THE APPLICATION OF THE JUST-IN-TIME PRODUCTION PHILOSOPHY TO THE PHARMACEUTICAL INDUSTRY IN SOUTH AFRICA

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I, KEITH JOHN BALCHIN, submit this thesis for the Degree of Master in Industrial Administration.

I claim that this is my original work and that it has not been submitted in this or in a similar form for a degree at any University.

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ABSTRACT

This thesis researches the "Just-in-Time" (JIT) production philosophy and its application in the pharmaceutical industry in South Africa.

While JIT is widely accepted in Japan and is gaining some acceptance in the USA, it is virtually unknown in South Africa. Studies of the JIT philosophy in the world at large have been largely confined to the use of JIT in repetitive mass production environments, such as is found in the motor industry. No prior studies have been conducted on the application of the JIT philosophy to the pharmaceutical industry in South Africa.

The **objectives** of the thesis are:

- To properly define JIT and establish the extent and nature of its components, having researched existing JIT systems in use throughout the world.
- To investigate the application of JIT in South Africa with particular reference to the pharmaceutical manufacturing industry.
- To determine to what extent JIT and Manufacturing Resource Planning (MRP II) can complement each other in improving productivity in the South African pharmaceutical industry.

The techniques used in carrying out the thesis work included literature searches, attending seminars and conducting surveys, whilst the author participated in a JIT pilot project in the pharmaceutical industry.

The thesis identifies 22 major practical components of JIT, researches them and describes the benefits, from improved quality to improved productivity, which can be achieved by progressive JIT implementation. The application of each component in South Africa is discussed, with particular reference to the pharmaceutical industry. The JIT concepts of Respect for people, worker involvement, total quality control (TQC), purchasing and minimising set-up times are identified as the most relevant to the South African situation. The compatability of JIT and MRP II, and their respective strengths and weaknesses, are discussed at length.

The thesis concludes that JIT has great relevance in the pharmaceutical industry. However, simply copying Japanese JIT methods, without adaptation and understanding of the underlying philosophy, will achieve very little. What is required is a fundamental change of attitude amongst management and workers, based on extensive education and training.

GLOSSARY

Bill of Materials - A listing of all the components and quantities required to make a product.

Brainstorming - A group session in which ideas are freely expressed by all.

Clinical Trials - Experimental trials to ascertain the efficiency of medicines.

Generic Medicines - Substitute medicines with essentially the same ingredients as the original product.

Good Manufacturing Practice (GMP) - A code of practice for the pharmaceutical industry

Just-in-Time (JIT) - A term identifying a philosophy and set of goals for a manufacturing business.

Kanban - A Japanese inventory replenishment system.

Manufacturing Resource Planning (MRP II) - A computer-based production planning and control system.

Material Requirement Planning - The concept of "exploding" a bill of materials into a structured list of components.

Medicines Control Council (MCC) - A statutory body governing the registration, manufacture and sale of medicines.

Preventive Maintenance - The planned maintenance of machinery designed to prevent breakdowns.

Quick Fix Solution - A solution which can implemented quickly to solve a problem without much planning.

Quarantine - A term for product which has been isolated pending quality approval.

GLOSSARY (Cont'd)

Set-up Reduction (SUR)	-	The reduction of the time and effort required to change a machine from producing one product to another product.
Total Production Maintenance (TPM)	-	A term for broader preventive maintenance involving all employees participating in group activities.
Total Quality Control (TQC)	-	An overall system of quality based on defect prevention and statistical process control.
"What if"	-	Establishing the effect of changing variables on a predicted end result.
Zero Defects	-	The concept of producing quality products such that all items produced conform to specifications.

INTRODUCTION

The economic success of Japanese industry has resulted in many in-depth studies of that nation's approach to manufacturing management. The principal objective of these studies has been to establish to what extent the successful Japanese techniques can, and should, be adopted by other industrialised countries. Following on from studies of "quality circles" and "Kanban" inventory replenishment systems is the current interest in the "Just-in-Time" philosophy, or JIT for short.

The term "Just-in-Time" identifies a philosophy and a set of goals for a manufacturing business. This philosophy is at the core of Japanese production management and their success in quality and productivity improvement. JIT defies a single universally accepted definition. To some people JIT means having the right part at the right place at the right time, in exactly the right quantity - no more or less - with respect to parts, tooling, capacity, money and energy. To others it is an inventory control and reduction system, even a "zero inventories" system. Still others consider it to be simply the systematic elimination of waste. In fact, JIT is much more - "it is an inventory control system, it is a quality and scrap-control tool, it is a streamlined plant configuration that raises process yield, it is a production line balancing approach, and an employee-involvement and motivational mechanism"[1] Reinforcing these definitions is the underlying philosophy that "... no matter how good you are, or how good you get, you should constantly strive to improve, constantly working to make the product faster, more productively, and with fewer resources. It means meeting the competition and squeezing them by seizing a design advantage, a quality advantage, a cost advantage, or a service advantage, and passing it on to the customer"[2]. Taking JIT to its extreme means instantly manufacturing the product at the right price, with the right quality, when the customer needs it. In practical terms this cannot be achieved, but a company should, nevertheless, strive to make progress towards the ultimate goals of JIT. It is apparent that JIT is a journey and not a destination.

INTRODUCTION (Cont'd)

JIT originated in Japan, with the most frequently discussed example of JIT being the production control system at Toyota, although Henry Ford's sequential assembly line was essentially an element of JIT. Toyota uses Kanban, a specific Japanese inventory replenishment system, which frequently leads to the false conclusion that Kanban is synonymous with JIT and that it is the only way to apply JIT. Furthermore, it is frequently assumed that since Toyota is a mass producer, JIT only applies to repetitive manufacturing. Neither of these conclusions is correct, as Kanban is simply one way to apply JIT (Quality Circles and Manufacturing Resource Planning are other ways) and JIT applies to repetitive, job shop, batch or any other type of manufacturing.

This thesis researches the JIT production philosophy and its application in South Africa, with special emphasis on the pharmaceutical industry.

JIT is currently gaining popularity in manufacturing plants outside Japan, most notably in the U.S.A. While JIT has undoubtedly succeeded in Japan and is gaining acceptance in the U.S.A., it is virtually unknown in South Africa, and this warrants investigation, especially in view of the poor productivity in the latter country. While the initial aim of JIT was to reduce inventory levels, in its developing form it is associated with total quality control and greater productivity stemming largely from improved forecasting, business planning, production scheduling, process control and facilities utilisation, all highly relevant in South African industry.

That JIT has relevance in many industries, large and small, has been shown by the results achieved in Japan and the U.S.A. JIT was chosen as the subject of this thesis because this philosophy is relevant in South Africa, but must be adapted to local conditions.

JIT is particularly relevant to the pharmaceutical industry in South Africa because:

(i) The Total Quality Control philosophy is compatible with the industry's quality standards, which are becoming increasingly stringent.

(ii) Generic substitution of medicines by pharmacists may soon become legal. This will inevitably result in greater competition within the industry and will force manufacturers to improve productivity.

INTRODUCTION

(iii) Growing concern about the high cost of medicines in South Africa and the increased need for South Africa to export manufactured goods, including pharmaceutical products, will force the local industry to become more competitive internationally. If local industry is to compete with the likes of the Japanese, their methods must be investigated and adopted, whenever such methods can make local industry more competitive.

(iv) Pharmaceutical inventories largely comprise high-value finished products, raw materials and components. Reduced inventory levels can be achieved with JIT which in turn can lead to greater profitability.

(v) JIT is linked to flexible manufacturing. The pharmaceutical industry in South Africa produces a large range of products in relatively small batches, and hence has a great need for flexibility.

(vi) Manufacturing Resource Planning (MRP II) has been adopted by a number of pharmaceutical manufacturers in South Africa and is likely to become a norm in the industry. The interface between JIT and MRP II should therefore be investigated.

The objectives of this thesis are:

(i) To research the JIT philosophy as practiced in the world at large.

(ii) To investigate the application of JIT in the pharmaceutical industry in South Africa.

(iii) To determine to what extent JIT and MRP II can complement each other.

LITERATURE SURVEY

The JIT philosophy is a new concept to most of the industrial world, with interest having initially spread from Japan to the U.S.A. The number of books on the subject is limited, and comprises primarily texts on individual Japanese manufacturing management techniques, rather than studies of them collectively as the JIT philosophy. The focus of these books is on repetitive manufacturing, as is found in the motor car manufacturing industry, where Toyota of Japan is the most frequently studied JIT user.

Most current literature on the JIT philosophy emanates from the U.S.A. in the form of articles in journals and copies of papers presented at seminars. A comprehensive list of such articles and papers is included in the Bibliography.

Works to date place considerable emphasis on the JIT techniques and the Japanese philosophy towards quality and employees, but largely ignore the application of the JIT philosophy in other industrialised nations.

This survey has not revealed any literature pertaining to JIT in the pharmaceutical industry, either in South Africa or abroad.

CHAPTER ONE

THE JUST - IN - TIME PHILOSOPHY

1.1 THE COMPONENTS OF JIT

1.1.1 The Scope of JIT

As stated in the Introduction, the JIT philosophy has no single definition. The reasons for this are two-fold. Firstly, JIT is a dynamic philosophy, having evolved over some twenty years in Japan, during which time it changed and enlarged considerably. Furthermore as it is adopted in different parts of the world, it necessarily evolves to suit local conditions and attitudes. Secondly, it is important to appreciate that the JIT philosophy comprises numerous components. The JIT philosophy permeates these components in terms of common goals (most notably the elimination of waste and Just-in-Time production), common attitudes and similar techniques. The very fact that JIT encourages innovation, inevitably results in the addition of new components and the evolution of old components. Figure 1.1 lists the major components of JIT and the most likely potential benefits resulting from a successful JIT approach in manufacturing. The list is not exhaustive and will in time be extended. The potential benefits naturally depend on the degree of JIT implementation.

The Components and Potential Benefits of JIT

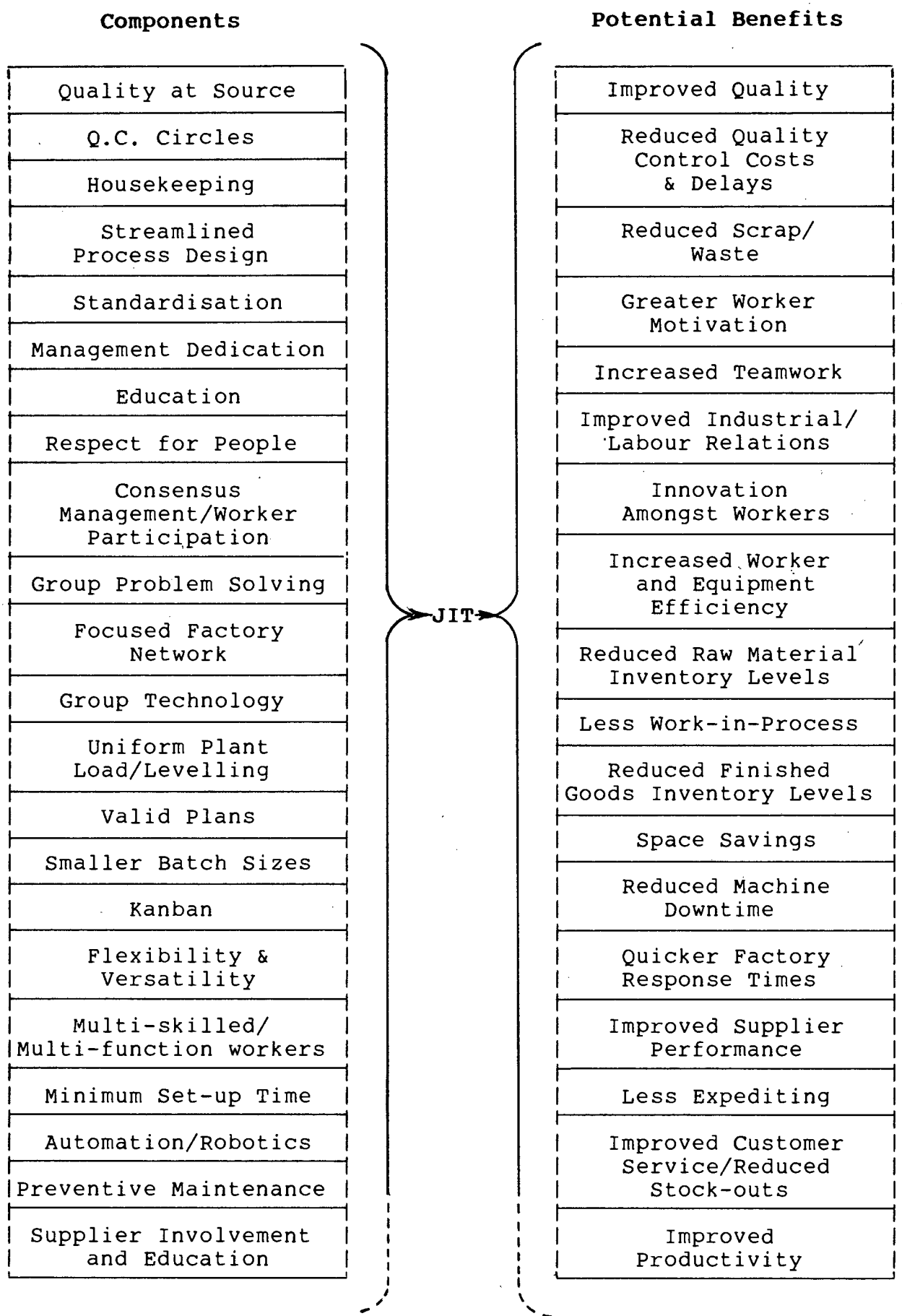


Figure 1.1

1.1.2 Quality at Source

The traditional approach in most industries is that some scrap is tolerated. This is considered to be inevitable primarily because the cost of "zero defects"/Total Quality Control (TQC) is perceived as being too high. The actual scrap is usually monitored and formulae are used to predict it and define what scrap levels are acceptable.

In contrast, the JIT approach is to strive for "zero defects". Productivity is achieved through quality, thus ensuring defect free products at competitive prices. The basic concept is that quality must be built into the product and process, not checked afterwards, thus eliminating the cause of defects. It must be proved that the process is capable of producing products consistently to the right quality.

At the heart of JIT is the need to establish control over all activities, such control being at the lowest possible level. The inherent capability of the process must be controlled, thus ensuring quality at source and avoiding scrap.

When defects do occur they must be analysed to find the assignable causes. The process is not permitted to continue unchecked and the cause of defects is eliminated at source, even if this entails the workers stopping production until this is achieved.

Great emphasis is placed on the workers' reponsibility to ensure quality, and not simply the Quality Control (Q.C.) department.

The aim is to provide quality control, sometimes automated, of every process rather than rely upon inspection of lots for only selected processes. Wherever possible the measures of quality should be clearly evident, visual, simple and understandable. For example a simple graphical presentation of quality control information is more useful than a computer print-out of numbers. After all our society is data rich and information poor.

1.1.2 Quality at Source (Cont'd)

The quality at source concept applies as much to the quality of systems as it does to the quality of processes of manufacture. For example defects in a production planning and scheduling system must be rectified at source, not out on the factory floor.

For reasons of social responsibility the pharmaceutical manufacturing industry must strive for zero defects. Already much of the JIT approach to quality is applied. For example manufacturing processes are validated and documented prior to commencing production to ensure, inter alia, that the processes are capable of producing products consistently to the right quality. Automatic quality control of all products is on the increase. Examples of this are tablet presses with facilities to weigh every individual tablet produced, missing label detectors and bar code checking. Because it is so relevant to the pharmaceutical industry the quality at source/TQC concept is expanded in Chapter 2.

1.1.3 Quality Control Circles

A quality control circle is a small group of people who do similar work, who meet regularly in company time on a voluntary basis to identify problems, analyse the causes, recommend solutions and whenever possible implement the solutions. The underlying JIT philosophy of quality circles is not only concerned with quality improvement but also with cost reduction and an increase in productivity.

There is a very great need in South Africa to improve product, process and system quality, as well as an urgent need to encourage worker participation in problem-solving and decision-making. The quality circles concept, adapted to suit local conditions, offers a means of improving quality and increasing worker involvement. This concept is elaborated further in Chapter 2.

1.1.4 Housekeeping

Housekeeping in the JIT sense means more than just a clean factory. In terms of JIT housekeeping, the goal is to establish an attitude that each person is responsible for his or her equipment and the surrounding environment. This involves ensuring that machinery and the environment are clean and safe, tools are in the right place, information is communicated and controls are implemented.

This concept of housekeeping is essential in the pharmaceutical industry. Good housekeeping helps to reduce the risk of product contamination, incorrect formulations, labelling errors, etc. Employees must be self-disciplined and self-motivated in maintaining housekeeping standards.

In South Africa the National Occupational Safety Association (NOSA) has a management by objectives (MBO) programme for improving safety standards. Housekeeping, in the JIT sense, is an essential component of this programme. For this reason a company's safety programme should be viewed not as a necessary evil, but rather as a means of achieving greater productivity. Such productivity improvements may be quickly and easily realised by applying the principles of good housekeeping.

1.1.5 Streamlined Process Design

Streamlining process design means essentially that the process must be designed to ensure the shortest possible production times. The ultimate goal is to design manufacturing processes that are so slick that the product is manufactured the instant it is required by the customer. While this is not practical, the correct application of JIT techniques such as Kanban, "one minute" machine set-ups, etc. can bring manufacturing close to this ultimate goal.

Implicit in the concept of streamlined process design are the requirements that the process is easily controlled, as simple as possible and capable of producing consistent good quality.

The prime objective of streamlined process design is to minimise inventories, whilst ensuring quality and guaranteeing good customer service levels. All inventories including raw materials, work-in-process (WIP), finished goods and scrap should be minimised. The desire to minimise inventory stems from the high cost of inventory relative to the overall costs of manufacturing, typically as shown in figure 1.2.

PIE CHART OF TYPICAL MANUFACTURING COSTS

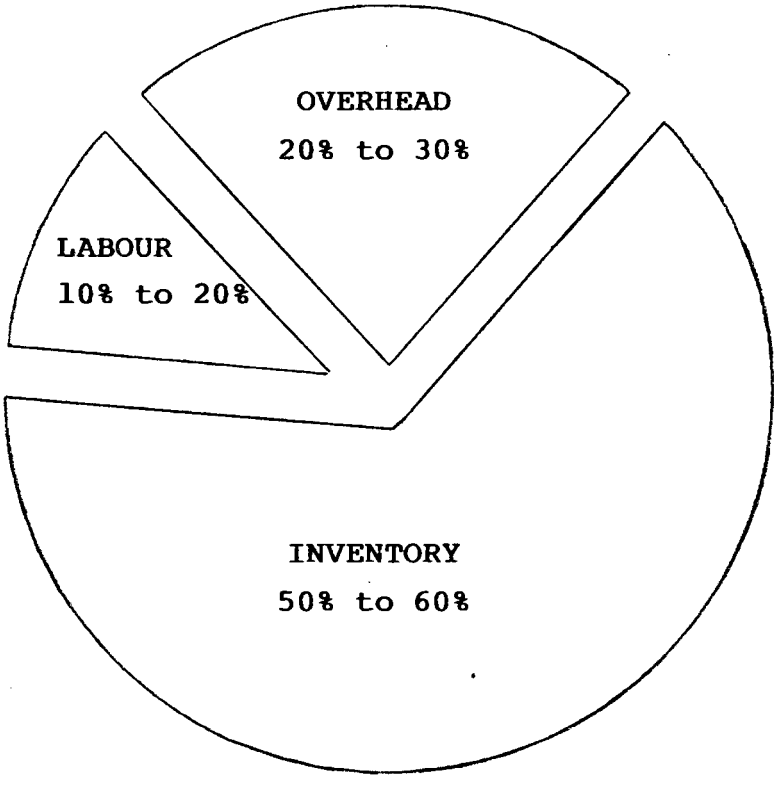


Figure 1.2

1.1.5 Streamlined Process Design (Cont'd)

Pharmaceutical manufacturers usually incur high inventory costs. The prime reason for this is the requirement that essential drugs should never be out-of-stock. Inventory levels are kept high **"just-in-case"** supplier deliveries are late, product is rejected by quality control or production delays occur. In other words, the broad process of manufacturing pharmaceuticals is not sufficiently streamlined and predictable to produce finished goods **"just-in-time"** to meet demand and avoid an out-of-stock situation.

The day-to-day production problems that cause manufacturers to protect themselves with a "sea" of "just-in-case" inventory are manifold. Some typical problems encountered in the pharmaceutical industry are shown in figure 1.3. The "sea of inventory" cushions manufacturers from the effects of these problems and therefore the pressure to address them is removed, or at least reduced, thus unintentionally ensuring the survival of such problems.

The JIT philosophy challenges this "just-in-case" approach by advocating that one manufactures only the **minimum** necessary **units** in the **smallest possible quantities** at the latest possible time. Implementing this philosophy without streamlining the manufacturing process is likened to lowering a "sea" of inventory and exposing the "rocks"/ production problems. Streamlining the process must be applied in the broadest sense including not only process design, but also the other JIT components outlined in this Chapter.

SOME REASONS FOR HIGH "JUST-IN-CASE" INVENTORY LEVELS IN THE PHARMACEUTICAL INDUSTRY

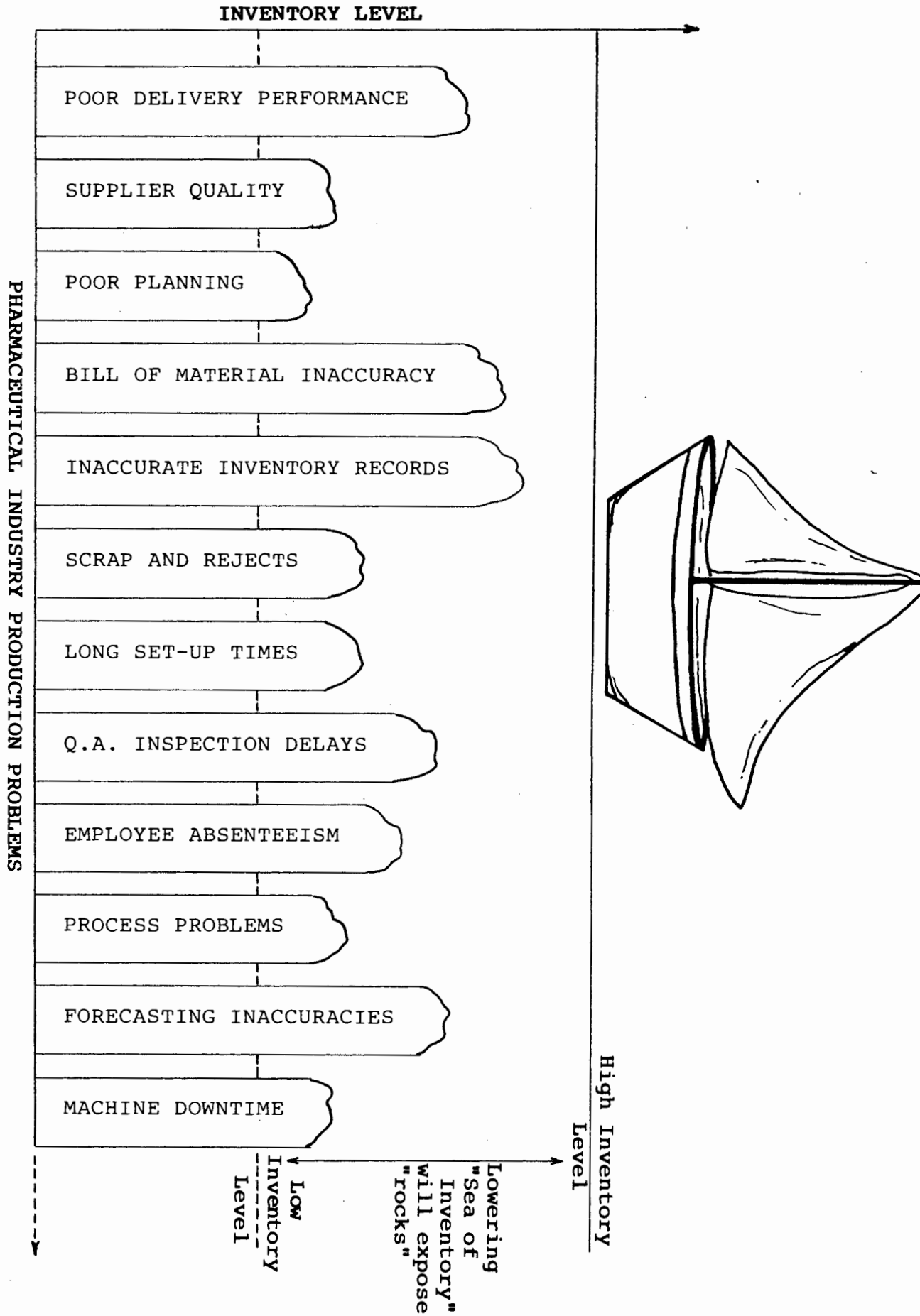


Figure 1.3

1.1.6 Standardisation

Standardisation of jobs leads to a more uniform, invariable and hence predictable output rate. Standard production cycle times, standard routings, standard set-up procedures and standard containers are all examples of standardisation that already is or could be applied in the pharmaceutical industry.

