ORGANIZATION AND PERSONNEL

ORGANIZATION

- A social unit of people that is **structured** and **managed** to meet a need or to pursue **collective goals**.
- All organisations have a management structure that determines relationships between the different activities and the members and subdivided and **assigns roles responsibilities and authority to carry out different tasks.**

ORGANIZATION STRUCTURE

- In establishing an **organisational structure** for the **manufacture** and **quality assurance** of health and similar products, the most generally accepted view is that there should be **two separate persons** each with overall **responsibilities** for **production** or for **quality control,** neither of whom is responsible of other.
- The EU GMP Guide states: The heads of production and quality control must be **independent** of each other

PERSONNEL:

Personnel are assigned in the operation involved in the **processing, manufacturing, packaging control of drug products**. Hence, they must possess **sufficient knowledge by virtue of education, training** and experience to competently **perform the assigned tasks.**

W.H.O. guidelines on Good Manufacturing Practices (GMP) very appropriately mention this in operating remark about personnel – it says, “the establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture and control of pharmaceutical products and active ingredients rely upon people.”

TYPES OF PERSONNEL

- Research

- Production
- Quality control
- Marketing

Research

Requires team work ability to understand appreciate problems of one another.

Production

Should be capable of successfully co-ordinating the manpower, materials, machinery to produce maximum quality output.

Quality Control

Should have capacity to work meticulously with precision.

Marketing Personnel

Should possess good communication skill, good personality, convincing ability.

21 CFR part 211- cGMP Practices for finished pharmaceuticals:

Subpart B- Organisation and Personnel:

- 211.22-Responsibility of quality control unit.
- 211.25-Personnel qualification.
- 211.28-Personnel responsibility.
- 211.34-Consultants

Responsibilities of quality control unit:

- Authority to **approve or reject all components**, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the
- Authority to **review production records** to assure that no errors have occurred

- Adequate laboratory **facilities for the testing and approval** (or rejection) of components
- Responsibility for approving or rejecting **all procedures or specifications** impacting on the identity, strength, quality, and purity of the drug product

Personnel qualifications:

- Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have **education, training**, and experience, to enable that person to perform the assigned functions.
- There shall be an **adequate number of qualified personnel** to perform and supervise the manufacture, processing, packing, or holding of each drug product.

Personnel responsibilities:

- Personnel engaged in **the manufacture, processing, packing**, or holding of a drug product shall **wear clean clothing** appropriate for the duties they perform.
- **Protective apparel,** such as head, face, hand, and arm coverings, shall be worn as necessary to **protect drug products from contamination.**
- Personnel shall practice good sanitation and health habits.
- **Only personnel authorized by supervisory** personnel shall enter those areas of the buildings and facilities designated as **limited-access areas.**

Consultants:

- Consultants **advising on the manufacture, processing, packing**, or holding of drug products shall have sufficient **education, training**, and experience, or any combination thereof, to advise on the subject for which they are retained

TRAINING

The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.

TRAINING OF EMPLOYEES:

- Training may also be defined as the acquisition of technology which permits employees to perform their present jobs to standards.
- It involves human performance on the job, the employee is presently doing or is being hired to do.
- "A person is called trained person when he has appropriate knowledge, skill & attitude"

NEED OF TRAINING

- To induce an awareness in the employees towards the concept of cGMP
- To generate a feeling of high performance through contribution by both employees and management.
- To make the person proficient in their duties.
- To manage safe, healthy and troublefree environment in the production department.
- To demonstrate about cleanliness, general hygiene and personnel health.
- To develop the communication and technical skills in the employee.
- To demonstrate about handling and storage of drug products.
- To ensures the use of safety measures in case of emergency

TYPES OF TRAINING

1. Induction Programme.
2. On Job Training (OJT).
3. Class Room Training (CRT).

4. Outside Training

INDUCTION PROGRAMME

- The induction training is a type of training given to the newly joined employee in the industry to make him familiar with the new working environment.
- It usually occurs on the first day and includes background on the industry, its policies and procedures for the wellbeing of ultimate consumer.

