Process Analysis for Capacity Improvement : Case study of M&H manufacturing company limited

by

Ms. Pinnuch Lohitkoopt

Submitted in Partial Fulfillment of the
Requirements for the Degree of
Master of Science
in Technology Management
Assumption University

February, 2003

Process Analysis for Capacity Improvement: Case study of M&H manufacturing company limited

By

Ms. Pinnuch Lohitkoopt

Submitted in Partial Fulfillment of the Requirement for the Degree of Master of Science in Technology Management Assumption University

February, 2003

The Faculty of Science and Technology

Master Project Approval

Project Title	Process Analysis for Capacity Improvement: Case study of M&H manufacturing company limited
By	Ms. Pinnuch Lohitkoopt
Project Advisor	Dr. Wisanu Tuntawiroon
Academic Year	2/2002

The Department of Technology Management, Faculty of Science and Technology of Assumption University has approved this final report of the **three** credits course. **MT6900 Master Project,** submitted in partial fulfillment of the requirements for the degree of Master of Science in Technology Management.

Approval Committee:

(Dr. Wisanu Tuntawiroon)
Advisor

(Krit Phunratanamala)
Committee Member

(Asst.Prof.Dr. Thotsapon Sortrakul)
Committee Member

(Dr. Tibrat Sangroengrob)
Committee Member

Faculty Approval:

(Dr. Soonthorn Pibulcharoensit)
Program Director

.P of. Supavadee Nontakao)
Dean

February / 2002

ACCKNOWLEDGMENTS

I am indebted to the following people and organizations. Without them, this project would not have been possible.

I need to express sincere gratitude to my advisor, A. Krit Phunratanamala. His patient assistance, guidance, and constant encouragement led me until the project completion.

My grateful thanks to Mr.Krit Sakdakornkul, pharmacist supervisor and other staff at M&H manufacturing Co., Ltd those who provide time and convenience during the process study and data collection.

Finally to my parents, who all played majors roles in my life, I wish to extend my love and thanks for their support, encouragement and patience.

ABSTRACT

This project is a case study of M&H manufacturing Co., Ltd, medicine manufacturer. The issue is unexpected increasing demand in animal medicine products. This cause us not to produce medicines to follow the customer's needed quantity with the existing capacity. Since our competitive priority is on time delivery, we have to find alternative to solve this problem. Therefore, this project will concentrate on manufacturing capacity improvement and aim to decrease throughput time of each production batch and to increase number of finished batch per day.

Time measurement was bringing to find the bottleneck of whole process. The four short-term alternatives are proposed for capacity improvement, which are summarized below.

1. Use parallel line at the bottleneck
2. Use automatic form, fill and seal machine to facilitate the process
3. Use overtime with the existing facilities
4. Add another work shift with the existing facilities

Finally, the fourth alternative, use 2 work shifts, is the solution that was chosen for implementation. Since, it gives maximum five batches a day because, it not only help to meet the demand, but also possible in practical implementation. Moreover, the 2-shifts work plan leaves a capacity cushion for the future demand.

During the manufacturing process, dust leakage is another problem that waste time to clean the building when switching to produce other product. Using air lock with air pressure is a proposed alternative to be installed for reducing the dust in long-term plan. To build air lock the production line has to paused for a construction period.

This project is case study of high investment of expensive technology machine which, could not solve the problem of company. On the other hand, only simple method, as adding a work shift turned to be the most suitable solution in facing situation.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

BIOGRAPHY

Name:	Pinnuch Lohitkoopt
Born:	8 May, 1977
High school:	Srinakarintarawirote Patumwan Demonstration School
	Triam Udom Suksa Phayatai
University:	The Faculty of Pharmaceutical Science, Chulalongkorn University
Work experience:	1999-2001: Apakorn Kieattiwong Hospital of Royal Thai Navy
	2001-present: M&H manufacturing Co., Ltd.

I. INTRODUCTION

1.1 General background of the company

M&H Manufacturing Co., Ltd. is one of the pharmaceutical manufacturers in Thailand. The Company achieved ISO 9002 and Good Manufacturing Practice (GMP) certified. We produce the generic drugs for both human and animal to serve local market and export to the neighboring countries.

We have facilities for producing many kind of dosage forms such as, tablets, capsules, syrups, sterile injection, etc.

Our company is pretty much concerned about quality of our products. It starts from the beginning, the formulation process to do a pilot batch then expand the batch size through the production stage then pass the medicine to the quality control system and finally transport our product to the customers, such as, hospitals, drug stores and clinic.

The present situation in pharmaceutical business has high competition especially the generic drug market. The generic drug companies make effort to sell their own brand products with many strategies and marketing plans. They all attempt to gain market share for keeping the companies survive.

We also have made the medicines in our own brand for selling. However, in high competition, we have to add the alternative channel in order to gain more revenue. Fortunately, our factory has the complete facility of production, which includes production area, laborers, warehouse, and reliable quality. Many companies confidently hire us to make their products. In other word, we call "Toll manufacturing".

Toll manufacturing is another way for the manufacturers with not much investment. It is attractive for the company who has complete facilities of production and laboratory. Doing toll business does not need to think about marketing plan and sale volume. The customers of toll business are companies who do not have production

facilities. Thus, they will hire the manufacturing company to produce their medicines. When the products are finished, the manufacturer will send to customer. The manufacturer receives the service fee. After that, it is the responsibility of customer to plan market strategy.

For M&H manufacturing Co., Ltd., we have done the toll business since we established the company. With that role, we have a good reputation in the quality of production and QC laboratory.

As reasons why other companies hire us to produce their medicines, for instance, multinational companies, they do not have their own plant in Thailand. Therefore, we act like their production department following the order. Our competitive priority is on time delivery. We try to finish the customers' orders to send at due date that customers need.

1.2 Problem statement

According to the contracted manufacturing customer, demand is increasing. Especially the animal medicine products, which demand forecast of the present year is almost double from the last year record. This cause us not be able to produce medicine following the orders on time with the existing capacity.

From the past, the animal product line could produce two batches per day, when the demand increase from the normal production schedule plan as an urgent order but it happened occasionally. The company used the over time manufacturing to correct this problem, which could finish three batches per day.

To do overtime, it costs for company such as additional labor payment in overtime rate. Moreover, the overtime still could not meet the demand of customers.

As the nature of our production line, it is a batch process. When we switch from one product to produce another product, we change the ingredient, package size, but use the same mixing machine, and other equipments. The finished animal medicine product is

powder dosage form. It is easy to generate dust, to protect the contamination of one medicine to other medicine; we have to clean all of the machine, equipment, and production room from ceiling to floor. Moreover, we also clean the walking area out of the production room, since there is dust leak from the corner of the production door and spread on floor wall and ceiling. This activities waste time about 4 hours to 1 day for cleaning and drying.

1.3 Objectives

The objectives of this project are as follows:

1) To study the production process of animal medicine for process improvement.
2) To improve capacity of the process in both short term and long term aligning with the increased demand forecasting.
3) To study the current technology for process improvement with proper recommendation of adopting technology.

1.4 Scopes of work

The scope of this project aims to improve the manufacturing process of animal medicine product. To meet the customer demand, this project intends to shorten the throughput time of each production batch. Inaddition, we try to reduce dust in the manufacturing building area. The area of this project can be classified in the following topics:

1) Measure time usage in every step in existing manufacturing process.
2) Find the bottleneck of the process.
3) Search for the alternatives to relieve the bottleneck and reduce throughput time.
4) Measure the time usage, throughput time after use of each alternative.
5) Find the amount of batch that each alternative could produce in a day.

6) Compare the amount of batch of each alternative, which one could meet the demand.

7) Select the suitable alternative to be short-term solution.

8) Calculate the maximum capacity after using the alternative.

9) Find the long-term solution to cope with increasing demand.

10) Find the method to reduce dust leakage problem.

1.5 Methodology

This project used the observation and time measurement method to study for process analysis. Time measurement will be useful to consider which step is the bottleneck of process. Use Microsoft Excel, solvers add in to calculate the maximum capacity after using alternative.

1.6 Study plan

This project plan could be divided into six phases, which are process learning, data collection, summarized data, identify bottleneck, finding alternatives, analyze and evaluation.

Week number	November				December				January				February			
Task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Process learning	■	■														
Data collection		■	■	■	■	■										
Summarize data						■	■									
Identify bottleneck								■								
Find alternatives								■	■	■	■					
Analyze and evaluation										■	■	■	■	■		

Figure 1-1 Project study plan.

II. LITERATURE REVIEW

2.1 Manufacturing process

2.1.1 Batch process

Manufacturing companies are referred to by a variety of terms that describe something about their manner of operation (James B., 1992). The facility, equipment and operating methods (the production system) that a company used depend on the type of product that it offers to customers. The influence of customization and volume generate five process types.

1. Project process
2. Job process
3. Batch process
4. Line process
5. Continuous process

For pharmaceutical manufacturing, process (Robert E. et al, 1995) is one of the batch processes. The medicine production is a serial process; the stages of production are similar for all products. The unit operations have characteristics that allow production in batches or lots.

Batch process can be considered a hybrid of the job shop process and line process (Robert E. et al, 1995), since batch process offer less flexibility than the job shop but more efficiency, gained primarily from less product variety, higher volume and more dominant material flows.

A batch manufacturing facility (James B., 1992) makes some intermediate variety of products and intermediate volumes of each. The volume of any one item is not sufficient to justify dedicating volume of each, so a few or several products share the production resources. The company will make one or more batches of one product, then switch over

the equipment and make one or more batches of another item. Eventually it will repeat production of the items.

Production equipment (James B., 1992) in batch manufacturing must be capable of performing some variety of tasks. After a batch is completed, the equipment may be set up anew to run some other item. The ability to change back and forth quickly is important.

2.1.2 Process management

Process management (Eugene H., 1993) is a concept that forces a focus on the flow of work independent of whether work is a product or service and independent of organization. The product or service output of a firm is the result of a series of work activities that comprise transformation of material and information. This set of work activities that produce an output is known as a process.

The principles of process management have been applied to analyze and improve key processes of its business operation. Functions such as finance, purchasing, product release, marketing, and product development have applied this concept with excellent payback in terms of cost savings and operational effectiveness.

From an operation viewpoint, a process is a bounded set of interrelated work activities each having prescribed inputs and outputs. It has a well-defined beginning and end. A process is essentially "a method for doing things" The main purpose of a productive process is to create from a set of inputs one or more outputs of greater added value than the inputs.

Output is fundamentally the result of a transformation or set of transformations. In the model shown in figure 1-1, inputs whether they are material, equipment, other tangible objects, or various kinds of information, are converted by a series of activities into an output that is provide to a recipient.

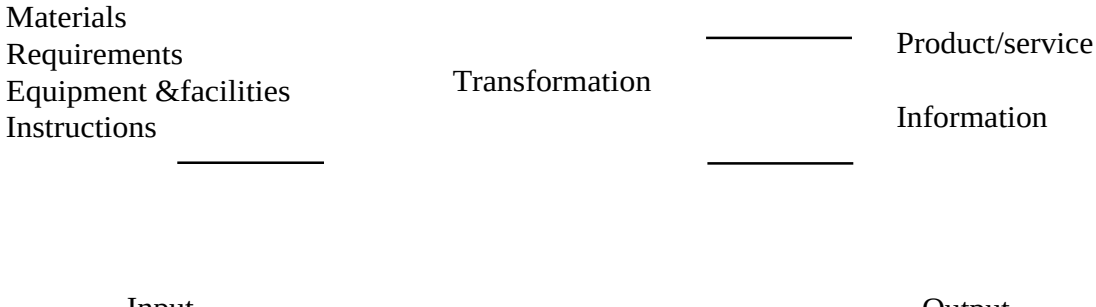


Figure 2-1 Transformation model.

A physical transformation involves converting raw or semi-finished material, together with certain information relative to the conversion, into an output of higher benefit. Location transformations involve movement of objects or material from one place to another, and storage as in moving and warehousing.

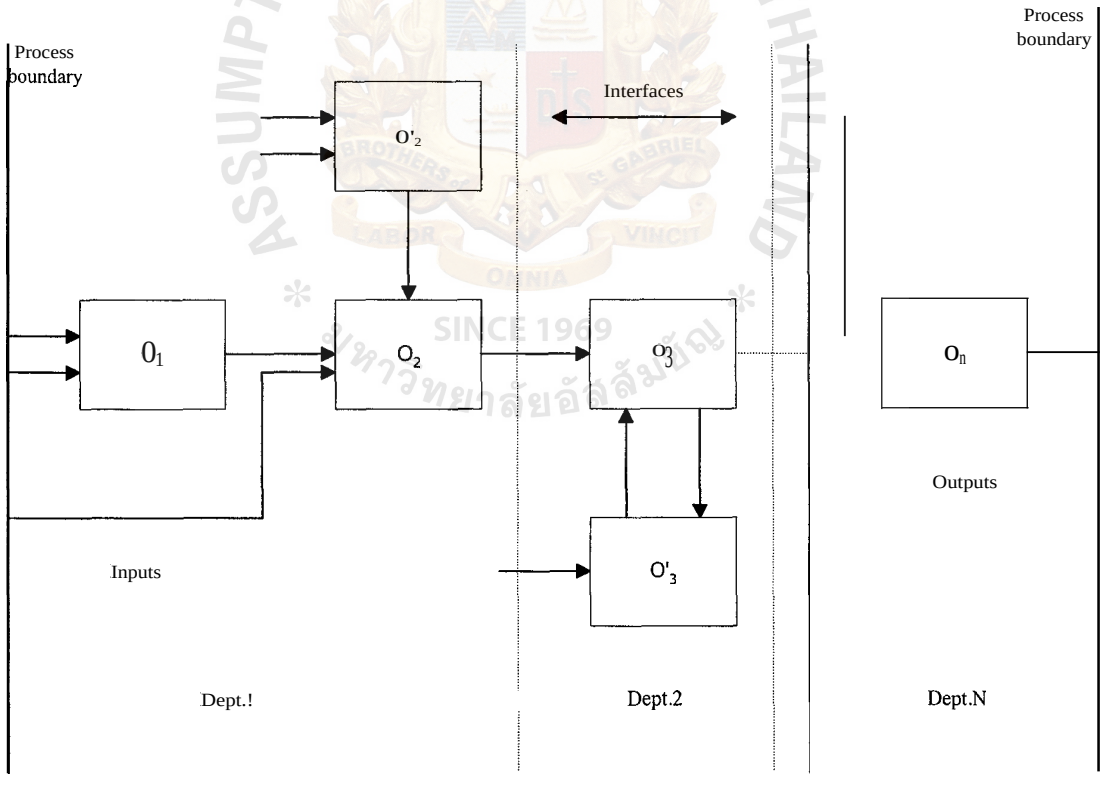


Figure 2-2 generic process models

From a generic process model, figure 2-2, a process generally begins with inputs such as raw or semi-finished material or data of various kinds. Certain prescribed transformations are performed at operation O_1. Activities are defined by formal documentation such as process specifications, operational descriptions or routings, instructions of various kinds, drawings, and so on. The end result of the 0_1 operation is a work product of higher added value that is then moved to a succeeding operation, 02, where other activities are performed. The output progressively gains in value until it exits the last operation, O_n, as a final output or end product, In many physical and informational type processes, work flows from a position of lowest added value on the input side to a position of highest added value on the output side. However, there are exceptions in certain types of processes where the highest added value may occur early in the process.

Operation O'2 may be thought of as a control and measurement point where the work is sampled and statistical process controls may be applies. $0'_3$ may be a form of a "re-do" operation such as rework or reconciliation, and O_n may be a final verification or a shipping-staging transfer step. Note that the generic process shown has well-defined boundaries (inputs to 0_1, output at O_n). Boundaries delineate the input and output sides of the work flow domain. Internal to the process are interfaces or points of contract between major activities or sub processes such as those shown between 0_2 and 0_3 in the figure. Interfaces demarcate the point at which work flows between process elements in different organizations, such as operator A in depar ment 1 and operator B in department 2.

2.1.3 Characteristic of a process

Process management has been implicit in well-managed production operations, resulting in processes that are under real-time management control and providing products to the consumer that meet cost, quality, and volume requirements. Chemical, pharmaceutical, and high technology operations, however applying the same concepts to

service and support activities have not been widespread, although the payoff in quality and productivity improvement can be substantial.

The principles of process management have their origin in the characteristics of a well-managed manufacturing process. To identify its general attributes and develop a foundation for process management, a well-managed manufacturing process has the following characteristics:

1. *Clearly defined ownership.*

Traditionally, ownership of a manufacturing operation is generally clear and explicit: it resides with a manager. The manager responsible for the operation is readily identifiable. This manager understands the organization mission, its output, and what he or she is accountable for, In addition, there are standards by which the manager's performance is judged, such as cost, schedule, and quality. A process owner, whether an individual or a team, is fully responsible and must manage the process to the targets set on these standards. Further, an owner has the authority to change or oversee a change in the process within this or her area of jurisdiction.

2. *Defined boundaries.*

Manufacturing processes have a clearly defined beginning and end. The final out put, or deliverable, as well as the input(s) required to create it are clear and unambiguous. What is sometimes not clear, however, is whether output specifications truly reflect customer requirements and whether input specifications represent what is needed in the ensuing transformations. The lack of understanding of requirements on either the input side or output side underlie many business processes. In a well-managed manufacturing process, requirements problems are minimized through conscious effort aimed at specifying the work product as it proceeds from one operation to another.

3. *Documented flow of work.*

Workflow in a manufacturing process is generally documented in great detail. Documentation provides a permanent record of the manner in which a physical transformation takes place for production purposes. This record also provides a reference point or baseline from which any changes are to be made and serve as a means for replicating the process. Finally, documentation also serves as both a training and reference aid for the personnel involved in the process.

4. *Established control points.*

Control points serve as a means for regulating the quality of work. Because of natural variation that occurs in physical processes, control points are established to manage variation. These points involve such activities as inspection, verification of required characteristics, and disposition of discrepant material.

