Basic Principles of GMP

Sanitation and Hygiene



WHO - EDN

Module 3

Slide 1 of 26

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.



WHO - EDM

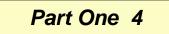
Module 3 Slide 2 of 26

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





WHO - EDM

Module 3

Slide 3 of 26

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

• 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



WHO - EDM

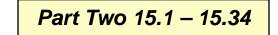
Module 3

Slide 4 of 26

Sanitation and Hygiene

Avoidance of Cross-Contamination I

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





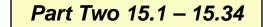
WHO - EDM

Sanitation and Hygiene

Avoidance of Cross-Contamination II

• Segregated areas and separate facilities for

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





WHO - EDM

Module 3 Slide 6 of 26

Sanitation and Hygiene

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



WHO - EDM

Module 3

Slide 7 of 26

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



WHO - EDN

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)





WHO - EDN

Slide 9 of 26

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





WHO - EDA

Slide 10 of 26

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*



WHO - EDM

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*
 - オ checklist useful



Sanitation and Hygiene

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.



WHO - EDM

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



WHO - EDM

Module 3 Slide 15 of 26

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



WHO - EDM

Module 3 Slide 17 of 26

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



WHO - EDM

Module 3

Slide 18 of 26

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



WHO - EDM

Module 3 Slide 19 of 26

Sanitation and Hygiene

Personnel Hygiene – III

Contact between product and operator

↗ avoid direct contact

Slide 20 of 26

- ↗ 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



WHO - EDN

Sanitation and Hygiene

Personnel Hygiene – IV

Clothing and changing facilities

Slide 21 of 26

- 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



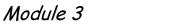
WHO - EDN

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

WHO - EDM



Slide 22 of 26

Sanitation and Hygiene

Group Session - Option 1

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



WHO - EDM

Sanitation and Hygiene

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?



WHO - EDM

Slide 24 of 26

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

WHO - FD

Module 3 Slide 25 of 26

5 of 26

Sanitation and Hygiene

Possible Issues – II Hygiene

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



WHO - EDM

Module 3

Slide 26 of 26