ORGANIZATION AND PERSONAL

BP606T

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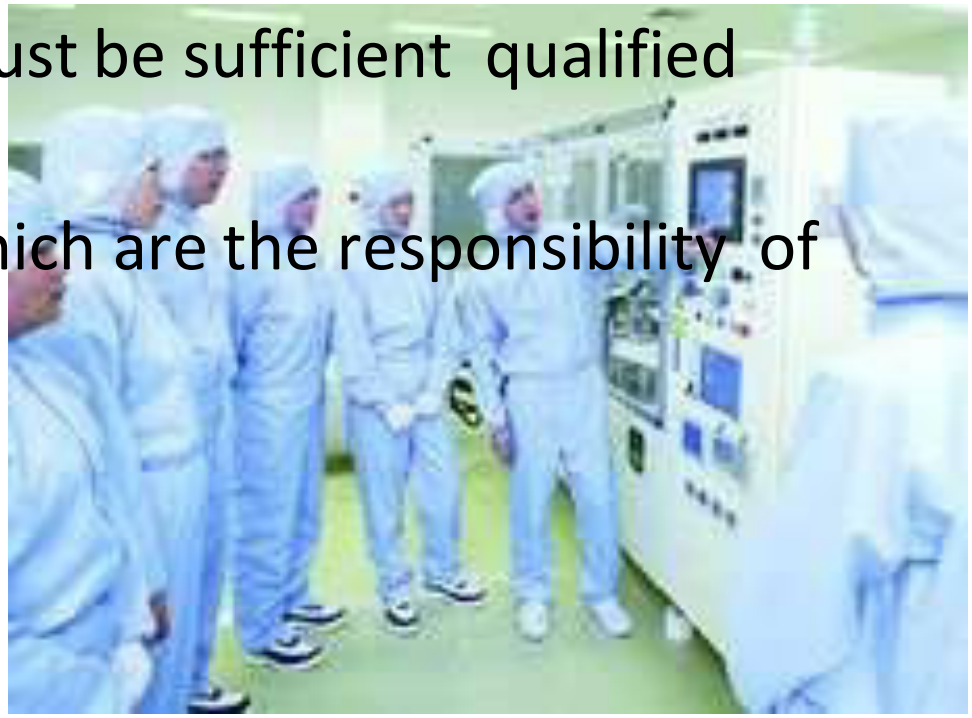
Principle

The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture of medicinal products relies upon people.

•For this reason there must be sufficient qualified personnel to carry out all the tasks which are the responsibility of the manufacturer.



Principle

- Individual responsibilities should be clearly understood by the individuals and recorded.

•All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs.

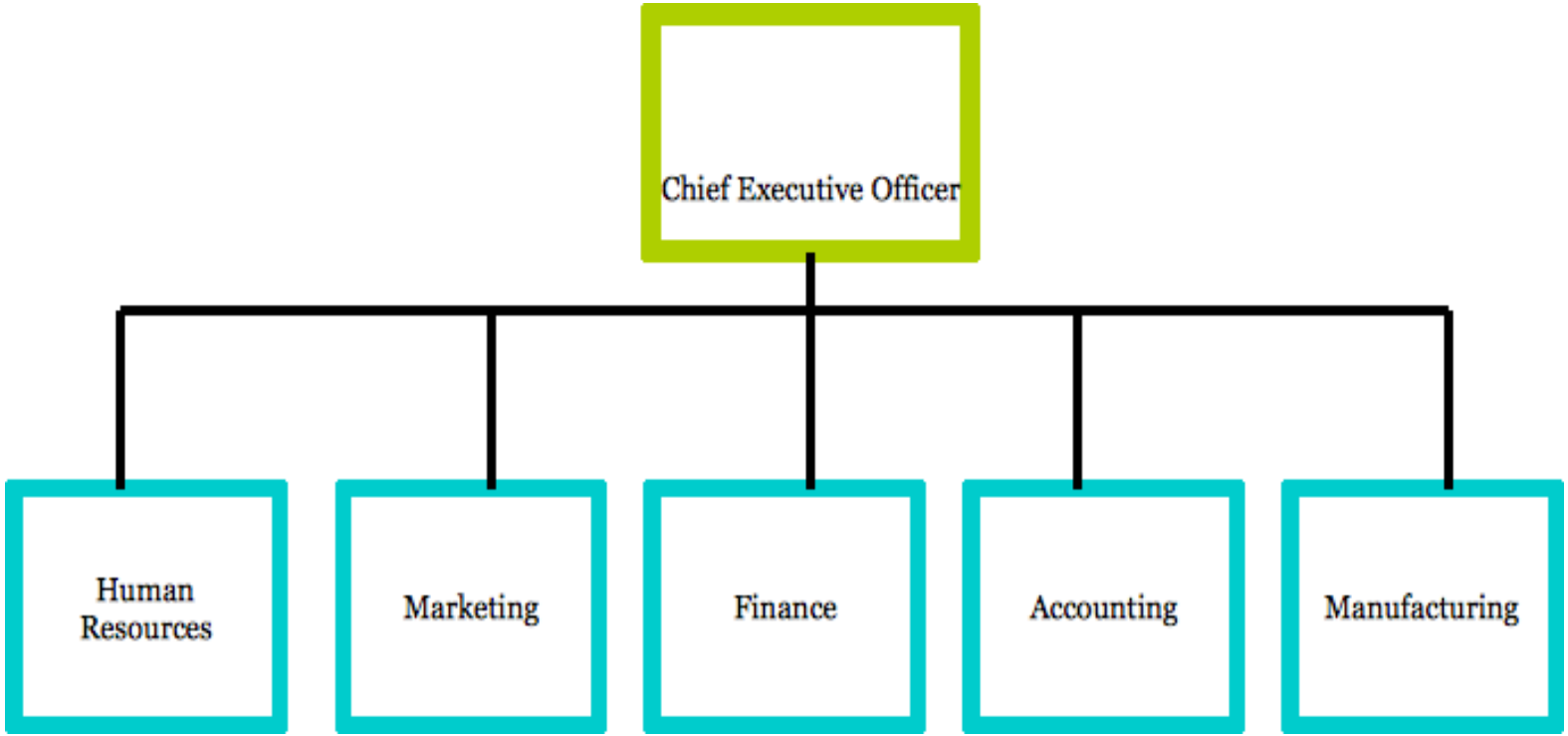
General

- The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience.