Standardisation helps to reduce work-in-process, part of the inventory reduction goal of JIT. It also helps to compress production times. Standardisation in JIT is in no way intended to restrict a manufacturer's production capabilities, maximum flexibility and versatility being part of the JIT philosophy.

1.1.7 Management Dedication

All too often top management pays only lip service to being committed to new manufacturing systems. Typically, responsibility is delegated with little further involvement after the initial interest.

Executive understanding and full management commitment and involvement is a prerequisite for the successful implementation of JIT. A measure of the degree of commitment required is the expectation that the Chief Executive Officer should agree to the need for personal JIT education.

The reasons why management dedication is so important are as follows:

(i) Implementing JIT involves educating people to change their attitudes, which takes a long time. Management must promote the necessary attitude changes and set a continuing example.

(ii) Initially, company attitudes, politics and power struggles will work against JIT. Without management commitment JIT implementation will falter in the face of such negative attitudes.

1.1.7 Management Dedication (Cont'd)

(iii) If consensus management and worker participation in decision-making are to have any credibility with workers, these ideas must be practiced and supported at the highest level.

(iv) JIT implementation is initially very time consuming. Management must be prepared to allow all employees to devote time and effort over an extended period.

(v) JIT is not a "quick fix" solution to a company's manufacturing problems. To succeed requires perseverence, therefore management must continue to motivate employees throughout the implementation period and beyond. All too often South African CEO's expect quick results with the minimum of effort.

1.1.8 Respect for People

In contrast to Japan "It can probably be accepted that we in South Africa tend to follow the methods used in the United States and in Europe. Our colonial history, our academic system and the origin of our Management Text Books are all Western. Our 'system' tends therefore to be more exact, more 'Taylor-like', making use of:

- formal controls
- job design
- specialisation
- scientific methods of personnel selection
- appraisal and promotion
- decision-making

1.1.8 Respect for People (Cont'd)

It is forever aiming at objectivity and at exactness. It is forever trying to eliminate subjectivity and emotion".(3) This frequently leads to the mistaken belief that Japanese success in manufacturing, through JIT, is based on long standing cultural differences and therefore cannot be emulated. While there is no doubt that attitudes in South Africa must change if JIT is to succeed, this does not require accepting Japanese culture but rather depends on developing their respect for people in our local populace.

The Japanese respect for people has four cornerstones, namely:

- lifetime employment
- company unions
- attitude towards workers
- the manner in which automation/ robotics is implemented

Lifetime employment in Japan means permanent long-term employment. Companies usually hire new employees once a year and retain them, barring serious misdemeanours, until their retirement. In practice there is a fixed core of permanent employees, with the headcount determined by management to meet their projected "levelled" production. Seasonal or temporary boom fluctuations are catered for by employing temporary workers or sub-contracting the excess work. Temporary employees are made aware at the outset that they are not "lifetime employees". In times of economic difficulty management resorts to salary and bonus reductions, reduced working hours or releasing temporary workers. This no redundancy policy greatly increases the loyalty between the individual and the firm.

1.1.8 Respect for People (Cont'd)

Furthermore "lifetime employment" encourages employers to increase benefits for employees and invest in training, in the knowledge that employees will stay with the firm long enough to yield economic returns on such investments. This job security encourages employees to trust the company and accept changes, including automation, without perceiving them as threats to their jobs. In contrast, many South African companies adopt a "hire and fire" attitude which seriously mars the relationship between employer and employee.

Fortunately the pharmaceutical industry has a somewhat better record in terms of "lifetime employment", with long service frequently the norm, especially amongst direct labour. The reasons for this include:

(i) The inherent stability of the industry in the face of booms and depressions in the country's economy.

(ii) The influence of multi-national companies in the industry and their application of international codes and standards in their employment policies.

(iii) Employees are respected and trained more because of the need for them to be committed to the industry's quality standards, and the risk of disgruntled employees sabotaging products.

(iv) The relative profitability of the industry allows for better benefits and more investment in human resources.

1.1.8 Respect for People (Cont'd)

Company unions rather than national trade unions are a feature of Japanese industry. The employers respect for employees is such that the employees feel management will consult with them in the best interests of all concerned within the company, without the need to resort to national or regional cross-company collective bargaining. The result is fewer work disruptions and greater interest by individual employees in the progress of their company, from which they expect and receive tangible benefits.

The attitude to unions within the pharmaceutical industry is not uniform. In parts of the country, most notably the Vaal Triangle, national trade unions are powerful whereas in areas such as the Western Cape, there is little interest in national trade unions. In the latter areas there are no company trade unions as such, but there is a growing interest in meaningful Works Councils.

Attitude to workers is a broad, continuously evolving, manifestation of a company's respect for its workers. It has traditionally meant practising a management style which is appropriate for motivating, rewarding and communicating with workers whilst acting in the best interest of the company, society and the employee. Japanese attitudes, however, reflect a holistic concern for employees. Employees are regarded as essential resources of the firm and the growth of the whole person, rather than merely his or her job skills, is emphasised.

Unfortunately in South Africa, management's attitude to workers is heavily influenced by racial, cultural and political factors. Socio-economic factors are frequently confused with such factors.

For example, peoples' views and attitudes to work are expected to conform with their race, a particularly pernicious and widespread form of racism. In reality, low I.Q.'s, lack of motivation and such traits in a section of the population reflects prevailing socio-economic conditions, not cultural or racial identities.

1.1.8 Respect for People (Cont'd)

It is interesting to note that

"According to *Sowell's research, it turns out that at the turn of the century when Jews and Japanese in the USA were two of the lowest socio-economic groupings with family incomes near the bottom, they were found to have correspondingly lower than average I.Q.'s. There were social scientists at the time who concluded that Jews and Japanese were inherently inferior. However, today, with no affirmative action programmes to assist them, they occupy the two top positions in the USA. If the average American family income is taken as 100, the average Jewish family income is 172 and the average Japanese is 132. This suggested that IQ is correlated not with race so much as with socio-economic position. Other evidence of this is that according to the Guiness Book of Records the Japanese, as a nation, have the highest national average IQ of 107. The Japanese IQ has risen in correspondence with the rise of the Japanese 'economic miracle' which, according to some statistics, now places the Japanese at the top of the quality of life index"(4).

Some employees, including the majority of those in the S.A. pharmaceutical industry, believe that a solution lies in affirmative action, the most notable example of which is the Sullivan Code. Such programmes actively work to improve socio-economic conditions for their disadvantaged employees and the community at large. Unfortunately while for the most part the activities of these programmes are commendable, they do inevitably generate a measure of "inverse racialism". For example, a black employee who is promoted for reasons of colour rather than ability, is hardly likely to feel that management respects him as a worker. A better approach is the JIT holistic concern for workers, which will develop them and uplift them while remaining essentially "colour blind".

*A renowned black American researcher and philosopher.

1.1.8 Respect for People (Cont'd)

The subject of **automation/robotics** is an emotive one, with workers and trade unions usually opposed to the implementation of such new technology. Japanese workers differ markedly in their attitude with their country possessing the greatest degree of automation and the largest number of robots in the world. Their positive attitude towards new technology stems from their perception that automation/robotics does not pose a threat to their jobs. This attitude exists because automation/robotics is normally justified on the grounds of:

(i) The process being dangerous and automation/ robotics is a means of ensuring the safety of employees.

(ii) The process being mundane and therefore an insult to the intelligence of the employee.

This approach is new in South Africa, where automation/robotics is normally justified in terms of headcount reductions and the perceived ability of automated processes to produce consistent good quality products, an attitude which hardly shows respect for the workers.

1.1.9 Consensus Management

Consensus Management or collective decision-making is at the core of JIT. All employees have a sense of running the company, because virtually nothing gets done unless all the employees who should be involved are consulted and agreement is reached. The emphasis is on teamwork rather than competition within the company. As a result of this, employees are kept informed, all factors are considered, everyone has time to adapt themselves to the emerging decision and all are committed once a consensus has been reached. This can be a lengthy procedure, but because of the consensus amongst all concerned, implementation is quick and successful.

1.1.9 Consensus Management (Cont'd)

In contrast, South African managers tend to make quick decisions, without consulting all employees concerned, with the result that implementation of the decisions is slow, due to employee resistance and unforeseen problems. In the pharmaceutical industry, largely for legal and social responsibility reasons, there is more consultation and employee involvement. However, this tends to be confined to procedural matters, rather than JIT concepts such as quality circles, group problem-solving, etc. Typically the trend in South Africa is from a dictatorial management style to a more patronising style. JIT consensus management involving all employees is a much better alternative.

1.1.10 Group Problem-solving

This concept is closely related to that of Quality Circles, but is broader in scope and group composition. With Group Problem-solving a multi-disciplinary group or team is formed to solve a particular problem or set of problems. Unlike Quality Circles the group may tackle problems that are not quality-related and which may, for example, include JIT implementation problems. Furthermore the group does not comprise members who do similar work, as is the case with Quality Circles, but rather draws from mixed disciplines at all levels in the company. The object of this is to promote debate - for example technical assumptions are challenged by non-technical members of the group. Typically the group is disbanded once the problem or set of problems is solved.

Although not confined to quality problems, this concept and its application are discussed further in Chapter 2 on Total Quality Control.

1.1.11 Focused Factory Network

The publicity frequently given to Japanese industrial giants, such as Toyota, Mitsubishi, etc. has led to the mistaken belief that Japanese manufacturing is composed largely of such giant diversified corporations. In reality, Japan is a nation of small manufacturers making up JIT Focused Factory Networks, with some 180 000 plants employing less than 30 people.

A focused factory network is an inter-dependent grouping of small manufacturers or service organisations, each highly proficient in its area of expertise. The existence of a focused factory network enables a company to concentrate on its area(s) of business. Thus for example, Toyota is an assembler of vehicles and not a manufacturer of vehicle components. As an assembly operation, Toyota relies on reliable just-in-time component deliveries from a focused factory network supplying it and other similar companies. The constituent companies in the focused factory network concentrate their efforts on what they are best at doing.

There is likely to be a high degree of initial resistance to the focused factory network concept in South Africa. This is because existing South African factories tend to be large, especially in the process industries. However, one can achieve focused networks within large factories by splitting them up in terms of management and business units. This will enable the internal elements within the factory focused network to become more proficient in their particular areas of expertise.

1.1.11 Focused Factory Network (Cont'd)

The pharmaceutical industry in South Africa does not benefit from the existence of a focused factory network. Manufacturers are typically not specialised, but instead produce a diverse range of products, from the processing of raw materials through to the distribution of the finished products. The limited size of the local market cannot support a focused factory network of suppliers, except for finishing supplies and basic raw materials - components also in demand in other local industries. The development of a focused factory network for the pharmaceutical industry can be achieved by expanding the market through exportation and entry into the black market, having developed a more "Africanised" product range rather than marketing the current predominantly "Western" pharmaceuticals.

1.1.12 Group Technology

The group technology concept is not a new one, having been originally developed by Henry Ford, when he put machines together to form a production line. The underlying principle is that specific production departments are undesirable, primarily because the existence of such separate departments, frequently physically some distance from each other, promotes shipping delays and encourages the build-up of excessive work-in-process inventories.

Technology and machines are physically grouped together so-as to ideally produce the entire product in one area, thus minimising delays and work-in-process inventories by achieving flow rather than batch production in the area, as well as saving space and improving control and worker identification with the complete product. Clearly to be effective, group technology must include flexibility and versatility, both of machines and worker skills.

1.1.12 Group Technology (Cont'd)

Group technology is conspicuously absent in the pharmaceutical industry, in part because of regulations in the industry which have encouraged not only the separation of departments, but separation within departments. For example, the manufacture of a tablet, by departments/specific areas would typically be as shown in figure 1.4, with each listed location being physically separated from the next.

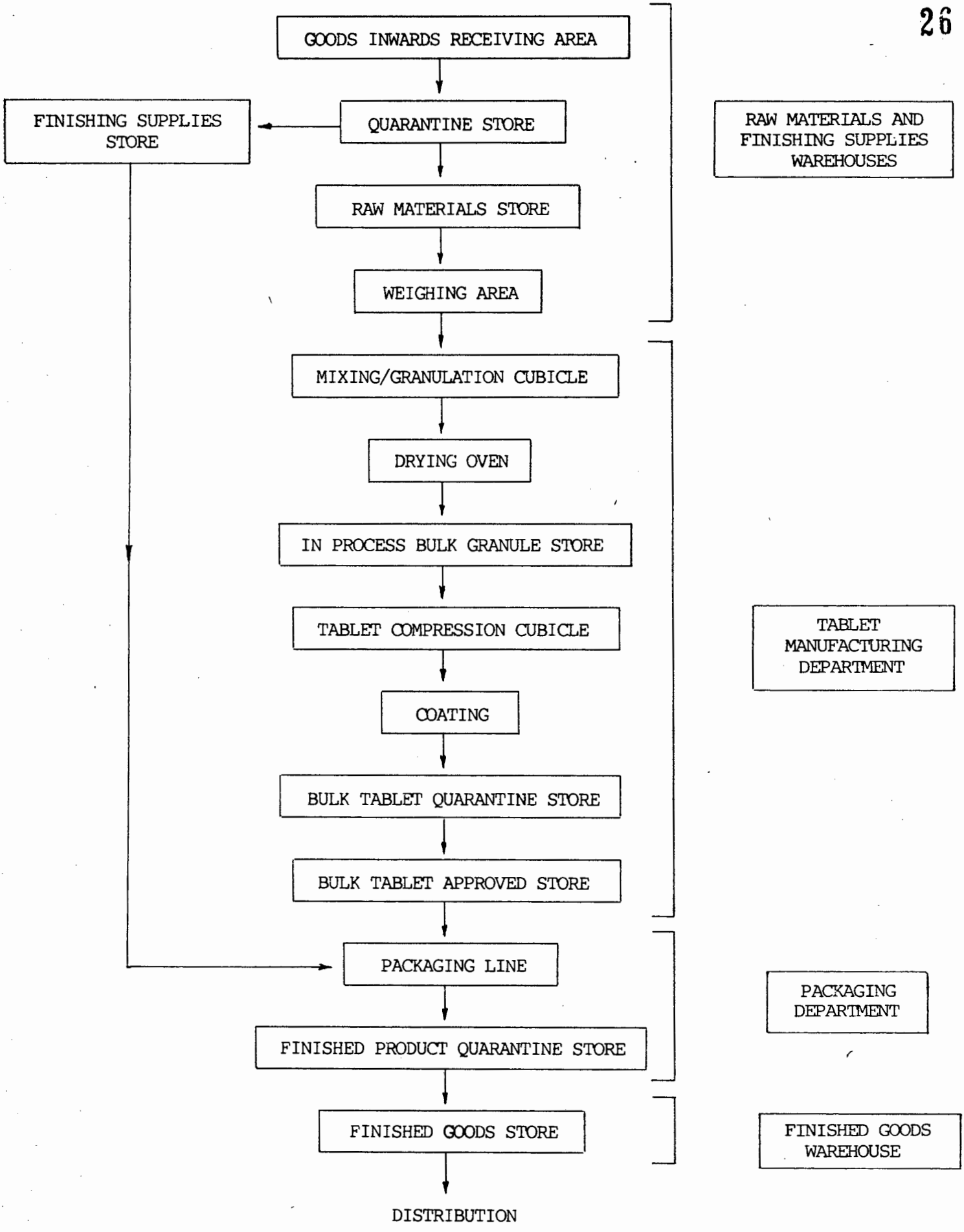

GOODS INWARDS RECEIVING AREA
FINISHING SUPPLIES STORE
QUARANTINE STORE
RAW MATERIALS AND FINISHING SUPPLIES WAREHOUSES
RAW MATERIALS STORE
WEIGHING AREA
MIXING/GRANULATION CUBICLE
DRYING OVEN
IN PROCESS BULK GRANULE STORE
TABLET COMPRESSION CUBICLE
TABLET MANUFACTURING DEPARTMENT
COATING
BULK TABLET QUARANTINE STORE
BULK TABLET APPROVED STORE
PACKAGING LINE
PACKAGING DEPARTMENT
FINISHED PRODUCT QUARANTINE STORE
FINISHED GOODS STORE
FINISHED GOODS WAREHOUSE
DISTRIBUTION

Figure 1.4

1.1.12 Group Technology (Cont'd)

Clearly in this example, as in most pharmaceutical processes, there are substantial internal shipping times/delays and an accumulation of work-in-process. Traditionally Medicines Control Council (MCC) and Good Manufacturing Practice (GMP) requirements have necessitated that manufacturers segregate manufacturing areas and processes. However, such requirements/regulations are not "sacred cows". For example the MER National division of Dow Chemicals in South Africa has recently installed an MCC approved computerised bar code control system. Under this system, product is not quarantined by location into separate stores, but instead the current unapproved or approved status of the product is recorded in the computer with attendant controls. This is best illustrated by the warehouse which is not segregated into the traditional quarantine, raw materials, finishing supplies and finished goods areas. Instead each item is bar-coded and a reading of the bar code at any stage will, when entered into the computer, give the current status of the item. The controls include a system which prevents a reach truck (by isolating electrical power) from entering a warehouse aisle to remove an item with a quarantine status. Unfortunately, such systems involve large capital investment. However, group technology can be applied in the pharmaceutical industry in many cheaper ways, including the simple repositioning of machinery.

1.1.13 Uniform Plant Load/Levelling

The concept of uniform plant load is disarmingly simple - if you sell a product daily, then make it daily and keep your plant load level, particularly in terms of direct labour hours. This means that ideally products are manufactured in small batches, with the same product mix, on a daily basis. Whenever possible, the products should be made to meet demand and not to stock, which clearly requires short manufacturing lead times. The concept of short manufacturing lead times is at the heart of JIT and involves streamlined process design, minimum set-up times, etc.

1.1.13 Uniform Plant Load/Levelling (Cont'd)

The uniform plant load must be planned in advance and matched to the factory's equipment and labour capabilities, thus ensuring that the production rate is synchronous to the demand rate. To take a simple example, if the demand for a product is 480/day and the manufacturing plant works 8 hours/day then the uniform plant load rate is 1 finished unit/minute (480 units/day ÷ 8 hours/day ÷ 60 minutes/hour = 1 unit/minute) The entire process should then be geared to a rate of 1 unit/minute, including component receipts and assembly stages.

In reality to achieve a uniform plant load, a manufacturer must:

(i) Reduce batch sizes

(ii) Level direct labour hours

(iii) Strive to maintain a consistent product mix

(iv) Reduce manufacturing lead times

(v) Set a realistic uniform plant load level relative to the theoretical plant capacity - i.e. allow for planned maintenance, change-overs, Q.C. circles, on the job training, etc.

(vi) Re-assess customer requirements - frequently products may be delivered over a period rather than in a discrete large batch, thus aiding uniform plant loading

(vii) Re-assess supplier requirements - place weekly orders rather than larger monthly orders, giving the supplier an order horizon and listing the priorities, thus using small supplier receipts to match the uniform plant loading

(viii) Re-assess transport, goods receiving and despatch requirements to match smaller, more frequent batches of product

1.1.13 Uniform Plant Load/Levelling (Cont'd)

The primary benefits of uniform plant loading are reduced work-in-process inventory, reduced indirect labour to move and manage that inventory and more efficient direct labour utilisation.

The pharmaceutical industry has traditionally produced to stock and held significant safety stocks, largely because of the medical/moral implications of drugs being out-of-stock. Uniform plant loading is not usually achieved because of long manufacturing lead times, seasonal fluctuations in demand and inaccurate forecasting. However, particularly with the aid of other JIT tools and improved planning and control with say Manufacturing Resource Planning (MRP II), uniform plant loading is achievable in the industy. Already smaller batch sizes and split batches are being produced, capacity planning is more accurate and supplier requirements are being re-assessed, as discussed in later chapters.

1.1.14 Valid Plans

To succeed, JIT requires effective control of all aspects of the manufacturing process, preferably at the lowest possible level. Without valid plans, there can be no effective control, for a lack of valid plans results in crisis management. The required plans include business planning, production planning, master production scheduling, material requirements planning and capacity planning.

The implementation of the JIT concepts produces huge productivity improvements and savings, but "all this will go for naught, though, if we do not have the right amount of the right raw material on hand at the right time. In order to get this right, the planning functions mentioned above become more important, because there are no spare raw materials (safety stock) and no ability to move manufacturing orders more quickly through the shop (no dead time between operations)"(5).

1.1.14 Valid Plans (Cont'd)

In other words valid plans are essential because the whole JIT production process is so "fine-tuned". Plans cannot be made once a year and then "cast in concrete", but must rather reflect changing forecasts, etc. However, time fences must be applied, within which changes are strongly resisted, thus ensuring schedule stability/zero variation to schedule.

As discussed in Chapter 6, Manufacturing Resource Planning (MRP II), is being widely adopted in the pharmaceutical industry. The benefits of MRP II include the relative ease of maintaining valid plans.

1.1.15 Smaller Batch Sizes

Even in South Africa, where the market is relatively small, pharmaceutical manufacturers tend to make products in large batches. In contrast, the JIT approach is to cut machine set-up times so much that it is economical to run very small batches. "The ideal is to make one piece just in time for the next operation. In management terms, the economic order quantity has been cut down to approach one". (6)

The obvious advantage of smaller batch sizes is a saving in inventory carrying costs due to the lower average inventory level as shown in figure 1.5.

LARGE BATCH PRODUCTION VERSUS JIT SMALL BATCH PRODUCTION

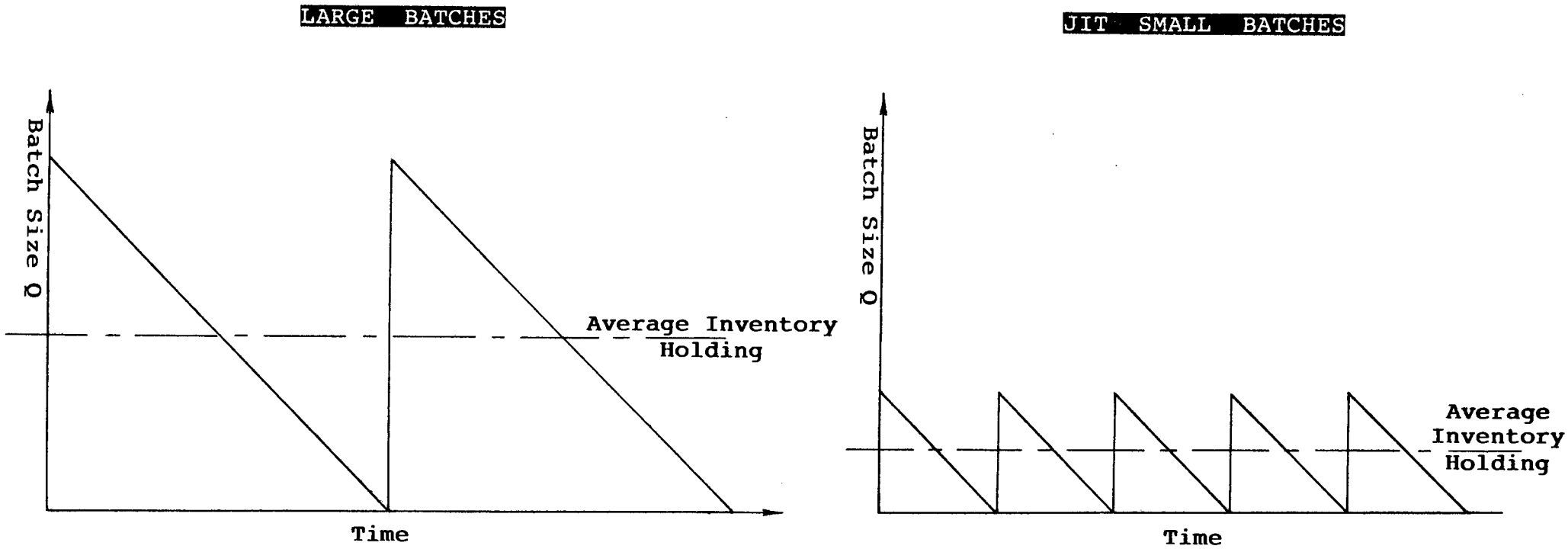


Figure 1.5

1.1.15 Smaller Batch Sizes (Cont'd)

The Japanese have found some other less obvious, but very important benefits of small batch sizes, namely improved quality, worker motivation and productivity. This is best illustrated by an example, "Say a worker makes one piece and hands it to a second worker whose job is to join another piece to it, but the second worker cannot make them fit because the first worker has made a defective part. The second worker wants to meet his quota and does not like being held up, so he lets the first worker know about it right away. The first worker's reactions are predictable; he tries not to foul up again and tries to root out the problem that caused the defective part. The typical Western way, by contrast, is to make parts in large lots - a whole forklift truck load or two week's worth, maybe. The second worker might find ten percent to be defective, but he does not care. He just tosses a defective part into a scrap or rework bin and grabs another part. There are enough good ones to keep him busy, so why complain about defectives?"(6) Thus wasted labour hours and wasted material are reduced by not allowing large amounts of defective product to be produced, because defects are detected quickly and the cause rectified.

Finally small batches enable production to track demand more closely, particularly in a rising or falling market or for seasonal production, as found with certain pharmaceutical products.

