PRODUCTION MANAGEMENT

PRODUCTION

- Production is defined as the step by step conversion of one for of material into another form through chemical or mechanical process to create or enhance the utility of the product to the user

Production management

- It is the process in which the raw material is converted into finished goods & products. It deals with the decision making regarding the quality , quantity, cost, etc. of production.
- Production in pharmaceutical company consists of the creation & maintenance of a clearly defined organization & makes effective & coordinated use of personnel, land, buildings & equipment, including the management of inventory assets.
- The production management when done in a pharmaceutical company is known as Pharmaceutical Management.
- Its main aim is to produce goods of right quality & quantity by time at minimum cost, also tries to improve the efficiency of the product.

Importance of production management

- Important role to the business firm or the industry.
- Satisfy the customer's needs and achieve its objectives & maintain the reputation, goodwill and image.
- It helps to introduce new products.
- It helps to face competition in the market by making products of right quality, quantity and at time.
- It also facilitates optimum utilization of resources such as manpower, machine, etc.

OBJECTIVES OF PRODUCTION MANAGEMENT

- **Right Quality:** The quality of product is established based upon the customers needs. The right quality is not necessarily best quality. It is determined by the cost of the product and the technical characteristics as suited to the specific requirements.
- **Right Quantity:** The manufacturing organization should produce the products in right number. If they are produced in excess of demand the capital will block up in the form of inventory and if the quantity is produced in short of demand, leads to shortage of products.
- **Right Time:** Timeliness of delivery is one of the important parameter to judge the effectiveness of production department. So, the production department has to make the optimal utilization of input resources to achieve its objective.
- **Right Manufacturing Cost:** Manufacturing costs are established before the product is actually manufactured

PRODUCTIVITY

- Defined as the ratio of output to input. If we increase the output and reduce the input then we can increase the production efficiency
- Reduction in wastage of resources such as labor, machines, materials, power, space, time, capital, etc.
- Human endeavor (effort) to produce more and more with less and less inputs of resources so that the products can be purchased by a large number of people at affordable price. Implies development of an attitude of mind and a constant urge to find better,
- Cheaper, easier, quicker, and safer means of doing a job, manufacturing a product and providing service.

General ways of increase output are :	General ways of decrease input are:
1. Process improvement	1. Improve quality
2. Regulate work flow	2. Minimize waste
3. Use more modern equipment	3. Reduce the cost of labor
4. Train and motivate employees	4. Reduce cost of supply

Methods to Increase Productivity:

1. Just in time Inventory
2. Outsourcing
3. Operations research
4. Value engineering
5. Total quality management

Master Production Instructions (1)

To ensure the uniformity from batch to batch, master production instructions for each intermediate & API should be prepared, dated & signed by one person & independently checked, dated & signed by a person in the quality unit.

It should include following information:

- Name of intermediate or API being manufacture & an identifying document reference code, if applicable.
- A complete list of raw materials & intermediates.
- An accurate statement of the quantity & ratio of each raw material or intermediate to be used, including the unit of measure.
- The production location & major production equipment to be used.
- Detailed production instructions including the following:-
  - Sequences to be followed
  - Ranges of process parameter to be used
  - Sampling instructions & in-process controls with their acceptance criteria where appropriate
  - Times limits for completion of individual processing steps &/or the total process where appropriate
  - Expected yield ranges at appropriate phases of processing or time

Where appropriate, special notation & precautions to be followed or cross references to those.

The instructions for the storage of intermediates or API to ensure its suitability for use, including the labeling & packaging materials & special storage conditions with time limit, where appropriate

Batch Production Record(1)

Batch production record should be prepared for each record should be prepared for each intermediate & API & should include complete information relating to the production & control of each batch.

The batch production record should be checked before issuance to ensure that it is the correct version & a legible, accurate reproduction of appropriate master production instructions.

Documentation of completion of each significant step in the batch production records (batch production & control records) should include the following information:

- Dates and, when appropriate, times
- Identity of major equipment (eg, reactors, driers, mills) used
- Specific identification of each batch, including weights, measures, and batch numbers of raw materials, intermediates, or any reprocessed materials used during manufacturing.

- Actual results recorded for critical process parameters .
- Any sampling performed
- Signatures of the persons performing and directly supervising or checking each critical step in the operation
- In-process and laboratory test results
- Actual yield at appropriate phases or times
- Description of packaging and label for intermediate or API
- Representative label of API or intermediate if made commercially available
- Any deviation noted, its evaluation, investigation conducted (if appropriate) or reference to that investigation if stored separately
- Results of release testing

Good Manufacturing Practices: Production and Process Controls (2)

1. Written procedures; deviations

Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

2. Charge-in of components

The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient.

Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate.

Each component shall be added to batch by one person & verified by second person.

3. Calculation of yield

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing processing, packaging, or holding of the drug product

4. Equipment identification

All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch

5. Sampling and testing of in-process materials and drug products

It is done to assure batch uniformity and integrity of drug products

It is established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

6. Time limitations on production

When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product.

7. Control of microbiological contamination

Appropriate written procedures (including validation sterilization process), designed to prevent microbial contamination in the drug product purpoting to be sterile , shall be established & followed.

8. Reprocessing

Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics.

Reprocessing shall not be performed without the review and approval of the quality control unit.

Materials management (3)

- Materials management involves planning, programming, organizing, directing, controlling & coordinating the various activities concerning the material
- The production manager found it necessary to develop an organized body of knowledge on this subject.
- The resulting set of related disciplines is known as material management.
- Materials management is grouping of management functions supporting the complete cycle of material flow, from the purchase & internal control of production materials to the planning & control of work in process to warehousing , shipping & distribution of the finished product.