5. *Established measurements.*

Measurements provide a statistical basis for controlling the flow of work and managing variation. In addition to verification of the conformance of the final work product to specifications, in-line measurements are inherent in any well-managed process. Measurements serve as a factual basis for taking corrective action on variations that may occur. Statistical techniques such as the control chart serve as useful tools for managing variations in many operations of a repetitive nature.

6. *Control of process deviations.*

In managed processes, corrective action is performed in a timely manner and from a statistical basis when an undesirable variation occurs. Feedback and regulation are the heart of process control and, without control; the process loses its capability of providing consistent output quality.

2.1.4 Process analysis

Process analysis (Eugene H., 1993) is a systematic way of defining the activities and tasks within an operation, generally at a departmental or work-group level.

Process analysis (L.P. Alfred, 1984) may be defined as the subdivision or resolution of a manufacturing process into its constituent operations and attendant material movements, so that each operation and internal handling may be studied and its necessity in furthering the process determined.

2.1.5 Process improvement

Process improvement (Lee J., 2002) is the systematic study of activities and flows of each process to improve it. Its purpose is to "learn the numbers," understand the process and dig out the details. Once a process is really understood, it can be improved.

One must look for ways to streamline task, cut expensive materials or service, improve the environment, or make jobs safer. One must find the ways to trim costs and delays and improve customer satisfaction.

2.1.6 Process improvement model

There is an eight-step process improvement model (Arthur R. and Irving J., 1992) that provides the structure needed to facilitate process improvement activities. It is important to follow the steps of the model to help ensure success of the improvement effort.

Step]: Define the problem in the context of the process

Although both process and results are important, the focus must be on the process, not specific results. To define the problem in the context, we must answer several questions such as, what are the outputs of the process. Who are the customers both internal and external customers? What are the customers' requirements?

A better approach to problem solving may be to first form an improvement team. The team can determine the needs and expectations of various customers by talking with them. These needs and expectations should drive the improvement effort.

Step2: Identify analyze, and document the process

Developing good solutions to problems is quite difficult unless everyone has a full understanding of the current process. Teams must identify and document every activity, however minor. For instance, what is done, who does it, why it is done, how long it takes. Check sheets and process maps are effective tools in this step of the overall improvement model.

Step3: Measure current performance

The team must assess the strengths and weakness of the current overall process. How well are we doing now? Measures of product or service quality, on-time delivery, waiting time, total cost, total processing time and the number of processing steps all may be useful. Then determine which factors are most important; the team must talk to the customers.

Step4: Understand why the process is performing as it is

The team must pay attention to find the causes of the problems that the performance measure brought to light.

Step5: Develop alternative solutions and select the best one

Next, the team begins to develop alternative solutions to the problems it noted. It will evaluate various alternatives on how well they might contribute to the performance measure established earlier as critical measure. Then choose the best for implementation. In this step management should make the team aware of any critical constraints that might affect its solutions.

Step6: *Develop strategy and implement the alternative chosen*

Any alternative that is poorly implemented will stand little chance of providing the results expected. The strategy should include when, where and how to implement the alternative. Generally, implementation on a small scale is better, until it could assess the performance of the improved process.

Step7: *Evaluate the results of the new process*

The performance measures used to evaluate the new process should be the same measure identified in step3. Only then can the team make an accurate comparison of the pre-improvement and post-improvement processes.

Step8: *Commit to continuous improvement of the process*

If the assessment of the improved process is favorable, the company must take care to ensure that the improvement activity continues.

2.2 Throughput

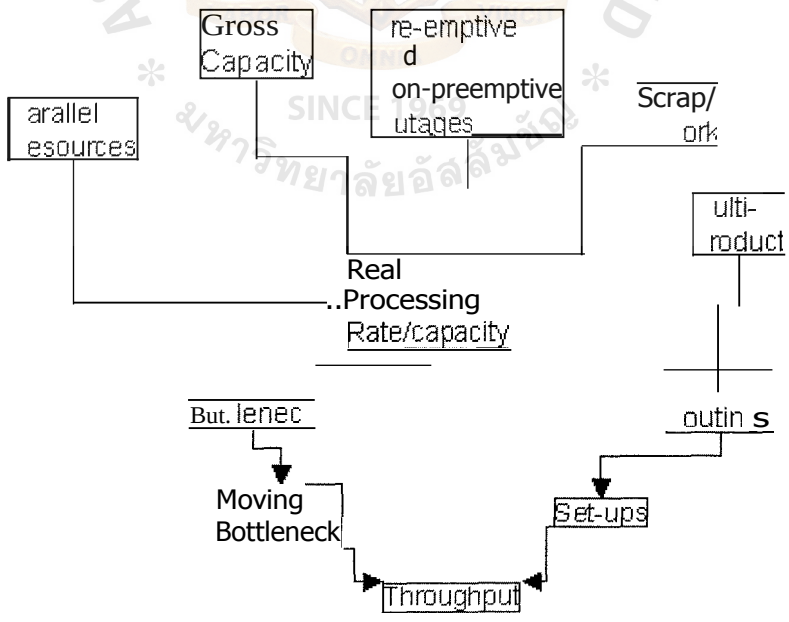


Figure 2-3 Factors that affect throughput

Throughput is the amount of product per unit of time that the factory is capable of producing. The term Capacity to indicate the volume of production a given machine is capable of, but the term Throughput is very similar. It will be worthwhile to distinguish between those terms.

Capacity is the volume of production obtainable with a fully functioning machine or workstation, where the emphasis is on a single unit of production such as a machine. The time that a machine is operating, whether one shift or more, is an important factor in expressing its capacity.

Throughput is the volume of production obtainable from a facility such as a factory, and must reflect the effect of a variety of capacities at the series of workstations passed through, as well as other effects such as breakdowns and set-ups. The term system capacity has also been used in production literature to indicate the same concept.

Capacity is somewhat fixed, often being based on the rated speed of a machine, while throughput is somewhat variable, depending on what breakdowns have occurred, or other disruptive events. A value for throughput to be used for planning purposes must be a statistical average.

Just as capacity has a time assumption (1 shift, 2 shifts or whatever), throughput is a reflection of an aggregate of time assumptions, given that different work centers may work different hours. If any area changes its hours of work, throughput may be affected (but not necessarily if the area already has excess capacity, in which case adding more capacity doesn't affect throughput).

The factors, which affect throughput (those in the diagram figure 2-3)

1.Real Processing Capacity

In discussion of Real Processing Capacity, let us think of a single machine, or a shop of

similar machines. We need to get a handle on what this facility can realistically produce.

2.Gross Capacity

In simple terms, capacity (Robert E. et al, 1995) is the productive capability of a facility, usually measured as a quantity of output per unit of time, the rate of output that can be achieved from a manufacturing or service process. Most commonly, capacity refers to the maximum productive capability of a facility or the maximum rate of output from a process.

The most important factor is obviously the gross capacity of the facility. .By this, we mean the volume of production obtainable when the facility is operating at its best. As mentioned before, a time assumption is necessary (for example, number of shifts, or number of days in the working week, and so on). If the capacity is expressed as per day, then the number of shifts or hours would have been taken into account. If the capacity of the facility is stated as per week, then the number of days worked would have been taken into account.

1. Pre-emptive and Non-pre-emptive Outages.

Pre-emptive outages are those, which happen unexpectedly, such as breakdowns. Being unexpected, it is impossible to tell how long a machine will run until it next breaks down. However, if a record is kept over a long period detailing how long the machine ran between breakdowns, and how long it took to repair in each case, then we can plot statistical distributions to describe each. We then get two averages, the Mean Time to Failure (MTTF) and the Mean Time to Repair (MTTR). Over the long term, it is obvious that capacity is reduced by pre-emptive outages, the amount calculable using the MTTF and MTTR values.

Non-pre-emptive outages are outages, which are planned. For example, meal breaks and preventative maintenance (PM) are such. These will detract from gross capacity, although is arguable that such outages could be built into the original gross capacity figure rather than as a later deduction.

2.Parallel Resource

More often than not, parallel resources are needed to complete an operation, the most common. example being machine and operator. Where the two resources overlap 100% (an operator is wholly dedicated to a machine, for example), then the capacity of the machine is unaffected. Even when the operator is multi-tending, as long as no machine is held up for want of operator attention, the capacity is unaffected. The problem arises when the multi-tending operator cannot keep up with all machines requiring attention.

Obviously, the hold-ups detract from the capacity of the machines. However, it is a problem to be able to calculate the extent of the hold-ups. This is not a simple calculation as meal breaks, and illustrates the need for sophisticated computer software tools.

Pushing our scenario further, operators may be so thinly spread in relation to machines that labor instead of machines becomes the resource determining capacity. In other words, on a given day, only a proportion of machines can be run due to the availability of people.

There are factories where capacity was determined by the labor hours of the operators. This was because of a huge variety of products from different machines, and only a proportion of machines were manned on any day.

It would be nice to present a simple algorithm to account for parallel resources, but this problem is best left to intelligent tools, or where such are absent, the usual planning recourse to a significantly large fudge factor.

1. Scrap/Rework

If 5% of items made on the machine are scrapped, then 5% of capacity has been lost. To compensate, jobs released to the machine must be factored up to make sure of getting the required good output. So far it seems a simple calculation. But suppose the scrapping happens at a later operation (an assembly containing the part in question is scrapped). Then the calculation is not such a simple matter, as it must include all scrap - wherever occurring - affecting the item in question.

Where items can be reworked off line, then the loss of capacity is limited only to those items, which cannot be recovered. However, the rework introduces a cycle time delay to the reworked items, which will be considered in other pages. If the rework is carried out in-line, the effect on capacity depends on how much time is required to rework a faulty item versus the time to make a new item.

2. Bottlenecks

A bottleneck (Lee J., 2002) is an operation that has the lowest effective capacity of any operation in the process and thus limits the systems' output.

Manager might relieve the bottleneck by redesigning the process, (Lee J., 2002) either through process reengineering or process improvement. When the Real. Processing Capacity was computed, it was in relation to a single resource (e.g. a machine). In reality, most manufacturing processes are composed of multi-stage routings, at each of which a given resource operates on the product. It seems common sense to balance the capacity at each stage to be roughly equal: for example, suppose 1000 units of product are required

per week, then all stages should have a capacity of 1000 a week, and if any stage has significantly more, then that capacity is wasted.

However, it frequently happens that different stages have significantly different capacity than the others. Reasons why this should be so are:

- An excess of a resource exists for historical reasons, perhaps being purchased for a past level of demand for that particular resource which no longer exists.
- A resource balances theoretically at the gross capacity level, but detractors such as outages and rework make the real processing capacity much lower.
- Changes in shifts may increase or decrease the available hours of work per day and thereby increase or decrease capacity.
- Skill shortages may constrain the capacity of a particular resource.

For a well-established routing, it often happens that one stage has much less capacity than others, resulting in a bottleneck do. It follows that the throughput of the routing is constrained to the capacity of the bottleneck.

In figure 2-4, it is assumed that the bottleneck resource is known. It is impossible for work to be throughput at a rate greater than the bottleneck capacity, so this determines the rate at which work should be released.

It is, of course, possible to release work at the historical average capacity of the bottleneck. In practice, this is what many firms do, not explicitly in relation to the bottleneck, but in relation to average throughput, which must of course derive from the bottleneck.

However, Release from Bottleneck systems goes one better. They release work based on the real time status of the bottleneck. The diagram illustrates how:

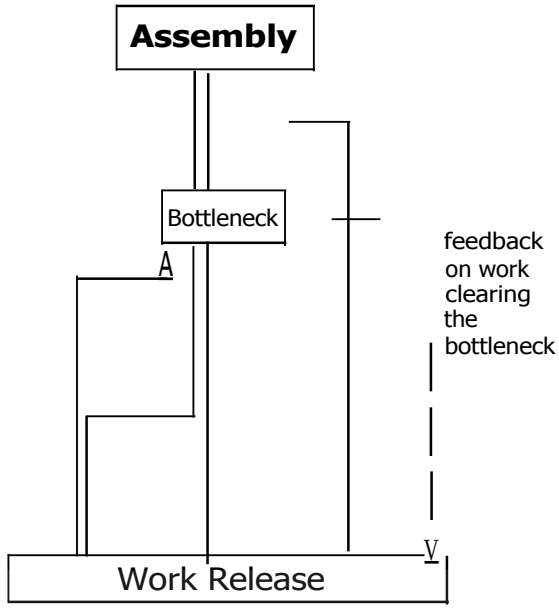


Figure 2-4 Bottleneck

Work is released a pre-determined lead time needed to take it to the bottleneck. However, it is only released based on feedback from the bottleneck on the rate of work passing through. So, if the bottleneck slows down for any reason, work release is choked off. In effect only a fixed amount of work is allowed on to the shop floor at any time.

2.2.1 Throughput time

The amount of shop time for the job is called throughput time or job flow time (Lee J., 2002). It is the sum of the moving time between operations, waiting time for machines or work orders, process time (including setups) and delays resulting from machine breakdowns, component unavailability, and the like.

2.2.2 Cycle time

Cycle time is time between completions of successive items on the line (James B. 1992).

Cycle time is defined as the time between the release of one model, until the release of the next (Robert E. et al, 1995).

2.2.3 Productivity

Productivity (Lee J., 2002) is the value of outputs (goods and services) produced divided by the values of input resources (wages, cost of equipment, and the like) used:

$$\text{Productivity} = \frac{\text{Output}}{\text{Input}}$$

Labor productivity is an index of the output per person or hour worked.

Multifactor productivity is an index of the resources used in production, such as the sum of labor, materials, and overhead costs.

2.2.4 Utilization

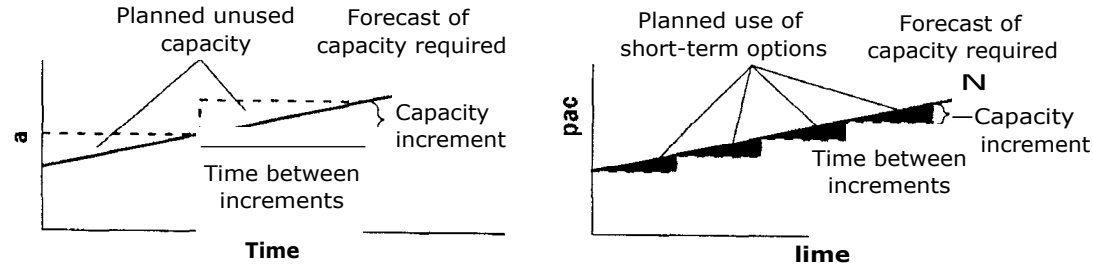
Capacity planning requires knowledge of the current capacity of a process and its utilization. Utilization, the degree to which equipment, space, or labor is currently being used, is expressed as a percent;

$$\text{Utilization} = \frac{\text{Average output rate}}{\text{Maximum capacity}} \text{ X } 100\%$$

The average output rate and the capacity must be measured in the same terms-that is, time, customers, units, or dollars. The utilization rate indicates the need for adding extra capacity or unneeded capacity.

2.3 Capacity strategies

Timing and sizing expansion (Lee J., 2002) is one of the capacity strategies, when to expand and by how much. Figure 2-5 illustrates two extreme strategies: the expansionist strategy, which involves large, infrequent jumps in capacity, and the wait-and-see strategy, which involves smaller, more frequent jumps.



(a) Expansionist strategy

(b) Wait-and-see strategy

Figure 2-5 Two capacity strategies

The timing and sizing of expansion are related; that is, if demand is increasing and the time between increments increases, the size of the increments must also increase. The expansionist strategy, which stays ahead of demand, minimizes the chance of sales lost to insufficient capacity. The wait-and-see strategy lags behind demand, relying on short-term options such as use of overtime, temporary workers, subcontractors, stock-outs, and postponement of preventive maintenance to meet and shortfalls. However, these options have their drawbacks. For example, overtime requires payment of time and-a-half wages for some employees and may result in lower productivity or quality during overtime hours. Nonetheless, some mix of short-term options might make the wait-and-see strategy best in certain situations.

Several factors favor the expansionist strategy. Expansion may result in economies of scale and a faster rate of learning, thus helping a firm reduce its coats and compete on price.

The conservative wait-and-see strategy is to expand in small increments, such as by renovating existing facilities rather than building new ones. Because the wait-and-see strategy follows demand, it reduces the risks of over expansion bases on overly optimistic demand forecasts, obsolete technology, or inaccurate assumptions regarding the competition.

2.4 Time study (Biolab, 2001)

The purpose of time study is to find out the standard time of doing each assigned job of employees. This method assist department making decision on what is the number of appropriate employees? Time study also uses to compare the efficiency of operation process before and after improvement. Moreover, it is helpful to calculate the capacity of manufacturing line.

During the time study, the employees who work at that measurement period must have experience and skill to do their assigned job. It is very important for those employees to work as usual activity, not in tense feeling.

Method of time study

1. Measure the time of each step in process, some steps take very few second and difficult to measure could be combined together.
2. Collect the time data and find the average value.
3. Assign the rating factor following the rate of worker as this table.

Table 2-1 Rating factor of working time study

Factor	**Working rate**
0	Worker do nothing
50	Work very slow
75	Work in constant rate, not in hurry
100	Normal working rate
125	Hurry and confident
150	Fast speed, attempt and concentrate

4. Find normal time from this formula

$$\text{Normal time} = \frac{\text{Average time} * \text{Rating factor}}{100}$$

5. Assign the extra time normally use 5%, but if process provide break time, it will be 4%. This extra time is allowed for private activity, fatigue, late, fixed or adjust machine, power failure, etc. that could happen during manufacturing process.
6. Find the standard time of each operation step

   This standard time will the represent time of each operation step for further calculation that base on this process.

$$\text{Standard time} = \frac{\text{Normal time} * 100}{100 - \% \text{ extra time}}$$

2.5 Research paper

In 2001, Thomas A. Gresik and Edward C. Mansley studied about the strategic effects of batch processing. They used a duopoly game in which firms commit to a batch technology before competing in sales quantities. They emphasized that the larger batch sizes lower unit production costs. Many firms produce in batches. The firm's technology allows the batch size to be flexible in order to reflect variations in demand. A flexible manufacturing system allows a multi-product firm to produce several products on the same equipment. The purpose of their study is to study the impact of batch processing in a duopoly model of quantity competition when the batch size choice implies long-run technological commitment.