1.1.16 Kanban

Kanban is a Japanese word which literally translated means "visible record", but is more generally taken to mean "card". The typical Japanese Kanban system, as employed by Toyota, uses cards to signal the need to deliver more components, and similar cards to signal the need to produce more parts. It is a manual system, similar to re-stocking a supermarket shelf. Unfortunately Kanban has a bad "Japanese postcard" image throughout much of the Western industrialised world. This is based on the misconception that the cards are all there is to Kanban, when in fact the system is a means of applying part of the JIT philosophy. Through Kanban, the Japanese have achieved benefits which include reduced inventories, quick problem identification (eg. production bottle-necks) and rapid problem resolving. Informed observers of Kanban see the principles behind the card system.

Many production ordering and control systems in use throughout the world, use manual card systems, but they all differ from Kanban in that they are **"push"** systems not **"pull"** systems. Under a **"push"** system a batch of material/components is "pushed" along to the next worker, regardless of whether or not he or she needs them. The result is large work-in-process inventories and hidden, unrectified production problems, as discussed in section 1.1.15 above. In contrast, the Kanban **"pull"** system ensures that a worker "pulls" materials, components, sub-assemblies, etc. only when he or she needs them. Each worker produces only what the next worker requires, and starts production only when the next worker has taken the last item. There are thus no buffers, and problems at any individual work-station will shut down the whole production line, hence the need for quick problem identification and resolution. The Japanese believe that this kind of "knife edge" production acts as an incentive to productivity and increases worker motivation and responsibility, and has contributed to their country leading the world in terms of productivity.

1.1.16 Kanban (Cont'd)

Kanban has not been widely adopted outside Japan, partly because of its over-simplified "Japanese postcard" image and partly because it is best suited to repetitive production. Furthermore it is important to appreciate that: "There is an important limitation to the use of Kanban - Kanban will work well only in the context of a JIT system in general, and the set-up time/lot size reduction feature of JIT in particular. A JIT program can succeed without a Kanban system, but Kanban makes no sense independently of JIT". (7)

The pharmaceutical industry, with its medium and large batch production, has not yet adopted the Kanban system. Despite this, the industry can learn some lessons from the Kanban concept, namely:

(i) Production control systems can be used as indicators, providing that, like Kanban, their response time is quick. Too many systems provide historic information, typically it takes days to enter the data and weeks to produce the print-out of results.

(ii) Paperwork should be simplified or eliminated.

(iii) The KISS (Keep It Simple and Stupid) principle should be applied wherever possible. Systems work best, when like Kanban, they are simple, reliable and understood by all workers.

1.1.17 Flexibility and Versatility

The JIT objectives, particularly the reduction of batch sizes, means that a factory must accommodate a greater product mix at any one time than is the case with large batches, scheduled sequentially and spending days or weeks in processing. Flexible and versatile production systems are required to accommodate small batch or "mixed model" manufacturing, without the need for re-setting, training or re-configuration of production facilities.

1.1.17 Flexibility and Versatility (Cont'd)

Reduction in batch sizes towards the goal of a one unit batch size is achieved over time in a series of small steps, which requires built-in flexibility in the production system, since continuing change is expected.

Many industries, and the pharmaceutical industry in particular, have factories, equipment and systems designed and selected for very specific products and product ranges. This lack of flexibility stems from the traditional belief that, provided the production cost of a product is kept low, the market will automatically expand to take up production capacity. In an increasingly competitive world this assumption is no longer valid and all too frequently over-designed plant space is used for inventory storage, until the market catches up and the space is again required for production capacity. To overcome this industry must be flexible enough to adapt to changing markets, and versatile enough to be able to introduce varied new products into the market-place quickly, ahead of competitors.

There are a number of ways in which manufacturers can improve flexibility and versatility, including:

(i) Simplifying the systems and equipment used and concentrating on essentials.

(ii) Using group technology and U-shaped layouts to enable workers to work on more than one machine and provide assistance, where required to others.

(iii) Utilising two or more small, lower capacity pieces of equipment in place of one inflexible high capacity machine.

(iv) Using inherently flexible and programmable equipment and systems such as robots and CAD (Computer Aided Design) and CIM (Computer Integrated Manufacture).

(v) Employing multi-skilled/ multi-function workers.

1.1.18 Multi-skilled/Multi-function Workers

As stated above, manufacturers can improve their manufacturing flexibility by employing multi-skilled/multi-function workers. This component of JIT implies that one worker can perform two or more jobs and possesses a variety of skills, thus making it possible to move workers from one work centre to another. This increases productivity and teamwork, and encourages streamlined process design.

The JIT concept of levelled production, as discussed earlier, is usually based on labour hours. Production is planned and executed using levelled labour which is ideally fully utilised. Full labour utilisation is achieved by mixed product production, which requires multi-skilled/ multi-function workers.

As stated in section 1.1.8 the pharmaceutical industry in South Africa has a record of long-term employment, particularly amongst direct labour. Long-term/permanent employment makes it realistic for workers to rotate jobs within the company, thereby developing a number of skills and the ability to perform numerous functions. This job rotation, in addition to ensuring the required worker flexibility, has the following benefits:

(i) Workers learn different aspects of the business.

(ii) Individual workers become generalists and are therefore better able to appreciate the consequences of their actions on the rest of the organisation.

(iii) Employees establish a network of co-workers, with whom they can work to achieve their goals.

1.1.19 Minimum Set-up Time

The JIT concept of producing very small batches, as discussed in 1.1.15 above, is only economical if set-up time is minimised. Furthermore, the smaller the batch size, the less scrap can be tolerated, hence the need for consistently accurate, as well as quick, machine-setting.

Many managers fail to realise that set-up cost is real and significant, but not unalterable, unlike some manufacturing costs. With ingenuity and determination set-up time, and hence cost, can be progressively reduced. Almost all manufacturing plants can apply this JIT principle, sometimes with spectacular results.
"A Toyota campaign to cut set-up times began in 1971. In that year it took an hour to set-up 800 ton presses used in forming auto hoods and fenders. About five years later the set-up time was down to 12 minutes. This compares with 6 hours for a U.S. competitor; and Toyota was running lot sizes of just one day's worth of output per set-up versus a reported 10 days' worth for the U.S. competitor. But the 12-minute set-up time is still too long. Toyota strives for **"single set-up"**, which means single digit - i.e., less than 10 minutes. Toyota has often been able to reduce set-up time to less than 1 minute, which is called **"one-touch set-up"**.

Even without adopting the JIT philosophy the South African pharmaceutical industry, with its small volumes and large product ranges, has typically a large number of machine set-ups for the volume of goods produced. In spite of this, as in most industries, little or no attempt has been made to reduce set-up costs. Some possible reasons for this include:

(i) There is a tendency for managers, particularly those who have not come up through manufacturing or engineering, to scrutinize large obvious costs, like direct labour, but to neglect set-up cost and other less obvious costs such as inspection, scrap and reworking. Set-up is treated as a given, unalterable, cost.

1.1.19 Minimum Set-up Time (Cont'd)

There is a tendency to watch operator efficiency, with the emphasis on time study etc., while the overall factory efficiency is low.

(ii) Prior to the arrival of JIT there was little awareness of the chain reaction of benefits which stem from reducing batch sizes, and hence there was little motivation to cut set-up times.

(iii) Manufacturers frequently use a variety of different makes of a given type of machine, bought on the basis of price from a number of different suppliers. With mixtures of equipment makes, developing set-up time saving modifications is more costly.

(iv) There is, not surprisingly, a widely held view that one should not tamper with machines and tooling designed by the experts at manufacturers of such equipment. However, altering bought-out machines and tooling to facilitate quick set-up is widely practiced in Japanese industry. Sometimes the Japanese go further to obtain the solution to the set-up time problem and retire the bought-out machine in favour of a purpose-built machine built in-house.

The JIT concept of minimising set-up time is discussed further in Chapter 5, where some practical examples in the pharmaceutical industry are discussed.

1.1.20 Automation/Robotics

Japan has more industrial robots than any other country in the world, and yet their unemployment rate is lower than countries such as the United Kingdom, where workers and trade unions resist robotics and automation for fear of increasing unemployment. The reason for this is the JIT concept of respect for people, as discussed in section 1.1.8, based on the belief that providing full employment is a prime social purpose of running a business and that such employment aims to improve the quality of life of employees. Automation/robotics is favoured when the process is too monotonous, dirty, dangerous or difficult or where automated quality control is desirable, but not simply for saving labour.

With the adoption of this JIT philosophy comes self-confidence in automation/robotics, as is evident in Japan. Prior to adopting JIT manufacturers in that country and elsewhere were sometimes proud of being behind the times, after all: "Not being on time meant a greater likelihood of success in automation as they learned from the failures of others. With the greater move toward the world market-place, manufacturers cannot afford to wait". (9) The pharmaceutical industry has been very conservative in its approach to automation/robotics. However, the notable exception has been in the trend towards automated quality control, where manufacturers throughout the world are being forced to comply with industry norms. Examples of such automated quality control are automatic tablet weight checking, missing label detection, etc.

With the acceptance of process automation workers undergo a transition from "doers" to "machine monitors". This transition does not come easily, but it is important to get people out of direct control in the manufacturing loop to ensure the quality level, by eliminating the human error factor. Sooner or later people make mistakes, mistakes which could be life threatening in the case of the pharmaceutical industry.

1.1.20 Automation/Robotics (Cont'd)

As the world market continues to demand better quality, error rates must continue to approach zero, something which can only be guaranteed by automation/ robotics, coupled with JIT concepts such as quality at source, quality circles, group problem-solving, etc.

Resistance to automation prevails in the pharmaceutical industry not only because of the high capital investment required and the prevailing regulations which present barriers to change, but also because changes frequently have to be made to the product design to facilitate automation. For example, the introduction of automated fluidised-bed drying of granules, prior to tabletting, usually requires product reformulation. Reformulation is normally a lengthy and expensive procedure, involving research and development, clinical trials and approval from the Medicines Control Council.

Automation is by no means confined to manufacturing machinery and applies to systems as well, particularly those employing computers. Examples of such system automation include inventory control with the aid of bar codes, elements of Manufacturing Research Planning (MRP II), computer-aided design, etc. Frequently, as in the pharmaceutical industry, the automation of systems precedes automation/robotics in manufacturing.

1.1.21 Preventive Maintenance

The JIT philosophy cannot be successfully implemented without effective preventive maintenance to ensure the maximum machine "up-time" or availability. Equipment breakdowns can shut down whole production lines in a JIT factory, with its minimal work-in-process buffers.

1.1.21 Preventive Maintenance (Cont'd)

The JIT concept of preventive maintenance (PM) is known as **Total Productive Maintenance (TPM)**, a broader term for PM with all employees participating through small group activities, rather than the usual system in which operators devote themselves to production and the maintenance department's crews are responsible for maintenance. Conventional maintenance crews have difficulty in maintaining equipment used in JIT production, partly because the number of machines is usually large, and there is a high degree of automation, and partly because the high machine utilisation makes maintenance scheduling difficult. Instead each operator is made responsible for routine maintenance of his own equipment.

According to the Japan Institute of Plant Engineers (JIPE) the definition of TPM includes:

- Maximising equipment effectiveness/aiming for zero failures.
- The establishment of a total system of PM covering the whole life of equipment.
- Involving all departments, such as equipment planning, production and maintenance
- Participation by all employees from top management to direct labour.
- The promotion of PM through motivating employees using small group autonomous activities.

1.1.22 Supplier Involvement and Education

It is not unusual, particularly in the pharmaceutical industry, for purchased components and raw materials to account for 50% or more of the cost of the product. Thus suppliers inevitably play an important role in the success of any manufacturer. This is especially true of the JIT manufacturer who relies on a focused factory network of suppliers to provide the correct components and materials at just the right time, in just the right quantities at just the right quality.

Buyers should not select suppliers on the basis of price alone. Performance, and above all commitment to the JIT philosophy, are of paramount importance, suppliers being viewed by the manufacturer as "co-makers".

It is apparent that suppliers must become involved in the manufacturer's organisation, at least to the extent of pricing, quality and meeting order schedules, and must be educated in the necessity of reliably fulfilling these needs. This clearly requires a two-way flow of information. Initially this is best achieved by exchange visits to verify arrangements, with the manufacturer visiting the supplier and vice versa. The team designated to visit each visitor should, as a minimum, comprise representatives from Purchasing and Quality Assurance. The Quality Assurance representative should work with the supplier to review the supplier's operation (although constructive suggestions should be made), with definition of the manufacturer's requirements and assessment of the supplier's capabilities the prime tasks.

During the supplier's visit to the manufacturer it is important that:

- Manufacturers convey their commitment to suppliers in the JIT programme.
- The benefits of JIT to both parties are stressed.
- The manufacturer is committed to firm order schedules for a given time period.

1.1.22 Supplier Involvement and Education (Cont'd)

- The supplier is educated in all relevant aspects of JIT, sometimes by way of a joint presentation to a number of vendors.

- The supplier is made fully aware of what is expected in the joint working relationship.

- The supplier tours the manufacturer's facility, thereby becoming familiar with how his goods serve the manufacturer.

The JIT materials management approach and the role of suppliers is discussed further in Chapter 4.

1.1.23 Education

The JIT philosophy relies heavily on employee involvement, which ensures that the company stays competitive, produces quality products, retains market share and stays in business, thereby ensuring employment. Such involvement, if it is to be successful, is dependent on employees being educated, both in terms of personal job related knowledge and in terms of knowledge of the company, its purpose, its systems and its future goals. Such education can, as indicated in Section 1.1.22 above, extend beyond the company's own employees and should include suppliers and sub-contractors.

Education is perhaps the most fundamental JIT requirement in South Africa, where employees frequently do not understand even the basic principles of capitalism and free enterprise. Without employee education attempts at JIT will come to naught. Education is the key to releasing latent people potential.

1.1.23 Education

Education should extend to all employees at all levels in the company, with the techniques and content selected to match the intellect of the employee and his/her position within the company. Such education will usually be in the form of:

- reading of articles and presentation of papers
- audio-visual presentations
- attendance at seminars and symposiums
- discussions between employees

Later education gives way to training which typically comprises:

- training in the actual "software" of JIT
- job skills training, including the development of multi-skilled operatives
- guidance in "on the job" group problem-solving

1.2 THE POTENTIAL BENEFITS OF JIT

1.2.1 An Overview

Much has been made of the Japanese success with JIT, not without justification. Results such as a 50% reduction in factory space and a 500% improvement in quality have been cited. However, it must be appreciated that it has taken the Japanese some 20 years to implement JIT. Results in other countries will depend principally on the degree of implementation and people's attitude to JIT. The potential benefits are numerous and far-reaching, as outlined throughout this text, and comprise largely those summarised below.

1.2.2 Improved Quality

Product quality is achieved through the JIT Total Quality Control (TQC) concept. Not only is quality improved, but it also becomes predictable. Furthermore, the TQC approach enables quality to be built into the product, while keeping its price competitive. Carried through to its ultimate goal, JIT ensures "zero defects".

1.2.3 Reduced Quality Control Costs and Delays

Inspection is the prime source of quality control costs and is a major cause of production delays. JIT aims for "zero defects" production by building in quality at source, analysing defects and eliminating their causes and controlling the inherent capability of the process. As this is implemented the number of defects declines rapidly and confidence in the process is established, with resulting reduced quality control costs and delays.

1.2.4 Reduced Scrap/Waste

JIT aims to eliminate all waste, both of materials and time, and to make full use of labour. Small batches and reduced work-in-process inventories mean that a worker quickly learns the effects of his workmanship, and is therefore motivated to improve his performance, thereby reducing scrap. Added to this is the JIT concept of quick accurate machine set-ups, which reduces material and labour wastage during set-ups.

1.2.5 Greater Worker Motivation

With JIT production employees' efforts and workmanship are clearly visible and are in themselves a reward, which motivates them to continue to improve. Workers are also motivated by the respect with which they are treated, their participation in decision-making, their education by the company and a sense of "belonging" to the company stemming from the "holistic" concern for employees. Furthermore the goals of the company are clear to all employees, who are motivated to help to achieve these goals, at least in part because they view their own future as being synonymous with that of the company.

1.2.6 Increased Teamwork

The whole JIT philosophy is based on teamwork. Employees are continually encouraged to work together for the mutual benefit of themselves and the company. Examples of this are quality circles, consensus management and group problem-solving. The benefits of increased teamwork include:

- improved industrial relations
- less need for explicit controls
- improved productivity
- decision-making with full knowledge of the facts
- quick implementation of new ideas and products
- reduced dependence on individuals to guarantee the success of the company
- willingness to disclose problems and seek solutions

1.2.7 Improved Industrial/Labour Relations

The JIT philosophy, will its respect for people and its promotion of consensus management, has encouraged company unions rather than national trade unions. The principal benefits of having company unions are in the area of industrial/labour relations. Such benefits include few strikes or work stoppages, consultation and bargaining with the interests of the particular company and its employees in mind and fewer restrictive work practices.

1.2.8 Innovation Amongst Workers

Education, respect for people, consensus management and group problem-solving are all JIT concepts that encourage innovation. The latent creative potential of all employees is developed, and their ideas discussed and implemented whenever possible. Group problem-solving sessions usually include the use of techniques such as brainstorming, resulting in innovative ways of solving problems to the benefit of both employer and employees.

1.2.9 Increased Worker and Equipment Efficiency

Levelled production, valid plans, group technology, flexibility, quick set-ups, multi-skilled workers, total preventive maintenance, etc. all help to ensure high labour and equipment utilisation and greater efficiency. This ensures that the company remains competitive. High equipment utilisation and efficiency motivates capital investment in equipment, since pay-backs/ internal rates of return (IRR's) are good.

1.2.10 Reduced Raw Material Inventory Level

JIT purchasing policy ensures that raw materials are delivered in just the right quantities at just the right time, thus virtually eliminating buffer inventories. The benefits of this reduced raw material inventory level include high stock turn ratios, reduced storage and less working capital tied up in raw materials, all of which increase profitability.

1.2.11 Less Work-in-Process

Streamlined process design, group technology, small batch sizes and Kanban all help to reduce work-in-process (WIP) inventories. The benefits of reduced WIP include reduced storage space, less capital tied up in WIP, quick exposure and resolution of quality problems and worker motivation, stemming from the high visibility of their workmanship.

1.2.12 Reduced Finished Goods Inventory Levels

An aim of JIT is to produce the finished product just-in-time for when it is required by the customer. Products are thus not made to stock in large quantities and finished goods inventory levels are kept low. The benefits of low finished goods inventory levels include reduced storage space, less capital tied up in finished goods inventories (the most valuable inventories), less risk of holding redundant stock in a falling market and less risk of holding stocks, such as medicines, which have exceeded the stated shelf-life/expiry date.

1.2.13 Space Savings

Reduced raw material, work-in-process and finished goods inventory levels will result in space savings, for a given factory output. The benefit of these space savings is reduced fixed overhead, which improves profitability.

1.2.14 Reduced Machine Downtime

The introduction of Total Preventive Maintenance (TPM) reduces machine downtime due to breakdowns. This, together with minimum set-up times, ensures maximum machine utilisation. The benefits of this are improved productivity and more attractive returns on investment in equipment.

1.2.15 Quicker Factory Response Times

The whole JIT philosophy helps to minimise production lead times, whilst increasing flexibility. The result is quicker factory response times, which enable production to respond quickly to changes in product demand. For example a pharmaceutical manufacturer producing cough and cold remedies is faced with a winter peak in production, the date of onset which varies from year to year. To avoid risking being out of stock, the manufacturer builds-up large buffer finished goods inventories in autumn. Such large finished goods inventory holdings are costly and are only necessary if the factory cannot respond quickly enough to rising demand.

1.2.16 Improved Supplier Performance

Due to supplier involvement and education the supplier becomes a "co-maker" with the manufacturer. The benefits of this include on-time deliveries of small lot sizes, predictable quality which reduces in-house inspection and shortened lead times.

1.2.17 Less Expediting

Negotiated long term purchasing agreements are a feature of JIT. This together with supplier education and involvement, as well as providing order horizons, demonstrates a commitment to the supplier on the part of the manufacturer. In return the supplier delivers on time, more often than not in the absence of expediting. Expediting is costly in terms of time and money, so less expediting frees up time for other purchasing functions and saves costs such as telephone calls, telexes, etc.

1.2.18 Improved Customer Service/Reduced Stock-outs

The JIT concepts of built in quality, streamlined process design, quick set-ups, total preventive maintenance, etc. all help to ensure consistent product quality and short manufacturing lead times. A benefit of this is improved customer service/reduced stock-outs, in spite of reduced inventory buffers.

1.2.19 Improved Productivity

The overriding benefit of JIT is improved productivity. JIT aims to ensure the most efficient use of labour and machines. Non-production elements of product such as queues, quality inspection delays, machine downtime, set-up delays, etc. are reduced or eliminated whenever possible. The benefit is the production of goods/services to the right quality at the right time, having incurred the minimum costs in terms of labour, overhead and materials.

1.3 IMPLEMENTING JIT IN SOUTH AFRICA

1.3.1 Adapting JIT for South Africa

There is a widely held belief that JIT has developed and succeeded in Japan, because of the Japanese culture. Furthermore, "Some managers argue that Japanese success is primarily due to the supportive government policy, to low cost financing, friendly unions and exchange rate advantages. They blame the decline of productivity in South Africa on aspects such as excessive tax, the size of the South African Civil Service, government regulations, politics, cultural differences and low education. Yet there seems to be a growing consensus amongst experts that the Japanese managerial practices hold the key to the country's success. Granting that Japanese management practices are a key to Japan's success, a lingering question still remains unanswered. Can or should South Africans emulate the Japanese experience - could it lead to revival of South African competitiveness internationally?" (3)

In reality these beliefs are based on misconceptions. The JIT philosophy as practiced by Japanese management is not based on culture, government support, etc., but on the attitudes of management and workers alike. It took the Japanese approximately 20 years to develop and implement JIT, largely because people's attitudes had to be changed through education and training. In view of South Africa's poor productivity it is clear that attitudes must likewise change in that country. However, a realistic approach is required, bearing in mind South Africa's socio-economic position and the broad scope of JIT. To an extent JIT must be "South Africanised" if it is to succeed. Furthermore, the most practical aspects of JIT must be identified and adopted, rather than attempting to emulate Japanese JIT in its entirety.

The need to "South Africanise" JIT stems largely from differences in management philosophy. The Japanese tend to view companies as human communities which serve the interests of their members, namely employees, managers, shareholders and the public.

1.3.1 Adapting JIT for South Africa (Cont'd)

Profits are important but secondary to the social purpose of the business, an attitude which engenders a common sense of purpose amongst all employees. In contrast, South African managers tend to serve the profit motives of their shareholders, with the interests of employees and the public of secondary importance. The result is a more exploitive attitude towards employees. Another major difference is that the Japanese managers, unlike their South African counterparts, view employees as being as intelligent and responsible as they are. Finally, Japanese managers tend to view groups as superior to individuals in solving problems. In contrast South African managers tend to rely on individual effort and initiative. These management attitudes, coupled with historical and geographical differences, have resulted in different attitudes amongst the working populace in the two countries.

JIT can be adopted in South Africa by a combination of changing local attitudes and adapting JIT concepts. Companies in relatively stable and dominant industrial positions, such as the majority of pharmaceutical manufacturers, can more easily adopt JIT than those in weak and unstable positions. Indeed many pharmaceutical manufacturers have already developed some of the necessary management and worker attitudes to implement JIT, largely because of their industrial positions and because of international connections and the influence of the Sullivan Code*, etc. "Lifetime" employment and major investment in education and training are the two most prevalent employment practices. In contrast, struggling companies tend not to look beyond current operational results, and attitudinal changes are unlikely.

Not all JIT concepts require adaptation or changes in local attitudes for implementation. Technically orientated concepts such as total quality control, minimum set-up times and total preventive maintenance can be implemented without much resistance.

* A U.S. code of practice for U.S. subsidiaries operating in South Africa which covers employment ethics.

1.3.2 Engendering New Attitudes

As outlined above the successful implementation of much of the JIT philosophy in South Africa is dependent on changing local attitudes, which requires education. The first step in this process is to identify likely attitudes towards a new philosophy such as JIT. Such attitudes are likely to comprise:

- resistance to change, based on fears that past experience and knowledge will be discounted, job security will be threatened, coping with new challenges will be difficult, etc.
- mistrust of management motives
- cynicism in the form of "we have heard it all before" or "not another stupid idea"
- opposition to education and unwillingness to undergo re-training
- fear of participating in group problem-solving
- beliefs that bad suppliers, machine breakdowns, rejects, scrap and long machine set-ups are unalterable facts of life.

The next step is to start an education programme for all employees, with the specific initial objective of supplanting the above attitudes with the JIT philosophy.

This initial engendering of new attitudes must be followed up by further education during the JIT implementation steps covered in 1.3.4 below.

1.3.3 Identifying Key Practical Elements

In order to implement JIT, one must identify a manageable project, both in terms of size/scope and its ability to interface with other prevailing systems. In South Africa some elements of JIT are more obviously practical than others, and some elements are more suited to easy adoption by certain industries than others.

1.3.3 Identifying Key Practical Elements (Cont'd)

Key practical elements that can be adopted by the pharmaceutical industry are outlined below.