ON JOB TRAINING

- On job training is to be carried out after successful completion of induction training and is provided to each employee of the company.
- Department head/sectional in charge shall be responsible for conducting OJT.
- Department head/ head quality assurance department shall be responsible for evaluating training performance.
- On the job training shall be given as per the SOP's to the employees in their respective areas of operation according to the protocols of individual departments.

CLASS ROOM TRAINING

- An annual training calendar shall be prepared on topics identified by various departments.
- Decide the faculty to conduct the CRT. Faculty may be from the company or outside viz Expert, Consultant, etc.
- Collect the Literature of training module for each topic for CRT from the Faculty.
- Circulate the Authorized Training Circular to intimate the concerned persons. Keep a record for CRT conducted.

OUTSIDE TRAINING

- When a new equipment or instrument is introduced in the particular organization then a person is selected for out side training where the facility is available.
- The HOD is nominate the name of an employee for outside training.
- Based upon the information available from HOD, send intimation to HRD, Head – Plant Operation and Head – Quality Assurance and it shall be authorized by President – Technical Operations.

VALIDATION OF TRAINING

- Validation provides assurance that your training program is meeting expected standards.
- Validation is the certification process that assures trainees have achieved the skills and knowledge training was intended to provide.

EVALUATION

- On completion of each training it has been evaluated by preparing a set of question Paper.
- A Qualifying marks has been decided.
- If the trainee does not Qualify the Qualifying marks then he is been again given the retraining.

RETRAINING

- Remedial training is given when there is evidence that the original training was not adequate, resulting in a person who cannot correctly, safely, effectively or efficiently perform the task.
- Head – Quality Assurance and Head –HRD prepares the list of employees, which requires retraining.
- Prepare a report on the feedback from employee's on retraining.

PERIODIC REVIEW OF TRAINING

- The top management team shall review the training program with personnel department periodically.

- Department head shall review the Individual Training Plan with the employees periodically

TRAINING RECORD

Training records provide the evidence that the training was carried out. Quality assurance should audit training records periodically.

- Identification of training needs.
- Name of the course and its content.
- Name of the trainer.
- Name of the trainee.
- Venue of the training.
- Date and time of the training.
- Record of evaluation.

HYGIENE & PERSONAL RECORD

PERSONAL HYGIENE

- Good personal hygiene is required in pharmaceutical industries to safeguard the product and avoid any type of contamination that affects quality of medicinal product.
- Individual persons are responsible for quality of a medicinal product and hence collectively can be termed as “personnel”.
- Detailed hygiene programs should be established and adapted to the different needs within the factory.
- They should include procedures relating to the health, hygiene practices and clothing of personnel.
- These procedures should be understood and followed in a very strict way by every person whose duties take him into the production and control areas.

PERSONAL RECORDS:

- ❖ Educational, Personal details, resume and training records are kept current.

It maintains

- The minimum health requirement of personnel working in the factory must be given in writing.
- A pre- employment medical examination inclusive of eye- testing must be insisted.
- Periodic health check-ups should be carried to all personnel's.
- Special attention to be paid to persons with any communicable disease.
- Employees went for medical leave should submit a medical certificate from medical officer /nurse before join to work.
- Staffs should report about any infectious diseases of their (or) of the family enabling their temporary transfer to other work areas.

HEALTH RECORDS

Records of medical examination of factory persons are required for following reasons

1. To provide a medical history of every patient

2. To ensure product quality

3. To ensure that the health of operator not affected by repeated handling of highly potent toxic sensitizing materials.

4. Personal control measures include pre-employment medical examination for all employee's chest x- ray Wassermann test, tuberculosis test.

5. Periodic health check-ups should be carried to all personnel's and updated annually

Responsibilities

1. It is the responsibility of the Management to appoint designated manufacturing employee(s) to perform personal hygiene inspection on all employees. Designated employee(s) involved in personal hygiene inspection shall have the relevant training and/or experience.

2. It is the responsibility of the appointed manufacturing employee(s) to carry out personal hygiene inspection, record and report.

3. It is the responsibility of the Supervisor of the relevant departments and all employees to implement adequate corrective action/preventive action and ensured that they are followed-through.

