

# PHARMACEUTICAL FACTORY

## LOCATION

### [1] INTRODUCTION:-

The pharmaceutical industry is a major global economic force, which increasingly relies on the **safe and efficient** production of technically advanced products. This environment challenges the facilities professional who is charged to **plan, design, construct, validate, and operate complex manufacturing facilities** that meet world class pharmaceutical standards. The facilities professional must master the many dynamic, interacting industry forces and understand how they influence pharmaceutical manufacturing facilities, and must apply prudently good design practices in response to these challenges.

The pharmaceutical industry is an economic entity comprised of multi-product, multi-market companies. The industry's operating environment is complex because of economic, political, technical, and social influences within a growing global environment for product development and delivery. The pharma industry has grown in the last several decades and has become quite complex, promising to deliver valuable products that enhance the quality of life to an expanding global population that demands greater access and more affordable choices. The role of the facilities professional is increasingly important to the industry as it addresses sourcing and manufacturing delivery objectives.

Pharmaceutical manufacturing facilities are charged with meeting two significant objectives: They must perform and conform. Facilities deliver increasingly complex and valuable products configured in evolving, technically complicated dosage forms and therapies. Facilities must also comply with ever-changing and demanding regulatory oversight from the world's statutory bodies. These two fundamental challenges are addressed by facility professional's keen appreciation of the dynamic **forces shaping the industry and by prudent facility designs** that contribute to the enterprise's strategic long-term viability.

This seminar presents a broad overview of strategic industry driving forces to develop a **solid informational framework** for the facility professional's guidance. Key issues and concepts covered include speed to market, performance and conformance, cost of goods, risk management, and supply chain, as well as other issues that bear on facilities planning, design, delivery, and operation.

## **[2] PLANT LOCATION:-**

Plant location means the establishment of an industry at a particular place. The performance of an enterprise is considerably affected by its location. The selection of site for any enterprise mainly depends on its size and nature. Sometimes, The nature of the product itself suggest some suitable location.

- ❖ **A Small scale industry** mainly select the site where in accordance with its capacity, the local market for the product is available. It can easily be shifted to other place, when there is any change in the market.
- ❖ **But in the case of Large scale industries**, Where huge amount of investment has already been done the selection of proper site is very important.

### **IMPORTANCE OF PLANT LOCATION:**

The selection of appropriate location is important due to the following reasons :--

- Location of plant partially determines operating and capital costs. It determines the nature of investment costs to be incurred and also the levels of operating costs.
- Location fixes some of the physical factors of the overall plant designs. e.g. heating and ventilation requirements, storage capacity of raw material taking into consideration their local availability, transportation need for raw materials and finished goods, power needs ,cost of labours, taxes, land construction, fuel, etc.
- Each prospective location implies a news allocation of capacity to respective market area.
- Government sometimes plays an important role in the choice of location keeping in view the national benefits.

### **FACTORS RESPONSIBLE FOR THE PLANT LOCATION CHOICES:**

The choices of the plant location is based on the following factors :-----

- **Availability of Raw material:** An ideal location is one where the main raw material required to manufacture the product is adequately available. This will ensure regular supply of the material and will reduce the transportation costs.
- **Nearness to the potential market:** marketing of finished goods efficiently is an important function of an enterprise. If the plant is located near the market, then the management can keep close touch with their changes in market environment and formulate its production policies accordingly. Moreover, the transportation and other overhead expenses are reduced.
- **Location should be near to source of operating power:** in some industries, continuous and adequate power supply is needed.  
There are certain industries for which cheap electricity may be very important. In such situation, location of the plant near to the hydel-power situation will provide cheap electricity.
- **Supply of labour:** labour is one of the most important inputs in any industrial enterprise. There should be regular and cheap supply of labour, specifically the unskilled labour. If there is adequate supply of local labour near the plant, then naturally it will be available at cheaper rates.