Total Quality Control (TQC) is the logical next development from the prevailing traditional sampling techniques in the industry. Because of the prime importance of quality control in the industry the calibre of person employed in Q.C. departments is high, which greatly assists in successfully implementing TQC. Allied to TQC is the JIT concept of **Housekeeping,** a logical broadening of the traditional pharmaceutical hygiene practices. Employee awareness and participation is essential in the maintenance of quality standards in the industry. This can be achieved through **Group Problem Solving.**

In terms of **Just-in-Time Production** the key practical elements are:

- **Minimising Inventories** through **small batch sizes, group technology** and using JIT in conjunction with Manufacturing Resource Planning (MRP II).

- **Valid Plans** through improved forecasting, **uniform plant load/levelling** and proper scheduling, all in conjunction with MRP II.

- **Minimum Set-up times, Streamlined Process Design, Flexibility and Versatility** and **Preventive Maintenance** to achieve improved production lead times and maximum facilities utilisation.

- **Respect for People** and **Consensus Management/Worker Participation** in all aspects of the business.

Supplier Involvement and Education incorporating on-time deliveries, predictable supplier quality and negotiated long term contracts is the key practical JIT element for purchasing departments.

These practical JIT elements can be combined to form a Total Production System for the Pharmaceutical Industry as shown in figure 1.6.

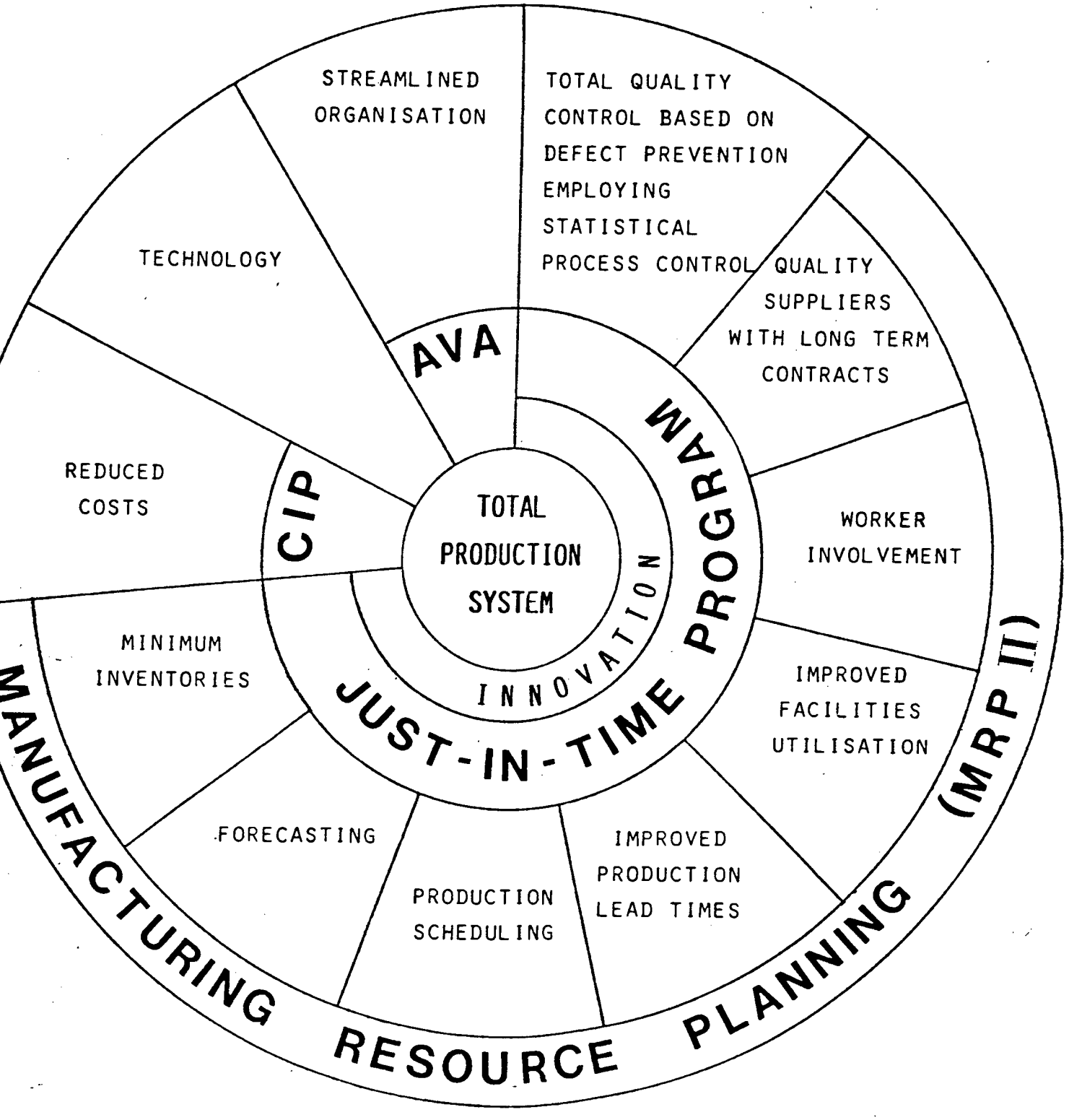

STREAMLINED ORGANISATION
TOTAL QUALITY CONTROL BASED ON DEFECT PREVENTION EMPLOYING STATISTICAL PROCESS CONTROL
QUALITY SUPPLIERS WITH LONG TERM CONTRACTS
WORKER INVOLVEMENT
IMPROVED FACILITIES UTILISATION
IMPROVED PRODUCTION LEAD TIMES
PRODUCTION SCHEDULING
FORECASTING
MINIMUM INVENTORIES
REDUCED COSTS
TECHNOLOGY
AVA
CIP
TOTAL PRODUCTION SYSTEM
INNOVATION
JUST-IN-TIME PROGRAM
MANUFACTURING RESOURCE PLANNING (MRP II)

Figure 1.6

1.3.4 Implementation Steps

To succeed JIT implementation in South Africa must be broken down into manageable elements and goals, as identified below.

(i) JIT requires the **full commitment** of management, starting with the chief executive officer/managing director, who must launch and oversee the project with the necessary commitment and involvement.

(ii) **Executive understanding** of JIT must be established, both in terms of the sweeping changes that JIT will bring and the time and effort that must be expended by all employees.

(iii) **Project justification** is a key element, without which the project will not be taken seriously, particularly if measureable goals are not included in the justification. The project should be justified in terms of key elements, tailored to the particular company. Goals should be set against these key elements, for example:

- raw materials inventory levels to be reduced by ....%, resulting in savings of R.....
- machine set-up times to be reduced by ....%, resulting in savings of R.....

(iv) The appointment of a **Project Leader** early on in the implementation period is essential. This individual must be motivated to act as a "disciple" or "champion" of JIT. The JIT implementation project is very time consuming and this appointment must be accompanied by the necessary executive acceptance and understanding.

1.3.4 Implementation Steps(Cont'd)

(v) A programme of **Communication, Education and Training** must be established to inform employees about JIT, motivate them to implement it and promote the necessary attitudinal changes. Such a programme should include audiovisual presentations, seminars, circulation of literature and a propaganda campaign to promote JIT.

(vi) **Multi-disciplinary Project Teams/Task Forces** should be established to tackle the previously identified key elements. Such teams should make regular presentations to a steering committee, chaired by the project leader.

(vii) **Progress Checks** must be made against the original project justification, particularly to determine whether or not the original goals remain valid after the involvement of employees in the project.

(viii) A **Total Project Plan** should be derived once some progress has been made with the individual key elements. This project plan should identify project constraints, capital expenditure requirements and required organisational changes.

(ix) Further **Detailed In-house Education Programmes** must be instituted to provide education in statistics and techniques such as brainstorming, Pareto analysis, "fishbone" analysis, etc. This is an on-going programme of education, involving small groups of employees (preferably less than 10) at a time. This education is required to implement the more sophisticated aspects of Total Quality Control and Group Problem Solving.

(x) **Current Performance** of the JIT project should be measured on an on-going basis.

1.3.4 Implementation Steps (Cont'd)

(xi) **New goals** should be set as the original goals are achieved.

These implementation steps are most likely to succeed if:

- A pilot approach to JIT is adopted rather than trying to implement a total project.
- All employees fully understand the principles of JIT.
- Initial projects are set for areas with the highest calibre people.
- The project is commenced as soon as possible and momentum is maintained.
- Progress is attempted through continuous small achievements, rather than large steps.

1.3.5 Potential Pitfalls in Implementing JIT

Despite JIT being a relatively new concept in South Africa, one can already learn from the mistakes of others and avoid potential pitfalls. The most common pitfalls are:

(i) Insufficient management commitment, involvement and leadership.

(ii) Sub-contracting the project to outside consultants, who do not have the necessary involvement, knowledge of the workers and processes, etc.

(iii) A lack of understanding of JIT and insufficient education. Any skimping on JIT education will cause implementation to fail.

(iv) Making JIT more complicated than necessary - its success depends on keeping it simple.

(v) Insufficient project management - the project must be professionaly managed with a well planned, tight, implementation schedule.

1.3.5 Potential Pitfalls in Implementing JIT (Cont'd)

(vi) Low enthusiasm - employees must be continuously motivated to achieve JIT successes.

(vii) Seeking instant perfection - the best results are achieved in discrete progressive steps.

(viii) Insufficient advertising of successes - in JIT as in so many things success breeds success.

(ix) Too much "crisis management", the antithesis of JIT management - "crisis managers" must be educated or moved if this fails.

(x) Not practising what one preaches. For example it is a mistake to try to get suppliers to implement JIT production when one has not achieved success oneself. Efforts should initially be confined to JIT delivery.

(xi) Failing to reduce the supplier base and thereby improve supplier performance.

This list is not exhaustive but contains the most likely pitfalls.

CHAPTER TWO

THE TOTAL QUALITY CONTROL CONCEPT

2.1 THE TOTAL QUALITY CONTROL CONCEPT

2.1.1 The Two Basic Approaches to Quality

There are two basic approaches to quality in manufacturing, namely:

- The **Acceptable Quality Level (AQL)** approach which implies that defects are acceptable as long as the number and severity are within prescribed limits. It is implicit in this acceptance of imperfections that defects are unavoidable unless large costs are incurred.

- The **Total Quality Control (TQC)/Zero Defects (ZD)** approach wherein all products conform to established specifications. The approach implies that "zero defects" is consistently achievable. The aim is to prevent defects.

The two basic approaches are discussed in detail below.

2.1.2 Acceptable Quality Level (AQL)/Defect Detection

The traditional approach of defect detection is associated with AQL. It is a process of detecting products with defects by a separate Quality Control (Q.C.) inspector, usually at the end of the manufacturing process. Detected defective products are either reworked/repaired by persons other than the Q.C. inspector or rejected as scrap by the Q.C. department. However, products containing defects may be acceptable, depending on prescribed limits and the efficacy of inspection.

This approach to quality is widely accepted because the combination of "total" quality and low prices seems impossible to many top managers. Almost invariably they regard quality as "goodness" and something which has "trade-offs". Too often quality is thought of as a measure of reliability, performance or durability that costs money to build into a product.

2.1.2 Acceptable Quality Level (AQL)/Defect Detection (Cont'd)

Such views indicate an ignorance of the true cost of defects. The true cost of defects such as inspection, reworking, scrap, production delays, warranty repairs, customer dissatisfaction and administration probably runs at between 15 and 20 percent in most companies.

Unfortunately many managers see the solution to quality problems to be an increase in Q.C. inspectors, which increases the efficiency of inspection, but does nothing to control the source of defects. The JIT approach is to control and then eliminate the source of defects.

Clearly the pharmaceutical industry cannot allow defective products to enter the market place. While attempts are made to plan the product and its manufacture to achieve the specified quality, the pharmaceutical industry still relies heavily on Q.C. inspection. The result is that entire batches are sometimes rejected, when the TQC concept would have ensured that the problem was quickly located at source and rectified.

2.1.3 Total Quality Control (TQC)/Zero Defects (Z.D.)/Defect Prevention

The Total Quality Control (TQC) system comprises a number of overlapping components including:

- **Quality at Source** - a means of preventing defects by ensuring that the system/ process is designed to build the product correctly the first time.

- **Successive In-Station Inspection** - the use of production workers as inspectors to detect defects, correct them without delay and ensure that they do not re-occur. Inspection takes place at each stage of manufacture and not just at the end.

2.1.3 Total Quality Control (TQC)/Zero Defects (Z.D.)/Defect Prevention (Cont'd)

- **Statistical Methods** - a scientific way of detecting actual and potential out-of-control processes. Defects are statistically analysed and processes are statistically controlled, thereby anticipating potential defects and enabling corrective action to be taken to prevent defects.

- **Group Problem-solving/Q.C. Circles** - the involvement of employees in groups/teams to solve problems and make suggestions for improving quality and production methods.

- **Housekeeping/Preventive Maintenance** - making production workers responsible for the cleanliness, orderliness and minor maintenance of their machines and immediate environs.

- **Quality Assurance** - overseeing and reviewing the entire process of manufacturing and distribution to determine the conformity of all products to specifications.

- **Supplier Quality Programme** - assuring that suppliers' quality systems are resulting in defect prevention and the supply of final products that meet the purchaser's specifications.

- **In-House Quality Control Programme** - the organisation and execution of quality control with the factory.

- **Quality Awareness** - education, training and propaganda campaigns to make all employees aware of the importance of TQC.

The TQC system is based on Defect Prevention and aims to achieve Zero Defects. This represents positive attitudes, namely:

- Defects can be prevented.

- Operators and machines are capable of achieving Zero Defects production.

- Workers can be trusted.

2.1.3 Total Quality Control (TQC)/Zero Defects (Z.D.)/Defect Prevention (Cont'd)

It is important to note that TQC applies to systems and not just products. The whole production process can benefit from the following advantages of using TQC:

- Quality is built into the product, not inspected into the product.
- The causes of defects are eliminated as soon after detection as possible and recurrence is prevented.
- The achievement of control over all activities at detailed level.
- Recognition of conformance to specifications as the only measure of acceptable quality - only "zero defects" is acceptable.
- Savings due to reduced inspection.
- Reduced reworking and scrap costs.
- Lower materials handling and administrative costs.
- Increased productivity through quality, with reduced costs and improved employee morale.

2.1.4 The Essential Requirements for a Successful Total Quality Control Programme

Industrialists around the world wonder how the Japanese achieved their dramatic turnaround in quality. "One authority, Kaoru Ishikawa, says that, "To practice quality control is to develop, design, produce, and service a quality product which is most economical, most useful, and always satisfactory to the customer. Q.C. begins with and ends with education. It is an acquired taste, and a chief executive officer can appreciate its flavour only after taking active leadership in its implementation. It took ten years for Q.C. education in Japan to show results, for quality to improve, and for productivity to rise .... Q.C. is not a magic formula.

2.1.4 The Essentials Requirements for a Successful Total Quality Control Programme (Cont'd)

It is a disciplined approach that requires overcoming many bad habits and adopting new ways of thinking and doing things". (10) To emulate this success is clearly a major task, but one which will be made much easier if we learn from the Japanese "cornerstone" of TQC success. This "cornerstone" is shown in figure 2.1

THE

TOTAL QUALITY CONTROL

"CORNERSTONE"

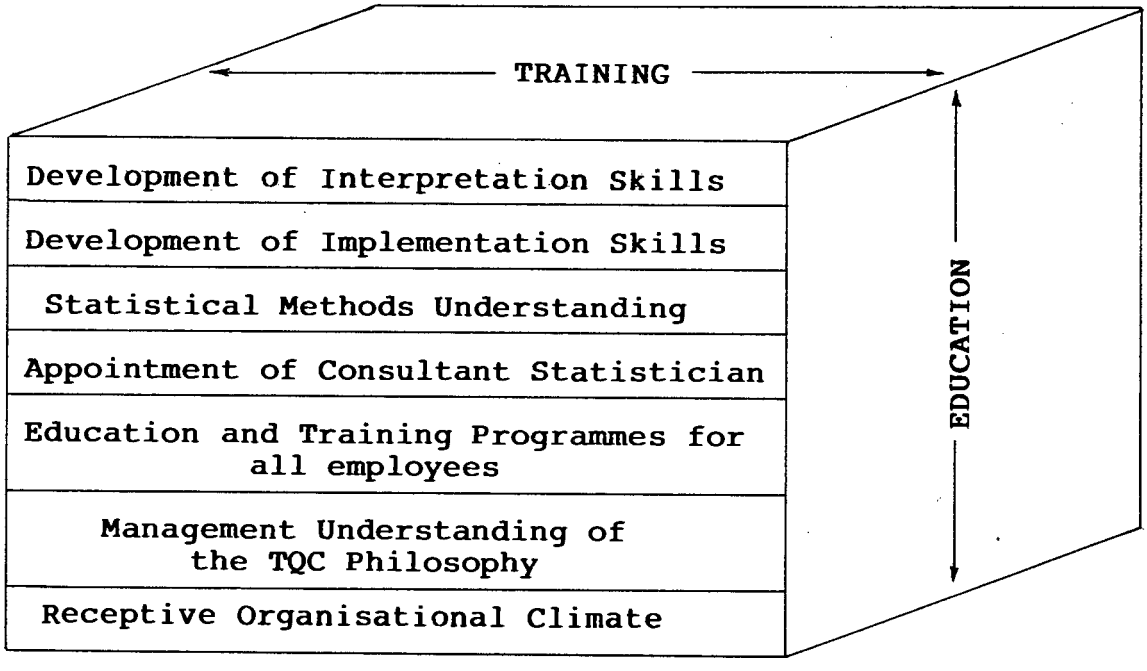


Figure 2.1

2.1.4 The Essentials Requirements for a Successful Total Quality Control Programme (Cont'd)

A Receptive Organisational Climate is the basic foundation, upon which the strength of all the other elements of TQC depend. To create a receptive organisational climate it is important to:

- Develop management commitment, involvement and leadership.
- Devise an overall corporate TQC plan.
- Create consistency of purpose towards quality improvement.
- Eliminate fear/resistance to change.
- Break down departmental barriers and encourage all to work as a team.
- Eliminate all numerical goals, work standards, posters and slogans, unless comprehensible to all employees and backed with easily understood methods.
- Ensure that a management structure exists that will further the TQC philosophy day by day.

Management Understanding of the TQC Philosophy is essential as the attitude to quality within the company stems from the top. Without management understanding, there will be no commitment, and without commitment there will be no involvement, leadership and motivation on the part of management.

Education and Training Programmes for All Employees promotes knowledge and understanding, but it is important to note that "what we provide as 'formal' education is less than a third of the total educational effort. Education does not end with assembling workers to receive formal instruction. At best, this instruction can only represent a small portion of their total education. It is the responsibility of the boss to teach his subordinates through actual work. In addition, he must learn to delegate authority to his subordinates.

2.1.4 The Essentials Requirements for a Successful Total Quality Control Programme (Cont'd)

What he must do is provide general guidelines and then let the subordinates work voluntarily. In this way, people will grow". (11)

The **Appointment of a Consultant Statistician** is necessary to provide instruction and leadership in implementing a statistical methods programme for process control and analysis.

Statistical Methods Understanding is vital as such methods are used and interpreted by workers in controlling and analysing processes. The **Development of Implementation and Interpretation Skills** in the workforce, is an essential prerequisite for delegating such responsibility.

Having established a TQC system based on the above "cornerstone", it is essential to validate the system by asking the questions listed in figure 2.2 and ensuring that the adjacent answers are fulfilled.

TQC SYSTEM VALIDATION

QUESTIONS AND ANSWERS

QUESTION	ANSWER
1. Can the product be made without defects?	YES, if: The product is always planned, developed and specified from Research through to Production and a full process capability analysis is undertaken.
2. Is the product being made correctly?	YES, if: Process control monitoring is in place and working at all stages of manufacturing.
3. Has the final product been made correctly?	YES, if: Quality Assurance is determining the conformity of all products to specifications.
4. Could the product be made better?	PROBABLY, if: The company is committed to the JIT concepts of • Streamlining Process Design • Quality at Source • Worker Participation • Quality Circles • Group Problem-solving • Group Technology, etc. and accepts the innovation that is developed.

Figure 2.2

2.2 PLANNING THE PRODUCT AND ITS MANUFACTURE

2.2.1 New Product Development

There needs to be a two-way flow of information between Product Development and Manufacturing to establish new product specifications and manufacturing feasibility that will result in a "zero defects" quality product. This two-way flow of information must ensure that:

- The quality relationship of each component to another is emphasised throughout the development process.
- The product is designed and specified with the manufacturing process capabilities in mind.
- The product designs and specifications are reviewed by all relevant departments such as manufacturing, purchasing/ suppliers, quality assurance, etc.
- Prototypes are produced for review by all concerned.
- Pre-product versions of the product are produced under "real" production conditions for scrutiny by all the relevant departments.
- The product and the process of manufacture are "fool-proofed" to make it as easy as possible for the job to be done correctly, and as difficult as possible for it to go wrong.

The TQC approach to new product development in the pharmaceutical industry is illustrated in the flow diagram shown in figure 2.3

NEW PHARMACEUTICAL PRODUCT DEVELOPMENT

FLOW CHART

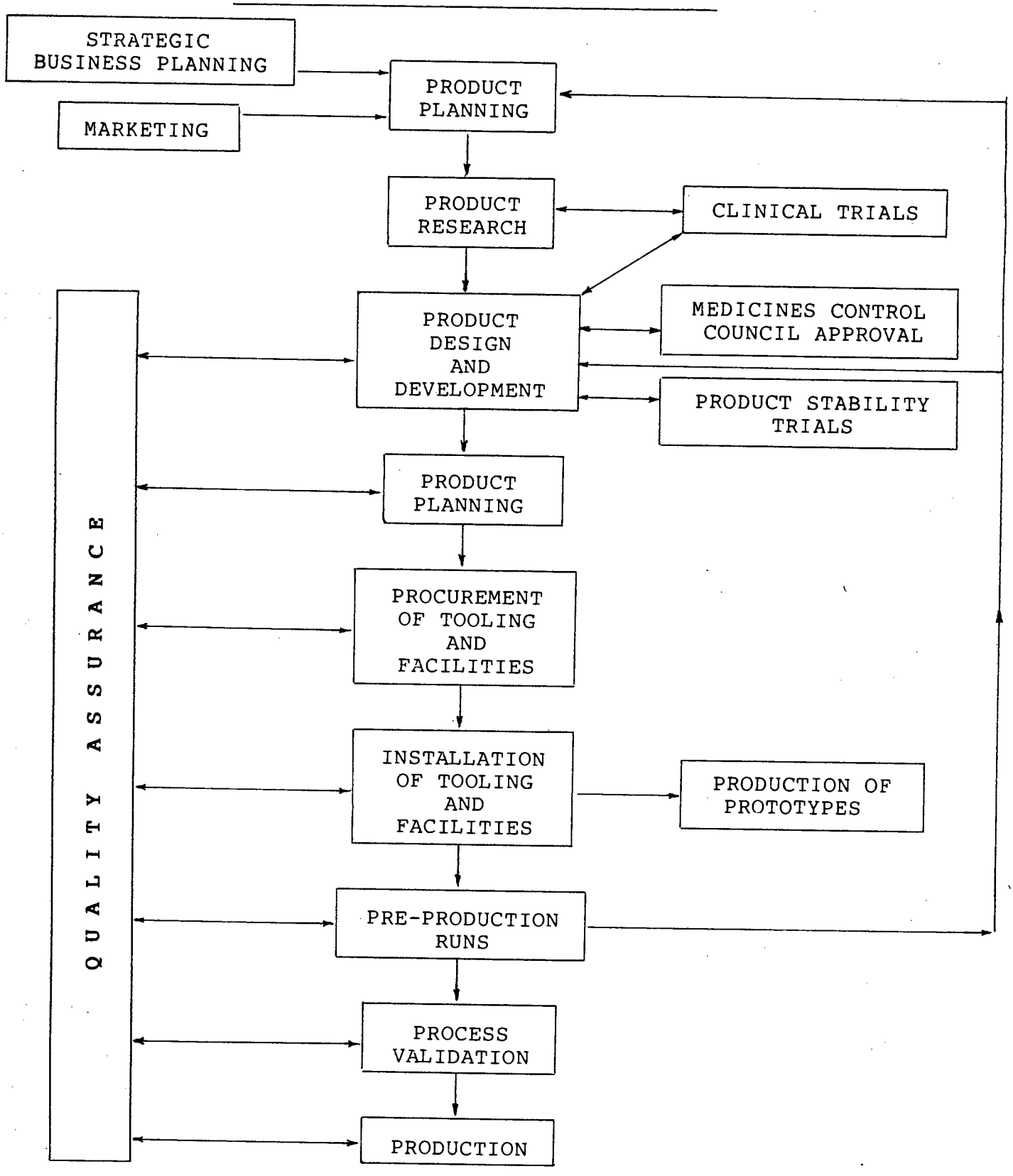


Figure 2.3

2.2.2 Specifications and Bills of Materials

Specifications and drawings represent the standards against which the quality of the product is judged - a defective product being one which does not comply with the specifications and drawings.

Specifications must be issued as separate documents from process instructions and must be clear and well-defined. It must be possible to measure specifications in a uniform manner to avoid confrontations and assure that quality products are produced. The measures of quality must be visible, simple and understandable by all, including the casual observer. The specification may also allow for automated measurements of quality, for example, tablet thickness and hardness in the pharmaceutical industry.