They consider a two-stage game. In the first stage, the firms simultaneously choose technologies that fix batch size and yield constant marginal costs per batch. In the second stage, the firms simultaneously choose sales levels. The strategic effects of batch production arise from three sources. First, larger batch sizes increase the range of sales levels over which the marginal cost of selling an inframarginal batches unit is relatively low. Second, the batch size choice generates discrete jumps in the marginal cost of sales at

quantities that correspond to an integer number of batches. Third, changes in batch size can change the average cost of production within a batch.

In the duopoly setting, they show that neither firm will choose a continuous cost technology in any sub game. This result suggests that not only should we expect to see firms producing with batch technologies, but also that the optimal batch size reflects strategic concerns as well as cost minimization concerns.

According to the study of Kosit A., 2000, Optimizing batch size of work in process by using a simulation technique. He collected time data by using time observation sheet to find normal time of each activity in process. He used simulation techniques, because it is the process of designing and creating a computerized model of a real or proposed system for the purpose of conducting numerical experiments to give us a better understanding of the behavior of that system at a given set of conditions. He applies the simulation technique by creating the current production line system using batch size equal to 5 units. He compared a created system with the real system and then we adjust the number of batch size; to find out the optimize batch size. After he completes the study, he found that the batch size should be 3 units per lot. And he can reduce work in process level 23% while line capacity and utilization are still maintained.

The future simulation will be used in three distinct manufacturing modes:

1. As a design and analysis aid for factory layouts, equipment decisions, alternative operating policies, problem evaluation, etc. These are the traditional roles currently played by simulation models.
2. As a tool for scheduling, particularly with automated systems. This use allows the decision maker to explore and plan changes to existing schedule and/or to find the optimal schedule starting with current conditions. For example, current conditions may include the fact that a particular piece of equipment has broken down. The

model would then generate an alternative schedule that would be used until the equipment was repaired.

3. As a part of real time, on-line control system. Such a system would periodically be activated, read the current conditions from a database, project the schedule forward, and then, depending on the results, leave well enough alone, modify the schedule, or call for human intervention.

A simulation model is often easier to justify to management or customers than any other analytical models. In addition, simulation might have more credibility because its behavior has been compared to that of the real system

An experimental problem arises when a need develops for specific system information that is not available from known sources. Some of the benefits associated with simulation such as new policies, organizational structures, and information flow can be explored without disrupting ongoing operations. Time can be controlled: allowing us to speed up or slow down a phenomenon for study.

Even though simulation has many disadvantages

1. Model building requires specialized training. The quality of the analysis depends on the quality of the model and the skill of the modeler.
2. Simulation results are sometimes difficult to interpret. Because the model is trying to capture the randomness of the real system, it is often hard to determine whether an observation made during a run is a significant relationship in the system or to the randomness built into the model.
3. Simulation analysis can be time-consuming and expensive. An adequate analysis may not be feasible given available time and/or resources.

He suggested that to conduct an applied simulation project for a real facility, the emphasis in on accuracy of input data and building a model that incorporates, as many real

complexities of the system that are required. If we need more accurate analysis, we need to collect more numbers of data such as standard time of each operation, mean time between repairs etc. and closely observe the real system.

In 2000, Pichai M. had studied about the inventory management at an electrical switchboard with using the method of material requirement planning (MRP) and economic quantity ordering (EOQ). His inventory strategy used basic functions of bill of material to plan the material consuming in the electrical switchboard, The basic spreadsheet software `Microsoft Excel' was used for calculate the planned order receipt and planned order release in MRP, holding cost also ordering cost in EOQ.

The major factor of manufacturing the electrical switchboard was the material planning before proceed all work, therefore the manufacturer has to control and estimate the dispatch date accurately.

As the complexity of situation increase as measured by the number of items to track. The extent of common components and the frequency of changes to the bill of materials, the complexity of setting up and maintaining an MRP system in a spreadsheet increased to the point where a specialized development program software might be more appropriate by using 'Microsoft Visual Basic' or 'Microsoft Access'.

III. EXISTING PROCESS

3.1 Business process of order handling

The contract manufacturing of medicine is the connection between two companies. The brand owner company (customer) hires our company as a manufacturer. Competitive priority for us is on time delivery. These following are the step of order handling matching with process flow picture: Figure 3-1

1. At the beginning of the year customer will forecast their demand and inform us needed items, quantities for each month in one-year period. The customers send the forecast by facsimile or e-mail directly to the business development manager, who has responsibility for the entire contract manufacturing for our company.
2. According to the contract, customer has to confirm the order at 3 months before the production processes begin, therefore planning department will be able to set up the suitable schedule.
3. When customer calls to confirm and fax the shop order and packing order, planning department will use these order documents to check the raw materials, packages, and other component whether it enough
4. After customer sent the order documents around 2 days, they will send us raw materials or packages (in case that customer supplies us). For the customer that order many batches for one time they may send raw materials batch by batch, only we could start the first batch.
5. When customer sent raw materials planning would check whether the item and quantity completely for manufacturing, and warehouse would receive those raw materials and package then add in stock card. For this step, it takes one day for average.

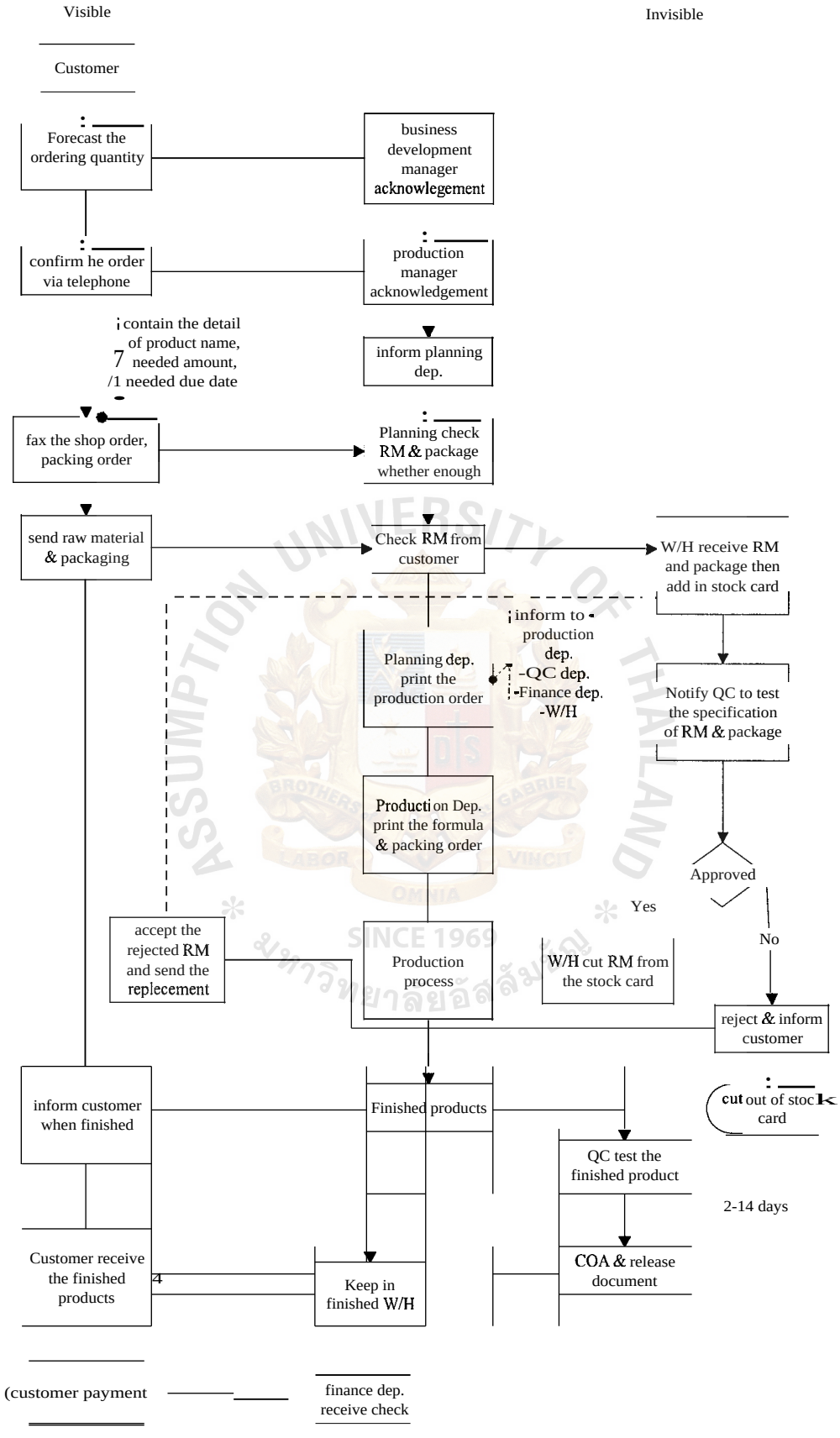


Figure 3-1 Order handling process

6. When all of the production processes' needs are completed, planning department will print the production order, which also inform the production department, quality control department, warehouse, and finance department. For this step, it takes one day for average.

7. When production department receives the production order, they will print the formula and packing order for using in production line. For this step, it takes one day for average.

8. After warehouse received raw material in the inventory, they will notify QC to sampling randomly for testing whether it follows the specification. The approval period takes 2-14 day depending on the item of raw material.

   If the raw material is not approved, QC will inform customer to send the replacement and in one-day warehouse will cut out of stock card.

9. The approved raw material will be weighted for using in production process warehouse will cut raw material and related components, such as bottles, aluminum foil, labels, etc from stock. This preparation period take 5-7 days. Then the production processes begin and finish in 1-2 days per batch. However, normally the order has more than 1 batch; therefore, the production process will continue and take more time.

10. Quality control department will sample the finished products from assembly line. The test result will come out in 2-14 days depending on item. This also includes the document preparation.

11. The finished products are kept in warehouse, waiting for customer to receive at the due date. The customer will be informed in one day to get their products when finished products are ready, attached with certificate of analysis and other necessary documents.

3.2 Manufacturing process

In the mean time, the production line of animal medicine is obviously in trouble. Due to the double increase of demand from customers, this cause us to use overtime production for finishing the products as customers need. Therefore, in this project, I will concentrate on the animal medicine line. The building of animal medicine is isolate from other human medicines. Normally, animal medicine is produced for farm animal such as pig, chicken, cow, etc. The dosage form will be dry powder or the mixing between medicine and bran, to be easier to feed animal, then packed and sealed in paper bags.

Initially, after production supervisor got the order from planning department, the workers in warehouse have to weigh the active ingredient to have amount exactly following the formula. This process is done at the raw material storage room under the control of supervisor then transfer to the production room.

In the production room, there is one mixing machine, which has maximum capacity at 810 kg. Mostly, we produce at 800 kg per batch and use five workers for one batch producing. The manufacturing process is in figure 3-2.

1. Before starting production process, the workers have to cover the room floor with papers to ensure that the finished product bag will be clean. In addition, this will protect the floor from chemical reaction also.
2. Then workers set up the mixing machine and other equipments.
3. Workers check the active ingredient's weight whether correct before mixing.
4. Workers weigh the other ingredients such as starch, bran following the formula.
5. Lift up active ingredient and starch to the 2n^{d} floor by elevator
6. Then, open lid of mixer, pour the 1st portion starch on screen, and sieve them into mixing machine.

7. Sieve active ingredient into mixer to be the 2nd layer.
8. Next, pour the other portion of starch and sieve into mixer.
9. Close the lid of machine and turn on switch to start mixing all ingredients until it is homogeneous. Then turn off switch.
10. Time of break and relax for worker. Waiting the dust sedimentation.
11. Open the valve of mixer to release the dead leg (not well mixed portion).
12. Set up for filling step.
13. Fill estimate weight of finished medicine into bag with manual control valve.
14. Use scale to weigh the filled bag and adjust to be 10 kg per bag.
15. One worker move the filled bag to the sealing machine one by one
16. Release air in bag then manually seal the inner bag (plastic) with heat-sealing machine.
17. Workers from filling step come to set up the paper bag sewing machine.
18. Sew the outer bags with semi-manual sewing machine.
19. The workers lay the finished products on wood pallet, prepare for moving to customer.
20. Start the next batch of same product in 10 minutes later. If there is no other batch of the same product waiting in queue, worker will clean the production area for preventive contamination to other product. The cleaning step means all the inside building area.

Table3-1 The time usage of existing process divided in 4 major sections

Section	Name of section	Detail of section	Steps involve
1.	Preparation	It starts from the beginning of a process, prepare all ingredients that needed and stop before using mixing machine.	1-8
2.	Mixing	This section starts from the worker turn on switch of mixing machine. As we use the maximum capacity of mixing machine, full of mixer, which cause its homogeneity, occasionally not meet as quality control specification. To protect the inappropriate test result, in this mixing period they have to stop machine for releasing ingredient from bottom of mixer and put it on top layer then start machine again to make it homogeneous. This section stop when medicine mixed well and worker turn off the switch.	9
3.	Break	Break period will happen after the mixing period, since workers have to use a lot of manpower in mixing period. 30 minutes break aim to protect fatigue muscle of workers.	10
4.	Packing	Packing period start from workers release the dead leg from the mixing machine, fill the 1st bag, adjust weight, seal the inner bag, sew the outer bag and lay finished bag on pallet. This section end when the 80^{th} bag lay on the pallet.	11-19

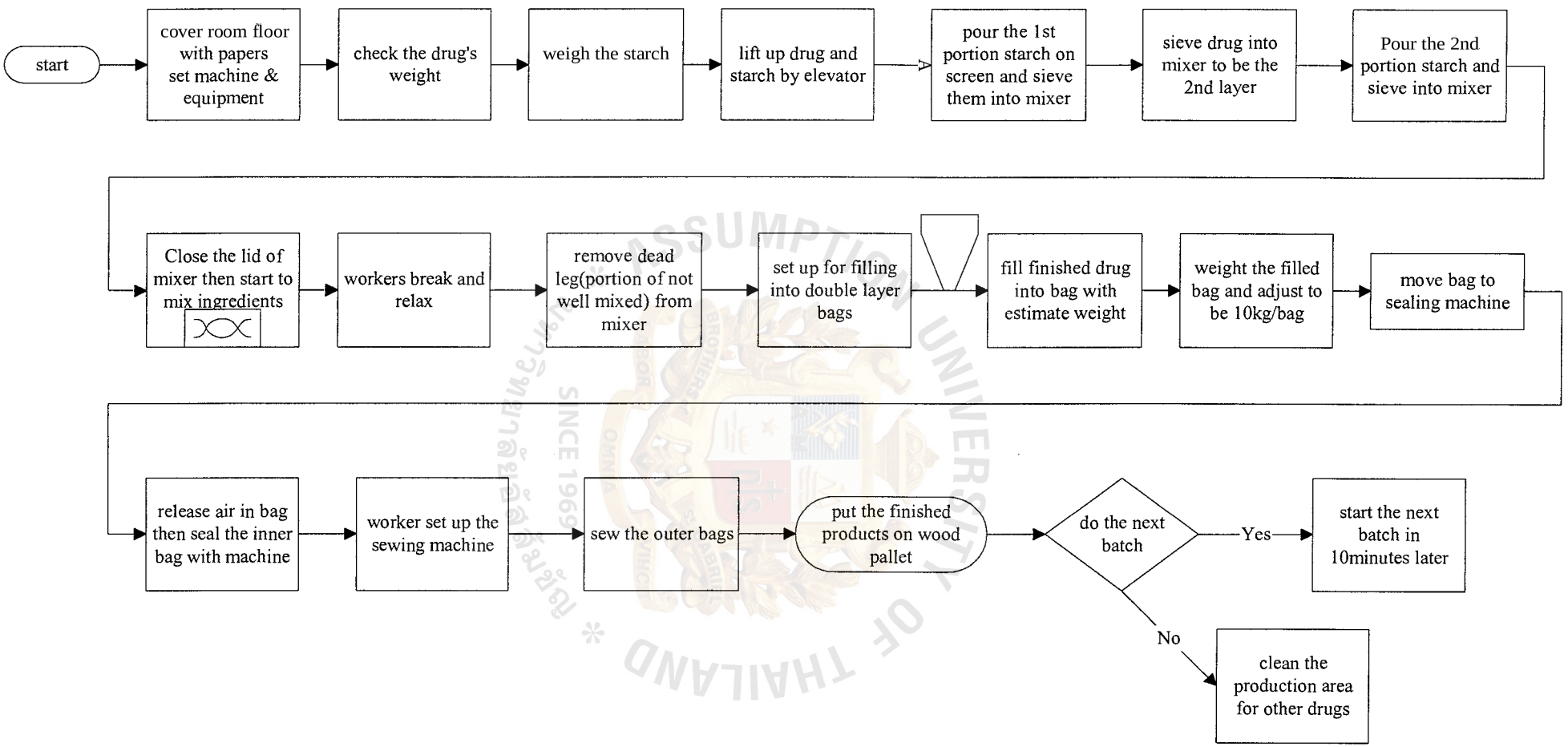


Figure 3-2 Manufacturing process

3.3 Increasing demand

Since, the government's new regulation of controlling the usage of animal medicine in country, 16 items of animal medicine were under control by government rules. Those could not have freedom import as the past for domestic animal treatment.

Fortunately, our customer's medicines products do not relate in those prohibit categories. The incidental benefit is the medicine that we have produced turn to be the substituted product in market, and the demand is unexpected increase.