3 M's Of Materials management

- Men
- Machines
- Method
- Money
- materials

FOCUS OF MATERIAL MANAGEMENT

To procure right materials

- In Right Quantity
- Of Right Quality
- At Right Time
- From Right sources
- At Right prices

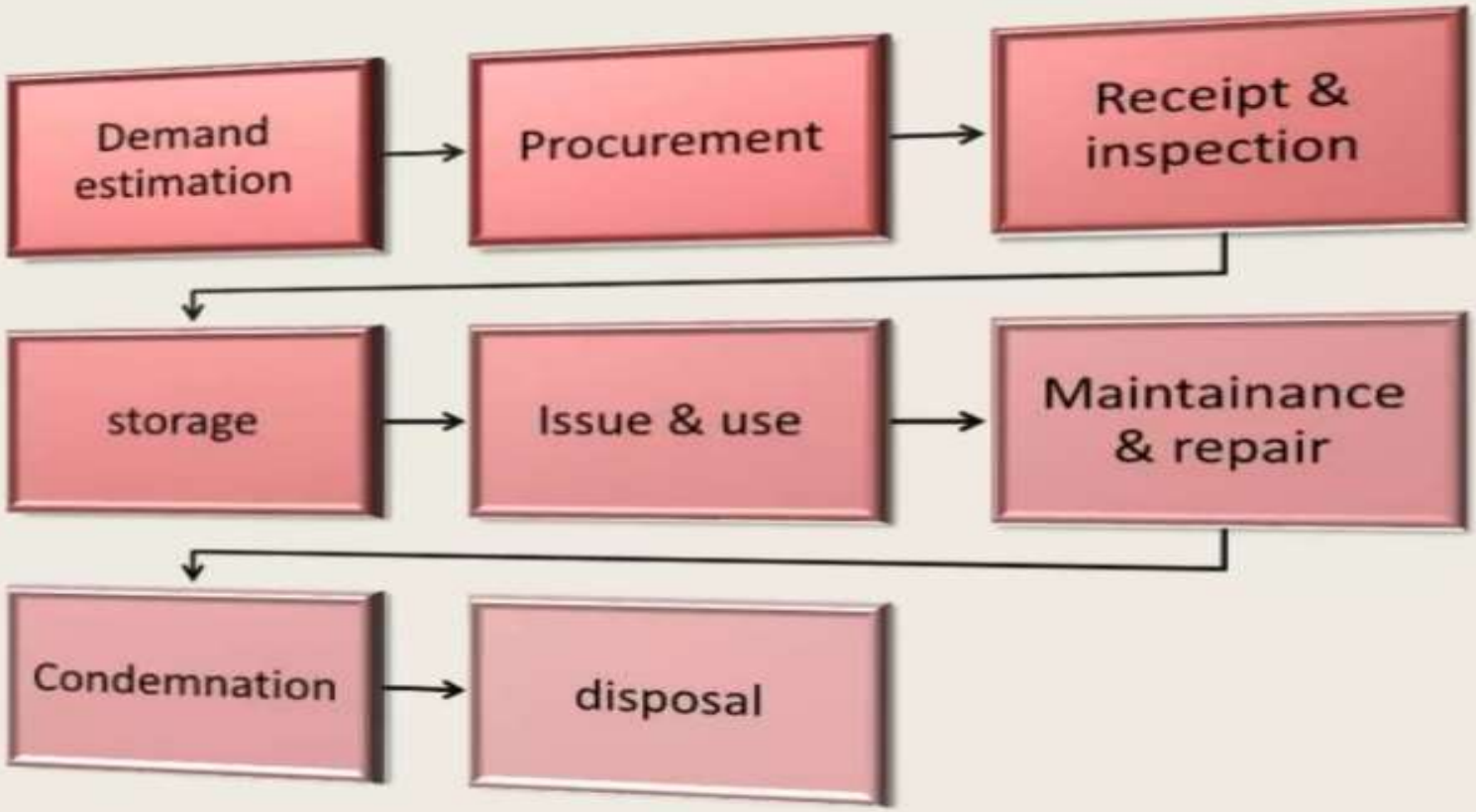
Functions of materials management

- Material planning & programming
- Raw material purchase
- Receiving, store keeping & warehousing
- Issuing of material
- Inventory control
- Value engineering
- Transportation of meterials
- Vendor development
- Vendor reting
- Dispose of scrap & surpluses

Advantages of materials management

- Material cost can be lowered
- Controlling of indirect cost
- Risk of inventory loss minimized
- Reduction in loss of time of direct labour
- Cost of material used in different department ascertained
- Control of manufacturing cycle
- Material congestion in storage places avoided
- Improvement in delivery of the product

Elements of materials management



Primary objectives of materials management

- Buying the best item at the lowest cost
- Reduction in inventory cost and High inventory turnover
- Maintaining the flow of production
- Maintaining the consistency of quality
- Optimization of acquisition and possession, resulting in lower cost
- Cordial relationship with supplier
- Maintaining good records
- Contribution towards competitiveness
- Personnel development

Secondary objectives of materials management

- Promotion of standardization with suppliers
- Development of reciprocal relations with customers
- Committees to decide on economic make-or-buy decisions
- Development of inter departmental relationships
- Can undertake acquisitions

Phases in material management

- Planning (Plans for capacity or production levels and required inventory levels
- Material utilization (efficiency of the flow of materials through the plant)
- Physical (storing, receiving and issuing of materials and physical checking of inventory of raw materials, work in process, finished goods, record keeping)
- Control or follow up (feedback and corrective action involved)

Challenges of material management

- Selection of appropriate vendors
- Land and storage cost increase
- Difficulty in forecasting demand accurately
- Scarce capital for investment in materials inventory
- Diversification of product lines
- Optimizing time and quantity for products
- Management of information