Periodically, it may be necessary to change specifications to improve the product or the ability to produce the product. A proper procedure must exist for establishing and implementing new and amended specifications.

In addition to developing specifications the new product development process must also develop product bills of materials. These bills of materials must be accurate, properly structured and up-to-date for effective TQC.

2.3 QUALITY AND THE EMPLOYEE

2.3.1 Successive and In-Station Inspection

One hundred percent inspection is a key element in the TQC system. This is made cost effective by either automating inspection or, more frequently, having the inspection operation performed by the production worker, rather than a separate non-production inspector. This changes the level of responsibility for inspection and rectifies some anomalies such as the frequent situation where a low paid inspector checks the work of a highly paid operator or machine setter.

Inspection by production workers must take place at all stages of manufacture if defects are to be detected as quickly as possible. There are two basic approaches:

- **Successive Inspection,** whereby a worker is required to inspect the work from the prior process, then perform his or her operation and finally transfer the component to the next process.

- **In-station Inspection,** whereby the worker performs his or her own operation and then inspects the work prior to transferring it to the next process.

In both cases it is important that:

(i) The process control procedure is used effectively.

(ii) 100% Inspection of each item at each process is performed, being brief and visual, automatic or with the use of an aid, such as a gauge or checking fixture.

(iii) Once a defect is detected, its cause must be corrected immediately, even to the point of shutting down the production line until it is corrected

(iv) A Q.C. inspector confirms that the process is back in control once the production worker has corrected the cause of the defect.

2.3.1 Successive and In-Station Inspection (Cont'd)

(v) A Q.C. inspector monitors, by sampling, the production worker's operation.

(vi) The production worker repairs defects whenever possible, rather than rejecting product as scrap.

2.3.2 Quality Control Circles

"A quality circle is a small group of people, usually between three and twelve, but normally eight, who do similar work, who meet regularly for about one hour per week or fortnight in company time, usually under the leadership of their foreman or supervisor, on a voluntary basis, to identify problems, analyse the causes, recommend the solutions to management and, where possible, to implement the solutions themselves". (11)

It is important to appreciate that quality circles are not a response to specific problems, unlike Group Problem-solving as discussed in 2.3.3, but a continuous study of the process. The initial assumption is that the causes of poor quality are not known and that process analysis is required to discover and remedy these causes. Clearly solutions found by quality circles and accepted by management will meet with little resistance to implementation.

Slavish copying of this Japanese concept of quality circles in South Africa is almost certainly doomed to failure. Even in the pharmaceutical industry, where production workers are relatively well-educated, motivated and quality conscious, there is likely to be a lack of enthusiasm for quality circles. To succeed quality circles require workers to be self-motivated, inclined to act collectively, educated in TQC and eager for improvement - attributes which are lacking in the early stages of JIT development, even in a sophisticated industry such as pharmaceutical manufacturing.

2.3.2 Quality Control Circles (Cont'd)

The best approach is to commence with Group Problem-solving of identified problems by multi-disciplinary teams including management participants, included for guidance and motivation. Management representation can be progressively withdrawn and replaced by production workers, thereby converting Group Problem-solving teams into Quality Circles.

2.3.3 Group Problem-solving

The idea of Group Problem-solving is to use multi-disciplinary teams of employees to solve specific problems, usually but not always quality related, using particular techniques. This JIT approach is based on the beliefs that groups solve problems better than individuals and that virtually all problems have assignable causes that may be rectified.

Group Problem-solving teams should preferably be multi-disciplinary, thereby assuring that technical assumptions are challenged by non-technical team members and vice versa. To avoid the risk of becoming "committees", with associated lack of results, the teams must follow defined problem-solving steps and employ particular techniques. The steps required in solving a typical pharmaceutical process control problem, such as tablet dissolution rate not meeting specifications (possibly due to granulation or compression problems), is shown in figure 2.4.

STEPS IN SOLVING A PHARMACEUTICAL PROCESS CONTROL PROBLEM

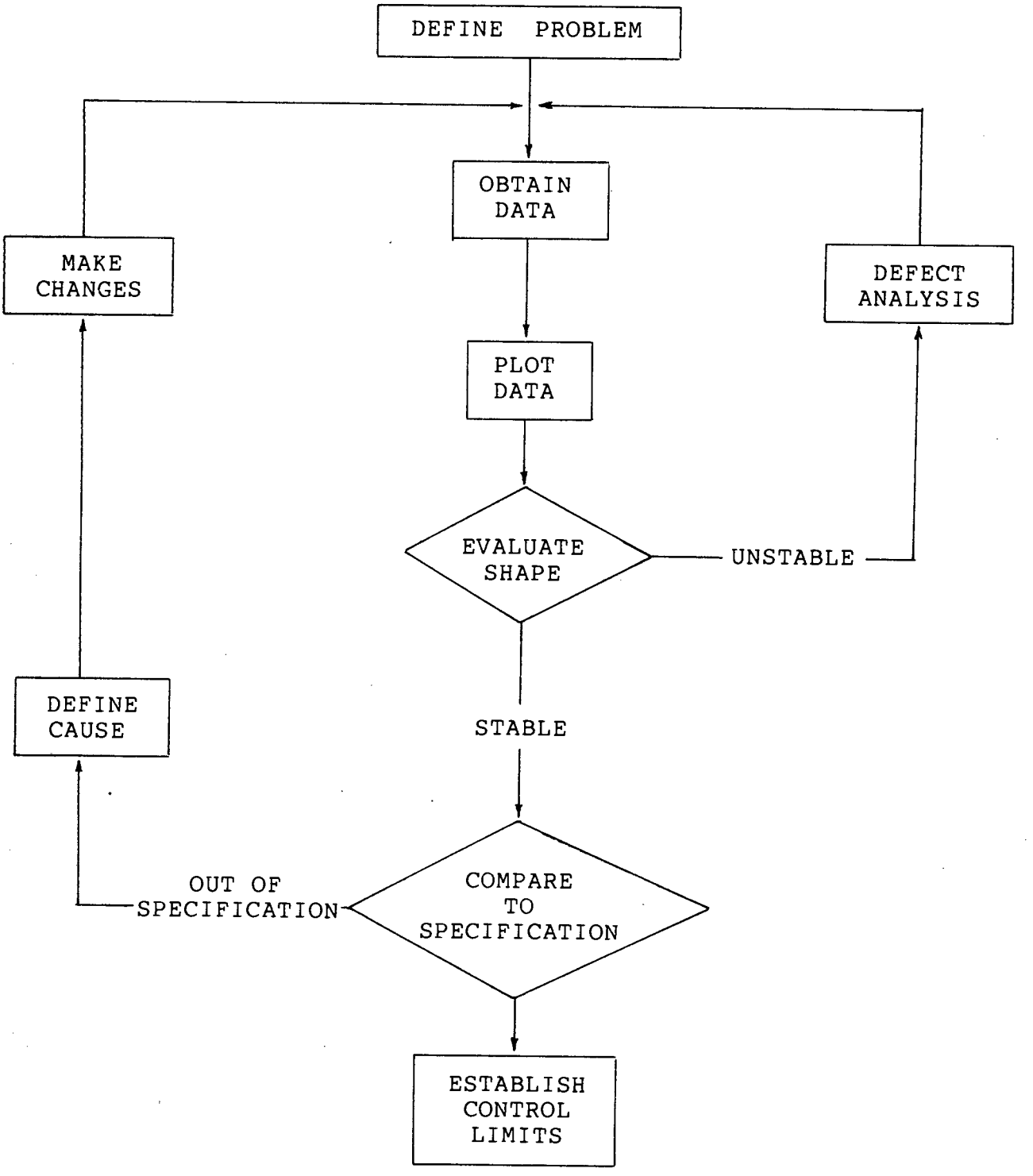


Figure 2.4

2.3.3 Group Problem-solving (Cont'd)

Amongst the uninitiated in JIT the approach to solving problems is to assign the task to individuals - a system which almost inevitably blames one person/machine for the problem. The result is a tendency to jump to a specific solution, whilst rarely getting to the root cause of the problem. Individuals seldom admit that a problem is their fault, which is often correct, as the problem is more frequently part of the system. It is therefore the system that needs to be changed, something that is far more likely to be achieved by a group than an individual.

The JIT approach through Group Problem-solving ensures that there is a logical problem-solving process which starts by determining the real problem, quantifying it whenever possible, determining the assignable causes and proposing the solution. Throughout the process the ability of a group of people to solve the problem is accepted as being superior to that of the individual. The tendency to go straight to the apparent cause of the problem is resisted by using a group of people and following the procedural steps of JIT problem-solving.

Defining the problem correctly is of paramount importance, particularly as the problem is not always what it appears to be on first inspection. This is illustrated by two examples found in pharmaceutical manufacturing.

1. A tablet press produces tablets that disintegrate too easily. The problem is initially defined as a mechanical fault on the machine which caused incorrect hardness setting. In reality the problem is in the powder granules, which are not the correct size to ensure proper binding during compression.

2. A new automatic cartoning machine produces cartons with flaps that are deformed and not tucked in correctly. The machine is blamed when in reality the carton supplier has not pre-broken the cartons sufficiently for use on an automatic machine.

2.3.3 Group Problem-solving (Cont'd)

Having defined the problem, it is important to define/develop the **objectives** of the problem-solving process. Without such a definition of objectives it will be difficult to determine when the problem has been properly solved.

Whenever possible, the problem must be quantified by obtaining data, plotting the data and evaluating the results.

In **obtaining data** it is important to unearth dormant data. Our society tends to be "data rich" but "information poor" - in other words we have a lot of data at our disposal which we fail to interpret. The answer is to **plot data** in the form of line graphs, histograms, etc., thereby revealing information about trends, process skews, etc.

The plotted data must be presented in simple, easily understood form to enable the team to **evaluate the shape** and determine whether the process is **stable** or **unstable.** A stable process shows consistency, but may or may not meet the specification. For example a tablet may be acceptable in terms of thickness if it is say 5mm thick, with a tolerance of $\pm$ 0,25. Plotting measured tablet thickness data might reveal the graphs shown in figure 2.5, depending on whether the data reveals stability or instability in the process.

TYPICAL GRAPHS OF TABLET THICKNESS DATA

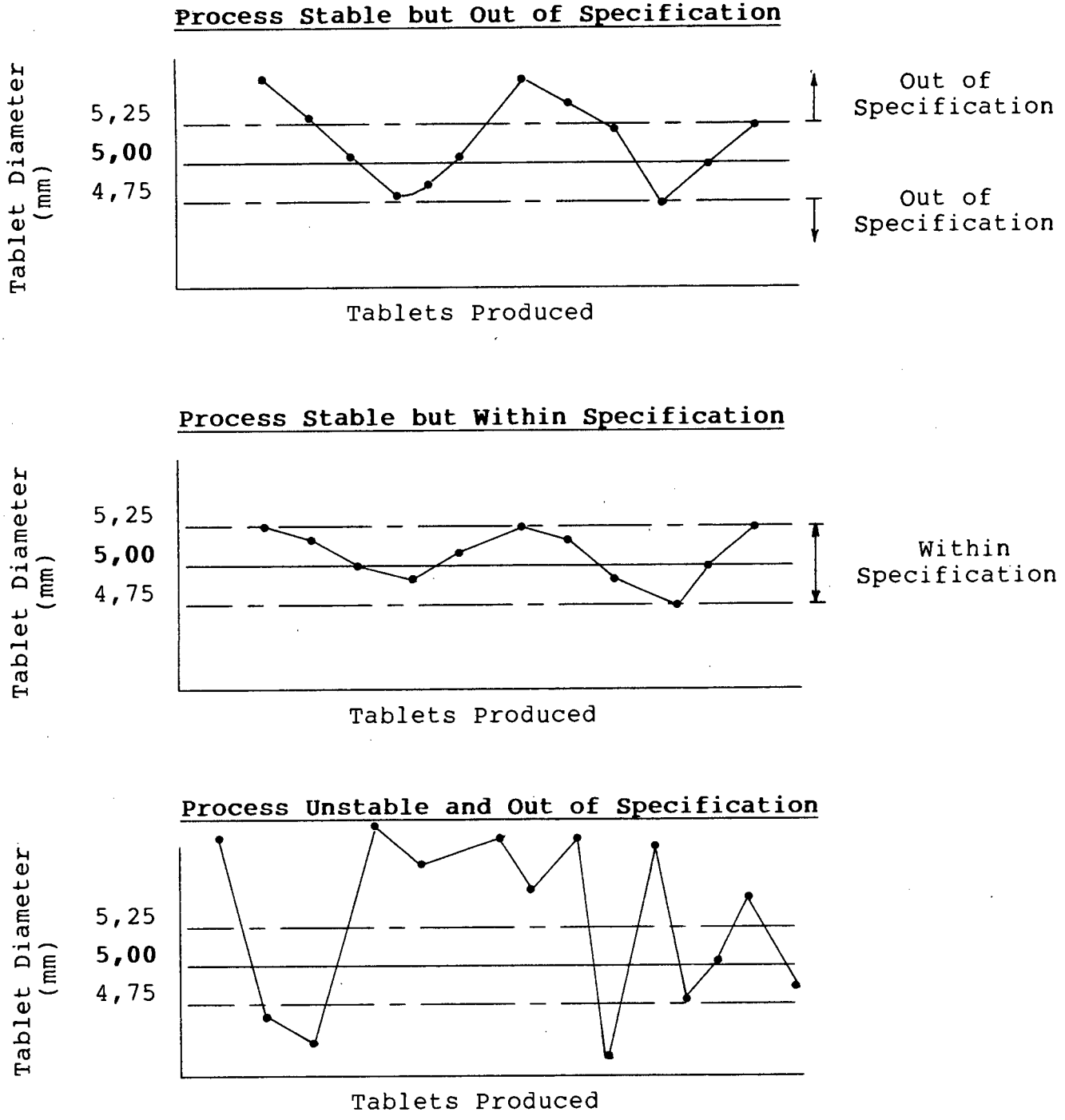


Figure 2.5

2.3.3 Group Problem-solving (Cont'd)

The plotted data is **compared to specification.** A stable process which produces product within specifications is the desired result. However, when the process is stable, but some product is out of specification it is clear that the process is potentially capable of producing product to specification.

The next step is to **define the cause** of the product being out of specification. In the case of the tablet thickness example, this could be wear on the tablet press affecting tolerances.

Having determined the cause of the non-compliance to specifications it is important to **make changes** and then repeat the data collection, plotting and evaluation process until such time as compliance with the specification is achieved.

If the evaluation of data reveals process instability (see Section 2.4.1) then one has to look further than "tolerance type" causes, as the process may not have the necessary capability. The correct approach is to undertake a structured **defect analysis.**

Defect analysis should commence with a "freewheeling" session of "brainstorming" to determine possible causes of defects. During this session no attempt should be made to analyse these possible causes. Instead they should be plotted on a "fishbone" diagram, as shown in figure 2.6.

The objective of using a "fishbone" diagram is to represent a meaningful relationship between an effect and its causes. There are usually four (or sometimes five) major types of causes - the "4 (5) M's" of

- **M**achinery
- **M**aterials
- **M**ethod
- **M**anpower
- (**M**iscellaneous)

2.3.3 Group Problem-solving (Cont'd)

Failure to relate to such basic causes, results in a tendency to blame individuals for causing the problem.

The essential requirements for constructing successful cause and effect diagrams are:

(i) Participation by everyone concerned - this will ensure that all ideas are considered.

(ii) No criticism - to encourage the free expression of ideas, criticism must not be permitted until after the diagram is completed.

(iii) Visibility - everyone in the group must be able to see the diagram easily, otherwise they will not participate fully.

(iv) Grouping of related causes.

(v) The diagram must not be overloaded.

(vi) Separate diagrams for separate problems.

(vii) The creation of a solution-orientated atmosphere - focus on solving problems rather than how they started.

(viii) Understanding each cause as it is mentioned, to ensure its proper placement in the diagram - ask the questions: Why; what; where; when and how.

CAUSE AND EFFECT/FISHBONE DIAGRAM

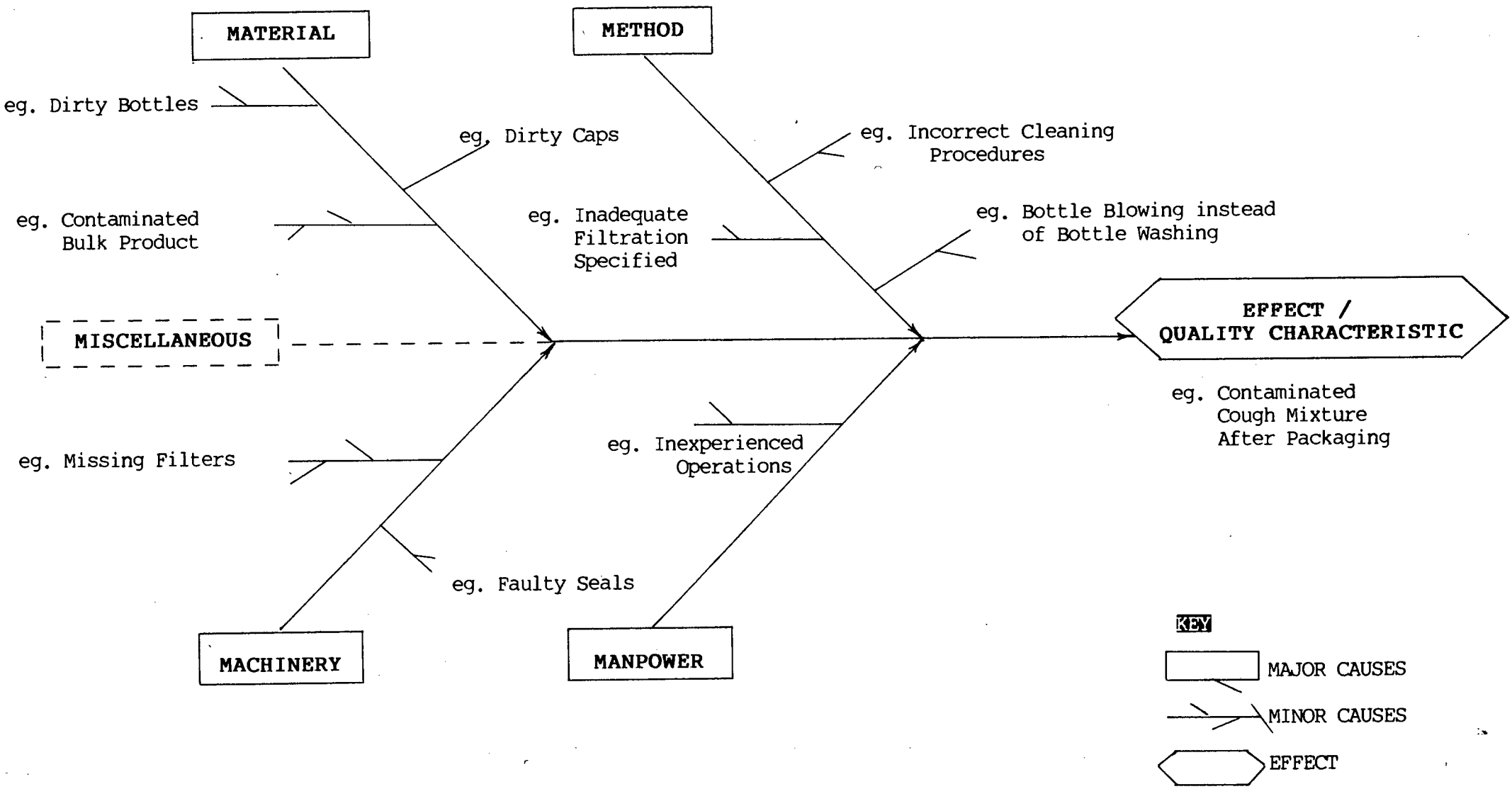


Figure 2.6

2.3.3 Group Problem-solving (Cont'd)

Having completed the diagram, the next step is to circle the most likely causes. The relative importance of each circled cause on the end effect should be estimated. If possible data should be obtained and plotted on a Pareto Diagram as shown in figure 2.7.

Pareto Diagram of Causes

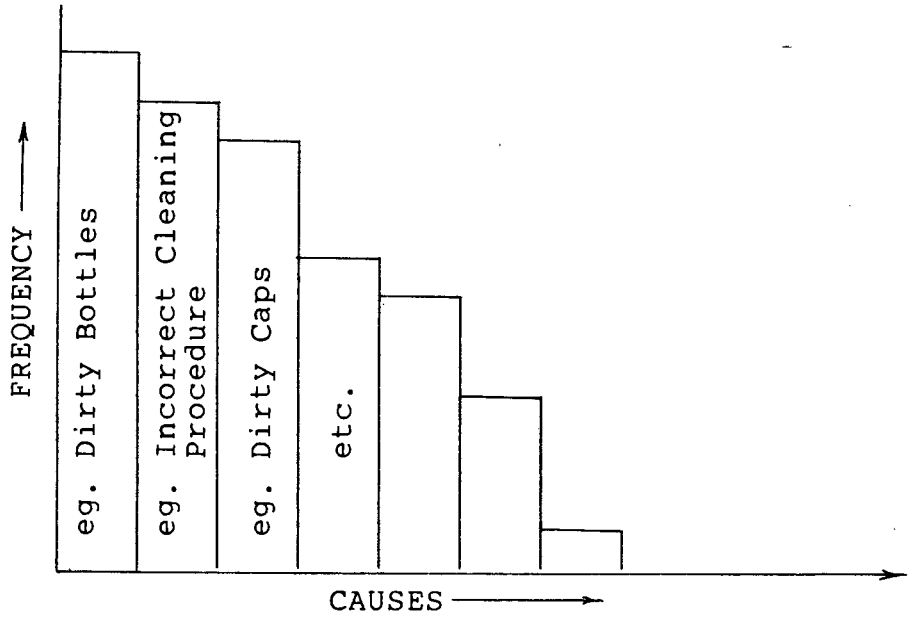


Figure 2.7

The causes are taken one at a time and worked on by the group to confirm or deny them. This approach avoids the tendency to go straight from the cause to a solution.

2.3.4 Housekeeping

Housekeeping in the JIT sense is a broad concept covering cleanliness, quality, safety and preventive maintenance, with specific reference to the production worker.

The production worker is made responsible for:

(i) Ensuring that his machinery and environs are kept clean.

(ii) Keeping his machinery and environs orderly and free from foreign materials, thus helping to ensure the quality of products.

(iii) Applying the safety motto of "A place for everything and everything in its place".

(iv) Undertaking minor preventive maintenance, such as oiling and greasing, thereby keeping machinery in peak condition for production.

Housekeeping in terms of cleanliness and quality, and to a lesser extent safety, has long been of paramount importance in the pharmaceutical industry. However, the concept of production workers participating in preventive maintenance is new, particularly in South Africa.

2.4 STATISTICAL PROCESS CONTROL AND ANALYSIS

2.4.1 The Role of Statistics in JIT

Statistical methods are used to monitor, control and analyse manufacturing processes. The role of statistics in JIT can be divided into:

- **Process Capability Analysis** which is conducted to determine if the manufacturing process is capable of satisfying design intent and verifying that the process output is within specifications.

2.4.1 The Role of Statistics in JIT (Cont'd)

- **Process Control** which is measured by plotting particular specified dimensions (eg. weight, thickness, hardness, etc.) for each part produced, or a pre-determined statistical sample, against established control limits (for example, as shown previously in figure 2.5).

- **Deviation Analysis** in which deviations from control limits and defects are analysed statistically, preferably using graphics, to determine the causes of deviation and the necessary corrective action required. It must be appreciated that statistics do not solve problems, they merely identify them and point managers and workers toward solutions.

  Detailed explanation and discussion of statistical techniques is beyond the scope of this thesis. Furthermore the application of statistical analysis has been covered in Section 2.3.3. The remainder of this section is therefore devoted to the applications of statistical control.

2.4.2 Statistical Control

The JIT concept of statistical control extends beyond the traditional inspection mode to include the use of data to plot trends and control the inherent capability of the process.

In the inspection mode, statistical methods are used to monitor manufacturing processes to determine whether the process is producing product within pre-determined specifications (in-control), or whether the process is producing product that deviates from specifications (out-of-control). At the heart of JIT is the necessity of having control over all processes to the extent that "zero defects" are achieved, i.e. all processes are in-control.

2.4.2 Statistical Control (Cont'd)

Graphical charts are used to plot process control data, the most useful being

- Average and range charts (X & R charts)
- Percent defective charts (P charts)
- Defects per unit charts (C charts)

Process control using data to plot trends is particularly useful because:

(i) Trends can be used to detect problems/changes before the process produces defective product, which provides the necessary time to take corrective action. A practical example of this is currently being implemented by a leading pharmaceutical manufacturer in South Africa with their tablet compression tooling. The production of dimensionally correct tablets is dependent on the tolerances of tablet compression punches and dies. Due to wear, the tolerances slowly become slacker. A micro-processor based digital measuring system has been installed for measuring compression tooling and producing statistics, including the plotting of trends. These trends are used to predict when tooling must be replaced in order to prevent the production of tablets which do not comply with dimension specifications.

