Basic Principles of GMP

# Sanitation and Hygiene



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# 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.



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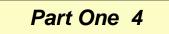
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# Sanitation and Hygiene

# Scope

All aspects of manufacturing

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





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# **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

• Effective cleaning and disinfection

*∧ choice of materials and chemicals, validation* 

Part One 11

- Drains
- Protection from insects, vermin and weather

*¬ from receipt of raw materials to despatch of released product* 



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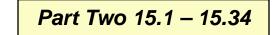
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# **Avoidance of Cross-Contamination I**

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





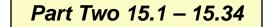
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#### **Avoidance of Cross-Contamination II**

• Segregated areas and separate facilities for

- *Iive vaccines and other biological materials*
- ↗ penicillin products
- ↗ campaign processing





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

- Ventilation systems and airlocks
  - ↗ design of ventilation system
  - ↗ incoming air should be filtered

  - **↗** airlocks
  - ↗ airflow patterns and equipment design
  - *¬ recirculation versus* 100% *fresh air supply*

Part Two 15.1 – 15.34



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### **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



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#### 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)





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#### **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





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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*



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### **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



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# **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*
  - オ checklist useful



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

Area clearance checks

- The area clearance check should be carried out by two people

  - ↗ 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.



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# **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



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# **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



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### **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



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# 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



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# 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



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# Personnel Hygiene – III

Contact between product and operator

**↗** avoid direct contact

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- ↗ if direct handling unavoidable, gloves should be worn
- *r check glove disinfection (for sterile production) and disposal*

#### Part One 10.20 - 10.23, 11.7 - 11.8



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# **Personnel Hygiene – IV**

Clothing and changing facilities

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- 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



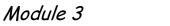
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# Personnel Hygiene – V

- 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

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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



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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?



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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

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Possible Issues – II Hygiene

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



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