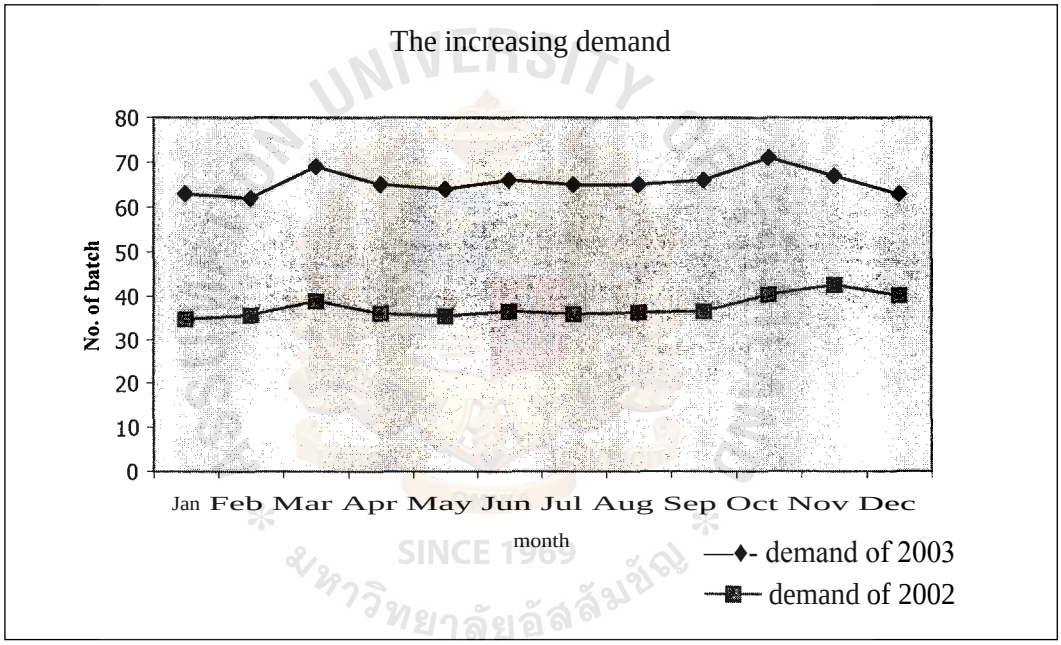


Figure 3-3 the increasing demand compared between years 2002 vs. 2003

The increasing demand is also our opportunity to present our production capability. Therefore, we have to manipulate and finish the order, as customer need.

Table 3-2 demand forecast of year2003 for highest volume of three products.

Product name	Unit	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
A	Kg*1000	15.2	13.6	18.4	15.2	16.0	17.6	15.2	15.2	17.6	18.4	18.4	15.2
	Batch	19	17	23	19	20	22	19	19	22	23	23	19
B	Kg*1000	22.4	23.2	22.4	24.0	22.4	22.4	22.4	24.0	22.4	24.0	22.4	22.4
	Batch	28	29	28	30	28	28	28	30	28	30	28	28
C	Kg*1000	12.8	12.8	14.4	12.8	12.80	12.8	14.4	12.8	12.8	14.40	12.8	12.8
	Batch	16	16	18	16	16	16	18	16	16	18	16	16
Total	Kg*1000	50.4	49.6	55.2	52.0	51.2	52.8	52.0	52.0	52.8	56.80	53.6	50.4
	Batch	63	62	69	65	64	66	65	65	66	71	67	63

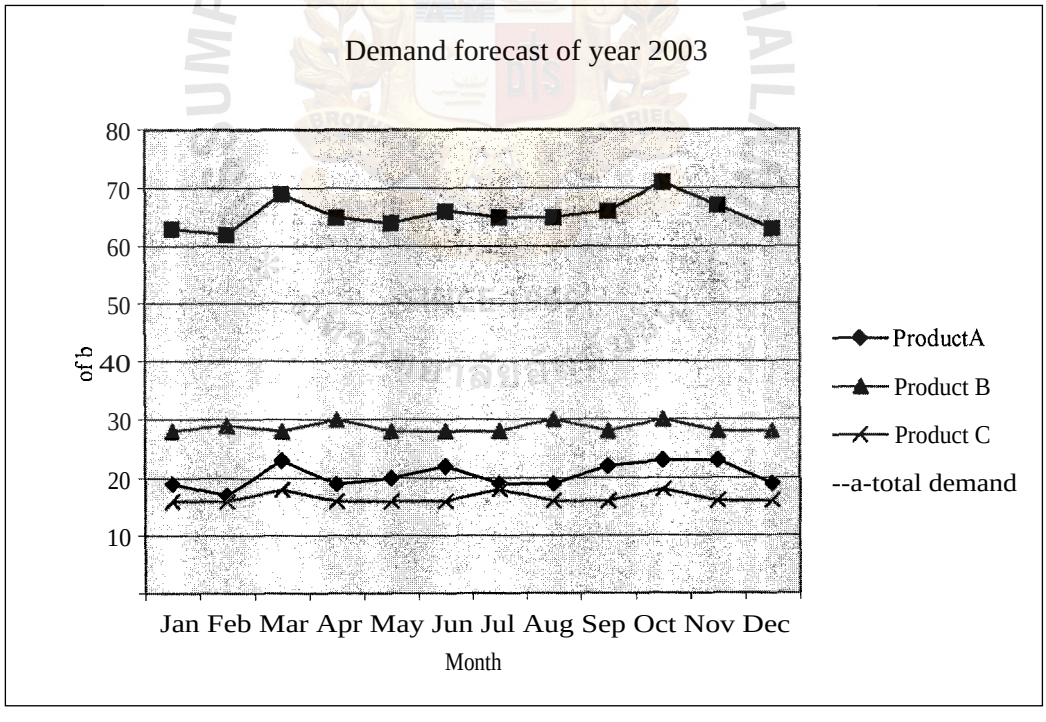


Figure 3-4 Demand forecast of year2003 for highest volume of three products

IV. METHODOLOGY

This project used the observation and time measurement method for process analysis. Using time measurement to consider, which step is the bottleneck of whole process.

4.1 Data collection

All details of the study are recorded on the time study form (Kosit, 2000). Table 4-2 is the observation sheet or time study form of animal medicine manufacturing process. The purpose is to know the production capacity. Before the real data collection, the preliminary time measurements present seem likes normal distribution. Therefore, the assumption of time usage of each step is going to be normal distribution. Each step was observed 30 data, and then finds the average time. The rating factor 100% refer to the speed of worker is in normal speed.

$$\text{Normal time} = \text{average time} * \text{rating factor}$$

$$\text{Standard time} = \frac{\text{Normal time}}{100\% - \%\ \text{extra time}} \times 100\%$$

Percent extra time is provided for fatigue activity or possible delay activity. In this process was assumed 4%.

To be the effective standard time, the observation should come from the workers who have been trained prior starting in the production line to prevent human errors in the process. In table 4-1 shows, the example of standard time calculation in step of sealing the inner bag.

Table 4-1 Standard time calculation of step sealing the inner bag.

Time data	n = 30	33.30,32.98,33.10,33.76,32.55,33.38,33.71,32.52, 33.06,32.96,33.57,33.56,32.93,32.86,34.42,32.87, 33.11,33.26,33.29,32.39,34.03,33.07,33.06,33.70, 33.41,33.75,33.30,32.11,33.76,32.14
Average time	X X / n	33.35 min
Rating factor	Normal working rate	100%
Normal time (NT)	Avg. time* rating factor	33.35 * 100%
	100%	= 33.35 min. 100%
Extra time	Normal extra time	4%
Standard time	NT *100	33.35 * 100
	100 – % extra time	= 35.10 min. 100 - 4

Table 4-2 Observation sheet for time study

Item no.	Work step	Freq.	Observation time (min)	Avg. time (min)	Rating factor	Normal time (min)	
						all	Unit
1.	Cover the room floor with paper	1	19.70,18.72,20.24,21.28,21.20,21.73,17.82,19.77,21.10,18.91, 19.31,18.31,18.15,19.02,19.23,17.88,19.43,19.60,20.13,19.63, 19.67, 19.63,21.34,19.91,19.81,19.49,21.97,20.87,22.38,19.35	20.01	100%	20.01	20.01
2.	Set up mixing machine	1	5.12,4.64,7.40,4.18,6.15,5.00,4.98,3.75,4.58,4.72, 5.35,4.18,5.01,4.45,4.46,4.74,5.41,6.83,6.13,6.73, 3.06,3.89,4.94,3.84,5.23,3.86,5.49,8.12,3.81,3.38	4.99	100%	4.99	4.99
3.	Check API weight	1	1.99,3 .64,1.85,1.56,1 .72,1.35,2.47,1.57,2.31,2.70, 1.78,1.90,2.60,2.55,1.95,1.98,1.90,2.80,2.29,2.18, 2.33,2.54,2.15,1.62,2.37,2.02,1.12,1.22,2.78,1.91	2.02	100%	2.02	2.02
4.	Check other ingre.wt.	1	5.37,4.53,4.61,4.86,6.49,5.01,4.91,5.09,5.45,4.57, 4.12,5.20,5.39,5.17,4.87,5.09,4.59,4.67,5.47,4.16, 5.18,5.10,4.63,4.97,4.86,4.70,6.32,4.89,6. 13,4.61	5.13	100%	5.13	5.13
5.	Lift up all ingre.	I	1.90,1.86,1.61,1.87,1.91,2.03,2.01,1.91,1.92,1.93, 1.78,1.89,1.85,2.05,1.98,1.92,1.72,1.74,1.83,1.84, 1.85,2.12,1.76,2.16,1.74,1.60,2.05,1.86,1.53,2.12	1.88	100%	1.88	1.88
6.	Pour &sieve 1st layer	1	4.17,4.54,4.29,4.67,4.26,4.61,4.22,4.57,4.43,4.34, 4.08,4.40,4.05,4.65,4.18,4,57,4.12,4.29,4.39,4.46, 4.81,4.52,4.29,4.27,4.34,4.17,4,45,4.57,4.33,4,26	4.37	100%	4.37	4.37
7.	Pour & sieve 2nd layer	1	1.71,1.65,1.47,1.53,1.67,1.76,1.22,1.37,1.60,1.30, 1.52,1.57,1.40,1.43,1.50,1.26,1.32,1.38,1.51,1.39, 1.50,1.35,1.71,1.75,1.18,1.46,1.32,1.40,1.63,1.43	1.50	100%	1.50	1.50
8.	Pour & sieve 3' layer	1	4.19,4.70,4.61,4.20,4.55,4.49,4.50,4.51,4.74,4.61, 4.37,4.20,4.44,4.41,4.19,4.15,4.33,4.29,4.75,4.16, 4.32,4.48,4.25,4.27,4.69,4.48,4.43,4.26,4.22,4.35	4.36	100%	4.36	4.36
9.	Mixing time	1	39.85,39.99,39.82,39.92,40.08,39.80,39.79,40.24,40.11,39.74, 40,10,39.79,39.83,40.20,40.19,40.13,40.26,40.12,40.28,39.69, 40.14,39.68,39.87,39.74,40.04,40.01,40.28,40.05,40.13,40.10	40.11	100%	40.11	40.11
10.	Worker break period	1	31.21,27.75,29.85,30.27,28.50,31.60,30.33,30.30,29.60,30.67, 29.59,28.95,30.36,31.65,30.42,30.74,29.99,29.34,30.90,28.73, 30.51,29.03,30.65,30.36,30.70,30.95,29.47,30.66,29.79,30.70	30.07	100%	30.07	30.07

Item No.	Work step	Freq.	Observation time (min)	Avg. time (min)	Rating factor	Normal time (min)	
						all	Unit
11.	Release dead leg	1	0.99,1.42,0.89,1.14,1.19,1.07,1.03,0.81,1.04,0.86, 0.83,1.02,1.02,1.13,0.88,0.88,0.78,1.20,0.82,1.23, 0.72,0.98,0.69,1.21,1.26,1.07,1.30,1.17,1.09,1.02	1.05	100%	1.05	1.05
12.	Set up for filling	1	1.22,1.23,1.28,1.11,1.01,0.79,1.36,0.94,1.29,0.89, 1.05,1.14,1.06,1.01,0.87,1.09,0.85,0.87,0.94,0.89, 1.00,0.70,0.80,1.20,1.07,0.59,0.74,0.83,0.97,0.74	1.00	100%	1.00	1.00
13.	Fill estimated wt into bag	80	12.96,13.53,13.03,13.20,13.01,13.11,13.06,13.51,13.30,13.57, 13.22,13.17,13.53,13.34,13.20,12.79,13.33,13.41,12.95,13.37, 13.13,13.03,13.31,13.16,13.50,13.35,13.17,13.60,13 A0,12.66	13.25	100%	13.25	0.17
14.	Adjust wt to 10kg/bag	80	13.62,13.23,13.29,13.52,13.29,13.52,12.96,13.18,13.62,13.05, 13.36,13.61,13.42,13.32,13.50,13.27,13.54,13.57,13.32,13.58, 13.38,13.06,13.50,13.87,13.30,13.20,13.75,13.43,13,46,13.71	13.37	100%	13.37	0.17
15.	Carry filled bag to sealing machine	80	5.23,3.98,5.09,4.62,5.34,4.87,6.48,4.93,6.31,4.15, 4.66,4.79,5.28,4.86,4.79,5.42,4.77,5.96,5.69,5.72, 5.61,4.50,4.24,4.60,5.17,6.43,3.92,5.27,4.80,5.01	5.03	100%	5.03	0.06
16.	Seal the inner bag	80	33.30,32.98,33.10,33.76,32.55,33.38,33.71,32.52,33.06,32.96, 33.57,33.56,32.93,32.86,34.42,32.87,33.11,33.26,33.29,32.39, 34.03,33.07,33.06,33.70,33.41,33.75,33.30,32.11,33.76,32.14	33.35	100%	33.35	0.42
17.	Set up the sewing machine	1	7.97,8.05,8.01,7.66,7.87,8.04,7.39,8.26,7.46,8. 18, 7.99,8.09,7.47,7.78,7.74,8.37,7.49,7.91,7.53,8.07, 8.32,7.03,8.13,8.64,8.27,7.45,8.86,8.15,7.98,9.04	8.04	100%	8.04	8.04
18.	Sew the outer bag	80	19.00,18.96,18.84,18.83,19.32,18.40,18.42,18.23,18.81,18.55, 19.67,19.42,19.18,20.08,18.56,17.98,18.47,18.02,18.95,18.48, 18.98,19.16,19.41,18.73,18.49,18.72,18.88,18.49,18.92,17.86	18.61	100%	18.61	0.23
19.	Lay finished bag	80	6.35,6.03,5.70,4.90,5.23,5.16,4.59,5.50,5.44,4. 50, 4.67,4.48,5.02,4.64,5.00,5.41,5.75,6.41,5.35,5.45, 4.89,4.01,4.24,4.96,5.42,6.11,5.17,5.79,4.18,4.58	5.10	100%	5.10	0.06

All standard time is summarized in Table 4-3.

Table 4-3 Standard time of operations (n = 30)

Item No.	Work description	Standard time
1.	Cover the room floor with paper	20.84
2.	Set up mixing machine	5.20
3.	Check active ingredient weight	2.10
4.	Check other ingredient weight.	5.34
5.	Lift up all ingredient	1.96
6.	Pour &sieve 1st layer	4.55
7.	Pour & sieve 2nd layer	1.56
8.	Pour & sieve 3rd layer	4.54
9.	Mixing time	41.78
10.	Worker break period	31.32
11.	Release dead leg	1.09
12.	Set up for filling	1.04
13.	Fill estimated weight into bag	13.80
14.	Adjust weight to 10kg/bag	13.93
15.	Carry filled bag to sealing machine	5.24
16.	Seal the inner bag	34.74
17.	Set up the sewing machine	8.38
18.	Sew the outer bag	19.39
19.	Lay finished bag	5.31

4.2 Finding bottleneck

This project, tries to relieve the bottleneck of process, and after looking through the standard time of all. The step that takes time more than any other is the mixing step with the existing machine, which is the critical step for the homogeneity of medicine. Therefore, in short-term plan, we could not reduce the mixing time.

For that reason, we have to concentrate to the packing section. In these steps, the workers have to do it bag by bag manually.

As customer order, we have to use the bags, which come from customer supply. The bag has two layers, inner is plastic and outer is paper. Workers have to seal the inner bag then sew the outer paper bag.

While the observation, the filled bags were waiting for inner bag sealing step, and there is only one worker, who has skill, operate the sealing machine.

Besides, in table 4-3, the item number 16; seal the inner bag also the obvious bottleneck, which take time more than any others do.

Thus, this project will concern to reduce time usage at the sealing inner bag step.

4.3 Finding through put time

From standard time of each step, all were rearranged to find time usage of one production batch, as in table 4-4. The workers that need are five per batch, suppose: A, B, C, D, and E were assigned in each task.

Table 4-4 Through put time of one production batch

Step	Worker	Standard time/unit	Start	End
Cover floor with paper	ABCDE	20.84	0.00	20.84
Setup mixing machine	ABCDE	5.20	20.94	26.14

Check weight of active ingredient	AB	2.10	26.19	28.29
Check weight of other ingredients	AB	5.34	28.34	33.68
Lift up all ingredients	CDE	1.96	33.73	35.69
Pour & sieve 1st layer	BCDE	4.55	35.74	40.29
Pour & sieve 2nd layer (AI)	BCDE	1.56	40.34	41.90
Pour & sieve 3rd layer	BCDE	4.54	41.95	46.49
Mixing time	ABCDE	41.78	46.51	88.29
Workers break time	ABCDE	31.32	88.31	119.63
Release dead leg	AB	1.09	119.65	120.74
Setup for filling	AB	1.04	120.76	121.80
Fill 1st bag with estimate wt.	A(B)	0.18	121.82	121.99
Adjust wt of 1st bag	(B)C	0.18	122.01	122.19
Move bag to sealing machine	D	0.09	122.21	122.30
Release air & seal inner bag of 1st bag	(D)E	0.46	122.32	122.76
Fill the 80th bag with estimate wt.	A(B)	0.18	135.82	135.99
Adjust wt of 80th bag	(B)C	0.18	136.01	136.19
Setup the sewing machine	AB	8.38	136.09	144.30
Sew the outer bag of 1st bag	AB	0.26	144.32	144.57
Lay the 1st finished bag on pallet	C	0.09	144.59	144.68
Release air and seal inner bag of 80th bag	(D)E	0.46	157.32	157.76
Sew the outer bag of 80th bag	AB	0.26	163.92	164.17
Lay the 80th finished bag on pallet	C	0.09	164.19	164.28

From start until a batch finished, consumes time for 164.28 minutes or 2.738 hours (approximate to 2hours and 45minutes).