(ii) Trends can be used to provide decision points which indicate when action must be taken. Too often unnecessary adjustments are made to a process based on limited unrepresentative data changes that would cause deterioration rather than the intended correction. As an example, process control of tablet thickness might reveal a trend which indicates a mean thickness greater than the specified mean. The tablet press should then be adjusted to produce tablets thinner by the difference between the actual and specified means, thereby achieving better process centering.

2.4.2 Statistical Control (Cont'd)

The recent trend in many industries, including the pharmaceutical industry, is towards the purchse of automated machinery which includes automated statistical process control. For example, a number of South African pharmaceutical manufacturers have sophisticated tablet presses which automatically monitor all tablets produced in terms of weight and thickness, reject tablets that are not within specification and adjust to compensate for trends, based on decision points. Furthermore, the operator is provided with full statistical data, including charts, on tablets produced.

2.5 QUALITY ASSURANCE

2.5.1 Quality Assurance Responsibilities

Under the JIT Total Quality Control (TQC) System, the Quality Assurance function must plan and be responsible for the overall effectiveness of the process control function, thereby ensuring that company wide activities produce and ship quality products.

Specific responsibilities comprise:

- Assuring process validation.
- Assuring quality products from suppliers.
- Assuring the final product is a quality product.
- Monitoring the quality control functions performed by production.
- Assuring that testing equipment such as gauges, scales, etc. is performing properly and effectively.
- Monitoring the quality control function of suppliers.
- Collecting, interpreting and publishing data on quality.
- Statistical process and quality control including the planning and operation thereof.
- Education and training in the use of statistics.
- Establishment of procedures.
- Compliance with quality rules and regulations.
- Quality audits.

2.5.1 Quality Assurance Responsibilities (Cont'd)

Of the above responsibilities, quality audits requires special mention, especially because of its importance to the pharmaceutical industry. Such audits should cover procedures, methods, inspection equipment and conformance to rules and regulations. Performance to plan is essential in a TQC system.

In the pharmaceutical industry such audits frequently take the form of challenging procedures. For example, an audit of a recall procedure would challenge the procedure to "recall" a "defective" batch of product by providing distribution details for the particular batch of the product. There is a trend in the South African Pharmaceutical industry towards computerising such recall procedures.

2.5.2 Awareness Programmes

An essential ingredient for the success of TQC is awareness of the importance of quality amongst all employees. While JIT in itself encourages awareness, it is nevertheless necessary for the Quality Assurance Department to provide on-going awareness programmes. Such programmes should include:

- Publicity of the company's quality policy statement.
- The development of company quality slogans such as:
  - "Get it right first time";
  - "You can't test quality into a product"
  - "Q.A. is a service department, not a control department";
  - "Only production departments can affect the quality of a product".
- Education and training.
- Publicity of quality results achieved.

As part of its awareness campaign, a South African pharmaceutical manufacturer has made an animated video on health and hygiene and their importance in terms of quality in the pharmaceutical industry. This video is shown to all employees.

2.6 THE IN-HOUSE QUALITY CONTROL PROGRAMME

2.6.1 Outline of Programme

In terms of the JIT approach of TQC, the Quality Control Function has responsibility for planning, issuing instructions, providing inspection services, quality assurance and measuring customer reaction to the product, in much the same way as traditionally practiced. However, in terms of the in-house programme there are two major differences:

(i) Most inspection operations are the responsibility of manufacturing and are performed by production workers.

(ii) The responsibility to produce quality products is spread throughout the organisation - it is not solely confined to the Quality Control Function.

In practice this means major changes in the areas of receiving inspection and in-process control, with the necessary education and implementation programme.

2.6.2 Receiving Inspection

Traditionally in the Pharmaceutical Industry all incoming raw materials and components are delivered through the Goods Inwards Department to a quarantine store, where they remain until inspected and approved for release to manufacturing by the Quality Control Function. The aim of JIT is to reduce delays by changing this receiving inspection as follows:

(i) Supplier raw material and components are delivered directly to the production line where possible. In all such cases the supplier certifies that the shipment comprises quality approved raw materials/components conforming to specification. There is no receiving inspection, except for periodic audits on selected samples from supplier shipments.

2.6.2 Receiving Inspection

(ii) When it is impractical to deliver certified supplier shipments directly to the production line, they are delivered through the Goods Inwards Department to the Warehouse without being quarantined for inspection. Again periodic audits are conducted.

(iii) Uncertified supplier shipments are subject to the traditional receiving inspection.

(iv) Materials and components which do not conform to specifications must be returned to the supplier or repaired at the supplier's expense. The supplier must take corrective action to ensure "zero defects".

To date the South African pharmaceutical industry has made little progress in moving away from traditional receiving inspection of all supplier shipments. The main reasons for this are the prevailing rules and regulations, lack of confidence in suppliers, the absence of a local focused factory network and fear of certified shipments being damaged or contaminated during transit, distances and hence risk being greater in South Africa than in say Japan. The one exception is a gradual acceptance by internationally owned pharmaceutical manufacturers in South Africa of certified shipments from overseas and local affiliates without receiving inspection.

2.6.3 In-process Control

Aspects of in-process control have been covered in Sections 2.3.3 and 2.4.2. To achieve successful in-process control, an education and implementation programme must be developed to ensure that in-house process control achieves the following objectives:

(i) Workers (or automated machines) must be able to determine immediately whether the process is producing good parts (in-control) or whether it is producing bad parts (out-of-control).

2.6.3 In-process Control (Cont'd)

(ii) The cause of the detected defect must be corrected immediately.

(iii) If not immediately correctible, the process should be stopped until corrective action can be taken.

(iv) Any defective product must be reworked or scrapped and must not be allowed to enter the production system.

This type of in-process control has long been practised in the South African pharmaceutical industry. Initially such in-process control was almost exclusively manual, but there is growing acceptance of automated process control. Some examples of both types of in-process control are outlined below.

2.6.3.1 Examples of Manual In-process Control:

- Tablets are sampled at regular intervals during compression on a tablet press. Hardness, thickness and friability measurements are taken by the operator who plots the data on control charts. Trends on such charts will indicate when corrective action, in the form of adjustments, should be taken to prevent the production of scrap.

- Blister-packaged tablets are visually checked for missing tablets prior to cartoning. On detecting a missing tablet the operator stops the blister-packaging machine, determines the cause of the defect (usually a tablet jammed in the feeding track) and takes corrective action prior to re-starting the machine.

2.6.3.2 Examples of Automated In-process Control:

- A blister-packaging machine is fitted with a missing tablet detection system which automatically rejects defective blisters. The machine is programmed to stop after detecting a pre-set number of defective blisters. The cause of the missing tablets is determined by the operator who takes corrective action prior to recommencing production.

2.6.3.2 Examples of Automated In-process Control: (Cont'd)

- Cartons leaving an automatic cartoner pass over a check-weighing machine which detects missing components within each carton. Again the machine rejects defects automatically as above.

- Automatic labelling machines are fitted with missing label detectors, bar-code readers and missing over-print detectors for automatic in-process control much as above.

2.7 QUALITY AND SUPPLIERS

2.7.1 The Role of Suppliers

Suppliers must be part of the TQC system to ensure that bought-out materials and components are within specifications. Suppliers should become an extension of the in-house TQC system and a co-operative and participating relationship with suppliers must be developed. This is achieved by:

- Involving potential suppliers early in the JIT programme.

- Reviewing potential suppliers to appraise their capability to meet quality criteria.

- Suppliers delivering in agreed small batches which has the effect on quality of:
  - shortening the response time for correcting quality problems
  - limiting material handling, storage and potential damage

- Negotiating long-term contracts, thus encouraging the supplier to make the necessary investments commensurate with producing quality products.

- Single sourcing of supplies with a view to establishing the necessary confidence in the supplier's ability to produce quality products.

- Assisting suppliers in implementing their own TQC systems.

JIT relationships with suppliers are dealt with further in Chapter 4.

CHAPTER THREE

THE
JUST - IN - TIME
PRODUCTION SYSTEM

3.1 APPLYING JIT IN THE FACTORY

3.1.1 An Overview

The application of the JIT philosophy with respect to quality, human relations, facilities utilisation, purchasing and the interface with Manufacturing Resource Planning (MRP II) is discussed extensively in other Chapters. The purpose of this Chapter is to discuss further the concepts which relate specifically to production scheduling and production control within the manufacturing area.

3.1.2 The Objectives of JIT In the Factory

JIT in the production area is intended to ensure that each process is supplied with material in the quantity and at the time required to meet production plans. JIT on the factory floor is designed to:

- Eliminate waste by preventing over-production in terms of
  - no more than is required
  - no earlier than is required
- Deliver material in a timely manner
  - at the required time
  - in the required quantity
  - at the required location
  - in the designated manner and container
- Replace only the material that has been used by the subsequent operation.
- Produce only what is required to meet the production line rate.
- Ensure zero variation to schedule.

3.1.3 Scheduling

Any manufacturing system will only succeed, particularly at the shop floor level, if it has the ability to issue firm production schedules far enough in advance to permit the timely ordering of materials and planning of production, both in-house and by the suppliers. A JIT scheduling system is designed to achieve this whilst remaining flexible enough to accept schedule changes, as long as the changes represent modifications as opposed to major alterations. The system is kept flexible by:

- Small frequent batch sizes
- Minimum set-up times
- Flexible and versatile machinery
- Multi-skilled/multi-function workers
- Limited inventories
- Simple and direct lines of communication

As discussed earlier, JIT scheduling makes for a rate based "pull" system, typically like "Kanban", rather than a "push" system. All subsequent scheduling of in-house and supplier components is generated by the final assembly schedule. As the end product assembly rolls off the line, a requirement is created to replace the parts that are contained in that assembly at each previous process working back to incoming components and raw materials.

3.1.4 Floor- scheduling and Control

The on-floor scheduling and control is achieved using a "Kanban" type system, usually comprising two circulating documents

- A **Production Authorisation** document to produce a specified quantity by a specified time.
- A **Delivery Authorisation** document to deliver a specified quantity by a specified time to a specified location.

3.1.4 Floor Scheduling and Control (Cont'd)

These documents usually take the following different forms:

- A **card** used in-house.
- An **electronically transmitted document** to the supplier.
- A **colour-keyed object** - useful in regions such as South Africa where illiteracy is high.

3.1.5 The Goal of Absolute JIT

Absolute JIT, like zero defects, may never be achieved in the factory. The one part replacing one part approach to JIT is impractical in most cases. Nevertheless, the theory is valuable because generally speaking the closer we can come to achieving absolute JIT, the more productive the operation.

The cost to set-up and run small batches must be weighed against the cost of maintaining an inventory, although of course reduced inventory is not the only benefit of small batch JIT production. This can be quantified by plotting charts of the type shown in figure 3.1. Such charts can be used to establish an economic batch size, or at least identify its approximate optimum size.

ESTABLISHING THE ECONOMIC BATCH SIZE

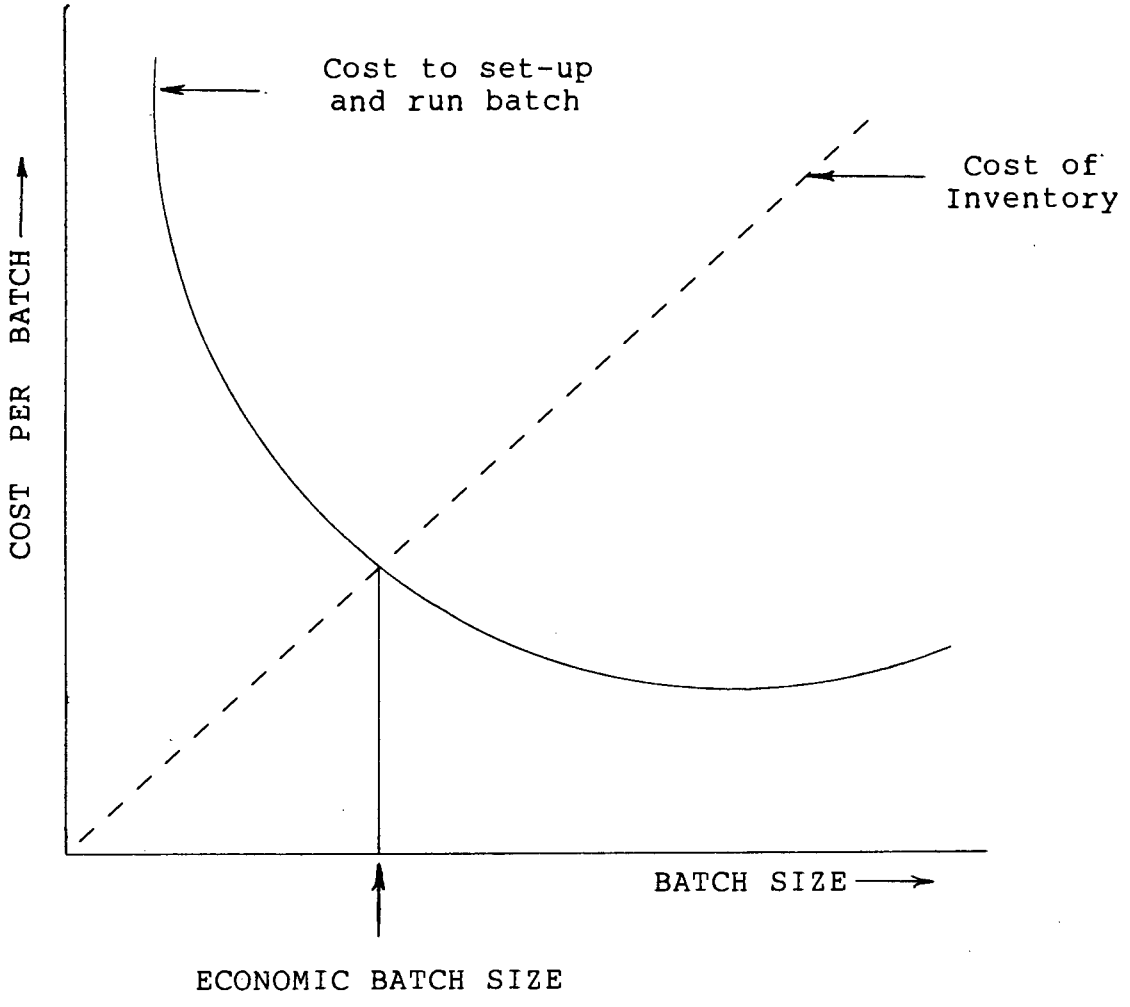


Figure 3.1

3.1.5 The Goal of Absolute JIT (Cont'd)

Factors which reduce the economic batch size include:

- Reducing set-up cost - reducing time and quality (cost) of labour required.
- Production costs - improve productivity.

Factors to be considered when determining inventory levels:

- Transit times.
- In-plant storage capacity and ability to protect inventory against damage.
- Time to start-up production.
- Time to produce.
- Time to re-order.

As with all JIT applications, the emphasis in reducing batch sizes is on progressive steps rather than drastic changes.

3.1.6 Materials Handling

With small lot sizes and frequent deliveries materials handling becomes a very important factor in making JIT Production work. The ultimate goal of JIT materials handling is no material handling. In practice, materials handling can be kept to a minimum by:

- Tying as many operations as possible into the assembly line.
- Using Group Technology to keep sub-assembly operations close to where the sub-assembly is used on the final assembly line.
- Whenever possible, a part from one worker should be handed to the next worker or placed within his reach.

3.2 JIT IN THE SOUTH AFRICAN FACTORY

3.2.1 Scheduling

The "Kanban" type scheduling system described in Sections 3.1.3 and 2.3.1.4 is most suitable for repetitive mass production. As such it has found acceptance in a few South African companies, such as Toyota South Africa, producing a limited product range. No South African pharmaceutical manufacturer has yet implemented a "Kanban" type system, for reasons elaborated in Chapter 6.

3.2.2 Absolute JIT

The tendency in the pharmaceutical industry towards smaller batches is quite marked. The principal restraining factor is a reluctance to drop inventory levels too fast because of:

- long and sometimes erratic delivery times, particularly on imported raw materials and components
- the medical and marketing consequences of being out of stock
- a failure, thus far, to reduce production start-up times significantly by faster machine set-ups, pre-production Q.C. inspection times, etc.

3.2.3 Materials Handling

Most pharmaceutical plants are deliberately designed to be spacious, thereby distancing processes from each other and consequently reducing the risk of cross-contamination. Unfortunately this frequently leads to materials handling delays, which adversely affects JIT small batch production. Some possible solutions to this problem include:

- mechanised materials handling, eg. use of liquid pumps, conveyors, hopper lifts, etc.
- use of barriers between processes rather than distances.
- removing distances and physical barriers and relying on procedures and employee education and training.

CHAPTER FOUR

PURCHASING FOR JUST - IN - TIME PRODUCTION

4.1 ESTABLISHING A JIT PURCHASING PROGRAMME

4.1.1 Introduction to JIT Purchasing

In dealings with suppliers, if a supplier delivers consistently late and has quality problems, the buyer tends to look for a new supplier, instead of trying to assist the supplier to improve. Furthermore, buyers chop and change suppliers based on marginal differences in prices. In contrast, the JIT approach is to remain loyal to suppliers and help them to improve as "co-producers".

In essence, JIT purchasing involves:

- Establishing a JIT purchasing programme
- Evaluating suppliers' capabilities
- Involving suppliers in the customer's design and engineering phases to assure that the supplier can meet specifications
- Issuing specifications to suppliers
- Negotiating purchase contracts
- Ensuring that the supplier certifies that parts shipped conform to specifications
- Ensuring that the supplier manufactures and ships raw materials/components in the exact quantity, to specification, just-in-time for production and working with the supplier to quickly and permanently rectify the causes, if these objectives are not being met
- Monitoring suppliers' performance

4.1.2 Establishment of a JIT Purchasing Programme

The initial scope of the JIT Purchasing Programme should be limited to a few suppliers. Typically these would be suppliers of A or B items as determined by an ABC or Pareto analysis. This means that the programme should concentrate on the few suppliers who typically supply the bulk of the important bought-out items. Again, as with all JIT, the goal is reached in progressive steps.

4.1.2 Establishment of a JIT Purchasing Programme (Cont'd)

The first step in establishing the programme is supplier education. Usually this starts with a supplier/vendor education seminar. The most important suppliers are invited to attend a seminar at which the JIT programme is outlined and the role and importance of the supplier is stressed.

The programme will have to be tailored to suit the manufacturer, depending on the size, nature and geographical position of the business. For example, JIT delivery of raw materials and components may be extremely difficult for a small manufacturer. Because of the small value of the orders, the manufacturer may not have the necessary leverage with suppliers to demand frequent deliveries. In this case, it would be more appropriate to shift the emphasis of the programme to supplier quality and certified deliveries. Similarly the geographical remoteness of South African pharmaceutical manufacturers from their overseas suppliers inevitably affects the programme.

All members of the purchasing and materials management department must be involved in the JIT Purchasing Programme. It is a team effort and all members must work towards common goals and treat suppliers consistently.

From a practical point of view a "discrete" or "as required" purchase order sizing policy can be impractical, unless the supplier has a successful JIT programme, for several reasons including:

(i) The suppliers' set-up costs can preclude economic production of small batches.

(ii) Transportation costs may make small, frequent deliveries uneconomical.

(iii) Receiving, inspection, material handling and order processing costs encourage the consolidation of small requirements into larger replenishment orders.

4.1.2 Establishment of a JIT Purchasing Programme (Cont'd)

(iv) The suppliers' frequent failure to deliver on the promised date.

(v) The suppliers' delivering defective materials at a higher rate than expected.

(vi) The requirement of top management that inventory buffers must be kept to service "rush" orders for key customers.

It is essential to consider these problems when establishing the JIT Purchasing Programme, so that it may be tailored to suit the particular circumstances.

4.1.3 Defining Specifications

To avoid disagreements between purchasing and the supplier concerning defective raw materials and components, it is essential that specifications be properly defined in advance. A thorough review of all drawings, material specifications and dimensional specifications must be conducted by product development, manufacturing and quality assurance, in consultation with suppliers, prior to placing orders. This review must ensure that specifications are:

(i) Needed in the detail provided. Too little specified detail may cause product to be accepted when it is defective. Too much specified detail will cause confusion and delays.

(ii) Clearly stated - specifications must be clear, concise and as simple as possible.

(iii) Achievable - over stringent specifications may not be achievable by the process, and even if they can be met the cost of production will rise.

(iv) Measurable - What is to be measured?
- How is it to be measured
- What tolerance/variation is acceptable?

Having reviewed specifications, it is essential to provide feedback on the necessary corrections.

4.2 EVALUATING SUPPLIERS

4.2.1 Evaluating Suppliers' Capability

The traditional attitude in South Africa favours multi-sourcing of suppliers. In contrast "The trend in Japan is to reduce the number of suppliers. They feel a single-source supplier has a greater incentive to reduce price, improve quality, and ship on time". (11) This JIT approach stems from a belief in locating the best supplier and working in co-operation with that supplier. The aim is to work with existing suppliers or locate new suppliers with the objectives of:

- reducing lead times
- reducing on-hand inventories
- having parts and materials certified as meeting quality specifications, delivered in the quantity and at the quantity and at the time required.

To accomplish this, requires that the suppliers be evaluated by a team comprising purchasing, quality assurance and manufacturing representatives. Such evaluation should include visits to suppliers.

Areas of evaluation should include:

- Manufacturing organisation
- Key personnel in terms of qualifications
- Machinery and equipment
  - capacity
  - quality
  - preventive maintenance
  - set-up times
  - quality inspection facilities
- Storage space for inventory
- Materials handling

4.2.1 Evaluating Suppliers' Capability (Cont'd)

- Quality Assurance and the existence of written procedures, organisation and practice, covering:
  - areas of responsibility
  - quality control methods
  - defect prevention systems
  - quality assurance methods to determine conformity of end products to specifications
  - product and specification changes
  - quality problem-solving and correction

The evaluation team should submit a written report, in a standard format, to the purchasing department on their evaluation results.

A South African pharmaceutical manufacturer, currently pursuing a JIT purchasing programme, has found that most suppliers need to take corrective actions recommended by its evaluation team. Suppliers should be given conditional approval, providing they have agreed to implement the necessary changes.

4.2.2 Evaluating Supplier Quotations

Suppliers that have been unconditionaly and conditionally approved should be requested to quote only on items they are qualified to supply. This is of paramount importance. Even in the pharmaceutical industry their is a tendency to assume that because a supplier is qualified/approved to supply a particular item, and has a good track record, he can be automatically relied on to perform as well with different items. For example, an approved, reliable supplier of paper labels cannot automatically be approved to supply self-adhesive labels, as the technology of production is substantially different.

Requests for Quotations should be standardised to include the following:

- Part Number
- Specifications
- Estimated annual volume
- Estimated quantity and frequency of shipments
- Method of transportation
- Packaging/container requirements
- Specialised handling requirements (eg. for cytotoxic substances in the pharmaceutical industry)
- A request for a breakdown of the part price to include purchase price of item, tooling cost, container/packaging and freight in order to facilitate later negotiation with one selected potential supplier
- A proposed contract period
- A commitment to providing JIT implementation assistance

Such detailed standardised quotes can then be fairly evaluated.

4.2.3 Purchasing Agreements

JIT production and TQC systems require close co-operation between the purchasing company and the supplier, as well as requiring significant investment in time and money by both parties. To provide the necessary incentive to suppliers, they should be issued with contracts that are progressively extended beyond the traditional one year agreements. These agreements are frequently called **"Negotiated JIT Long-Term Contracts"**.

These purchasing agreements should give the supplier visibility and commitment on the part of the purchaser. An example of this is a contract which provides:

- A 3-month commitment to the supplier to purchase a certain number of units. In the event of a default the buyer pays.
- A one month firm schedule.

4.3 SUPPLIERS' PERFORMANCE

4.3.1 Monitoring Suppliers' Performance

Suppliers' performance must be monitored in terms of quality, delivery and productivity.

Quality Performance monitoring is undertaking by Quality Assurance. When shipments fail to meet specifications reports are compiled indicating the defects nature and cause as well as the corrective action taken. Comments are also made on the degree of supplier co-operation. Quality Assurance and Purchasing periodically rate suppliers based on these reports.

Delivery Performance monitoring is undertaken by Manufacturing or Purchasing. Delivery reports indicate early or late deliveries and over or under supplies. Again supplier co-operation is assessed and period ratings are compiled.

Productivity Performance monitoring rates the suppliers material and labour costs against industry standards.

4.3.1 Monitoring Suppliers' Performance (Cont'd)

The ratings from these individual measures are combined to provide the overall rating of the supplier, which determines whether or not the suppliers overall performance was acceptable or not. Purchasing then reviews the overall rating with the supplier and then informs the supplier of the extension or non-extension of the contract.

4.3.2 Suppliers' Performance Recognition

Good overall supplier performance should be puclicly recognised. This is easily achieved by inviting the best suppliers to an annual presentation seminar, aptly named **"Our Partners in Excellence"** by one South African pharmaceutical manufacturer. Suppliers are invited to visit the plant and attend a presentation on the year's accomplishments in terms of JIT and associated programmes such as MRP II and projected goals. Usually awards are made to the best supplier.

