line. The key indicators for packaging lines include downtime, efficiency, performance, practical capacity utilization and maximum capacity utilization. Downtime was calculated for the kitting line as part of the reliability analysis earlier in this chapter and found to be 6.4% due to equipment failures, and 6.88% overall. Target hours (TH), net production hours (NPH), and gross production hours (GPH) were calculated in section 4.3.1 for Alcon's kitting line. Thus, the performance indicators for the kitting line are calculated as follows:

% Efficiency = (TH/NPH)) x 100 = (3,334/3,600) x 100 = 92.60%

% Performance = (TH/GPH) x 100 = (3,334/3,840) x 100 = 86.81%

Practical Capacity Utilization = (NPH/GPH) x 100 = (3,600/3,840) x 100 = 93.75%

Maximum Capacity Utilization = (GPH/8,760) x 100 = (3,840/8,760) x 100 = 43.84%

It is critical to develop and use common terminology when benchmarking packaging line performance. It is also important to benchmark using maximum capacity, because the maximum capacity indicates the total spare capacity available without additional capital investment. In most industries, this additional capacity can be added by simply changing the operating plan to include a third shift, weekends, etc. However, some industries, such as the pharmaceutical industry, cannot simply add a third shift to add capacity because the third shift is used for required cleaning operations.

6.4.2 Industrial Performance Measures of Packaging Lines

Five performance measures proposed by the Siebel Institute of Technology, PMMI's Packaging Productivity Committee, Ford Motor Company, Moubray (1997), and Zepf (1995, 1996) are reviewed and discussed in this section.

Siebel Institute of Technology'*s General Principles of Packaging Line Design and Control* (1998) defines packaging line efficiency as "real production per period divided by the total possible production during an equivalent period." PMMI's Packaging Productivity Advisory Committee (PMMI 1993, 1995, 1997) defined system efficiency (SE%) as "actual saleable product throughput divided by the theoretical throughput of a packaging system for a given period of time x 100" (PMMI 1997). Thus,

$$SE\% = [(\text{actual throughput/period})] / [(\text{theoretical throughput/period})] \times 100,$$

which is equivalent to Siebel Institute of Technology's definition of packaging line efficiency.

PMMI designed a survey based on a hypothetical line consisting of nine packaging machines, and asked each respondent to report average efficiencies for each machine and calculated an overall efficiency for the entire packaging line. PMMI (PMMI 1993 and 1995) reported that the average packaging line had a systems efficiency (SE%) of 72.3% in 1993 and 87.4% in 1995. The average reported SE% by industry is shown in Table 6.10.

Table 6.10 Packaging System Efficiency (SE%) for North American Industries (PMMI 1995)

Industry	SE%
Chemical Products	92.1%
Pharmaceutical/Medical	88.8%
Food	87.2%
Beauty/Cosmetics	86.2%
Other	85.9%
Non-Food Household Products	85.4%
Beverage	84.2%
Average	87.1%

Overall equipment effectiveness (OEE) and Overall Machine Effectiveness (OME) provide additional insight into packaging line performance by also considering availability and yield. Overall equipment effectiveness (Moubray 1997) is defined as

$$\text{OEE} = \text{inherent availability} \times \text{efficiency} \times \text{yield}.$$

OME (Ford 1990) is also the product of three variables indicating the percentage of time the machinery is available (uptime), how fast the machine is running relative to its design cycle time, and the percentage of the resulting product that is within quality specifications.

$$\text{OME} = \text{inherent availability} \times \text{speed ratio} \times \text{yield},$$

where:

- inherent availability = % of time that a machine operates satisfactorily
  = MTBF/ (MTBF+MTTR),
- speed ratio (or performance efficiency) = (Actual production/time period)/(design production/time period), and
- yield (or quality ratio) = (good product/total product produced).

Ford's OME goal for individual machines is 99%, and 85% for the overall line/plant. There are two important items to note. First, efficiency in OEE, and speed ratio in OME are equivalent to Siebel's line efficiency and PMMI's systems efficiency. Secondly, OEE and OME are equivalent measures.

OME and OEE are widely used to access effectiveness but they do have several limitations because they assume that all three variables have equal weightings, and increased speed will increase apparent OME/OEE even when increased speed may cause additional equipment failures (Moubray 1997).