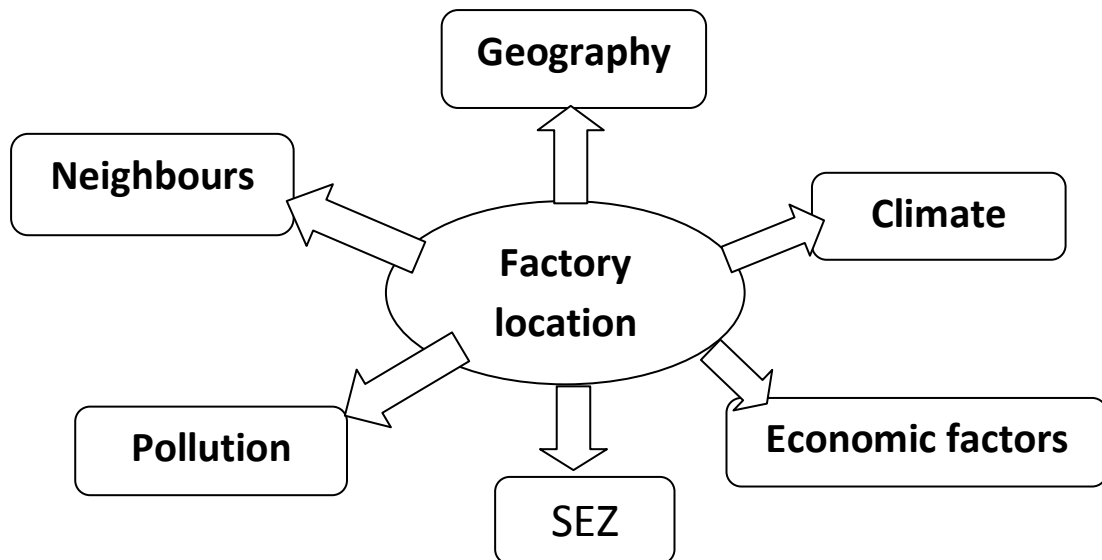
- **Transport and communication facilities:** Transport is very important for bringing raw materials, fuel from different places, marketing of finished products etc. The region well connected with rail, road, water and air transport system is considered to be more appropriate for the location of the plants.  
Similarly good communication facilities, such as, postal and telecommunication links are of great significance towards the success of an enterprise. Regions with good communication system should be given priority for the selection of the sites.  
Similarly, industries producing goods for exports may be located near ports or airports.
- **Suitability of land and climate:** sub-soil of the location should be able to support the load likely to be placed on it. Similarly, climatic conditions viz humidity, temperature and other atmospheric conditions should be favourable for the plant. For the example, humid atmosphere is not suitable for the formation of pharmaceuticals.
- **Integration with other group of companies:** new enterprise owned or operated by a single group of companies should be so located that its work can be integrated with the work of the associated establishments.
- **Availability of housing, other amenities and services:** good housing facility, adequate shopping centre, theatres, cinema halls, restaurants, local transport facilities, rail services and sufficient availability of gas, water supply, drainage, disposal of waste, can easily attract good staff.
- **Local building and planning regulations:** proposed location should not be infringe local regulations and bye-laws. A discussion with survey department of the local authority is most desirable. Laws for the construction of buildings, local taxes etc. should be taken into consideration for the selection of site.
- **Safety requirements:** industries likely to cause pollution or processes explosives in nature should be located in remote areas.
- **Miscellaneous considerations:** The consideration like low interest on loans, special grants, low rentals, attitude of residents, towards the industry, living standards etc. helps in locating in the site of plants.

### **SELECTION OF SITE:**

Once an appropriate area is chosen for certain plant, next step is location analysis to choose suitable site in that area. The choice of site is important both for objective and subjective reasons.

The following points should be kept in mind for the selection of the site:-

1. It should be well connected with **rail, road and river transports**.
2. There should be **efficient sewage system** for the disposal of water and waste materials.
3. The **surroundings** should be good and peaceful.
4. The **sub-soil** should be capable of bearing the load of the building plant and equipment.
5. There should be **sufficient land** to meet the present as well as the future space requirements of the plant. There should be provision for the parking of transport and sufficient space for residential accommodation for staff and labour.



Site can be selected both in urban or rural areas.

- **Urban area** can provide better transport and communication system with sufficient labour supply. There can also be adequate security arrangements as well as other social services like medical, entertainment, restaurants, educational etc. But in urban area, cost of land and labour wages are likely to be on higher side.
- **Rural area** can provide cheaper land and labour with scope for further expansion. The local taxes and expenditure on other amenities is likely to be very low. The main shortcomings of rural plant site lies in scarcity of skilled labour, good shopping complexes, entertainment facilities, school and colleges and other amenities. In general, rural location is good for large plants.

### [3] **PLANT LAYOUT:-**

Once a decision about location of the plant has been taken, next important problem before the management is to plan suitable layout for the plant. Efficiency and performance of good machines and sturdy building depend to a great extent on the layout of a plant.

Plant layout is the method of allocating machines and equipment, various production processes and other necessary service involved in transformation process of a product with the available space of the factory, so as to perform various operations in the most efficient and convenient manner providing output of high quality and minimum cost.