- The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.

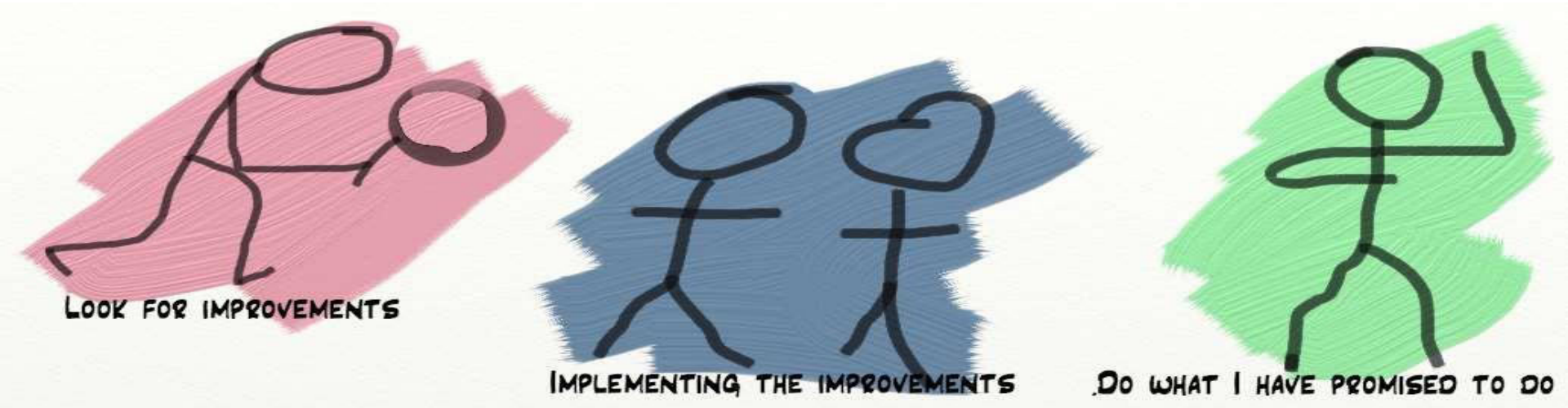
General

- The manufacturer must have an organization chart.
- People in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities.



General

- There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of Good Manufacturing Practice



Key Personnel

Key Personnel include:

- the head of Production
- the head of Quality Assurance
- the head of Quality Control

Responsibilities of the Head of the Production Department

- to ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality
- to approve the instructions relating to production operations and to ensure their strict implementation

Responsibilities of the Head of the Production Department

- to ensure that the production records are evaluated and signed by an authorized person before they are sent to the Quality Control Department
- to check the maintenance of his department, premises and equipment

Responsibilities of the Head of the Production Department

- to ensure that the appropriate validations are done
- to ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.

Responsibilities of the Head of Quality Control Department

- to approve or reject, as he sees fit, starting materials, packaging materials, and intermediate, bulk and finished products
- to evaluate batch records
- to ensure that all necessary testing is carried out

Responsibilities of the Head of Quality Control Department

- to approve specifications, sampling instructions, test methods and other Quality Control procedures
- to approve and monitor any contract analysts
- to check the maintenance of his department, premises and equipment

Responsibilities of the Head of Quality Control Department

- to ensure that the appropriate validations are done
- to ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.

Joint Responsibility

- the authorization of written procedures and other documents, including amendments
- the monitoring and control of the manufacturing environment
- plant hygiene
- process validation
- training
- the approval and

monitoring of suppliers of materials

Joint Responsibility

- the approval and monitoring of contract manufacturers
- the designation and monitoring of storage conditions for materials and products
- the retention of records

Joint Responsibility

- the monitoring of compliance with the requirements of Good Manufacturing Practice
- the inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality.

TRAINING

TRAINED PERSONNEL=QUALITY PERFORMANCE =CONTINUAL IMPROVEMENT

- LESS PRONE TO ERRORS
- LESS DEVIATIONS FROM STANDARDS
- REDUCE AMOUNT OF REWORK
- REDUCE AMOUNT OF REJECTS

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

- Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

Training

- Visitors or untrained personnel should, preferably, not be taken into the production and quality control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.

Personnel Hygiene

- 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.

Personnel Hygiene

- All personnel should receive medical examination upon recruitment.
- It must be the manufacturer's responsibility that there are instructions ensuring that health conditions that can be of relevance to the quality of products come to the manufacturer's knowledge.

Personnel Hygiene

- Steps should be taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of medicinal products.

Personnel Hygiene

- Every person entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.

Personnel Hygiene

- Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or

personal medication in the production and storage areas should be prohibited

- In general, any unhygienic practice within the manufacturing areas or in any other area where the product might be adversely affected, should be forbidden.

Personnel Hygiene

- Direct contact should be avoided between the operator's hands and the exposed product as well as with any part of the equipment that comes into contact with the products.

Personnel Hygiene

- Personnel should be instructed to use the hand-washing facilities.

THANK YOU