Zepf (1993, 1995, 1996) defines packaging line performance "as a measure of profitability based on the ability to produce the needed quantity of quality packages in the time required to fulfill customer needs over a sustained period of time." Zepf (1996) has developed a performance measurement factor called the Performance Index (PI). The PI is a simple four factor model (system utilization, input efficiency, schedule capability, and speed factor) of packaging operations, and is defined as:

$$\mathrm{PI} = n \times \mathrm{U}_s \times \mathrm{C}_p \times \mathrm{S}_f$$

where:

n = input efficiency (output packages/all inputs),

U_s = system utilization (% of practical capacity utilization),

C_p = schedule capability (measure of actual time required to produce product versus the scheduled time),

S_f = speed factor = actual average output/achievable machine run speed.

Based on three years of research, Zepf (1995, 1996) has established the PI ranges for different industries in North America (see Table 6.11).

Table 6.11 PI Ranges for North American Industries
(adapted from Zepf 1995, 1996)

Industry	Present PI Ranges	Ideal PI Ranges
Beverage	0.45-0.80	0.80-0.90
Home-care products	0.15-0.40	> 0.60
Pharmaceuticals	0.10-0.50	> 0.60
Health-care products	0.15-0.55	> 0.70
Chemicals	0.10-0.40	> 0.75
Food	0.10-0.45	> 0.60

Zepf (1996) also identified some ideal values to target:

$n > 0.98$ (efficiency of all inputs)

$U_s > 0.80$ (system utilization)

$C_p > 0.90$ (capability)

$S_f > 0.95$ (speed factor)

$PI > 0.67$.

Further, as shown in Table 6.12, Zepf (1997) published recommended speed factor guidelines for multi-product packaging lines.

Table 6.12 Speed Factor Guidelines for Multi-product Packaging Lines (Zepf 1997)

S_f Range	Status
0.98 to 1.0	Excellent
0.95 to 0.97	Good
0.90 to 0.94	Satisfactory
0.84 to 0.89	Poor
<0.84	Bad

The PI for Alcon's new kitting line is:

$$PI = (n)\,(U_s)(C_p)(S_f) = (0.99)[(11{,}760-808.87)/11{,}760](0.9)(55/65) = 0.702.$$

Thus, the kitting line is performing above the ideal level for the home-care, health-care, pharmaceutical, and food industries but was lower than the ideal level for the beverage and chemicals industries.

Zepf (1995) points out that his PI index has "no relationship or equivalence" to PMMI's productivity index, even though some of the definitions are similar. One limitation of Zepf's PI is that it only provides a relative comparison to other packaging lines, but provides no suggested routes of performance improvements.

6.6 Conclusions

Three years of operational data (4/1998 – 4/2001) was analyzed to evaluate the performance of the Alcon's kitting line. During this period, the kitting line averaged a rate of 55 kits/min, scrap rate of less than 0.1%, downtime of 6.4% due to equipment failure (6.88% for all reasons), and produced over 24.8 million kits. The actual downtime experienced was acceptable even though it was higher than the initial specification of 5%. The initial downtime specification of 5% was somewhat arbitrary because Alcon had no experience with an integrated robotic packaging line. The MTBF, MTTR, and inherent availability analysis may be used to identify opportunities to improve the equipment performance and thus reduce system downtime. Improvement opportunities should be justified using an appropriate cost-benefit analysis. The MTBF, MTTR and inherent availability calculations should be performed on an ongoing basis to identify adverse trends in downtime and to evaluate line performance. An analysis using Zepf's packaging line performance index indicates that the new kitting line was operating more efficiently than the average pharmaceutical packaging line in North America.

