UNIT - 2

Organisation and Personnel

Personnel are the backbone of the backbone of the manufacturing unit. There must be a sufficient number of qualified and trained to ensure one achieves the desired product quality.

Individual responsibilities should be made clear to the personnels for their respective tasks.

All personnels should be aware of the principles of GMP.

Key Personnel of an organisation include:

→ Head of Production (HoP)

→ Head of Quality Control (HoQC)

→ Authorised person

Personnel Responsibilities

→ Personnel involved in aseptic manufacturing, proussing, packaging and handling of drug products should wear clean clothing.

→ They should wear protective apparels such as coverings for head, face, hands and arms to protect drug products from contamination.

→ Personnel should follow good satitation habbits

→ Should not wear jewellery or make up in production/QC areas.

→ Eating, drinking, chewing, smoking should be restricted in production and storage areas.

→ Entry should be limited to authorised and trained personnels only.

→ A personnel should be physically fit to work.

→ Any individual having an illness should report to the supervisor regarding the health issues.

Personnel Training

→ The manufacturer should provide training for all the personnel for their respective duties.
→ Newly recruited personnel should be provided appropriate training.
→ Training records should be kept.

Training System

- An accurate description of the elements needed in a strong training system.

i) description of the job role.
ii) Specific training for each role.
iii) Training plan to complete the training.
iv) Training materials
v) Qualified trainers
vi) Post-training evaluation
vii) Documentation and book keeping system.

Training Plan

Training plan should be designed and implemented in such a way that each individual receives right traing at right time. Training plan should include the following:

→ Training topic or courses.
→ Mode of training
→ Sequence of training
→ Approximate time of training
→ Indication when the Individaal is trained.

Levels of Training

The employee's curriculum includes three different levels of training: The first level of training is an overview or general training conducted by the site HR. The second level of training is held within the functional area. The third level of training is most specific to the employee and involves one-to-one training.

Personnel Hygiene

→ All personnels should undergo health examinations.
→ Undergo periodic eye examinations.
→ Personnels should be trained in personal hygiene.
→ Instructed to wash hands before entering production areas.
→ Any individual found to have an illness should not be allowed to handle, packaging in-process materials or products.
→ To ensure protection from contamination, wear clean body coverings, appropriate to their duties.
→ Reusable clothes should be disinfected and sterilised.
→ Direct contact between the unprotected hands of personnels and raw materials or products should be avoided.
→ Avoid cosmetics such as face powders, hair sprays, perfumes, aftershave, etc.

Personnel Records

Personnel records are records pertaining to employees of an organisation.

→ All records are kept in systematic order in HR.
→ Such records are helpful to a manager in various decision-making areas
→ Keep an update record of leaves, transfers, turnovers, etc.
→ Other personnel records include: employee records, training records, health records, miscellaneous, etc.

Premises

The location, design, construction and layout of premises is a vital part of GMP.

Premises refers to the buildings and facilities where pharmaceutical processing is done. These places must comply with cGMP requirements.

Location

The factors for selecting the location:

1) Nature of manufacturing and testing performed.
2) daily production levels
3) Number of products to be processed
4) Availability of power, water, workforce and closeness to transport hubs.
5) Climatic conditions and hygiene levels.
6) Enough storage space for raw materials, in-process and finished products.

Design & Construction

- A suitable premises reduces the risks of errors and any kind of adverse effects on the product quality.
- The premises should follow the conditions laid down in the Factories Act, 1948.

The following guidelines should be followed during plant design and construction:

1) Walls → The walls should be positioned such that they enable orderly movement of raw materials and personals.
2) Floors → Floor coverings should be durable, easily cleanable and resistant to the chemicals.
3) Ceilings → In the manufacturing areas, ceilings should be of seamless plaster or gypsum board with a smooth finish.
4) Services → Provisions should be made for drainage, water, steam, electricity and other services for easy maintenance.

5) Lighting → Adequate amount of light should reach the working space.

Plant Layout

Plant layout is the area within the factory building where machinery, equipment, furniture, etc. are arranged to permit quick flow of materials.

A proper layout can work efficiently if processing, storage and and handling areas are in coordination with each other.

Importance of Plant Layout

→ easy production flow
→ flexibility of operation
→ makes economic use of building
→ promotes effective utilisation of manpower
→ provides employee's convenience.
→ provides safety
→ provide comfort at work
→ provides max. exposure to natural light.

Types of Plant Layout

1) Product Layout
2) Process Layout
3) Fixed position or location layout
4) Combined layout

Maintenance

Any building used in the manufacture, processing, packing, or holding of a drug product shall be in a good state of repair.

Maintenance includes a check on:

- Spoilage of plaster
- Peeling off of paints
- Ceiling leakages
- Water, steam, gases pipeline leakages
- Loose or broken tiles
- Improper closing of doors, windows, electrical wiring
- Missing tube lights.

Sanitation

→ All areas must be cleaned regularly and cleaning records must be maintained.
→ Wastes from manufacturing areas must be disposed in a safe manner.
→ Inflammable and toxic wastes must be stored in a segregated area.
→ Restrooms, toilets and refreshment area must be located far from manufacturing.

Environmental Control

→ control the level of microorganisms and air-borne particles.
→ Environmental monitoring can be of two types:- microbiological control & particle control
→ Devices for collecting air-borne particles should be calibrated.
→ Gases that come in contact of products should be free of micro-organisms.

Maintenance of Sterile Area

sterile products are mainly produced by 2 methods:

1) Aseptic processing (no microbial growth)
2) Terminal sterilisation → sterilisation is the very final stage of processing.

In order to maintain sterility, careful attention needs to be given to:

→ the environment
→ the personnel
→ the container
→ the holding period of the product before filling into the final container.
→ The sterlising filter.

The solutions and liquids are sterilised through a sterile filter.

Contamination Control

Contamination is the presence of any foreign substance in the products. It may be;

1) Physical : Hair, dirt, dust, pollens
2) Chemical : Cleansing agents, lubricants
3) Microbiological : Bacteria, moulds, spores, yeasts

Prevention of cross-contamination requires;

1) Proper sealing, separation and storage of raw materials.
2) Proper cleaning of all equipments
3) Ensuring that all air conditioning systems are serviced and maintained properly.

Main sources of contamination

1) Environment
2) Equipments used
3) Operators
4) Raw materials and packaging materials.

If contamination has been suspected to occur, the supervisor should be informed immediately. In this way, the contaminants can be detected easily.

Equipments & Raw Materials

All the manufacturing process or control activities depend upon the good performance of the equipment.
Equipments may be single system or piece, or integrated system.

Selection of equipment

Equipment selection depends on the following factors :

1) Operating criteria
2) Availability of spares (extra) and servicing
3) Maintenance
4) Environmental issues
5) Cost
6) availability of designs and maintenance manuals

Purchase specifications

while purchasing an equipment, keep in mind the following things:

1) Desired output capacity → should process desired quantity products.
2) Product characteristics → the product processed should be safe, effective and of desired quality.
3) Ease of operation → must be easy to use
4) Ease of cleaning and maintenance
5) Good reputation of supplier

Equipment Maintainance

Types of equipment maintenance:

1) Breakdown maintenance → people wait until equipment fails.
2) Corrective maintenance → preventive maintenance.

Raw Materials

These are all the materials used in the manufacturing of products.
Raw materials can either be active drug or inactive drug.

Purchase specifications for raw materials

Following points should be considered:

1) approved and adequate specifications
2) the specifications of the material should be specified in pharmacopoeia.
3) Quality parameters like bulk density, particle size should be specified.
4) Purchase from approved suppliers and manufacturers.
5) Consistency in quality, delivery and price
6) Check materials on following things:
   - name of the manufacturer or supplier
   - name of the product
   - batch number
   - date of manufacturing and expiry

Steps for purchasing of Materials

1) Purchase requisition
2) selection of suppliers / vendors
3) Inviting quotation
4) Placing the order
5) Receiving the material
6) checking the invoice or bill
7) Recording of bills
8) Releasing the payment to the supplies.

Maintenance of stores for raw materials

The handling and storage of materials should be in such a way that degradation, adulteration and cross-contamination can be prevented.

Given below are the standard specifications:

1) Storage area specifications
   i) sufficient capacity
   ii) First-in First-out rule (FIFO)
   iii) First Expiring First Out (FEFO)
2) Storage conditions
   (i) Room temperature / RH = 30°C / 60%
   (ii) low temperature storage at 2-8°C.
3) Labelling of materials in storage area
   (i) name of product
   (ii) batch number
   (iii) status of content
   (iv) Expiry date
4) Checklist before storage
   Integrity of package and seal
5) Checklist during storage
   (i) Separation of rejected materials
   (ii) Quality of materials