V. IMPROVEMENT AND ANALYSIS

5.1 Short term alternatives

5.1.1 Alternative I: Use parallel line at the bottleneck

Add another hot seal machine to run parallel line into the existing process. Since the bottleneck of whole process is at the inner bag sealing step, another sealing machine should be added to relieve the bottleneck. With expectation that, the filled bags that wait in queue will be less, standard time of sealing will be divided in half, and then throughput time will be less. The result of throughput time after implementing another sealing machine is in Table 5-1.

Table 5-1 Throughput time after add another sealing machine

Step	Worker	Standard time/unit	Start	End
Cover floor with paper	ABCDE	20.84	0.00	20.84
Setup mixing machine	ABCDE	5.20	20.94	26.14
Check weight of active ingredient	AB	2.10	26.19	28.29
Check weight of other ingredients	AB	5.34	28.34	33.68
Lift up all ingredients	CDE	1.96	33.73	35.69
Pour & sieve 1st layer	BCDE	4.55	35.74	40.29
Pour & sieve 2nd layer (AI)	BCDE	1.56	40.34	41.90
Pour & sieve 3rd layer	BCDE	4.54	41.95	46.49
Mixing time	ABCDE	41.78	46.51	88.29
Workers break time	ABCDE	31.32	88.31	119.63
Release dead leg	AB	1.09	119.65	120.74
Setup for filling	AB	1.04	120.76	121.80
Fill 1st bag with estimate wt.	A(B)	0.18	121.82	121.99
Adjust wt of 1st bag	(B)C	0.18	122.01	122.19
Move bag to sealing machine	D	0.09	122.21	122.30

Release air & seal inner bag of 1st bag	(D)E	0.46	122.32	122.76
Fill the 80th bag with estimate wt.	A(B)	0.18	135.82	135.99
Adjust wt of 80th bag	(B)C	0.18	136.01	136.19
Setup the sewing machine	AB	8.38	136.09	144.30
Sew the outer bag of 1st bag	AB	0.26	144.32	144.57
Lay the 1st finished bag on pallet	C	0.09	144.59	144.68
Release air and seal inner bag of 80th bag	(D)E.F	0.40	139.82	...140.2(
Sew the outer bag of 80th bag	AB	0.26	163.92	164.17
Lay the 80th finished bag on pallet	C	0.09	164.19	164.2[illegible]

As table 5-1, the throughput time is not changed from the existing process, 164.28 minutes. Certainly, the new hot sealing machine could reduce time of sealing the inner bag step and seal the last bag early, but the sealed bags have to wait for the next step, setup sewing machine. It seems the bottleneck is changed to other step.

Thus, the throughput time is still the same, after implementing another sealing machine, it does not meet the project objective. By the way, this new machine needs one more worker who has skill to operate it, which increases cost of production. The additional sealing machine also takes addition electricity supply.

5.1.2 Alternative II: Use automatic form, fill and seal machine

At present, the packaging technology has developed to be more automation. Such as the machine from Hamer Inc., Hamer model 820. Its feature could facilitate the user for filling and sealing to be finished bag with high speed, 30 bags per minute. With its capability would relieve the bottleneck in process. This equipment could help us to short cut the sealing and sewing step of process.

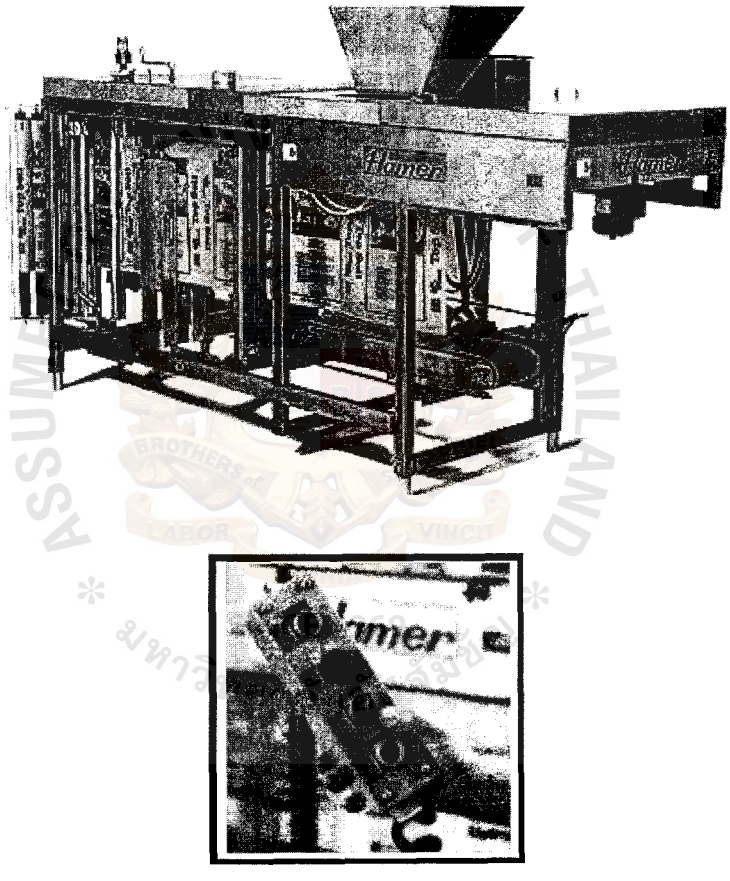


Figure 5-1 Automatic form, fill & seal packaging system: Hamer model 820

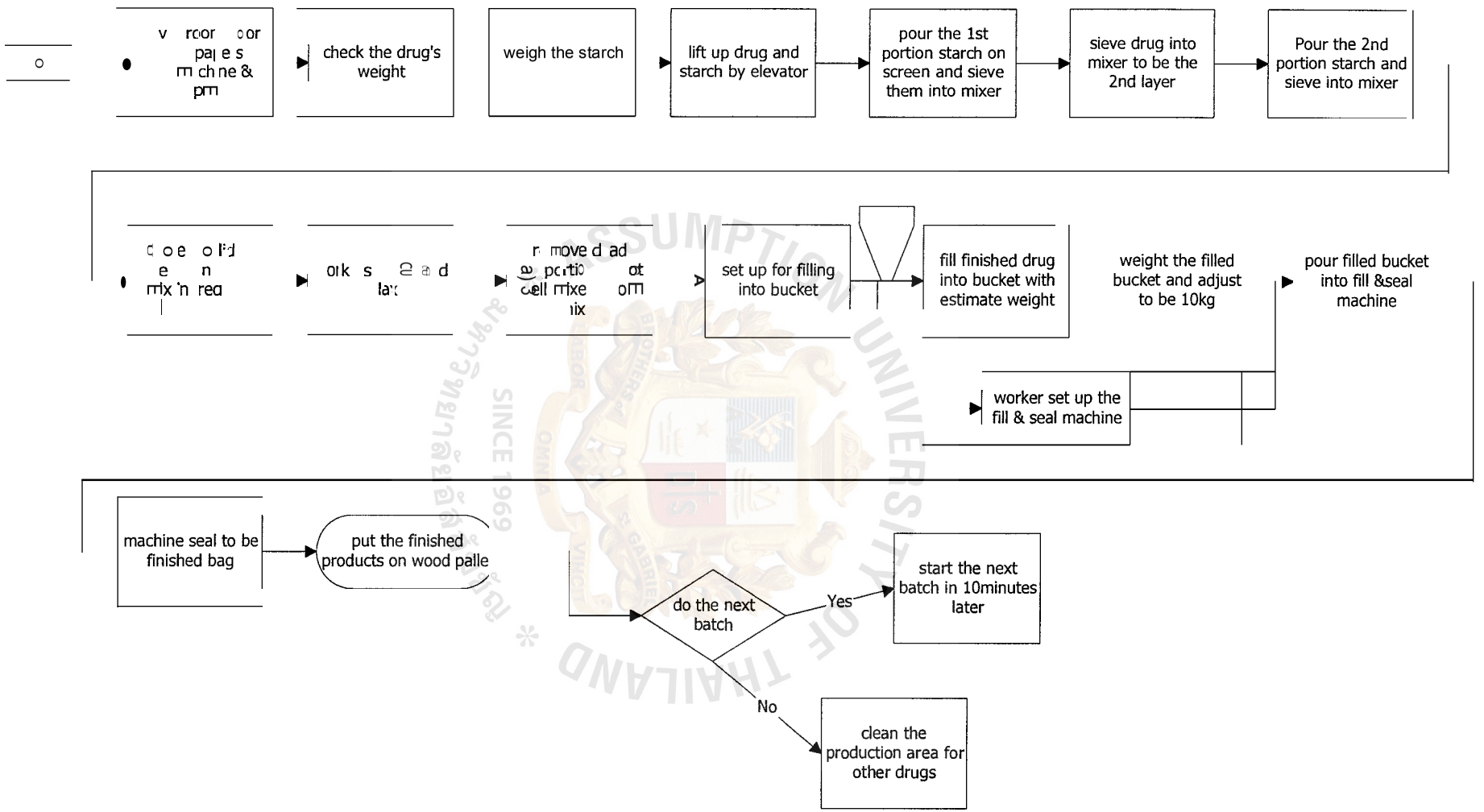


Figure 5-2 Manufacturing process after using automatic fill and seal machine

The result of throughput time after implement automatic machine show in table 5-2

Table 5-2 Throughput time after using automatic fill & seal machine

Step	Worker	Standard time/unit	Start	End
Cover floor with paper	ABCDE	20.84	0.00	20.84
Setup machine	ABCDE	5.20	20.94	26.14
Check weight of active ingredient	AB	2.10	26.19	28.29
Check weight other ingredients	AB	5.34	28.34	33.68
Lift up all ingredients	CDE	1.96	33.73	35.69
Pour & sieve 1st layer	BCDE	4.55	35.74	40.29
Pour & sieve 2nd layer (AI)	BCDE	1.56	40.34	41.90
Pour & sieve 3rd layer	BCDE	4.54	41.95	46.49
Mixing time	ABCD	41.78	46.51	88.29
Workers break period	ABCD	31.32	88.31	119.63
Release dead leg	AB	1.09	119.65	120.74
Setup for filling	AB	1.04	120.76	121.80
Fill 1st bucket with estimate weight	A(B)	0.18	121.82	121.99
Adjust weight of 1st bucket	(B)C	0.18	122.01	122.19
Setup the fill &seal automatic machine	DE	8.38	119.65	127.86
Fill 80th bucket with estimate weight	A(B)	0.18	135.82	135.99
Pour the 1st bucket into fill & seal machine	DE	0.09	136.01	136.10
Machine fill & seal the 1st finished bag	DE	0.04	136.12	136.16
Lay the 1st finished bag on pallet	AB	0.09	136.18	136.25
Adjust wt of 80th bucket	(B)C	0.18	136.01	136.19
Pour the 80th bucket into fill & seal machine	DE	0.09	143.07	143.16
Machine fill & seal the 80th finished bag	DE	0.04	143.18	143.19
Lay the 80th finished bag on pallet	ABC	0.09	143.21	143.29

From data in Table 5.2, the machine could reduce throughput time, from 164.28 minutes to 143.29 minutes, or approximately 20 minutes less. The throughput time is 34.48 percentages less from the existing process.

The improved process takes time for 143.29minutes or 2hours and 24 minutes, which we were not able to do two batches in four hours period in our normal working time schedule, neither 8.00am to 12.00am nor 12.45pm to 16.45pm.

Therefore, this project has split the improved process to be sections then put in the normal working time schedule for gain more finished batch as in Table 5-3.

Table 5-3 working time schedules after using the automatic fill & seal machine

Working time	Batch number	Assigned job
8.00-10.25	1	Finish whole batch
10.35-11.25	2	Prepare
12.00-12.45	Lunch	45 minute
13.00-14.35	2	Mix, break, pack
14.45-16.45	3	Prepare, mix, break
16.45-17.15	3	Pack

From table 5-3 the automatic filling machine could not help us increase a batch per day in normal working time. The third batch could not be done before 16.45,which are working time off. Thus, number of finished batch still is two batches a day.

With this machine we could analyze like this:

Advantage:

1) Reduce throughput time, because the machine could cut the sealing and sewing step.
2) Bags from this machine must be made of polyethylene. It gives good efficiency to protect medicine from water and moisture. In contrast, of

the pre-made bags those supply from customer, made from paper and plastic in side.

3) It is able to handle various bag size as following various products.

Disadvantage:

1) High investment for the machine, 65,000$,(www.hamerinc.com)
2) The machine could not automatically weigh the finished product before worker fill in a bag. It still needs to weigh the products in buckets then adjust the weight like the existing process and then pour into new machine.
3) We have to convince customers to change the bag material of their products.

5.1.3 Alternative III: Use overtime with the existing facilities

Normally, working time of production line is 8.00 am until 16.45 pm on Monday to Saturday. The capacity of animal medicine line is 800 kg per batch, for two batches a day. One batch is produced in the morning and the other in the afternoon.

The overtime of this, company has to extend working time from 16.45 pm until 21.30 pm. To get more 4 hours and a half period and the workers will get wage in overtime rate, 1.5 times the normal rate. We allow the dinner break for workers 30 minutes.

Each batch also split to be sections, aim to condense time, and then put the time usage of batch into the overtime schedule is shown in table 5-4.

Table 5-4 Working time schedule when add overtime with the existing facilities

Working Time	Batch number	Assigned job
8.00-10.45	1	Finish whole batch
10.55-11.45	2	Prepare
12.00-12.45	Lunch	45 minutes
12.55-14.50	2	Mix, break, pack
15.00-17.45	3	Finish whole batch
17.55-18.45	4	Prepare
18.45-19.15	Dinner	30 minutes
19.25-21.25	4	Mix, break, pack

From table 5-4 using overtime with existing facilities could finish four batches.

In table 5-5 show the calculation result from Microsoft Excel, solver function, about maximum capacity of overtime alternative with 4 batches a day. It presents that the overtime alternative could generate capacity to meet the demand, as the number of demand batch do not exceed their maximum capacity. There is some of percent utilization of overtime alternative almost reaches 100 percent or uses most capacity.

Table 5-5 Comparison of demand forecast vs. maximum capacity and percentage utilization of overtime alternative

Month	Product A (batch)			Product B (batch)			Product C (batch)		
	Demand	Max capacity	%utilization	Demand	capa ty	%utilization	Demand	Max capacity	%utilization
Jan	19	30	63.33	28	30	93.33	16	30	53.33
Feb	17	27	62.96	29	29	100.00	16	27	59.26
Mar	23	30	76.67	28	30	93.33	18	30	60.00
Apr	19	30	63.33	30	30	100.00	16	30	53.33
May	20	30	66.67	28	30	93.33	16	30	53.33
Jun	22	30	73.33	28	30	93.33	16	30	53.33
July	19	30	63.33	28	30	93.33	18	30	60.00
Aug	19	30	63.33	30	30	100.00	16	30	53.33
Sep	22	30	73.33	28	30	93.33	16	30	53.33
Oct	23	30	76.67	30	30	100.00	18	30	60.00
Nov	23	29	79.31	28	29	96.55	16	29	55.17
Dec	19	30	63.33	28	30	93.33	16	30	53.33
Total	245	363	67.49	343	366	93.71	198	363	54.55

5.1.4 Alternative IV: Add more work shifts with the existing facilities

Add one work shift is another way for solving the problem. The additional shift will start from 15.00 pm to 24.00pm. As table 5-5, there is overlap time between two shifts. In this issue, the second shift will be in charge at 15.00 to be readiness, change their clothes. The first shift will commit the work in process or semi-finish product to the second shift, then take shower, and go home at 16.45pm.

Table 5-6 Working time schedule when add one more shift with the existing facilities

Shift	Working Time	Batch number	Assigned job
1	8.00-10.45	1	Finish whole batch
	10.55-11.45	2	Prepare
	12.00-12.45	Lunch	45 minute
	12.55-14.50	2	Mix, break, pack
	15.00-16.30	3	Prepare, mix
2	16.30-17.15	3	Pack
	17.25-18.15	4	Prepare
	18.15-19.00	Dinner	45 minutes
	19.10-21.05	4	Mix, break, pack
	21.15-24.00	5	Finish whole batch

Advantage:

1) The output could reach five batches per day.
2) It is not necessary to pay wages in overtime rate
3) Good for short term solution; it could be reversed, if the demand is dropped down.

Disadvantage:

1) Worker may deny working on night shifts.
2) Workers may have low efficiency while working in night shift became of their drowsiness.

The alternative IV gave the highest number, five batches per day. So this 2-shift working plan should be the short-term solution. Then, use Microsoft Excel: solver function finding the maximum capacity of manufacturing. The needed information is company working day in each month and customer demand. These help us finding:

1) The maximum capacity to produce each product in each month

2) The appropriate day-duration for producing each product before switching to other products.

Table 5-7 Maximum capacities of year 2003 from solver calculation

Month	DAY OF PRODUCTION/MONTH			Using day	Working day after subtract cleaning day
	A	B	C		
January	7	11	5	23	23
February	6	8	7	21	21
March	7	10	6	23	23
April	7	10	6	23	23
May	7	9	8	24	24
June	7	10	6	23	23
July	7	9	8	24	24
August	7	10	6	23	23
September	7	10	6	23	23
October	8	10	6	24	24
November	7	8	7	22	22
December	7	10	6	23	23
Total batch capacity	420	575	385		
Total batch demand	245	343	198		
Total capacity	1380 batch/year				

The maximum capacity was formed from the best case of production line. The assumption is in one month the production room was clean only 3 days when switch from one product to other.

To illustrate, the appropriate production day-duration of three products by using February, it will be like this: Produce A for 6 days, then cleaning 1 day, then produce B for 8 days, stop for cleaning 1 day, produce C for 7days and then cleaning 1 day.

Table 5-8 Comparison of demand forecast vs. maximum capacity and percentage utilization of 2-shifts work plan.

Month	Product A (batch)			Product B (batch)			Product C (batch)		
	Demand	Max capacity	%utilization	Demand	Max capacity	%utilization	Demand	Max capacity	%utilization
Jan	19	35	54.29	28	55	50.91	16	25	64.00
Feb	17	30	56.67	29	40	72.50	16	35	45.71
Mar	23	35	65.71	28	50	56.00	18	30	60.00
Apr	19	35	54.29	30	50	60.00	16	30	53.33
May	20	35	57.14	28	45	62.22	16	40	40.00
Jun	22	35	62.86	28	50	56.00	16	30	53.33
July	19	35	54.29	28	45	62.22	18	40	45.00
Aug	19	35	54.29	30	50	60.00	16	30	53.33
Sep	22	35	62.86	28	50	56.00	16	30	53.33
Oct	23	40	57.50	30	50	60.00	18	30	60.00
Nov	23	35	65.71	28	40	70.00	16	35	45.71
Dec	19	35	54.29	28	50	56.00	16	30	53.33
Total	245	420	58.33	343	575	59.65	198	385	51.43

5.2 Cost comparison: overtime vs. 2-shifts.

Both of the alternative III (overtime) and alternative IV (2-shifts) could provide batch quantity as demand need. However, only one alternative will be chosen. Then, comparing the expense for labor cost should be concerned.

First, we have to find the total usage days of each alternative just enough demand, not all their capacity as in table 5-9. Calculation from demand of each month, each product divided by 4 batches or 5 batches, then, round answer up to be needed days.

Example: demand of January for A is 19 batches

Then, for overtime: 19/4 = 4.75 day, it is approximate to 5 days.

For 2-shifts: 19/5 = 3.8 day, it is round up to 4 days.

Table 5-9 Time usages of overtime and 2-shifts plan just to meet demand.

Month	Overtime (day)			2-shifts (day)		
	A	B	C	A	B	C
Jan	5	7	4	4	6	4
Feb	5	8	4	4	6	4
Mar	6	7	5	5	6	4
Apr	5	8	4	4	6	4
May	5	7	4	4	6	4
Jun	6	7	4	5	6	4
July	5	7	5	4	6	4
Aug	5	8	4	4	6	4
Sep	6	7	4	5	6	4
Oct	6	8	5	5	6	4
Nov	6	7	4	5	6	4
Dec	5	7	4	4	6	4
Total	204 days			173 days		

5.2.1 Overtime alternative: labor cost calculation

1. Labor cost in normal time period in date that use OT

= No. of worker * wages per day * OT day

= 5 worker * 165 Baht * 204 day

= 168,300 Baht

2. Labor cost in overtime period (Overtime is 4.5hr.but, payment is 1.5 fold of normal wages)

= no.of worker*(wage per day/8hr)*OT hr.*1.5*OT day

= 5 worker * 165 Baht/8hr*4.5hr*1.5*204day

142,003 Baht

3. Supervisors' wages in overtime period

no.of supervisor*wages of OT per day*OT day

1 supervisor*400 Baht/day*204 day

81,600 Baht

4. Labor cost for normal working date (not use OT)

no.of worker*wage per day*(all workday-OTday)

5worker*165Baht per day*(313-204) day

= 89,925 Baht

5. Total labor cost

= 168,300+142,003+81,600+89,925

= 481,828 Baht per year

5.2.2 The 2-shifts work plan alternative: labor cost calculation

1. Labor cost in 1-shift (day shift)

no.of worker * wages per day * 2-shift day

5worker*165 Baht*173day

= 142,725 Baht

2. Labor cost in 2-shift (night shift)

no.of worker * wages per day *2-shifts day

5worker*165 Baht*173day

142,725 Baht

3. Extra labor wages for night shift

no.of worker * extra pay per day *2-shifts day

5worker*100 Baht*173day

= 86,500 Baht

4. Supervisor extra pay for night shift

no.of supervisor*extra pay per day*2-shifts day

1supervisor*600Baht*173day

103,800 Baht

5. Labor cost for normal working date

no.of worker*wage per day*(all workday-2shifts day)

5worker*165 Baht*(313-173) day

= 115,500 Baht

6. Total cost

= 142,725+142,725+86,500+103,800+115,500

= 591,250 Baht

From labor cost calculation, the 2-shift work plan alternative uses 591,250 Baht, which higher than overtime alternative use at 481,828 Baht (different 109,422 Baht per year).

5.3 Decision making

Although, overtime alternative uses labor cost lower than 2-shift alternative for 18.50 %, but when considering the 204 days of overtime from all working day 313 days is 65.17% of a year. Only one worker team could not endure with hard work in condensed schedule like that for long period. Suppose one worker in that time is sick or absent without notice, the production line will have trouble to find a reserve worker in rush and hurry.

Moreover, the percent of utilization of overtime alternative of some months already reach the maximum capacity, if the demands increase again or new order from new customers, we could not provide capacity for the unexpected.

For that reason, we should use the alternative IV: 2-shift work plan to implement for solving in this project.

5.4 Solution implementation

From data in table 5-8, the utilization of new capacity from 2-shifts work plan for those three products is no more than 75%. There still have gap for filling more demand or other products demand before touching the maximum limit of capacity. Thus, for reducing the warehouse burden, planning department should set the production schedule for 2-shift working plan at the beginning of the month for producing all demand of those 3 products, until it meets the needed quantity. Then, stop the 2-shift work plan and use only 1-shift working as usual until the end of the month. Then, start 2-shift work plan again, do it like cycle.

To implement 2-shift working plan process needs at least 10 workers and 2 supervisors. For each shift use 1 supervisor and five workers, two of five workers must have skill for sealing and sewing step. Right now, there are five routine workers in animal product line who have rotated job in every task. For this reason, the supervisor has to separate five skilled workers to fill in each shift. Another additional five workers will be borrowed from other manufacturing line. They will work for animal line temporarily only in 2-shift weeks.

Suppose there are 2 weeks in month that have to run 2-shift. The workers and supervisors who work in morning shift in the 1st week will change to work in night shift in the 2nd week, and the other shift workers will do alternately.

The additional supervisors who will work on night shift comes from human product line, 4 supervisors will take his turn to work on night shift a week per round. For the issue of their own responsibilities, these need the cooperation from other supervisors when one supervisor has to absent in the morning (8.00-15.00), he will come to work at 15.00 until

24.00. Since there are four supervisors in human line, who take care of different product line, each line is located within the same building. Suppose supervisor of tablet line has to do nightshift, and then problem happen in the tablet line in the morning, other supervisor in other line would help to solve the facing obstacle.

In order to get successful implementation of 2-shift plan, the manager must convince the employees to realize the necessity why company needs additional shift. The explanation should be done together with giving incentive for the night shift employees. The incentive, 100 Baht per worker per night and 600 Baht for supervisor per night, will be added up to the normal wages, for inducing the employees willing to work in night shift.

5.5 Long term alternative

With assumption of the demand growth is 10% per year constantly, the maximum capacity of 2-shift plan could cover for 5 more years until year 2008, as shown in table5-10

Table 5-10 Demand forecast compare with maximum capacity

Demand	Product (batch per year)		
	A	B	C
YEAR 2003	245	343	198
YEAR 2004	270	377	218
YEAR 2005	296	415	240
YEAR 2006	326	457	264
YEAR 2007	359	502	290
YEAR 2008	395	552	319
YEAR 2009	434	608	351
Maximum capacity	420	575	385

Moreover, we could expand to run 3-shift by increasing 0.00am-07.00 am for additional capacity, to support more demand.

5.6 Dust leakage issue

For the problem of dust that leaks out of the production room to the walking path area, medicine dust could irritate the mucus membrane of people out of the room.

This is one of alternatives to cope with. Although the production room has used dust collector every time of producing, it is still not enough.

This project is trying to reduce the leak dust. Since, if we could reduce dust, we could reduce time to cleaning the building

From the start of establishing the building; company does not realize the dust issue as taken time of cleaning.

According to the Good Manufacturing Practice (GMP) regulations, all the pharmaceutical production buildings must have air lock for preventing the outside air (dirt air) getting into the production area air (clean air).

Air lock has ability to prevent the dust movement by controlling air pressure. The area that has positive pressure (higher pressure) always push dust particle away to the negative pressure area (lower pressure). Therefore, the air inside building must have higher pressure than outside air.

The existing building has an airlock in front of the building entrance for preventing outside air from entering.

Since the air lock is the technology that is used widely in this industry, it should build another air lock in front of the production room. The air lock will comprise of a space area and two doors. However, this air lock should be installd a high-pressure blower for opening during the production period, to create the positive pressure. Dust in the negative pressure air in production room could not leak out.

For this the result could not be predicted in percentage reduce until the real implementation.

Anyway, to build air lock the production line has to stop during the construction. Therefore, air lock should be built in the low demand period at the middle of the year.

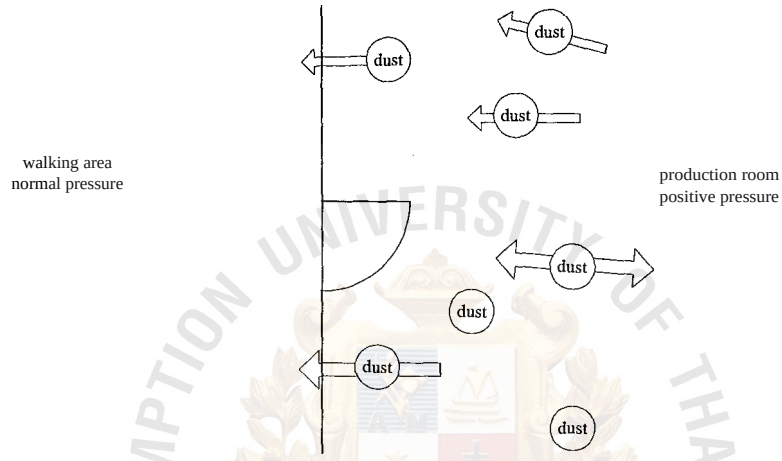


Figure 5-3 Dust leakage directions before implement air lock

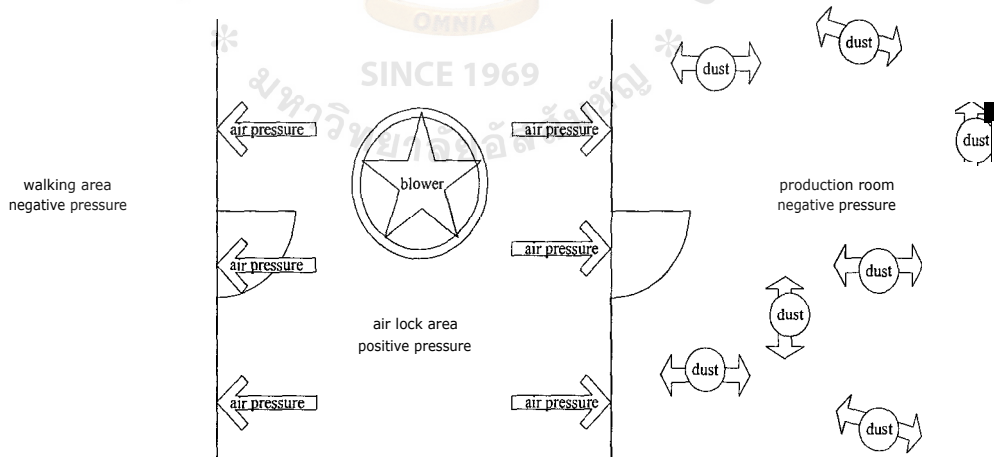


Figure 5-4 Production room after install air lock

VI. CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This project starts from the problem of unexpected increasing demand. With our existing production, its capacity 2 batches a day could not produce medicine following the customer order. As our competitive priority, on time delivery, this project tries to reduce time usage per batch and find the alternative to produce more batches per day.

The study result shows that the alternative IV: using 2-shift work plan give at five batches per day more than other alternative.

When calculating the maximum capacity of 2-shift work plan, it could cover demand for 5 more years within assumption of 10% demand growth.

To implement 2-shift work plan in short term we could use 2-shifts just to meet the demand in that month then switch to use 1-shift as usual for preventing the inventory problem.

For dust leakage problem, it should be a long-term plan, since to build air lock the production line has to stop for construction.

According to the result of this project, the automatic form, fill and seal machine, a high technology product could not bring the greatest result for solving the capacity problem. On the other hand, only the simple method like 2-shifts or working schedule adjustment becomes the best choice in this facing situation. While the demand, just increase and no one could guarantee how long lasting it is.

For that reason, we should not invest in fixed asset until we could ensure the customer demand or we have expansion strategies of animal medicine in own brand, which is another issue.

Therefore, this project could be an example of problem solving in manufacturing issue, which much investment in high technology product might not cure every problem.

It depends on the situation of each organization, as towhich alternative is the most suitable.

6.2 Recommendations

Further research should find cost and benefit that could generate from making effort to following demand. However, this project lack some confidential information about benefit that we charge from customers.

The assumption of 10% growth demand could be inaccurate, due to this increasing demand that we have faced never been expected before. Therefore, we have to see trend of demand in next 2-3 years. If it seems to be continually increased, the expansionist strategy or economies of scale may become interesting. Such as extend the batch size, purchase bigger mixing machine, automatic sealing machine, or build new building. Anyway, it is important to concern about financial risk and return of investment.

BIBLIOGRAPHY

1. Eugene, H. Melan. Process Management: methods for improving products and services, New York: McGraw-hill Inc,1993.
2. Internal training document of Biolab pharmaceutical company, "Time study for capacity improvement", 2001.
3. Kosit Anutarapongsakul. Optimizing batch size of work in process by using a simulation Technique, Assumption University, 2000.
4. Lee J. Krajewski, and Larry P. Ritzman. Operations Management: strategy and analysis, 6th edition, New Jersey: Prentice Hall, 2002.
5. Robert E. Markland. , et al. Operation Management : concepts in manufacturing and services, 2nd edition, Ohio: Southwestern college, 1988.
6. Roger, W. schmenner. Production/operation management: concepts and situation, 2nd edition, Science Research Associate Inc, 1984.
7. Thomas A. Gresik, and Edward C. Mansley, " The strategic effects of Batch Processing," International Economic Review, Vol.42, No.3, 2001.

APPENDIX A

Packaging system technologies in present market

800-927-4674

Packaging Syst
imer Inc
INTERNATIONA

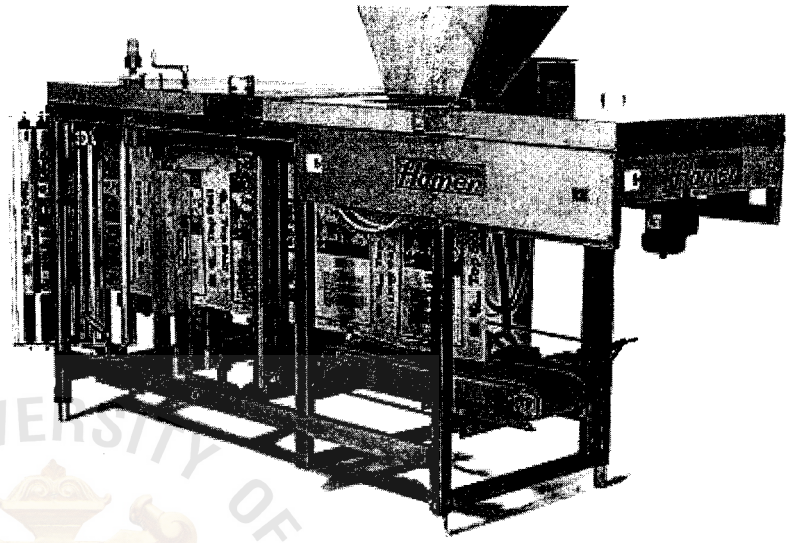
Newsle

AUTOMATIC FORM, FILL & SEAL PACKAGING SYSTEM
Hamer Model 820

Products Packaged

- Ice
- Soil/Bark/Mulch
- Salt
- Pellets
- Seeds
- Feeds
- Fertilizer
- Produce
- Dry Chemicals
- Cat Litter
- Dry Powders
- Food/Kindred

Remote control for ease of set up and operation is standard on Model 820



COMPARE THESE FEATURES

- **Labor Savings** typically equals one year investment payback
- **Uses preprinted, center-fold poly film** for up to 20% cost savings compared to premade open mouth bags.
- **Low compact design** permits easy integration in many packaging lines.
- **Vent holes are punched to** varying sizes and pattern specifications.
- **Versatile in handling various bag sizes and film thicknesses.**
- **Electrostatic eliminator** helps control static electricity build up on film.
- **Remote control unit** adds convenience and saves valuable set up and change over times.
- **Conveyor easily adjusts** to accommodate different bag sizes.
- **Optional auxiliary feed assembly** provides consistent, reliable delivery of materials which do not flow easily.
- **Microprocessor-controlled systems** and operations ensure reliability and consistent performance.
- **Corrosion resistant, heavy-duty construction** for ease of cleaning and long-lasting, trouble-free service.

Capacity:
Bag Sizes:
- Widths from 10" to 16"
- Lengths up to 35"

Poly Thickness: 1.75 mil to 6 mil

Installation Requirements:
Air 20cfm @ 80 psi
Electrical: 220 volt single phase, 40 amp.

Support Service:
Assistance with model selection and ongoing technical support is availible via a toll-free phone number.

Specifications subject to change without notice

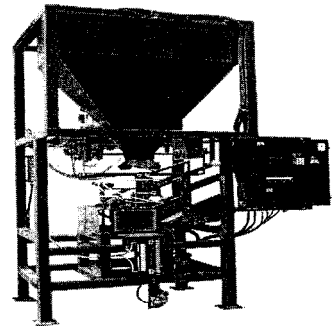
H.C. Davis Sons Manuf during Co., Inc.

Manufactures of Quality Machinery Since 1894

Bagging Equipment

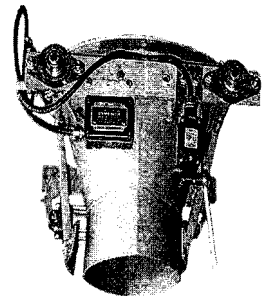
From mixing your product to bagging it for presentation in the marketplace, Davis Manufacturing can provide the equipment that you need! Bag directly from the mixer's outlet, or convey the product out of our mixer into a bagging hopper sized to fit your needs. We can also provide a bag filling scale, conveyor and method of bag closing. But we don't just stop there! We offer bag flattening conveyors, weigh conveyors and semi automatic palletizing machinery. We can provide a complete system manufactured to your needs, which is much better than a pieced together system which could have compatability problems.

Systems for gross weighing (weighing material as it is being placed in the bag) while not as fast as net weighing are much more economical. Gross weigh bagging scales are capable of 10 pound (43 kgs) to 110 pound (50kgs). Bag filling speed ranges from 4 to 9 bags per minute.

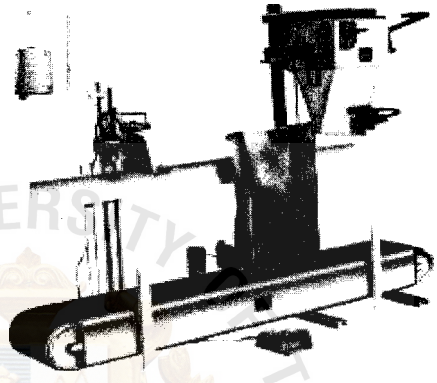


Systems for net weighing (weighing material before it is put into bag) range in size from ฝ pound (230 grams) to 110 pounds (50 kgs). Bag filling speed ranges from 10 to 25 bags per minute.

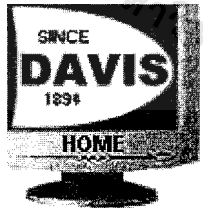
Send **E-mail**



Materials of construction are mild steel and stainless steel. Food Grade construction is also available. Manual bag placement as shown above or automatic bag placement also available.



Depending upon bag size, we offer 6", 12", and 24" bag conveyors to suit your needs. For bag closing, we offer belt conveyors with variable speed drives controlled by a foot pedal. These belt conveyors range in length from 7'8" to16'. Speciality conveyors include "V" (holds bag upright), incline, bag flattener, and bag kicker or knockdown conveyors. We can also provide various size hoppers to hold material so that bagging can be a continuous operation.



H.C. Davis Sons Manufacturing Co., Inc.
Box 395,
Bonner Springs, KS 66012-0395, U.S.A.
Telephone: 913-422-3000
Fax: 913-422-7220

Info@HCDavis.Com

HC DAVIS SONS MANUFACTURING

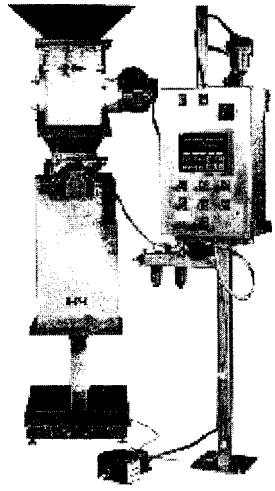
I-P-I Industrial Process nnovations Inc.
FILLING SYSTEMS

WELCOME
FILLING SYSTEMS
!BLENDING SYSTEMS
SIFTERS
UNLOADING STATIONS
CONTACT US

The New Leader In
Filling Technology Presents:

Accufill III Filling System

The most precisely accurate filler of free flowing & non-free flowing powders, flakes or granular materials of any type!



Accufill III Bag Filling System
click for a larger view

INNOVATIONS:

- combines bulk fill and dribble fill into one application
- fewer areas to clean
- fills 50 lb. bags in approximately 2 seconds within 2/100ths of a lb.
- complete stainless steel uni-body designed feeder
- logic controlled pneumatic stainless steel slide gate
- unique bag clamping system - fills 5 lb. to 100 lb. paper or plastic bags
- modular design provides flexibility on installation
- user friendly - developed through direct operator input
- unique agitator design ensures continuous product flow

Other Filling Applications Include:

- ***hoppers***
- ***drums***
- ***boxes***
- ***gaylords***

From 10 lbs. to thousands of lbs.

STANDARD FEATURES:

- dramatically increased flow through put to pinpoint accuracy
- instantly changes to any fill amount
- Teflon slide gate guides
- manual or fully automatic fill selections
- production control accumulators
- calibration control for kg. or lbs.
- digital display control panel - easy to read
- automatically shuts off when fill cycle is complete - never under weight
- ergonomic design reduces operator fatigue
- front access door panel for easy cleaning
- print port offers versatility in batch identification

back to top

BENEFITS:

- extremely compact design - small footprint
- faster, easier more complete cleanout and changeover
- fewer moving parts - less maintenance costs
- accuracy reduces product giveaways or short changes
- eliminates the need for check weighing equipment and personnel

OPTIONS:

- multiple product (25) memory fill weight controls
- Nema 4X enclosed control panel
- conveying systems for drums, boxes and/or container fills available
- "Easy Clamp" safety bag clamping system for bag filling
- automatic bag placing system
- available with automated indexing product handling conveyors
- custom designed agitator configurations for specific products
- various hopper sizes and designs
- custom hopper delivery conveying systems available
- bulk bag discharge systems
- auto tare and auto bag drop functions

back to top

ADAPTABLE:

- may be configured as a filling system for drums, cartons, full size IBCs, gaylord bins, hoppers or batching systems
- may be integrated with form fill and seal applications

back to top

| Welcome I Filling Systems I Blending Systems I Sifters I
I Unloading Stations I Contact Us

Industrial Process Innovations Inc. I-P-I

Site created and maintained by Taalwood Media Services
in cooperation with Status Technologies Inc

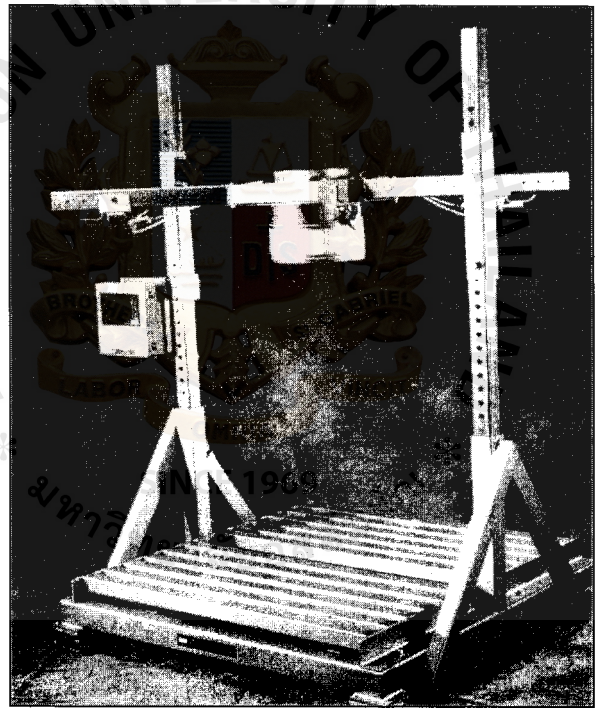
HARTMAN SCALE CO. INC.

BULK BAG FILLING SYSTEMS

Bulk bag filling systems can be custom built to your application. The basic unit includes a 60" x 60" platform scale (flat top or side rail design) with a 5000 pound capacity. The bag holding structure is fabricated with 3" structural tubing with an adjustable bag holding frame. The stainless steel main support posts and the bag clamp bars are pre-drilled at 2" increments to allow filling of many size bags.

Product is fed into the bag via screw feeder, pneumatic conveying system, slide gate or other means determined by the customer or dictated by the product. The batch controller provides two outputs for fast and slow speed filling. Preact compensation adjusts the final cutoff point to account for material in suspension. Analog output for speed control can be supplied to adjust speed of screw type feeders that require 4-20ma or 040 VDC input for speed control. .

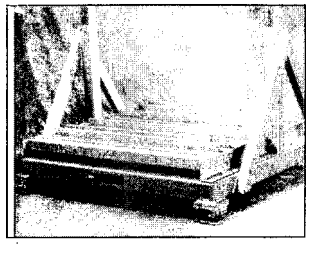
The operator would place a pallet on the platform scale, attach a bag to the frame, connect the fill chute to the inflatable seal provided, enter the desired target weight, dribble weight and preact weight into the controller, and press start. The controller would open the valve or start the feed screw to the full open or fast speed until the dribble (slow) point is attained. The controller will then close the valve to the dribble position, or slow the speed of the screw, and continue filling the bag at a slow rate for better control until the target weight is attained.



BULK BAG FILLING SYSTEM SHOWN

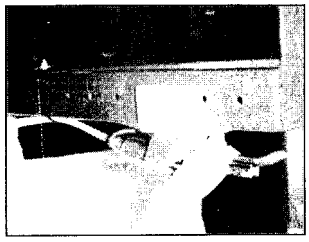
Please fill out a specification form so we can provide a quotation: Specifi **Fc**

FEATURES:

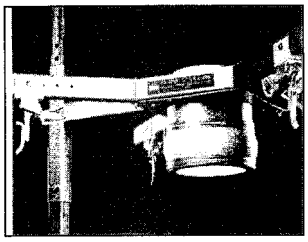


VIBRATION can be provided via a support system that can lift the container on the pallet and provide vibration to densify the product in the bag. This operation can cycle during the filling operation at programmable intervals.

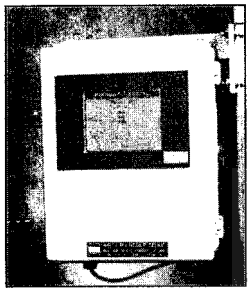
BAG CLAMPS provide a quick easy way to release the bag when filled as well as



hold the bag in place during the filling operation. Clamps are adjustable to accomodate different bag sizes.



BAG SEAL provides a positive seal to hold bag in place as well as provide a dust seal to help minimize dusting during the filling operation. Internal cavity and 3" dust collection port provided for easy connection to dust collection system.



DIGITAL CONTROLLER provides a *touch screen* operator interface to enter target weight and operation parameters. Operator has manual control of vibration and jog. Standard enclosure is nema 12 dust tight but other enclosures are available such as nema 4X stainless steel. Remote inputs are optional for PLC interface.

Controller Specifications

ADDITIONAL INFORMATION:

Bag stands can be fabricated with carbon steel and painted with industrial enamels or "Steel-it" epoxy. We also provide complete stainless steel construction.

Instrumentation can be self contained or we can provide signal conditioner for load cell signals for direct connection to PLC or distributive control system.

Motorized or gravity type conveyor sections can be provided to facilitate the loading and unloading of the filling system. The operator can push the filled bags out of the filling position and begin filling another bag while waiting for a fork lift.

We can custom fabricate any height or capacity unit and can provide a complete turn key package including feed system and or cutoff valves.

Please call for a quote on YOUR application. DEALER INQUIRIES WELCOME

Back to: Homepage/ **Main Menu**

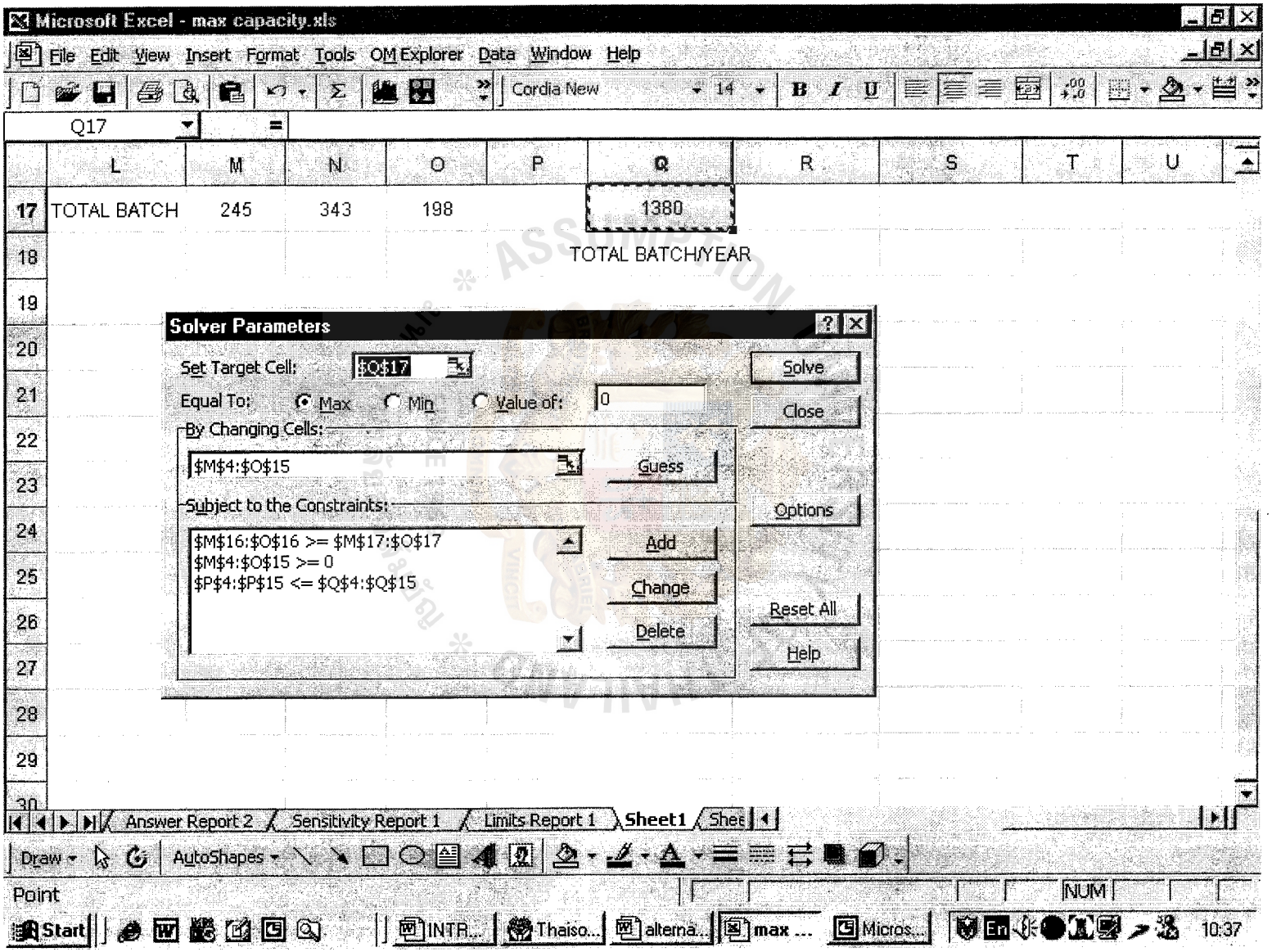
Hartman Scale Company Inc. 1-800-443-1164 Email:sale loadcells.com
This site last updated on: 08-09-00 By: Russ Hartman

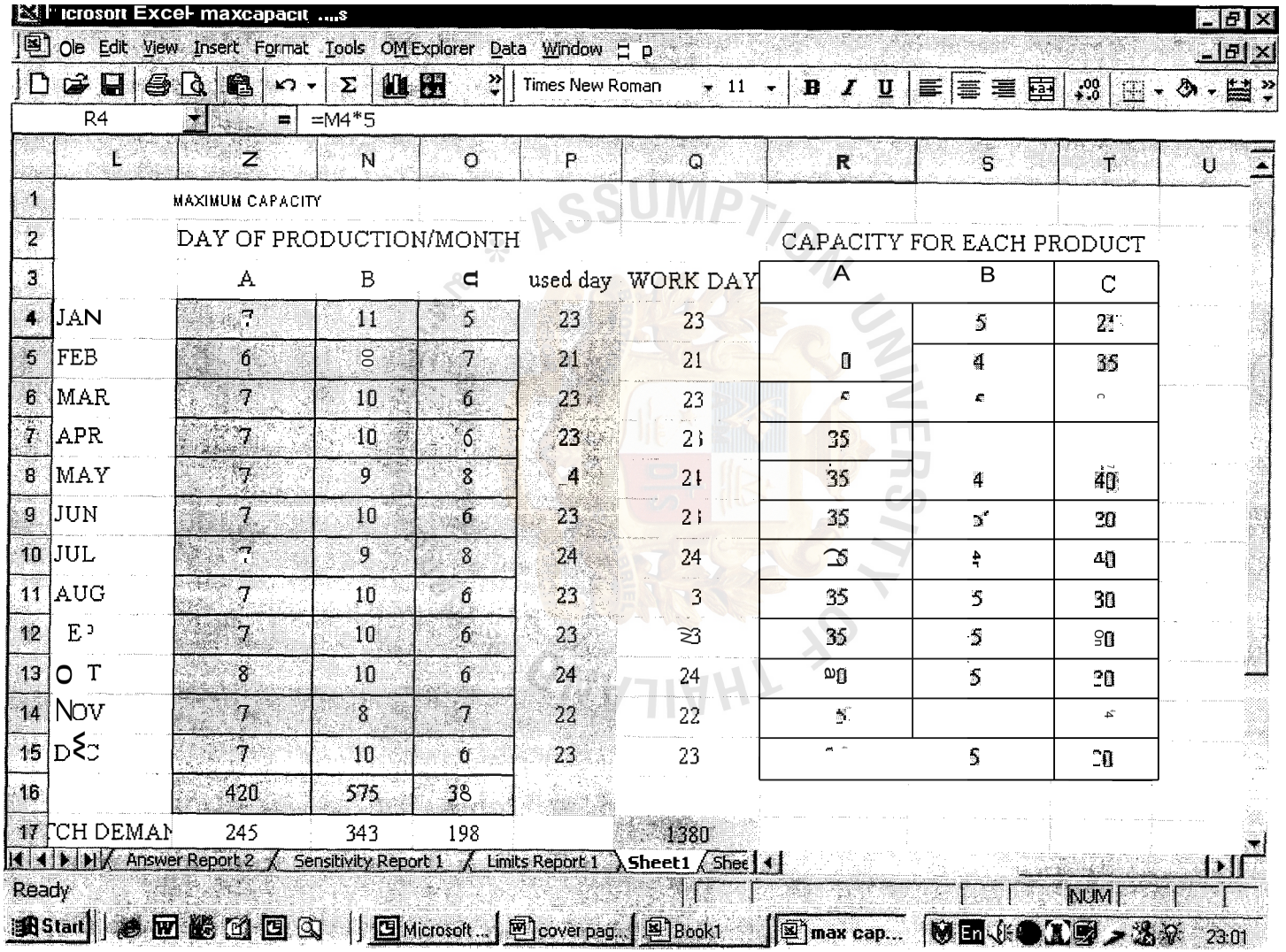
APPENDIX B

Microsoft Excel, solver function

for time study and maximum capacity calculations.