Planning the layout of a plant is a continuous process as there are always chances of making improvements over the existing arrangement. The disposition of the various parts of a plant along with all the equipment used is known as plant layout. It should be so designed that the functioning of plant would become very efficient.

A good layout results in comforts, convenience, safety, efficiency, compactness and profits. A poor layout results in congestion, waste, frustration and inefficiency.

## **ADVANTAGES OF A GOOD LAYOUT:**

A good layout can provide a number of advantages to workers and management. Some of these are given below:-----

### **I. To the worker:**

1. There are lesser number of operation and material handling.
2. There is reduction in length of hauls and motions between operations, which minimize production time as well as the activities of workers.
3. There is more labour productivity i.e. more output per man hour.
4. There is more safety and security to workers from accidents.
5. Better working conditions resulting in improved efficiency.

### **II. In manufacturing costs:**

1. Maintenance and replacement costs are reduced.
2. Loss due to waste and spoilage is minimised.
3. Improved quality of product with reduction in handling w.r.t. movement, time and cost.
4. Better cost control.

### **III. In production control and supervision:**

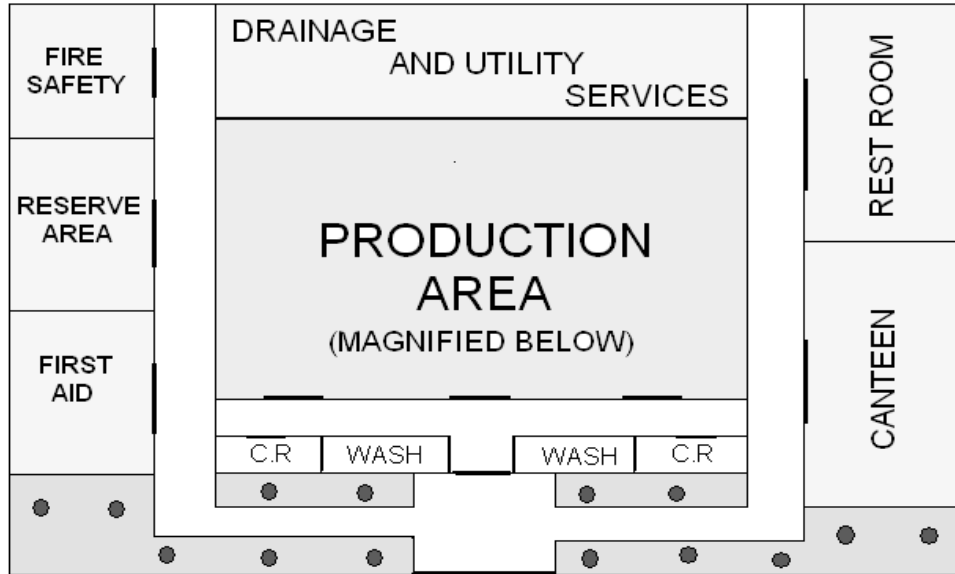
1. It provides more space for production operation.
2. There is efficient arrangement for receipt, transportation, and delivery of raw material and finished goods.
3. The cost and efforts in the supervision of production are minimized.
4. There is a better and convenient storage facility.
5. Control and supervision operations are provided at appropriate points.

## **FEATURES OF A GOOD LAYOUT:**

The good layout should possess the following basic characters:--

1. There should be sufficient space for the workers as well as for the equipment to perform their functions. This will ensure smooth and continuous flow of production process.
2. It must provide adequate safety and security to workers against accidents or injury. For example, provision of fire fighting equipment, first aid boxes, etc.
3. The arrangement of machines and equipment should be such that minimum material handling is necessary for low cost processing.
4. The store for in-process material should be such that minimum material handling is necessary for low cost processing.
5. The supervision, coordination and control of the activity should be effectively and easily executed.
6. There should be sufficient scope for making adjustment and modifications whenever any need arises.

**SAMPLE LAYOUT OF A PHARMACEUTICAL FACTORY**



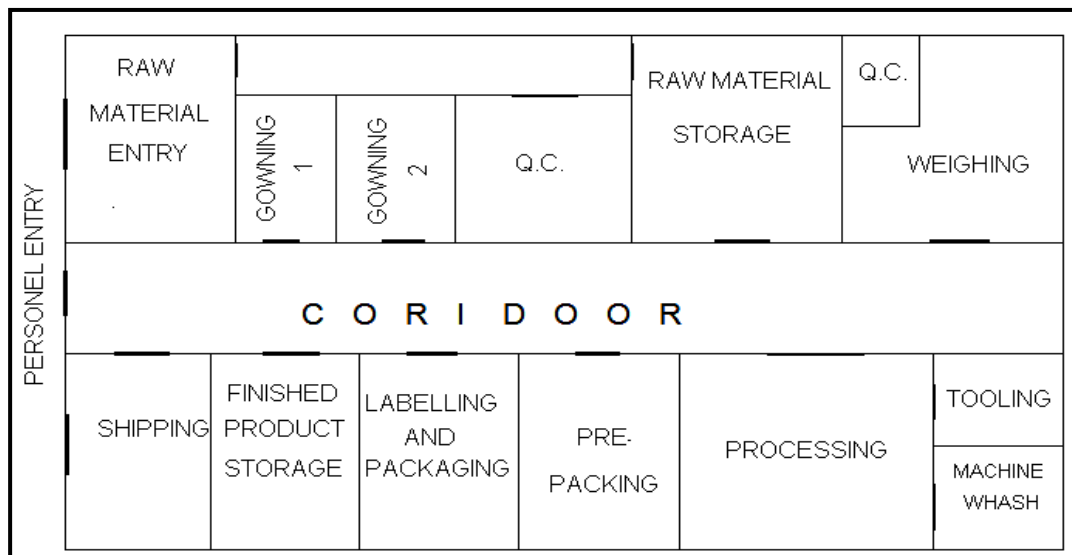
Good cGMP Design Features Include:

- Clear layouts
- Appropriate detailing and finishes
- Adequate room sizes and staging areas
- Presentation drawings that illustrate flows for people, product and equipment.

Flexibility:

- Able to adapt to different uses
- Able to bring new services to the rooms
- Ease off clean up
- Modulations

**SAMPLE LAYOUT OF A PRODUCTION DEPARTMENT**



### SAMPLE LAYOUT OF F&D DEPARTMENT

RAW MATERIAL STORAGE	DISPENSING	GRANULATION
<b>CORRIDOR</b>		
Q.C.	COATING	COMPRESSION

#### **[4] PLANNING:-**

- A plan is a course of action to be taken in future. It is a prescribed course of action.
- Planning is the process of deciding in advance what to do, how to do it, when to do it and who is to do it.
- It involves the selection of objectives, policies, procedures, and programmes from among alternatives.
- Planning is a mental exercise that requires imagination, foresight and sound judgments.
- It is thinking before doing.

#### **SALIENT FEATURES OF PLANNING:**

The following points highlight the nature of planning:

- 1. Planning is goal oriented :** planning is done to achieve certain objectives and all plans are linked with the goals of the organization. Planning identifies the action that would lead to the desired results quickly and economically.
- 2. Planning is future oriented :** planning seeks to manage future events to the best advantage of the organization. Scientific anticipation of future events is called forecasting which serves as the basis of planning. For example, manufacturer prepares the production plan of the next year after forecasting the demand.
- 3. Planning is intellectual process :** planning is a mental exercise and it involves the creative thinking and imagination. Management can prepare sound plans only when it has sound judgment, foresight and vision. Planning requires mental predisposition to think before acting. Planning is not mere guess work but involves logic and systemic thinking.
- 4. Planning is a primary function of management :** planning serves as the basis for all other functions of management. It precedes organizing, staffing, directing and controlling. All

these function are preformed within frame work of plans. Thus planning is the most basic function.

- 5. Planning is pervasive :** planning is required in all types of organization and at all levels of management. Every department prepares plans. However, the scope of planning may differ from one level to another. For example, top management plans for the whole of the organization, middle management prepares departmental plans, whereas the lower management prepares day to day operational plans.
- 6. Planning is continuous :** planning is ongoing process. Plans are prepared for a specified period say for one year. At the end of that period, new plans have to be prepared. Similarly, existing plans are required to be changed, if the conditions are changed. Thus planning is never ending exercise.
- 7. Planning involves choice :** planning is essentially the process of choosing from among alternatives course of action. If there is only one possible alternatives, there is no need for planning as there is no choice. The planning is needed when there are various alternatives to reach to a definite goal.
- 8. Planning aims at efficiency :** plans are prepared to achieve the objectives in the best way. Sound planning helps to achieve desired objectives at the minimum possible cost. It helps in optimization of resources. A good plan should provide maximum satisfaction to those responsible for its execution.

### **ADVANTAGES:**

1. Planning makes goals clear and specific. Plans serves as a guide for deciding what actions should be taken. With clear goals, activities become meaningful.
2. Planning helps the organization to keep on the right path.
3. Planning reduces the risks and uncertainly. Business enterprises operate in an uncertain environment. Planning enables to predict future events and prepares to face the unexpected events.
4. It improves the efficiency of operation because planning involves selection of the best possible course of action.
5. It provides basis of control. Planning provides the standard against which the actual performance can be measured and evaluated.
6. It promotes creativity, because only sound planning encourages creative thinking. This leads to growth and expansion of business.
7. It facilitates decision making. Planning involves forecasting of future conditions and helps the management to take correct decision.
8. It helps in coordinations. Planned targets and programmes serves as the basis of harmonizing the efforts of different departments, sections and individuals to achieve it.

### **LIMITATIONS :**

1. Planning is an expensive process. Money is involved in forecasting, collection of information and evaluation of alternatives. The cost of planning should not exceeds the gain expected from it.



2. Planning is a time consuming process. So it is not practicable during emergencies and crises, when quick decisions are necessary.
3. Planning creates a rigid frame work in the organization. Once the plans are formulated people tend to strictly adhere to them irrespective of changes in the environment.
4. Changes in business environment restrict freedom of planning for the management.
5. Planning creates a false sense of security because detailed planning gives a feeling among employees that everything has been taken care of.
6. Planning creates a psychological barriers, because executive have more regard for the present than future. Planning often involve changes which executives would like to ignore, hoping they would not materialize.
7. Planning is based on forecast which are estimates about the future. When forecasts are inaccurate, plans became misleading; therefore, blind reliance on plans may be dangerous.

### **STEPS INVOLVED IN PLANNING:**

Systematic approach to planning is necessary in order to prepare a sound plans. The steps involved in systematic planning are as follows:---

1. **Definition and description of objectives:** plans are prepared to achieve certain objectives or goals. The first step in planning is to define clearly the objectives of the business organization. The planning is required either to solve a problem or to exploit an opportunity to be utilized to achieve the objectives. For example, main objective of the company is to increase profits by 25% during the next year. So the production and sales targets should be decided on this basis.
2. **Determination of planning premises:** this is next step of planning. Planning premises are the assumptions about the future. The provide the environment or boundaries in which plans will be implemented. Planning premises are established with the help of forecasting. Planning premises may be of following types:
  - a) **Tangible and intangible premises:** assumption which can be expressed in quantitative terms are called tangible premises e.g. units of production, capital investments, time available etc. Intangible premises are employees morale, goodwill of the enterprise, motivation etc.
  - b) **Internal and external premises:** assumption about the internal working of the enterprise are known as internal premises. E.g. capital, machines, personnel etc. On the other hand factors outside the enterprise are called external premise e.g. changes in technology, population growth, changes in competition, government policies etc.
  - c) **Controllable and uncontrollable premises:** policies and programmes of the organization which can be fully regulated by the management are controllable premises. Uncontrollable premises are the external factors like trade cycles, political changes etc. which are beyond the control of management.
3. **Discovering alternatives courses of action:** once the objectives and planning premises are established, the various courses of action are discovered in order to achieve the established objectives. Information may be collected from primary and secondary sources. The data so collected will serve as the basis for development of an alternative course of action. The strength and weakness of an alternative course of action also need to be examined by the

management at this stage.

4. **Evaluation of alternative courses:** the various alternatives are evaluated and compared in terms of their expected costs and benefits, after objectives and scientific evaluation of different alternatives, the best alternatives is selected.
5. **Formulation of derivative plans:** once the basic plan is decided, the next step is to develop detailed plans for its implementation. These detailed plans refers to the policies, procedures, rules, programmes, schedules, budgets etc. for example, when pharmaceutical company decides to develop a new product, planning concerning the product design, procurement of funds, purchase of raw materials, training of personnel, advertising for the product have to be prepared.
6. **Communicating the plan:** plan should be explained to the subordinates in order to get their support in the execution of plans. Successful implementation of plans requires whole hearted cooperation and understanding of personnel.
7. **Receiving the planning process:** continuous evaluation of plans and the process of planning helps to detect shortcomings of the plans. All plans should be reviewed from time to time in the light of current circumstances and necessary action should be taken to keep them up-to-date.

### **[5] QUESTIONS :**

1. Draw a simple layout of pharmaceutical production plant along with F & D section? Write a note on utility services & sanitation programme in manufacturing premises?(2<sup>nd</sup> internal exam 2007)
2. Enlist the factors to be considered while selecting site for pharm.Plant what is utility services?(University exam 2005)
3. Discuss the factors affecting selection of pharma.plant site & design. Discuss about personnel facilities & personnel protection as per GMP. How the sanitation program in mfg, premises is carried out?(2<sup>nd</sup> internal exam ,2005)

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