CHAPTER FIVE

FACILITIES UTILIZATION

5.1 THE FACILITIES UTILISATION CONCEPT

5.1.1 Outline of the Facilities Utilisation Concept

In the JIT production system full utilisation of the worker is essential as planning is based on consistent daily production in terms of labour hours, not machine capacity capabilities. The manufacturing facilities must therefore always be available to fully utilise the available labour. Machine breakdowns, set-up delays, etc. which cause idle labour time, cannot be tolerated as they adversely affect the production plan.

5.1.2 Components of the Facilities Utilisation Concept

The principal components of the JIT Facilities Utilisation Concept are:

- Flexibility and Versatility
- Multi-skilled/Multi-function Workers
- Automation/Robotics
- Minimum Set-up Time
- Preventive Maintenance

These components have been discussed in Chapter 1 and need no further elaboration, except for Minimum Set-up Time, the techniques of which need further explanation as they are so relevant to the South African Pharmaceutical industry.

5.2 MINIMUM SET-UP TIMES

5.2.1 The JIT Approach to Minimising Set-up Times

Set-up problems and delays exist wherever a piece of equipment is used to produce a variety of products of differing configurations. The importance of set-up in JIT production has been discussed earlier, but can best be summarised as follow: "Reduction in set-up time is critical to the JIT philosophy and allows the numerous set-ups required to implement the uniform workload requirement. To produce parts in small lots, set-up times must be reduced to maintain economic feasability. The Japanese concept of single set-up means that a set-up must take less than 10 minutes (single-digit times.") (12)

5.2.1 The JIT Approach to Minimising Set-up Times (Cont'd)

The JIT approach to reducing set-ups identifies four elements:

(i) The separation of **internal set-ups** from **external set-ups.** Internal set-ups are those which cannot be done while the machine is running and external set-ups are those which can.

(ii) The conversion of internal set-ups to external set-ups whenever possible.

(iii) The elimination of the **adjustment process.** Adjustments to machines typically comprise 50 to 70% of the total set-up time and therefore constitute a major area for improvement.

(iv) The abolition of the set-up step wherever possible by:

- Standardisation of components within or across product lines.
- Producing various parts on small dedicated machines, rather than large multi-purpose machines.

Most machines, despite being designed by experts, tend to be designed with performance and cost as the criteria, whilst ease of set-up is neglected. This is particularly true of multi-purpose machinery. The JIT approach is to evaluate all prospective machinery purchases from an ease of set-up point of view, and not just the usual criteria. In addition, existing machinery is evaluated and modified if necessary to meet set-up reduction requirements. Finally machinery is sometimes purpose built to minimise set-up or avoid it altogether if possible.

5.2.2 Implementing a Set-up Reduction Programme

A successful Set-up Reduction (SUR) Programme is dependent on a disciplined progressive implementation strategy. The strategy should be as follows:

(i) Initially, the SUR programme should be implemented in one area, preferably critical in terms of JIT delivery.

(ii) An education and training programme should be developed and conducted.

(iii) The programme should initial commence with a **no cost/low cost** approach with limited funding. Capital items should be bought with set-up reductions in mind, but justified in the normal way by paybacks, etc.

(iv) Teams should be set-up to achieve SUR in specified areas.

(v) The SUR teams should be **action** teams and not **study** teams. This is best achieved by setting SUR goals to be achieved within specified time periods.

(vi) Savings made in set-up duration should be re-invested in more frequent set-ups to produce smaller batches in line with JIT.

(vii) Techniques of monitoring SUR should be developed and might include video recording, analysis sheets, etc.

5.2.3 Set-up Reduction Techniques

"When one observes the events taking place during a typical machine Set-Up, it becomes immediately apparent that much of the activity (or lack of it) is centered around factors which are not engineered into the process, and therefore cannot be bought out by large injections of capital/advanced technology. They are more likely to be the result of:

- The operator not knowing the next job
- Blunt/inappropriate tools
- Unclear specifications
- Lost or damaged tools or equipment
- Awkward access to work area or adjustment points" (13)

Such factors represent a major portion of what is known as external set-up time, as defined in Section 5.2.1, and should constitute the first target for the SUR programme. Internal set-up time is the time spent on the machine whilst in motion, or capable of being in motion, once the tooling, etc. has been changed. The relationship between running products and external and internal set-up is shown in figure 5.1

THE RELATIONSHIP BETWEEN PRODUCTION AND EXTERNAL AND INTERNAL SET-UP

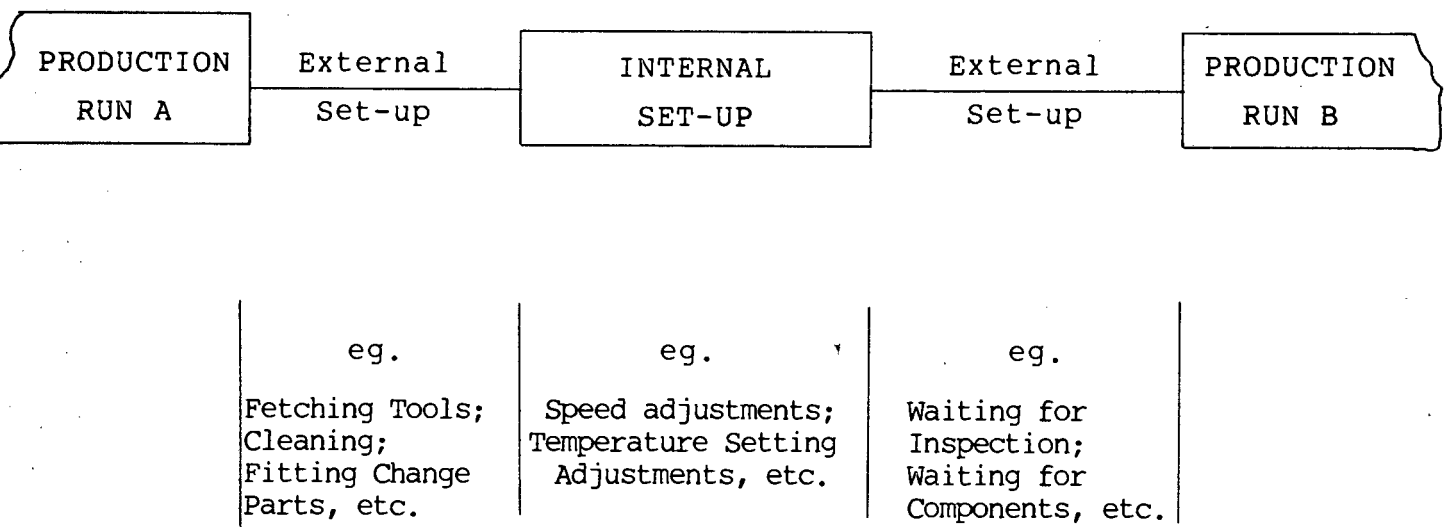


Figure 5.1

5.2.3 Set-up Reduction Techniques (Cont'd)

The technique is to attempt to eliminate the external set-up time by reducing first the non-engineering factors such as fetching tools and finding drawings and set-up instructions, and then the engineering factors. Having eliminated or minimised the external set-up the next step is to reduce the internal set-up, usually by eliminating adjustments.

An SUR programme must be based on appropriate recording and analysis methods. One method is to use a video camera to record what actually happens during a set-up, assuming that the presence of the camera does not influence the procedure. Whether recorded on video or simply observed the set-ups must be analysed. The best technique is to break the work down into elements, by type and duration, and then conduct a simple Pareto analysis to rank in highest order the time consumers, after which "brainstorming", etc. can commence. A sample of a Set-up Analysis Sheet is shown in figure 5.2.

SAMPLE SET-UP ANALYSIS SHEET

SET-UP ANALYSIS SHEET					
Team: ..... Date: ..... Written by:		From Job: ..... To Job: ..... Machine:		No: ..... No: ..... Asset/Plant No:	
Step No.	Work Performed	Work Cat. Symbol	Duration	Suggestions for Improvement	Action By

Key to Work Category Symbols

C : Clamp
A : Adjustment
CD : Cleandown
P : Problem, etc.

Figure 5.2

5.2.4 Set-up Reduction in the Pharmaceutical Industry

The South African Pharmaceutical Industry is typically characterised by relatively small batches of a large range of diversified products. Thus even without a JIT programme, there is a need for an SUR programme, all the more so because of additional external set- up components such as very stringent cleaning routines and inspections and line inspections by pharmacists, being peculiar to the industry. Some practical examples of set-up reductions that can be achieved in the industry are listed below.

(i) Forming and sealing tools for different product configurations in blister packaging can be fitted with quick release clamps and locating pins.

(ii) Cartons can be of standard dimensions across product ranges to obviate format changes on an automatic cartoning machine.

(iii) Ink-jet coders, with their data key input facilities, can be used instead of foil and ribbon printers, which require laborious type-face changes for different batch numbers and expiry dates.

(iv) Adjusting tools can form part of the machine, rather than using spanners and screwdrivers.

(v) Cleaning procedures can be reassessed - sometimes a pump through can replace a machine strip down and clean procedure.

(vi) A computer programme can be developed to list the set-up required for a changeover from any particular product to another. This instruction listing can include the specification of dimensions, volume settings, etc. Items completed are ticked off, which amongst other benefits, ensures set-up continuity during a machine-setter shift change.

Minimising set-up times is one of the easiest aspects of JIT to implement and yields among the most impressive results.

CHAPTER SIX

JUST - IN - TIME

AND

MANUFACTURING RESOURCE PLANNING

JIT +

6.1 MANUFACTURING RESOURCE PLANNING (MRP II)

6.1.1 The Concept of MRP II

Manufacturing Resource Planning (MRP II) is a computer-based information system which provides a model for planning and managing the entire manufacturing process, from strategic business planning through to distribution. An essential part of the system is the concept of exploding a manufacturing bill of materials in order to generate the ordered list of components required for manufacture. This concept is known as Material Requirements Planning (MRP or MRP I).

Computers are central to MRP II because of the large amount of calculation and re-calculation required to maintain a valid information system as rescheduling occurs, especially with a large number of products and components. However, it must be appreciated that MRP II is a 'people's system' made possible by the computer (Oliver Wight). Many MRP II implementation projects have failed because the users turned to the computer for an instant packaged solution when their manual production management system was inadequate, without due regard for the necessary motivation, organisation, education and training of their employees.

To be practical, MRP II requires a Master Production Schedule (MPS) to 'drive' it, by expressing manufacturing management policy on which products to produce and when. Furthermore, the MPS has to be valid in that it must be practical to implement. To achieve this, a rough-cut capacity plan is made and is inserted between the master schedule and material requirements planning module.

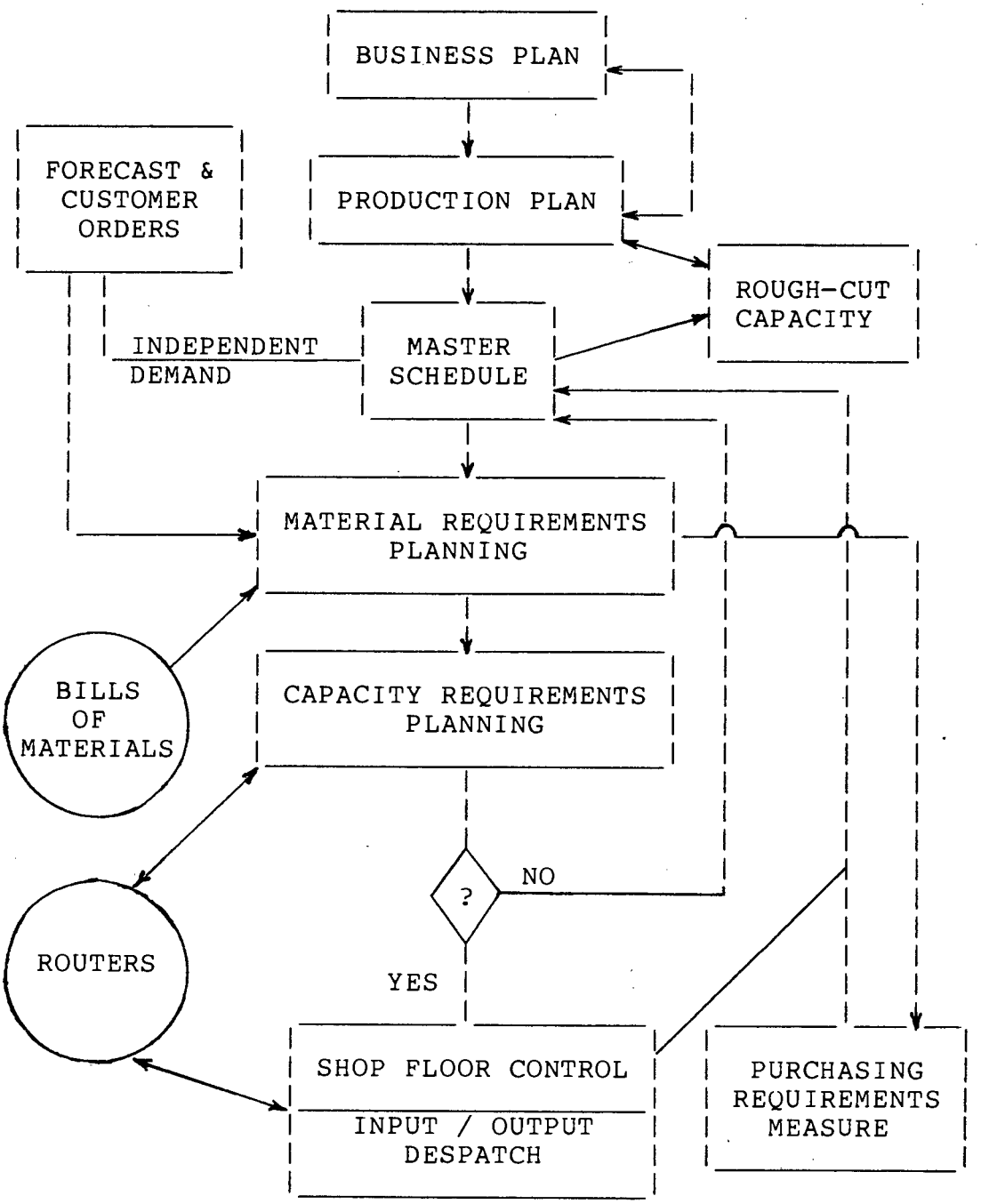
MRP II has developed considerably since its initial inception as an inventory ordering and control technique. With quick regeneration in the light of changes and with a valid master production schedule one has a formal system, where the computer system is a true representation of what is happening in the factory. However, for a formal system to work, one must have a high degree of discipline including record accuracy, accurate bills of materials and routings, education and training and management commitment.

6.1.1 The Concept of MRP II (Cont'd)

To allow MRP II to work as a scheduling technique at the detailed level, it is essential that Capacity Requirements Planning (CRP) be added. CRP translates the output of the Material Requirements Planning module into detailed loading and sequencing of machines. When CRP calculations indicate capacity problems, the MPS may have to be revised.

The Manufacturing Resource Planning concept, as practised by a leading South African pharmaceutical manufacturer, is illustrated in figure 6.1.

MANUFACTURING RESOURCE PLANNING (MRP II)



- EDUCATION AND TRAINING
- RECORD ACCURACY
- TWO WAY COMMUNICATIONS

Figure 6.1

6.1.1 The Concept of MRP II (Cont'd)

MRP II is a model of the manufacturing company, made by the employees and continuously updated by them, using the computer. The present valid data may be extended into what is likely to happen in the future, thus producing cash flow forecasts and facilitating simulations, including 'what if' questions as to future manufacturing quantities and proposed capacities.

6.1.2 MRP II in the Pharmaceutical Industry in South Africa

Manufacturing Resource Planning is relatively new in South Africa. In mid.1983 there were only approximately 130 MRP II users in the country, all of whom were in the early stages of implementing MRP II and very few of whom were in the pharmaceutical industry. This is surprising as MRP II has much to offer the industry.

Without MRP II pharmaceutical manufacturers in South Africa, like many other industries, tend to use informal manufacturing planning and control systems. Informal systems are potentially dangerous in the pharmaceutical industry, which by its very nature requires high standards of quality and accuracy and stringent controls. In a formal system, as provided by MRP II, all records must be up to date and accurate. For example, inventory accuracy is often surprisingly low in pharmaceutical manufacturing companies and actual inventory quantities differ from recorded quantities, inventory locations are incorrect and inventory withdrawals are not properly recorded. To be successful, MRP II must be based on high inventory accuracy which is continuously checked by cycle counting. The formal system of MRP II also requires accurate bills of materials. While the accuracy of bills of materials in the pharmaceutical industry is normally high in terms of content and quantities, it frequently falls down in terms of structuring. Accuracy in terms of component levels in bills of material is essential if MRP II is to succeed.

6.1.2 MRP II in the Pharmaceutical Industry in South Africa (Cont'd)

These and other accurate records in the formal MRP II system are part of Good Manufacturing Practice (GMP) as required in the pharmaceutical industry. GMP is that part of Quality Assurance which ensures that products are consistently manufactured to a quality appropriate to their use, that is, it encompasses both manufacturing and quality control procedures.

Once in operation, the formal MRP II system offers another great benefit to the pharmaceutical manufacturer, namely lot traceability. Through the computer-based MRP II system batches may be accurately traced through all stages of manufacture and distribution in the event of, for example, a faulty batch recall. This accurate system may also be used to check batch yields/reconciliations, another GMP requirement.

South African pharmaceutical manufacturers (with the exception of their government tender orders) produce for stock rather than to order. This means that the MRP II system is essentially driven by forecasts, which must be frequently updated, especially as they are usually seasonal. For example, suppliers of medications for coughs, colds and influenza must seasonalise their forecasts to allow for increased winter demand. However, these sales may peak earlier or later than expected in any particular winter. Forecasts and hence production, must be adjusted as a clearer sales prediction appears at the onset of winter. Similarly, advertising campaigns may boost sales more or less than expected, with a consequent need to adjust forecasts and production levels. A successful MRP II system will enable the pharmaceutical manufacturer to react promptly and efficiently to such changes in forecasted demand.

6.1.2 MRP II in the Pharmaceutical Industry in South Africa (Cont'd)

To many pharmaceutical manufacturers the MRP II concept, like the JIT philosophy, is regarded as being suited to engineering-orientated industries and not at all suitable for their industry, particularly in packaged software form. By tradition, pharmaceutical manufacturers resist changes, not always without good reason, and prefer manual systems with constant manual cross-checking and approvals. This further increases their reluctance not accept new concepts like MRP II and JIT. In practice the basic MRP concepts are relevant to all industries. Unfortunately, many pharmaceutical manufacturers who do accept MRP II, then attempt to modify the software to suit their existing systems rather than vice-versa. Carefully selected MRP II software may be implemented in a pharmaceutical manufacturing company without modification, with the emphasis placed on education and training.

A typical pharmaceutical manufacturer in South Africa imports some 60%, by value, of its raw materials. Such imported raw materials have long lead times, often in excess of a year, and therefore require an extended planning horizon, as facilitated by MRP II, if purchase orders are to be issued timeously.

A typical large pharmaceutical manufacturer in South Africa produces in excess of two hundred different finished products in discreet batches at frequent intervals. This generates a multiplicity of orders, frequently for raw materials or finishing supplies common to different products. The extended planning horizon of MRP II and its 'what if' and regeneration capabilities enable a vast number of groupings of common components to be ordered as economically as possible.

Planned maintenance should be a cornerstone of any successful manufacturing company. To many manufacturers, planned maintenance is a necessary evil which should at all times be kept to the absolute minimum to ensure the on-going operation of machinery. It is far more important to the pharmaceutical manufacturer.

6.1.2 MRP II in the Pharmaceutical Industry in South Africa (Cont'd)

Good Manufacturing Practice requires that products be produced to consistent standards. This is an especially important concept when patients are stabilised on essential drugs at specified dosage levels, as is the case with epileptics for example. This cannot be ensured without, inter alia, planned maintenance. For example, badly maintained tablet punches and dies would lead to inconsistent tablet weights.

GMP also requires stringent cleaning procedures, a form of planned maintenance, to avoid cross contamination between product batches. Pharmaceutical manufacturers can and should incorporate preventative maintenance require- ments planning (PMRP) into the MRP II system.

The adoption of MRP II by a customer leads to structural changes amongst vendors. The customer's MRP II system usually causes the number of vendors to shrink to those who can meet the responsibility placed on them by the slicker MRP ordering system and monitoring of deliveries, both early (frequently disruptive) and late. This is compatible with the trend amongst pharmaceutical manufacturers to expect ever-improving delivery and quality from their vendors.

For MRP II to succeed it must be fully accepted at all levels in the company. Generally the pharmaceutical industry in South Africa is highly disciplined and tightly controlled through procedures and monitoring. This makes MRP II slightly less difficult to impose in this industry than in other industries, provided of course that employees are sufficiently educated in the need for MRP II and its implementation. Furthermore, pharma- ceutical manufacturers in particular should note that procedures are not a substitute for training.

A fundamental principal of GMP in the pharma- ceutical industry is to establish procedures and systems as well as constant checking and training to minimise the risk of errors. Furthermore, errors that are found must be analysed and means must be devised to prevent reoccurrences.

6.1.2 MRP II in Pharmaceutical Industry in South Africa (Cont'd)

These principles must be carried over to the MRP II system if it is to succeed. After all, data is usually generated by people, except where sophisticated monitoring and transcription devices (eg. barcode readers) are employed, and is thus subject to error. In general it is essential to MRP II to make it as easy as possible for the facts to be entered into the computer system correctly, and as difficult as possible for them to be entered incorrectly, a concept entirely compatible with GMP.

Despite all the above ingredients for successful implementation of MRP II in the pharmaceutical industry in South Africa there are likely to be many failures. First and foremost MRP II requires an enormous amount of effort in terms of capital investment, education and training, implementation and on-going management and employee commitment. The concept of MRP II is disarmingly simple, but at the same time quite complex in terms of the interlocking support systems that must be developed and maintained. The result is an all-embracing formal system which is only as good as its weakest component.

6.2 JUST-IN-TIME AND MANUFACTURING RESOURCE PLANNING

6.2.1 The Common Goals of JIT and MRP II

JIT has helped Japan to become the world's industrial leader in terms of productivity. MRP II does not as yet have quite such an impressive record. However, despite this, there is much interest in MRP II in Japan. The reason for this is the growing realisation that the two systems are not mutually exclusive, indeed they have different strengths which can be used to complement and reinforce each other.

In contrast to Japan, the manufacturing sector in South Africa faces severe problems including high inventory, low productivity, poor and inconsistent quality and poor communications. These problems have not escaped the pharmaceutical industry, where a captive market and lack of competition in some areas have resulted in low productivity and expensive medicines. Unfortunately, there is a lack of urgency in addressing these problems. Many believe that the introduction of generic substitutions, even with its attendant problems, will bring down the cost of medicines. This is unlikely, unless it is accompanied by greatly improved manufacturing management. The correct application of the JIT philosophy in conjunction with MRP II offers the best solution to this malaise.

The goals of JIT and MRP II are identical, namely aiding manufacturing to get the right part to the right place with the right quality at the right time, while improving inventory turnover and productivity. Most companies do not achieve these goals, because they lack an effective means of translating top level plans into specific tasks that people can evaluate, execute and be held accountable for. A successful MRP II system will provide a formal system, built on a timely, accurate database, which will enable these goals to be achieved. However, to succeed, it must incorporate the JIT philsophy, particularly in terms of the principles of high respect for people and quality and the elimination of waste.

Unfortunately, these mutual goals of JIT and MRP II are frequently confused with their tools, which can conflict in some cases, unless selectively and properly implemented.

6.2.2 A comparison of the Mechanics of JIT and MRP II

Every manufacturing company has certain tools which it uses to perform its various functions. Traditionally the tools of MRP II and JIT, as employed by the Japanese in particular, are different, although the functions they perform are essentially the same. A clear distinction must be drawn between the JIT tools and the JIT philosophy. Generally speaking, it is the JIT philosophy that one should import from Japan, with only selective adoption of JIT tools, for such tools frequently conflict with other systems such as MRP II.

The origins of JIT lie in a highly repetitive environment where planning and production is by rate, rather than the batch orientated MRP II approach of managing production by units per work order. JIT, when using the Kanban system, does not use work orders, but relies on demand pull production control and rate based planning. Because of these fundamental differences it is inevitable that the tools employed are for the most part different. Broadly speaking, the tools of JIT are simple and manual, whereas the tools of MRP II are complex and require a computer.

In essence, every manufacturing company has to perform the same functions, however the tools they use differ. Figure 6.2 lists eight typical functions and the corresponding tools of JIT and MRP II that would be used.