Grooming:

1. Arrive to work with clean hair, teeth brushed and bathed daily.

2. Maintain trimmed, filed, cleaned fingernails without rough edges. No polished fingernails and artificial nails are permitted in the manufacturing area. Daily check will be conducted and recorded in Form-XX1.

3. Employees working in the manufacturing area must wash their hands properly before entering the processing area; then gloves shall be put on as required. Hands must always be washed:

- Before commencing work.
- Before wearing disposable gloves.
- Between performing different task.
- Immediately after using the toilet and returning to work station.
- After handling contaminated item or when unsanitary task has been performed i.e. taking out garbage, handling cleaning chemicals, wiping tables, picking up a dropped utensil, etc.
- After smoking, eating or drinking.
- After touching face, nose, mouth, skin, hair or other exposed body parts.
- After sneezing, coughing or nose blowing.

4. Wash hands only in designated sinks intended for the purpose. Turn off faucets in a sanitary fashion in order to prevent recontamination of clean hands.

5. Dry hands with single-use towels and dispose used towels in closed trash bin.

Proper Attire:

1. Wear clean properly secured coveralls, hair restraints and gloves at all times in the manufacturing area. Coveralls shall be sufficient to cover all personal clothing. They shall be changed daily.

2. Must not wear coveralls outside the manufacturing area. Remove coveralls, hair restraints and gloves before using toilet facilities, using lunchroom and exiting the manufacturing area.

3. Wear hair restraints at all times in the manufacturing area. All hair must be covered to prevent any possible contamination of health supplement products.

4. Employees with any facial hair (beards or mustaches) must wear beard nets.

5. Change to clean, non-skid, closed-toe work shoes that are appropriate for standing and working on manufacturing floors. Work shoes must be removed before using toilet facilities, using lunchroom and exiting the manufacturing area. Footwear must be easily cleaned and maintained in a clean condition.

6. Remove make-up, wrist watch and jewelry when entering the manufacturing area.

7. Proper attire will be checked daily and record in Form-XX1.

8. Store personal clothing and belongings in designated locker facility. Food, drinks, tobacco materials and personal medicine are not allowed to be stored in this locker facility.

Illness and lesion:

1. Employees shall not be a carrier of or diagnosed of being ill with the following communicable diseases: Tuberculosis, Cholera, Typhoid fever, Chickenpox, Dysentery, Measles, Mumps, Leprosy, Jaundice, Red eye, Lymphatic filariasis, Hepatitis and infectious skin diseases. Employees with these diseases must not be allowed in the manufacturing facilities and local health regulatory agency must be notified.

2. Report any flu-like symptoms, fever, diarrhoea, sore throat, constant sneezing, coughing, runny nose and/or vomiting to the supervisor. Employees with these symptoms will be sent home or re-assigned non food related duties or sick leave, whichever is most appropriate (FormXX2).

3. Report any lesions on the hand, wrist, or any exposed body part to supervisor (Form-XX2).

4. Minor cut and abrasion may be properly treated and bandaged. When hands are bandaged, disposable gloves must be worn to cover the entire bandaged area before commencing work.

5. Employees with serious lesions must not be allowed to handle raw materials, packaging materials, in-process materials, and finished products until the condition is improved.

Smoking, eating, and gum chewing:

1. Smoke only in designated areas. No smoking or chewing of tobacco shall occur inside manufacturing facilities.

2. Eat and drink in designated areas only.

3. Refrain from chewing gum or eating candy during work in the manufacturing area.

Monitoring

A designated employee will inspect subordinate employees when they report to work daily or at appropriate interval to be sure that each employee is following this SOP. The designated employee will monitor that all subordinate employees are adhering to the personal hygiene policy during all hours of operation.

Corrective Action

Any employee found not following this procedure will be retrained at the time of the incident.

Reference to other documents

Record of daily inspection on personal hygiene (Form-XX1) Daily employee illness report form (Form- XX2)

END OF DOCUMENT

REVISION HISTORY

APPROVAL Date Implemented: By:

Date Reviewed: By:

Date Revised: By: