

# *Basic Principles of GMP*

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## **Sanitation and Hygiene**



# *Sanitation and Hygiene*

## **Objectives**

- Review measures to ensure good sanitation in:
  - *premises*
  - *equipment*
  - *processes*
- To review measures to ensure good personnel hygiene
- Group session - to discuss the situation in your country and to look at some bad sanitation and hygiene practices in some photographs.



# *Sanitation and Hygiene*

## **Scope**

All aspects of manufacturing

- Personnel
- Premises
- Equipment
- Apparatus
- Production materials and container
- Products for cleaning and disinfection
- All potential sources of cross-contamination

**Part One 4**



# Sanitation and Hygiene

## Design of Premises

- Design
  - *Walls, floors, ceilings, ledges, drains, air supply, dust extraction*
- Prevention of build-up of dirt and dust to avoid unnecessary risks of contamination
  - *Cleaning programme, appropriate cleaning, cleaning records*
- Effective cleaning and disinfection
  - *choice of materials and chemicals, validation*
- Drains
- Protection from insects, vermin and weather
  - *from receipt of raw materials to despatch of released product*

Part One 11



# *Sanitation and Hygiene*

## **Avoidance of Cross-Contamination I**

- Segregated areas
- Ventilation systems and airlocks
- Clothing
- Closed processing systems
- Cleaning and decontamination

**Part Two 15.1 – 15.34**



# *Sanitation and Hygiene*

## **Avoidance of Cross-Contamination II**

- Segregated areas and separate facilities for
  - *live vaccines and other biological materials*
  - *penicillin products*
  - *campaign processing*

**Part Two 15.1 – 15.34**



# *Sanitation and Hygiene*

## **Avoidance of Cross-Contamination III**

- Ventilation systems and airlocks
  - *design of ventilation system*
  - *incoming air should be filtered*
  - *pressure differentials and air extraction*
  - *airlocks*
  - *airflow patterns and equipment design*
  - *recirculation versus 100% fresh air supply*

**Part Two 15.1 – 15.34**



# *Sanitation and Hygiene*

## **Avoidance of Cross-Contamination IV**

- Clothing
  - *protection of operator and product*
  - *highly potent products or those of particular risk - need for special protective clothing*
  - *personnel should not move between areas producing different products*
  - *garments need to be cleaned*

**Part Two 15.1 – 15.34**





# *Sanitation and Hygiene*

## **Avoidance of Cross-Contamination -V**

- Closed processing systems
  - *For example: totally enclosed water purification systems*
  - *tanks fitted with appropriate filtration - without removable lids*
  - *present special cleaning difficulties, sometimes use clean-in-place (CIP)*

**Part Two 15.1 – 15.34**



# *Sanitation and Hygiene*

## **Avoidance of Cross-Contamination VI**

- Cleaning and decontamination
  - *procedure for removing soil and dirt*
  - *remove all cleaning chemical residues or disinfectant residues*
  - *must remove or reduce micro-organisms*

**Part Two 15.1 – 15.34**



# *Sanitation and Hygiene*

## **Production Operations - Sanitation - I**

- Work-flow
  - *designed to avoid potential contamination.*
- Access
  - *to production areas restricted to authorized personnel*
  - *direct operators, QC staff, warehouse staff, maintenance personnel, cleaners*
  - *the more critical the area - fewer number of persons there*



# *Sanitation and Hygiene*

## **Production Operations - Sanitation - II**

### Simultaneous operations

- not permissible to process different products in different areas with a common ventilation system
- permissible to carry out secondary packaging activities for different products within a packing hall with adequate physical separation



# *Sanitation and Hygiene*

## **Production Operations – Sanitation – III**

### Area clearance checks

- Process of checking
  - *all materials and documentation from the previous batch removed*
  - *all plant and equipment thoroughly cleaned and appropriate status labelling*
  - *checklist useful*



# *Sanitation and Hygiene*

## **Production Operations – Sanitation – IV**

### Area clearance checks

- The area clearance check should be carried out by two people
  - *between batches of same product, acceptable for both checks to be carried out by production personnel*
  - *for product changeover, second check carried out by QC staff*
  - *all checks carried out in accordance with written SOP and results recorded on the batch documentation.*



# Sanitation and Hygiene

## Production Operations – Sanitation – V

- Cleaning and cleaning validation
  - *degree of cleaning depends on whether consecutive batches are of same or different product*
- Check cleaning agent is fully removed
- If possible hot water alone used for cleaning
  - *all cleaning and disinfecting solutions carefully prepared and expiry dated*
- Final rinse with purified water, or water for injection (for sterile products)
- Full records kept



# *Sanitation and Hygiene*

## **Production Operations – Sanitation – VI**

- Water systems
- Water - major constituent of most products
- SOP for cleaning and sanitisation of the water purification system should include distribution pipework
- Validation and removal of disinfectant before reuse





# *Sanitation and Hygiene*

## **Production Operations – Sanitation – VII**

- Maintenance and repair
  - *activities inevitable in manufacturing area.*
  - *Should present no risk to product*
- Whenever possible, all planned maintenance outside normal operating hours
- Emergency work in working area followed by thorough clean down and disinfection before manufacturing recommences
- Area clearance by QC



# Sanitation and Hygiene

## Personnel Hygiene - I

- Health examinations
  - *On recruitment for direct operators , repeated on regular basis*
- Training - check
  - *induction training for new operators includes basic personal hygiene training*
  - *written procedures - to wash hands before entering a manufacturing area*
  - *signs in changing rooms to reinforce hand washing*

**Part One 10.16 – 10.23**



# Sanitation and Hygiene

## Personnel Hygiene - II

- Illness
  - *staff with illness or open lesions should not handle starting materials, intermediates or finished products*
- Adverse conditions
  - *operators trained to recognize risks*
  - *willingness to report illness to the area supervisor*

**Part One 10.16 – 10.23**



# Sanitation and Hygiene

## Personnel Hygiene - III

- Contact between product and operator
  - *avoid direct contact*
  - *if direct handling unavoidable, gloves should be worn*
  - *check glove disinfection (for sterile production) and disposal*

**Part One 10.20 – 10.23, 11.7 – 11.8**



# Sanitation and Hygiene

## Personnel Hygiene - IV

- Clothing and changing facilities
  - *check changing rooms (handwashing, towels or hot air hand dryers)*
  - *check if used clothing stored in separate closed containers while awaiting cleaning*
  - *laundering of clean area clothing must be to SOP and in appropriate facility*
  - *check for procedure for sterilizing and storing clothing for use in sterile area*

**Part One 10.20 – 10.23, 11.7 – 11.8**



# *Sanitation and Hygiene*

## **Personnel Hygiene - V**

- Smoking, eating and drinking should not be allowed in any manufacturing area, including laboratories and storage rooms.
- Chewing of gum should be banned.
- There should be no plants kept inside any factory areas.
- Rest and refreshment areas should be separate from manufacturing areas.
- Toilets should not open directly into production or storage areas.

**Part One 10.20 – 10.23, 11.7 – 11.8**



# *Sanitation and Hygiene*

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## **Group Session - Option 1**

Look at the photographs in the handout and record as many sanitation and hygiene issues as you can



# *Sanitation and Hygiene*

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## **Group Session - Option 2**

You are inspecting a new factory. What are the key issues for sanitation and the key issues for personnel hygiene that the company should have in place?





# *Sanitation and Hygiene*

## *Possible Issues - I*

### *Sanitation*

- Mixed production
- Penicillins
- Product versus batch changeovers
- Water systems
- How long should a “cleaned” status last for?
- What should happen if a clearance check is required when no QC personnel are on duty?
- Procedures and records



# *Sanitation and Hygiene*

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## *Possible Issues - II*

### *Hygiene*

- Personal hygiene
- Health checks
- Dealing with health problems
- Personal responsibility
- Training records
- Frequency of handwashing