Example of time observation sheet


Microsoft Excel - max capacity.xls
File Edit View Insert Format Tools OM Explorer Data Window Help
Cordia New 14
Q17
L M N O P Q R S T U
17 TOTAL BATCH 245 343 198 1380
TOTAL BATCH/YEAR
Solver Parameters
Set Target Cell: $Q$17
Equal To: Max Min Value of: 0
By Changing Cells:
$M$4:$O$15
Subject to the Constraints:
$M$16:$O$16 >= $M$17:$O$17
$M$4:$O$15 >= 0
$P$4:$P$15 <= $Q$4:$Q$15
Solve
Close
Guess
Options
Add
Change
Delete
Reset All
Help
Answer Report 2 Sensitivity Report 1 Limits Report 1 Sheet1
Draw AutoShapes
Point
NUM
Start
INTR... Thaiso... alterna... max ... Micros...
10:37



Microsoft Excel- maxcapacit ....s

Ole Edit View Insert Format Tools OM Explorer Data Window

Times New Roman 11

R4 =M4*5

MAXIMUM CAPACITY

DAY OF PRODUCTION/MONTH

	A	B	C	used day	WORK DAY
JAN	7	11	5	23	23
FEB	6	8	7	21	21
MAR	7	10	6	23	23
APR	7	10	6	23	23
MAY	7	9	8	24	24
JUN	7	10	6	23	23
JUL	7	9	8	24	24
AUG	7	10	6	23	3
E?	7	10	6	23	23
O T	8	10	6	24	24
NOV	7	8	7	22	22
DEC	7	10	6	23	23
	420	575	38		
TCH DEMAN	245	343	198		1380

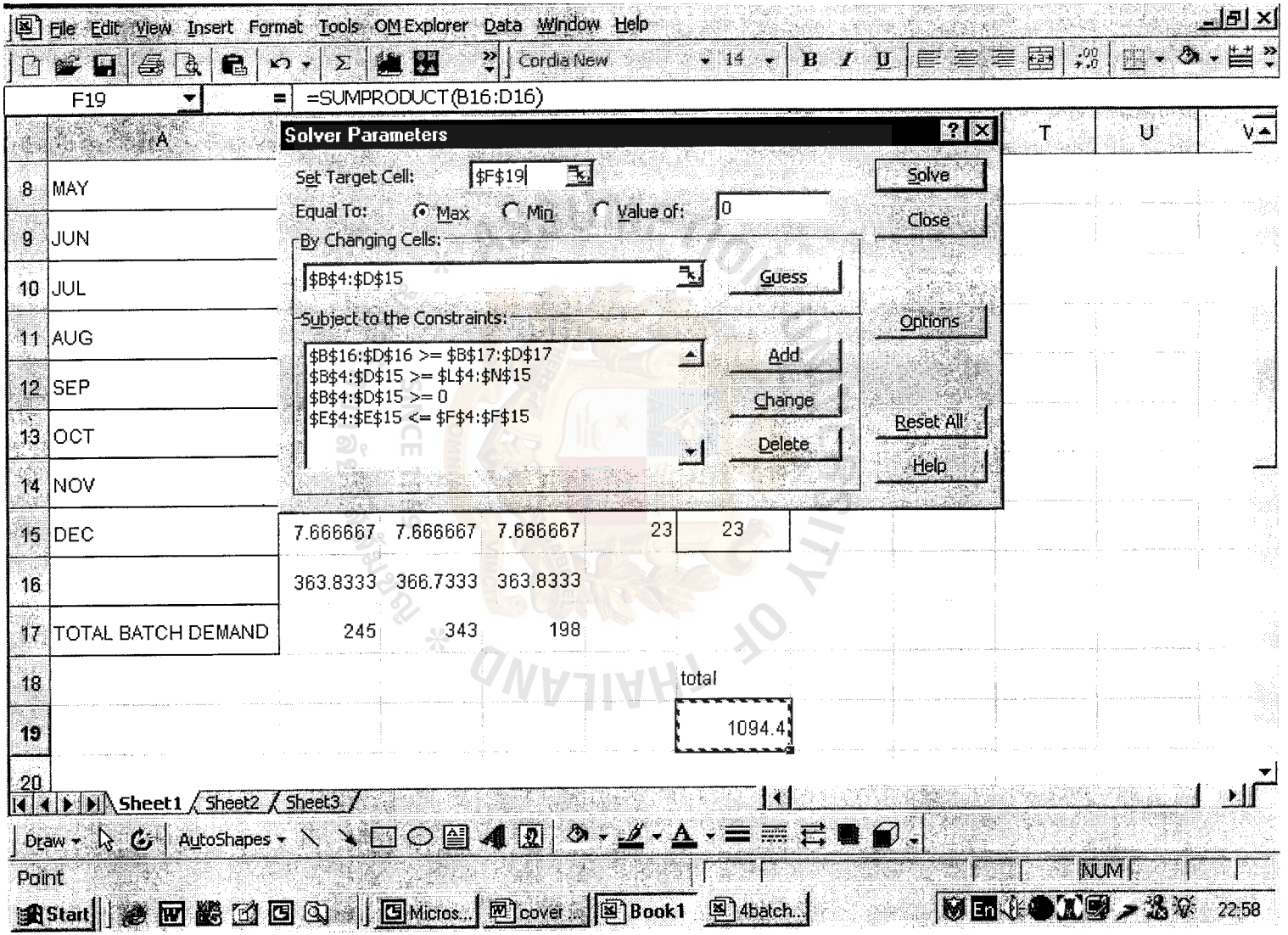
CAPACITY FOR EACH PRODUCT

A	B	C
	5	2
0	4	35
35		
35	4	40
35		30
35		40
35	5	30
35	5	30
0	5	20
	5	20

Answer Report 2 / Sensitivity Report 1 / Limits Report 1 / Sheet1 / Shee

Ready NUM

Start Microsoft ... cover pag... Book1 max cap... 23:01


File Edit View Insert Format Tools OM Explorer Data Window Help
F19
=SUMPRODUCT(B16:D16)
Solver Parameters
Set Target Cell: $F$19
Solve
Equal To: Max Min Value of: 0
Close
By Changing Cells:
$B$4:$D$15
Guess
Subject to the Constraints:
$B$16:$D$16 >= $B$17:$D$17
$B$4:$D$15 >= $L$4:$N$15
$B$4:$D$15 >= 0
$E$4:$E$15 <= $F$4:$F$15
Add
Change
Delete
Options
Reset All
Help
MAY
JUN
JUL
AUG
SEP
OCT
NOV
DEC
TOTAL BATCH DEMAND
7.666667 7.666667 7.666667 23 23
363.8333 366.7333 363.8333
245 343 198
total
1094.4
Sheet1 Sheet2 Sheet3
Draw AutoShapes
Point
NUM
Start
Micros... cover... Book1 4batch...
22:58

	Ele nt	m				g	m altume Elem nt	it	
	<	Coyer theroomfloor with paper	1		20.01	%	20	)1	20.84
	8	S up m' ingmac d	1		0.99	%	4	99	3.20
	3	<he " ctive ingred.	1		2.02	%	2	2.02	2.10
	4	ch " nthe in_ ft.	4		5.13	1 %	5.1	5.13	5.34
	5	Lidtup ingredie	1		1.88	100%	1.8	1.88	1.96
	6	Po 4 sieve the f lax	4		4.37	100%	4.3	4.37	4.55
	7	Pour 4 sieve S. 2 lla r	1		1.50	100%	1	1.50	1.56
	8	Po 4 sieve the 3rdlay	4		4.36	%	4.36	4.36	4.54
	9	N "	1		11	100%	4 11	11	< .78

Ready

NUM

Start | app... | cov... | Book1 | ob... | INT... | 22:44

Table 3.1. Observation Sheet (Time Study Form).

Observation sheet (Time study form)

Model : U8 — Operator's name : Parichart

Operation : Flex bond operation — Cell location : C22

Prepared by : Tan:mut — Shift : Day shift

Observation date : January 9, 2000 — Supervisor signature : Saitip

Element No.	Work element	Frey	Observation time					Avg. Time	Rating factor	Normal time	
										Element	Unit
1	Pick up Jit tool tray	5	1.28	1.22	1.69	1.78	12.1	2.08	100%	2.08	0.42
			1.04	1.67	1.32	1.3	1.21				
			1.37	1.48	1.4	1.59	1.98				
			1.97	1.93	1.84	1.78	1.71				
2	Loaded Jit tool into flipper arm	1	1.18	1.34	1.2	1.23	1.78	1.51	100%	1.51	1.51
			1.58	1.9S	1.16	1.67	1.84				
			1.94	1.52	1.31	1.69	1.5				
			1.16	1.54	1.98	1.19	1.34				
3	Turn Jit tool wedge	1	1.21	1.3	1.41	1.56	1.73	1.49	100%	1.49	1.49
			1.46	1.32	1.5	1.62	1.81				
			1.49	1.27	1.36	1.44	1.52				
			1.35	1.41	1.69	1.56	1.81				
4	Loaded FOS to flipper Arm.	1	2.48	2.22	2.81	2.45	2.56	2.52	100%	2.52	2.52
			2.13	2.49	2.57	2.61	2.53				
			2.43	2.51	2.64	2.43	2.51				
			2.87	2.35	2.49	2.57	2.81				
5	Applied epoxy	1	4.25	4.13	5.6	3.44	4.2	4.00	100%	4.00	4.00
			4.37	4.19	2.78	3.17	5.17				
			3.45	4.16	4.29	4.35	4.28				
			4.32	4.14	3.22	5.12	3.27				
6	Flipped flipper arm	1	1.12	1.34	1.68	1.49	1.27	1.36	100%	1.44	1.36
			1.37	1.11	1.25	1.34	1.47				
			1.59	1.65	1.48	1.74	1.23				
			1.35	1.84	1.35	1.43	1.68				
7	Push wedge on Jit tool	1	2.89	2.87	2.41	2.33	2.67	2.55	100%	2.55	2.55
			2.36	2.34	2.71	2.67	2.45				
			2.57	2.34	2.37	2.94	2.34				
			2.51	2.34	2.57	2.89	2.46				
8	Unload Jit tool to tray	1	1.69	1.37	1.4	1.57	1.39	1.39	100%	1.39	1.39
			1.2	1.4	1.49	1.14	1.43				
			1.28	1.95	1.25	1.38	1.27				
			1.02	1.38	1.4	1.46	1.38				
9	DNP data entry	5	1.32	1.21	1.14	1.28	1.35	1.32	100%	1.32	0.26
			1.29	1.16	1.51	1.34	1.32				
			1.65	1.27	1.32	1.11	1.46				
			1.46	1.18	1.24	1.23	1.52				
									Summarized time		15.50

APPENDIX C

WHO good manufacturing practices:

Main principles for pharmaceutical products

WHO good manufacturing practices: main principles for pharmaceutical products

Good practices in production and quality control [9,10]

15. Good practices in production [11]

15.1 *Principle.* Production operations must follow clearly defined procedures in accordance with manufacturing and marketing authorizations, with the objective of obtaining products of the requisite quality.

General

15.2 All handling of materials and products, such as receipt and quarantine, sampling, storage, labelling, dispensing, processing, packaging, and distribution should be done in accordance with written procedures or instructions and, where necessary, recorded.

15.3 Any deviation from instructions or procedures should be avoided as far as possible. If deviations occur, they should be approved in writing by a designated person, with the involvement of the quality control department, when appropriate.

15.4 Checks on yields and reconciliation of quantities should be carried out as necessary to ensure that there are no discrepancies outside acceptable limits.

15.5 Operations on different products should not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or cross-contamination.

15.6 At all times during processing, all materials, bulk containers, major items of equipment, and where appropriate the rooms used should be labelled or otherwise identified with an indication of the product or material being processed, its strength (where applicable), and the batch number. Where applicable, this indication should also mention the stage of production.

15.7 Access to production premises should be restricted to authorized personnel.

15.8 Normally, non-medicinal products should not be produced in areas or with equipment destined for the production of pharmaceutical products.

15.9 In-process controls are mostly performed within the production area. They should not carry any risk for the quality of the product.

Prevention of cross-contamination and bacterial contamination in production

15.10 When dry materials and products are used in production, special pre-cautions should be taken to prevent the generation and dissemination of dust.

15.11 Contamination of a starting material or of a product by another material or product has to be avoided. This risk of accidental cross-contamination arises from the uncontrolled release of dust, gases, vapours, sprays, or organisms from materials and products in process, from residues on equipment, from intruding insects, and from operators' clothing, skin, etc. The significance of this risk varies with the type of contaminant and of the product being contaminated. Among the most hazardous contaminants are highly sensitizing materials, biological preparations such as living organisms, certain hormones, cytotoxic substances, and other highly active materials. Products in which contamination is likely to be most significant are those administered by injection or applied to open wounds and those given in large doses and/or over a long time.

15.12 Cross-contamination should be avoided by appropriate technical or organizational measures, for example:

(a) production in segregated areas (which may be required for products such as penicillins, live vaccines, live bacterial preparations and certain other biologicals), or by campaign (separation in time) followed by appropriate cleaning;

(b) providing appropriate airlocks, pressure differentials, and air extraction;

(c) minimizing the risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air;

(d) wearing protective clothing in areas where products with special risk of cross-contamination are processed;

(e) using cleaning and decontamination procedures of known effectiveness, as ineffective cleaning of equipment is a common source of cross-contamination;

(f) using a "closed system" of production;

(g) testing for residues;

(h) using cleanliness status labels on equipment.

15.13 Measures to prevent cross-contamination and their effectiveness should be checked periodically according to standard operating procedures.

15.14 Production areas where susceptible products are processed should undergo periodic microbiological monitoring.

Processing operations: intermediate and bulk products

15.15 Before any processing operation is started, steps should be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels, or documents not required for the current operation.

15.16 Any necessary in-process controls and environmental controls should be carried out and recorded.

15.17 Means should be instituted of indicating failures of equipment or of services (e.g., water, gas) to equipment. Defective equipment should be withdrawn from use until the defect has been rectified. Production equipment should be cleaned according to detailed written procedures and stored only under clean and dry conditions.

15.18 Containers for filling should be cleaned before filling. Attention should be given to avoiding and removing any contaminants such as glass fragments and metal particles.

15.19 Any significant deviation from the expected yield should be recorded and investigated.

15.20 Checks should be carried out to ensure that pipelines and other pieces of equipment used for the transportation of products from one area to another are connected in a correct manner.

15.21 Pipes used for conveying distilled or deionized water and, where appropriate, other water-pipes should be sanitized according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.

15.22 Measuring, weighing, recording, and control equipment and instruments should be serviced and calibrated at prespecified intervals and records main-tained. To ensure satisfactory functioning, instruments should be checked daily or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due should be clearly indicated.

15.23 Repair and maintenance operations should not present any hazard to the quality of the products.

Packaging operations

15.24 When the programme for packaging operations is being set up, particular attention should be given to minimizing the risk of cross-contamination, mix-ups, or substitutions. Different products should not be packaged in close proximity unless there is physical segregation or the use of electronic surveillance.

15.25 Before packaging operations are begun, steps should be taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials, or documents previously used and not required for the current operation. The line clearance should be performed according to an appropriate checklist and recorded.

15.26 The name and batch number of the product being handled should be displayed at each packaging station or line.

15.27 Normally, filling and sealing should be followed as quickly as possible by labelling. If labelling is delayed, appropriate procedures should be applied to ensure that no mix-ups or mislabelling can occur.

15.28 The correct performance of any printing (for example of code numbers or expiry dates) done separately or in the course of the packaging should be checked and recorded. Attention should be paid to printing by hand, which should be rechecked at regular intervals.

15.29 Special care should be taken when cut labels are used and when overprinting is carried out off-line, and in hand-packaging operations. Roll-feed labels are normally preferable to cut labels in helping to avoid mix-ups. On-line verification of all labels by automated electronic means can be helpful in preventing mix-ups, but checks should be made to ensure that any electronic code readers, label counters, or similar devices are operating correctly.

15.30 Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing.

15.31 On-line control of the product during packaging should include at least checks on:

(a) the general appearance of the packages;

(b) whether the packages are complete;

(c) whether the correct products and packaging materials are used;

(d) whether any overprinting is correct;

(e) the correct functioning of line monitors.

Samples taken away from the packaging line should not be returned.

15.32 Products that have been involved in an unusual event during packaging should be reintroduced into the process only after special inspection, in-vestigation, and approval by authorized personnel. A detailed record should be kept of this operation.

15.33 Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced should be investigated and satisfactorily accounted for before release.

15.34 Upon completion of a packaging operation, any unused batch-coded packaging materials should be destroyed and the destruction recorded. A documented procedure should be followed if uncoded printed materials are returned to stock.

16. Good practices in quality control

16.1 *Principle.* Quality control is concerned with sampling, specifications, and testing as well as with the organization, documentation, and release procedures that ensure that the necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory. Quality control is not confined to laboratory operations, but must be involved in all decisions that may concern the quality of the product. The independence of quality control from production is considered fundamental. (Please refer also to Part One, section 3 (pp. 17-18).)

Control of starting materials and intermediate, bulk, and finished products

16.2 All tests should follow the instructions given in the relevant written test procedure for each material or product. The result should be checked by the supervisor before the material or product is released or rejected.

16.3 Samples should be representative of the batches of material from which they are taken in accordance with the approved written procedure.

16.4 Sampling should be carried out so as to avoid contamination or other adverse effects on quality. The containers that have been sampled should be marked accordingly and carefully resealed after sampling.

16.5 Care should be taken during sampling to guard against contamination or mix-up of, or by, the material being sampled. All sampling equipment that comes into contact with the material should be clean. Some particularly hazardous or potent materials may require special precautions.

16.6 Sampling equipment should be cleaned and, if necessary, sterilized before and after each use and stored separately from other laboratory equipment.

16.7 Each sample container should bear a label indicating:

(a) the name of the sampled material;

(b) the batch or lot number;

(c) the number of the container from which the sample has been taken;

(d) the signature of the person who has taken the sample; and

(e) the date of sampling.

Test requirements

Starting and packaging materials