TOOLS OF JIT AND MRP II

Functions	Description	JIT Tools	MRP II Tools
Rates of output of facilities	Top management's determination of the rates of output of families of products (eg. Cough Mixture, Analgesics, etc.) to meet the business plan.	Levelling	Production Plan
Products to be built	Finished Goods to be produced to meet forecasts in a make-to-stock situation or products to be produced to satisfy customer orders in a make-to-order situation.	Master Production Schedule (MPS)	Master Production Schedule (MPS)
Materials Required	Components required, both manufactured and purchased, to produce the products.	Kanban Cards	Material Requirements Planning (MRP)
Capacity Required	Output for key work centres and vendors to support the MPS.	Visual	Capacity Requirements Planning (CRP)
Executive Capacity Plans	Producing enough output to satisfy plans.	Visual	Input/Output Controls (I/O)
Executive Material Plans - manufactured items	Determining what manufactured items should be worked on in a priority sequence.	Kanban Cards	Despatch Reports
Executive Material Plans - purchased items	Bringing in the right purchased items from vendors at the right time.	Kanban Cards and unofficial orders	Purchasing Reports
Feedback information/ closed loop	Notification of what cannot be executed due to problems.	Andon Lights	Anticipated Delay Reports

Figure 6.2

6.2.2 A comparison of the Mechanics of JIT and MRP II (Cont'd)

In reviewing the functions listed in figure 6.1, it is important to note that each of the individual tools used represents only one key element within the manufacturing system. For example, Kanban cards (actual paper cards) in the JIT system and MRP in the MRP II system are not stand-alone systems and as such would produce few benefits if installed in isolation (the main reason why MRP II developed from MRP).

Establishing rates of output for manufacturing facilities is top management's responsibility. The JIT tool is to "level" the rate of output in order to stabilise the labour force. With the JIT emphasis on "life-time employment", great care is taken in determining these rates of output. It is only with great reluctance that a company like Toyota in Japan would expand or contract their labour force. Although most MRP II users do not as yet put quite the same emphasis on "life-time employment", the process of "production planning" is used for the same purpose of determining the rates of output of families of products. In the case of a pharmaceutical manufacturer, the rate of output tool would develop a production plan in terms of throughput of products, by line-of-business and family such as cough mixtures, analgesics, antibiotics etc. to execute the business plan.

In determining what products need to be built, both JIT and MRP II use a Master Production Schedule (MPS). The MPS specifies what products are to be built out through the planning horizon. With JIT, the planning horizon is typically three months, with the first month firm and the next two months tentative. In the case of MRP II, the approach is the same, except that with the power of the computer the horizon may extend much further. Typically, a South African pharmaceutical manufacturer would have a tentative MRP II MPS extending out in excess of twelve months, because of long lead times on imported components.

6.2.2 A comparison of the Mechanics of JIT and MRP II (Cont'd)

JIT and MRP II differ fundamentally in the tools used to determine the materials required for production. JIT uses two types of Kanban cards - a requisition card (authorising withdrawal of material from the feeding/ previous operation) and a production card (authorising the feeding operation to produce more of what is being withdrawn). It is a manual system. In contrast MRP II uses the material requirements planning module to produce computer-generated reports, typically a pick list authorising the issue of material needed and a shop order authorising operators to produce the item needed. This MRP II tool requires a structured bill of material, inventory records (on hand and on order) and an MPS to drive it. With the JIT Kanban tool, there is no bill of material explosion on the computer. Once a component is depleted on the final assembly line, a replenishment cycle is triggered from top to bottom, through the manufacturing process. This JIT tool would be unacceptable in the pharmaceutical industry, with its requirements for manufacturing batch records. The MRP II exploded bill of material concept, however, is entirely compatible, except for some reluctance by the authorities to accept computer-generated batch records. For example, if we wish to make 6000 litres of cough mixture, the computer explodes the bill of material for the particular product into components and component quantities for the batch, having multiplied the component quantity per litre by 6000ℓ. This standard tool of MRP II may be used to generate a manufacturing batch record, which is simply an exploded bill of materials, containing additional information such as product and component numbers, batch numbers and places to record checking signatures, etc.

Another crucial function is determining what capacity is required. With JIT it is a non-computerised visual approach. Through knowledge of the "levelled" daily output volume, the factory foreman and operators determine the required capacity to support the master production schedule, with the minimum amount of inventory on the factory floor.

6.2.2 A comparison of the Mechanics of JIT and MRP II (Cont'd)

For this approach to work, operators need to be multi-skilled and sometimes extra machinery is required, a combination which provides the necessary flexibility to respond to the capacity needs. With MRP II, the computer produces reports displaying the time phased loads per key work centre, both open shop orders (released) and calculated planned orders (unreleased). These reports are usually reviewed by planners and factory managers. Capacity is levelled wherever possible and, for example, decisions to work overtime are made when the load exceeds the capacity of the work station. This process is called Capacity Requirements Planning (CRP).

In executing the capacity plans in a JIT system the final assembly line will shut down quickly if not enough component parts are being produced. On the other hand, if work is accumulating behind a particular work centre then inventory is not at a minimum. In either case, factory personnel have to react if adjustments are required to alter the output. In contrast to this visual approach MRP II produces formal input/output reports. The hours of work into the key work centres should match the predictions that come from CRP. The hours of work out of the work centre should correspond to the previously agreed capability of the factory, to meet the capacity plans. If the input/output reports indicate significant deviations, then corrective action must be taken.

The traditional JIT tool for determining what manufactured item should be produced next is the Kanban card. The production cards are used to authorise the feeding operation to produce more of what is being withdrawn. The MRP II system issues a daily dispatch report for each work centre, listing all the jobs that are physically there in a priority sequence.

A Kanban card is also used to determine when purchased components are required. The presence of a card authorises a supplier to ship parts, while the absence of a card means that the supplier is not permitted to deliver.

6.2.2 A comparison of the Mechanics of JIT and MRP II (Cont'd)

This tool ensures in time deliveries, neither early nor late, in small lot sizes and frequent replenishments. The MPS is used to provide each supplier with a rolling, ninety day projection. With a MRP II system, computer reports advise what components should be bought and when, based on the MPS. As changes are made to the MPS, the reports recommend purchase orders that should either be scheduled in or scheduled out. With the extended MRP II horizon, the purchasing department is able to provide visibility to suppliers beyond the lead times.

In both systems, the notification that problems have occurred in executing the plan is manually generated. The means of communicating this information differs however. The traditional Japanese JIT tool is the Andon System, which translates into "lamp" or "light" system. The Andon is suspended over the final assembly line where it is visible to most of the factory. If an operator is experiencing difficulty in keeping up with the required production, he displays a yellow light. If the problem cannot be rectified, the operator displays a red light, as a warning that the final assembly line will soon shut down, which causes corrective action to be taken. With MRP II, the means of communicating the problems is the "anticipated delay report". These are generated from information provided by people in the factory and purchasing. The advice of expected delays in achieving schedules leads to a reassessment of the plan. Thus both systems have closed loops in that they provide for the feedback of information.

The above description, though not exhaustive, outlines some of the mechanics of JIT and MRP II. In assessing these traditional tools of JIT in isolation from the JIT philosophy, one would conclude that they were the outdated equivalent of a re-order point system, using Kanban cards instead of a two-bin system. In practice, these simple tools are combined with the JIT philosophy to produce arguably the most efficient production planning and control system in the world, as practiced by companies like Toyota in Japan.

6.2.2 A comparison of the Mechanics of JIT and MRP II (Cont'd)

Although more sophisticated, the tools of MRP II do not work well in isolation. They likewise must be applied with the right management philosophy, which will include education, respect for people and quality and in fact virtually all aspects of the JIT philosophy.

6.2.3 The compatability of JIT and MRP II

In South Africa, in common with most countries, pharmaceutical manufacturing is regulated by a statutory body and governed by strict legislation. The industry is thus bound to comply with certain manufacturing procedures and controls, including the use of works orders and discrete batches - concepts entirely compatible with MRP II, but foreign to the traditional mechanics of JIT. Furthermore, most manufacturing companies in South Africa do not have the volume or the repetitive characteristics to work in the same way as, say, Toyota in Japan, perhaps the most famous user of Kanban. Consequently, many manufacturers readily accept MRP II and discard JIT in the mistaken belief that it equates to Kanban and only applies in a repetitive manufacturing environment. In reality, Kanban is one way of applying JIT, whilst MRP II is another way. JIT can be applied to repetitive batch orientated or any other type of manufacturing operation.

The philosophy of JIT need not be backed up by any particular unique set of techniques - it is not an alternative to MRP II for example, but rather a complement. MRP II is "organised common sense" in the form of a computer backed planning and operating system for all functions of a manufacturing company, whilst JIT is essentially "the elimination of waste". MRP II serves to eliminate confusion through effective planning, scheduling and closed loop feedback. Confusion is wasteful, so MRP II is clearly an element of JIT.

6.2.3 The compatability of JIT and MRP II (Cont'd)

For a number of reasons MRP II is fast becoming the chosen system in the South African pharmaceutical industry. In addition to reasons of compatability with legal requirements, lot traceability, etc. previously outlined, there are other less obvious reasons for the industry to choose MRP II. These include the fact that many pharmaceutical manufacturing companies in South Africa are American subsidiaries, America being the bastion of MRP II. Furthermore, the industry is quick to adopt systems as standard, once a significant number of member companies employ them. Almost certainly elements of the JIT philosophy will likewise be adopted throughout the industry.

There are a number of basic lessons to be learned from the Japanese JIT philosophy, lessons which will help to ensure the successful implementation of MRP II.

The first lesson is teamwork, Japanese companies operate with a tremendous amount of team effort, in contrast to say South African companies, where much greater emphasis is placed on individual effort. With a project such as the implementation of MRP II a non-Japanese company would probably appoint an individual to motivate, install and manage the project. Without the emphasis on team work, the project would almost certainly fail.

The second lesson is that education is the common denominator for all successful systems. It is more important to have a technically imperfect system that the users (including shop floor workers and not just management) understand and want to make work, than a technically correct system without user understanding. A reputable MRP II software package is usually technically perfect. This, together with the perceived invincibility of the computer, causes many MRP II users to neglect education, without which MRP II will fail, being essentially a people's system. To quote Walter E. Goddard, "Too frequently we install systems **for** the users, not **by** the users."

6.2.3 The compatability of JIT and MRP II (Cont'd)

The third lesson, as discussed in the previous section, is not to copy the traditional Japanese tools blindly. Their JIT successes are not the result of these tools, nor how they use them, although undeniably they use them very well. The key to their success lies in the JIT philosophy and what they do before using their systems. Again to quote Walter E. Goddard, "The Japanese may agonize a long time before resolving an issue, but once consensus has been achieved, stand back. They'll get the job done by each member working with diligence to contribute to the cause as well as assisting all other members to do the same."(11)This is nowhere more essential than with the implementation of MRP II systems, where lengthy user education, motivation, discussions and familiarisation preceding module by module installation produces success, whilst "quick fix" installation fails.

The fourth lesson is the need for the commitment of every man in a company to his organisation's goals and objectives. For example, an MRP II implementation project requires the commitment of all employees from the chief executive officer (CEO) to the factory workers, and sometimes even cleaners, as in the pharmaceutical industry.

The fifth lesson stems from the underlying need for discipline in the JIT philosophy. A typical Japanese worker accepts responsibility for his area of production, does his job and does not blame others for his failures. The focus of JIT is on doing things right the first time, but when things go wrong then there must be sufficient discipline to correct the situation immediately. The same discipline is required amongst MRP II users. All MRP II systems have a great deal of tolerance, such as scrap factors, lead time allowances, etc. built into them. Without discipline, these tolerances tend to become slacker and slacker. Furthermore, slackness in recording events and following up exception messages are common failings in most MRP II systems. Too often an MRP II system helps to cover up weaknesses. MRP II users need to instil the discipline that prevails in a JIT environment.

6.2.3 The compatability of JIT and MRP II (Cont'd)

The sixth lesson is more subtle and concerns the morality of Japanese society. Western attitudes, and South African attitudes in particular, are frequently based on selfishness. To implement JIT and MRP II successfully our society must develop, like the Japanese, the right attitude of interdependence. Furthermore Japanese workers are less ashamed of the mistakes they make than their Western counterparts, and more willing to try to identify the reasons for the mistakes, rather than attempting to blame others. This Japanese morality extends to the treatment of suppliers. The JIT philosophy advocates helping suppliers to improve their quality and delivery, rather than chopping and changing suppliers for marginal price differences or quality or delivery problems that could be rectified. Finally, this lesson of morality must encompass the treatment of employees. The Japanese concepts of lifetime employment, respect for employees and frequent consultation with them encourage the development of constructive thinking and responsible attitudes, both vital ingredients for the success of JIT and MRP II systems. The South African pharmaceutical industry, being stable and requiring its employees and suppliers to be responsible, is generally ahead of the rest of this country's industry in terms of morality, but still falls short of Japanese standards.

Many MRP II users tend to focus on the planning of the manufacturing process, while many JIT enthusiasts tend to focus on the physical manufacturing process itself. To achieve excellence in manufacturing one requires both, something which is readily achievable with the two systems complementing each other.

Business plans are usually set at budget time, but for the planning process to work at all levels, plans must be reviewed and adjusted.

All planning, from business through tactical to operational planning, must be responsive or else one has reaction and crisis management, not planning. We can practice responsive planning using JIT and MRP II in parallel as shown in figure 6.3.

RESPONSIVE PLANNING

USING JIT AND MRP II

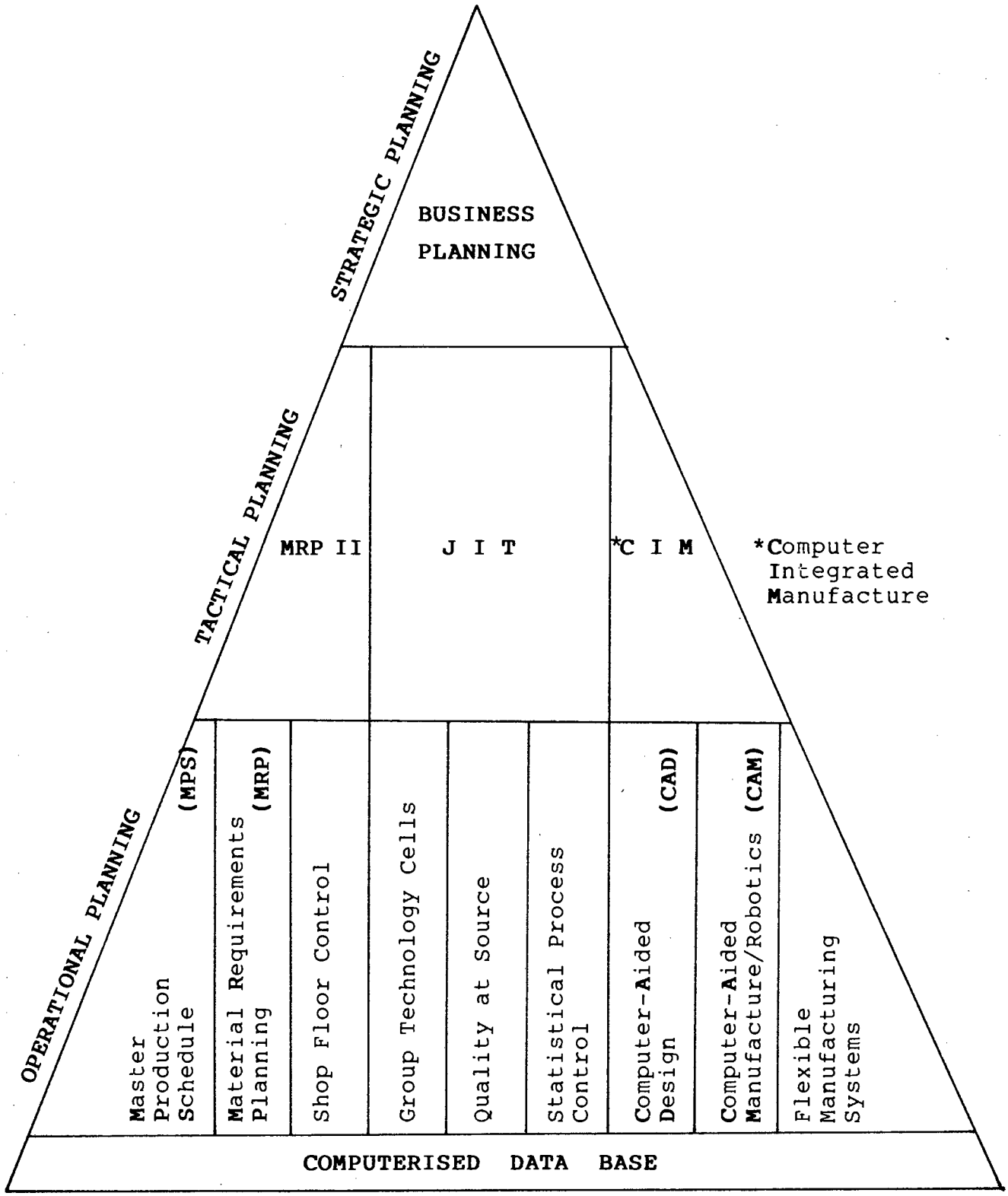


Figure 6.3

6.2.3 The compatability of JIT and MRP II (Cont'd)

Figure 6.3 shows the likely ideal planning relationships between JIT, MRP II and Computer Integrated Manufacture. The systems work in parallel using a common data base. For example with parallel computer aid design (CAD) and material requirements planning, product design changes are properly co-ordinated, as with packaging component or formulation changes in the pharmaceutical industry. In a similar way the JIT group technology cells planning philosophy is used in parallel with the routing and planning elements of shop floor control in MRP II.

Possibly the weakest element of MRP II is Capacity Requirements Planning (CRP). Many MRP II users use the infinite loading approach when faced with the complexity of detailed job sequencing and no attempt is made at optimisation. Even when finite loading is attempted reasonably uniform loading is frequently unattainable, particularly with large batch sizes. MRP II is a push system and therefore encourages work in process or buffer inventories. In contrast, traditional JIT is usually practiced in a repetitive environment, where it is relatively easy to establish a stable uniform plant load with a minimum of inventory. For an MRP II system to achieve a uniform plant load batches must be small, bearing in mind that the ultimate zero inventory system has a batch size of one unit. Furthermore, the MPS product mix must be adjusted to produce as constant a production pattern as possible. To achieve this, the JIT principles of quick set-up, flexibility of machinery, use of multi-skilled operators and continuous development of the production process to minimise bottleneck operations must be applied. Generally speaking, workers in the pharmaceutical industry in South Africa tend to be multi-skilled and machinery is versatile, both because of the wide range of products produced by most manufacturers. Set-up times are generally long because of equipment cleaning time and pre-production quality and pharmaceutical checking procedures. However, as discussed earlier JIT can be used to produce dramatic improvement in set-up times. Provided the JIT principles are applied, MRP II can achieve uniform plant loading for South Africa pharmaceutical manufacturers, except for seasonal product demand fluctuations, for which capacity must be adjusted through use of overtime or casual labour.

CONCLUSION

JIT can be applied to the pharmaceutical industry in South Africa, provided the attitudes of management, workers and suppliers can be changed. Such attitudinal changes will only come about through education and training involving all employees, with the full commitment of management. Successful implementation of JIT is based on understanding the JIT philosophy, not the implementation of JIT techniques imported from Japan. Where such techniques, as employed in Japan, are relevant, they should be adapated to suit local conditions.

JIT Offers no "quick-fix" solution to South Africa's quality and productivity problems. However, progressive planned implementation will move industry towards the ultimate goals of zero defects, the elimination of waste and the production of goods just when they are needed. Furthermore, as JIT is implemented the "quality of life" of both employees and suppliers will improve.

The thesis concludes that JIT in South Africa is far more than an inventory reduction programme. It should lead to

- improved quality
- greater productivity
- more amicable and stable industrial relations
- improved cash flows
- better relationships with suppliers

to name but a few of the potential far reaching benefits. However, such successes are dependant on the commitment of top management, education, training and a well planned implementation programme, free of the potential pitfalls identified in this thesis.

JIT is not a static concept, but rather a dynamic philosophy. As JIT is implemented, its achievements must be measured against pre-defined goals, and as the philosophy evolves, new goals must be set.

JIT is based on team effort, in the belief that with the correct education and training, employees as groups are more effective at solving problems and innovating than individuals.

Finally this thesis concludes that JIT cannot be pursued in isolation. Other manufacturing systems must be used in concert with JIT, especially Manufacturing Resource Planning (MRP II), which together with JIT forms part of a Total Production System for the pharmaceutical industry.

A P P E N D I X A:

REFERENCES

REFERENCES

1. **Benatar**, C.G. "How to trigger of a chain reaction of benefits"
Promat, August 1985, p.9

2. **Leng**, L.K., "MRP II is the way to do JIT"
Production Engineer, October 1985, p.30

3. **Spoelstra**, H.I.J. "Japanese Management Methods in South Africa"
Productivity S.A., June Vol.12 No.3, p.24

4. **Louw**, L.M. "The Influence of Race and Culture on Economic Performance and Prosperity"
(An address by Leon M. Louw, Executive Director of the Free Market Foundation of Southern Africa, to a Convention of the Soweto Chamber of Commerce and Industry, held on Thursday, 25 October 1984).

5. **MacKenzie**, N. "Adopt techniques which will give you a competitive edge - just-in-time"
Promat, May 1986, p.19

6. **Benatar**, C.G. "There's a simple solution to productivity problems".
Promat, July 1985, p.13

7. **Benatar**, C.G. "How to trigger off a chain reaction of benefits".
Promat, August 1985, p.9

8. **Schonberger**, R.J. "Why the Japanese Produce Just-in-Time"
Industry Week, 29 November 1982, p.58

9. **Finkel**, J.I. "CIM & JIT - Together they make the factory of the future work"
Production, April 1986, p.36

10. **Schultz**, L.E. "Achieving Quality Control Throughout the Factory
Automatic Engineering, January 1986, p.53

11. **Goddard**, W.E. "Kanban versus MRP II - which is best for you"
Modern Materials Handling, November 1982, p.40

12. **Finch**, B.J. & **Cox**, J.F. "An examination of just-in-time management for the small manufacturer : with an illustration".
Int. J. Prod. Res, 1986, Vol 24, No.2, p.331

13. **Lee**, D. "Set-up Time Reduction : Making JIT Work"
Management Services, May 1986, p.10

A P P E N D I X B:

BIBLIOGRAPHY

BIBLIOGRAPHY

1. **Barry**, J. "Three modern management concepts - MRP; JIT; CIM"
Modern Materials Management, August/September 1985, p.16 - 18

2. **Barry**, J. "Meeting the Challenge of Just-in-Time in South Africa"
Promat, February 1986, p.3 - 9

3. **Benatar**, C.G. "How to trigger of a chain reaction of benefits"
Promat, August 1985, p.9 - 13

4. **Benatar**, C.G. "There's a simple solution to productivity problems".
Promat, July 1985, p.13 - 16

5. **Bicheno**, J. "Manufacturing Resource Planning (MRP)"
The South African Mechanical Engineer, Vol 34, November 1984, p. 420 - 422

6. **Carstens**, D. "How we went about getting just-in-time to work for us
Promat, February 1986, p.12 - 13

7. **Finch**, B.J. & **Cox**, J.F. "An examination of just-in-time management for the small manufacturer : with an illustration".
Int. J. Prod. Res, 1986, Vol 24, No.2, p.331

8. **Finkel**, J.I. "CIM & JIT - Together they make the factory of the future work"
Production, April 1986, p.36 - 40

9. **Freeman**, N.B. "Quality on the Mend"
American Machinist, April 1986, p.102 - 112

10. **Goddard**, W.E. "Kanban versus MRP II - which is best for you"
Modern Materials Handling, November 1982, p.40 - 48

11. **Heyns**, H. "The quality of quality circles in South Africa - Japanese viewpoint"
Safety Management, April 1986, p.20 - 23

12. **Kirkland**, C. "Just-in-Time Manufacturing : What you need to know and why"
Plastics Technology, August 1984, p.63 - 68

BIBLIOGRAPHY (Cont'd)

13. **Lallande,** A. "Winning without inventory"
Datamation, 15 February 1986, p.60.2 - 60.7

14. **Lee,** D. "Set-up Time Reduction : Making JIT Work"
Management Services, May 1986, p.8 - 13

15. **Leng,** L.K. "MRP II is the way to do JIT"
Production Engineer, October 1985, p.30 - 32

16. **Louw,** L.M. "The Influence of Race and Culture on Economic Performance and Prosperity"
(An address by Leon M. Louw, Executive Director of the Free Market Foundation of Southern Africa, to a Convention of the Soweto Chamber of Commerce and Industry, held on Thursday, 25 October 1984).

17. **MacKenzie,** N. "Adopt techniques which will give you a competitive edge - just-in-time"
Promat, May 1986, p.19

18. **Mayer,** R.R. "A critical look at Kanban, Japan's just-in-time inventory system"
Management Review, December 1984, p.48 - 51

19. **Monden,** Y. "Toyota Production System"
Industrial Engineering and Management Press, Atlanta, 1983

20. **Schonberger,** R.J. "Why the Japanese Produce Just-in-Time"
Industry Week, 29 November 1982, p.57 - 60

21. **Schonberger,** R.J. "Japanese Manufacturing Techniques : Nine Hidden Lessons in Simplicity"
The Free Press, New York, 1982

22. **Schultz,** L.E. "Achieving Quality Control throughout the Factory"
Automative Engineering, January 1986, p.53 - 57

23. **Schundig,** G. "MAN arrives just-in-time to save Harley Davidson"
Material Handling Engineering, August 1984, p.28 - 35

24. **Spoelstra,** H.I.J. "Japanese Management Methods in South Africa"
Productivity S.A., June Vol.12 No.3, p.24 - 26

25. **Wheeler,** W.A. "Just-in-Time - It Works"
A paper presented at the SAPICS Conference in Mbabane, Swaziland, 16 - 18 June 1986