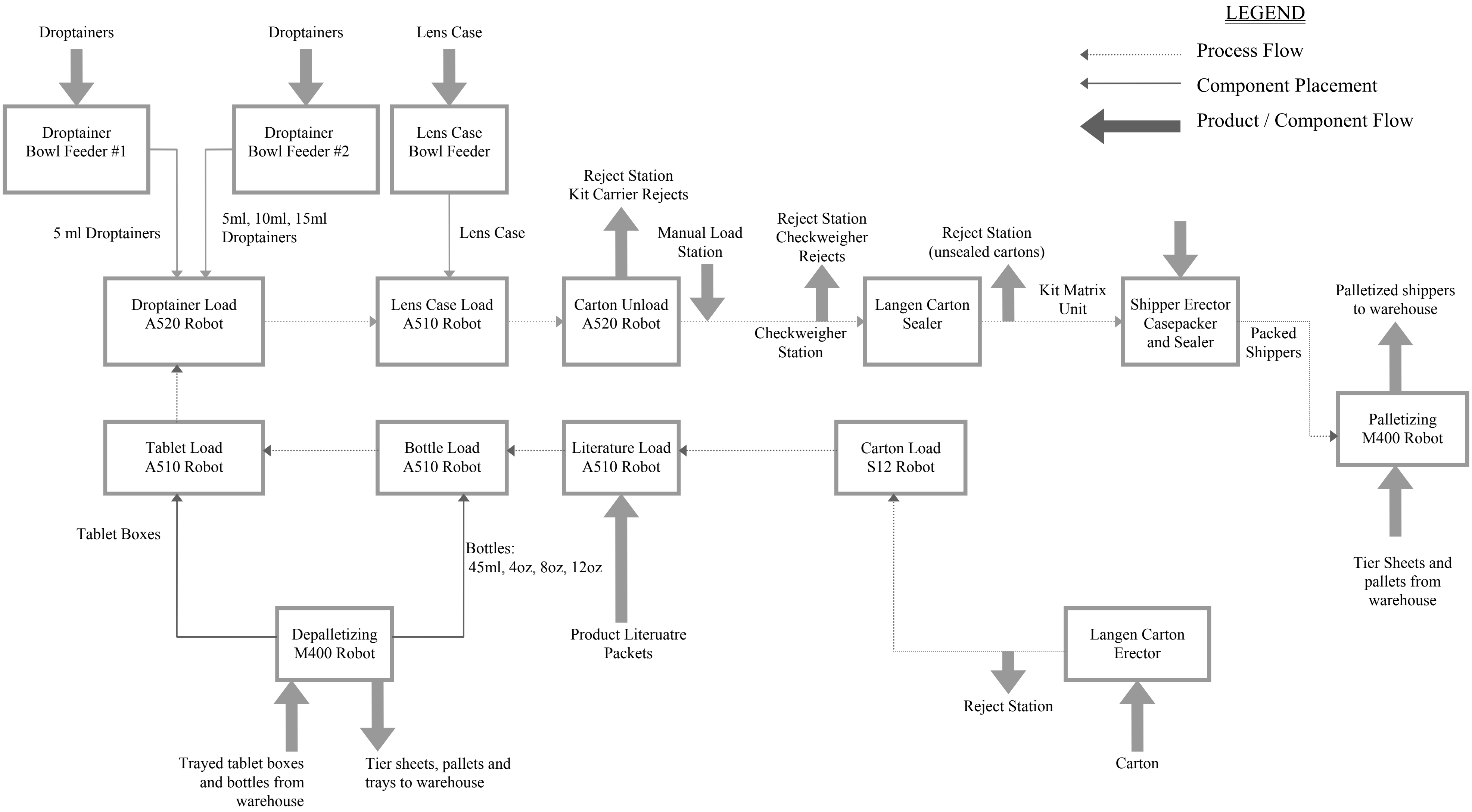


Figure 1 Kitting Line Six Process Flow Diagram

Chapter 7

CONCLUSIONS

This praxis provides the first steps towards developing a formal design methodology for flexible packaging lines. Packaging line flexibility and agility were defined, and guidelines for the design of flexible packaging lines (DFPL) were developed. These design guidelines were developed and demonstrated by successfully completing the design and implementation of a new flexible packaging line at Alcon Laboratories. The results of this project were evaluated using performance and strategic criteria.

7.1 Kit Automation Demonstration Project

The objective of this project was to design and implement a flexible robotic packaging line to replace the existing manual kitting operations, and to provide both the capability to produce existing lens care kits and the strategic flexibility to produce future products. The line was designed for the flexible assembly of ten different lens care kits requiring minimal changeover, and for the future possible expansion for kits containing 20 ml., 25 ml., 30 ml. and 16 oz. products. Because of product innovation, product standardization, and product changes by marketing only two of the original ten kits specified in the FRS remained active at the end of the project. Marketing added five new kits during the project. Four of these kits were within the planned product range and were incorporated into the project, but one new kit was outside the planned product range (the carton size was too small) so it was produced on one of the manual kitting lines. The most recent new kit was introduced in June 2002.

Ultimately marketing reduced the number of kit configurations for the domestic market so that 90% of the volume ended up in two primary configurations. This was such a major change that the need for a flexible line became questionable. However, with the recent proliferation of international kit configurations, the real strategic value of the kitting line might still be ahead as the business cycles back to multiple kit configurations.

The project also validated the concept of a flexible packaging line by successfully demonstrating its flexibility by accommodating significant product changes during implementation, validation, and subsequent production. New kits (within the project's original scope) were introduced faster, new components and kits (outside the original scope) were incorporated during the project at minimal cost due to the flexibility built into the line's design. Changing product mix, and the transition from multiple products (separate contact-lens care solutions, cleaners, etc.) to multi-purpose products drove many of these changes. Marketing driven changes included the addition of a new lens case (increase from three to four types), 5 ml., 20 ml., 25 ml., and 30 ml. droptainers (increase from three to seven sizes), a 2 oz. bottle (increase from four to five sizes), and the capability to package kits in either 12 or 24 kits per shipper. The 5 ml. and 2 oz.

components were outside the anticipated future requirements for the line. Enzymatic tablet product became obsolete with the introduction of a new liquid enzymatic cleaner in a 5ml. droptainer.

7.2 Performance

The kit automation project had a favorable financial return despite the delayed implementation schedule. Labor costs were substantially reduced and ergonomics were significantly improved. Labor savings are often only a small part of the savings realized in flexible automation projects, but this project has not yielded additional savings beyond the labor savings discussed. The 14-day sterility test for product release cannot be reduced and it remains the largest obstacle to realizing potential cost savings by reducing inventory. One potential strategic benefit is that the new kitting line provided additional reactive capacity (expanded from 50,000 to 75,000 by adding a third shift and six operators) that could be used for faster response or new product introductions. This reactive capacity could also be utilized instead of maintaining higher levels of safety stock inventory. However, we have not utilized this reactive capacity due to our product demand and thus have not realized any additional savings.

Three years of operational data (4/1998 – 4/2001) was analyzed to evaluate the performance of Alcon's kitting line. During this period, the kitting line's demonstrated performance averaged a rate of 55 completed kits-per-minute, scrap rate of less than 0.1%, downtime of 6.4% due to equipment failure, and produced over 24.8 million kits. These kits were produced with higher quality (fewer defects, and lower scrap) than with the previous manual process. The MTBF, MTTR, and inherent availability analysis was used to identify opportunities to improve equipment performance and reduce system downtime, and should be performed on an ongoing basis to identify adverse trends in downtime and to evaluate line performance. An analysis using Zepf's packaging line performance index indicates that the new kitting line was operating more efficiently than the average pharmaceutical packaging line in North America.

7.3 Flexibility

The DFPL guidelines developed as part of this praxis supports the four dimensions of flexibility (scope, cost-effectiveness, responsiveness, and robustness) for packaging lines. Like speed, flexibility is not the end objective. It is a strategic enabler so that a manufacturer can successfully compete. Servomotor-based equipment, robots, vision systems, flexible feeding systems, and auto-recovery systems enable packaging lines to be more flexible. But this flexibility does come with certain tradeoffs including increased costs (10-20%), reduced speed and more complex changeovers versus dedicated lines.

The actual flexibility realized may also be less than the potential flexibility designed into the system due to regulatory restrictions including: equipment validation, and FDA regulatory approvals on packaging materials and labeling changes. Required line clearances, which can take 15-30 minutes, may offset the potential advantages of automatic changeovers. Sterility testing of the product requires 14 days to complete and may offset the potential benefits of quick response. Validation testing requirements may prevent the rapid introduction of new products, loading stations, or the rapid-reconfiguration of a modular packaging line. For products requiring regulatory approval prior to manufacture, new product introduction (packaging and label changes included) may be delayed significantly, or not approved at all.

7.4 Applicability of Design Rules

The design for flexible packaging line (DFPL) guidelines developed in this praxis are a compilation of concepts known before starting the Kit Automation project and lessons learned during the course of the project. These DFPL guidelines are not unique to packaging applications and are generalizable for other assembly and manufacturing applications. The DFPL guidelines developed as part of the Kit Automation project were transferred within Alcon Laboratories, and were successfully applied in the design and implementation of several projects in the Ft. Worth plant and other Alcon facilities for the assembly and packaging of medical devices and pharmaceutical products

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