

# *Basic Principles of GMP*

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## Sanitation and Hygiene

**Section 3**



# *Sanitation and Hygiene*

## Objectives

- Review measures to ensure good sanitation in:
  - Premises and personnel
  - Equipment and apparatus
  - Processes, materials and containers
- To review measures to ensure good personal hygiene
- Group session - to discuss the situation in your country and to look at some bad sanitation and hygiene practices



# *Sanitation and Hygiene*

## Scope

High level of sanitation and hygiene practised – in every aspect of manufacturing. It covers:

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

**3.1**



# Sanitation and Hygiene

## Personal Hygiene (1)

- Health examinations:
  - *Before and during employment*
  - *Periodic eye examinations for those who do visual inspections*
- Training:
  - *Practices in personal hygiene*
  - *Written procedures and instructions*

11.1 - 2



# Basic Principles of GMP

- *Wash hands before entering production areas*
- *Signs in areas (e.g. changing rooms, wash areas, after using toilet facilities)*

11.1 - 2



# Basic Principles of GMP

- *Before entering production areas*
- *Can use disinfectants*

11.1 - 2



# Sanitation and Hygiene

## Personal Hygiene (2)

- Illness or open lesions:
  - *May affect the quality of products*
  - *Should not handle starting materials, intermediates or finished products, etc.*
  - *Instruction and encouragement to report to supervisors*
- Direct contact between product and operator:
  - *Should be avoided*
  - *Starting materials, primary packaging materials, intermediate and bulk product*

11.2 - 5



# Sanitation and Hygiene

## Personnel Hygiene (3)

- Protection of product from contamination:
  - *Clean clothes appropriate to activities and products*
  - *Including hair covering (e.g. caps), gloves*
- Check change rooms/changing facilities
  - *Hand washing, signs, drying of hands*
  - *Used clothing stored in separate closed containers while awaiting cleaning*
  - *Washing (laundry) of clothing - SOP followed and in an appropriate facility*
  - *Procedure for disinfecting, decontamination and sterilizing when required*

11.6





# ***Sanitation and Hygiene***

## **Personnel Hygiene (4)**

- Smoking, eating and drinking not allowed in production areas, laboratories and storage areas
- No chewing (e.g. gum), or keeping food or drinks allowed
- No plants kept inside these areas
- Rest and refreshment areas should be separate from manufacturing and control areas

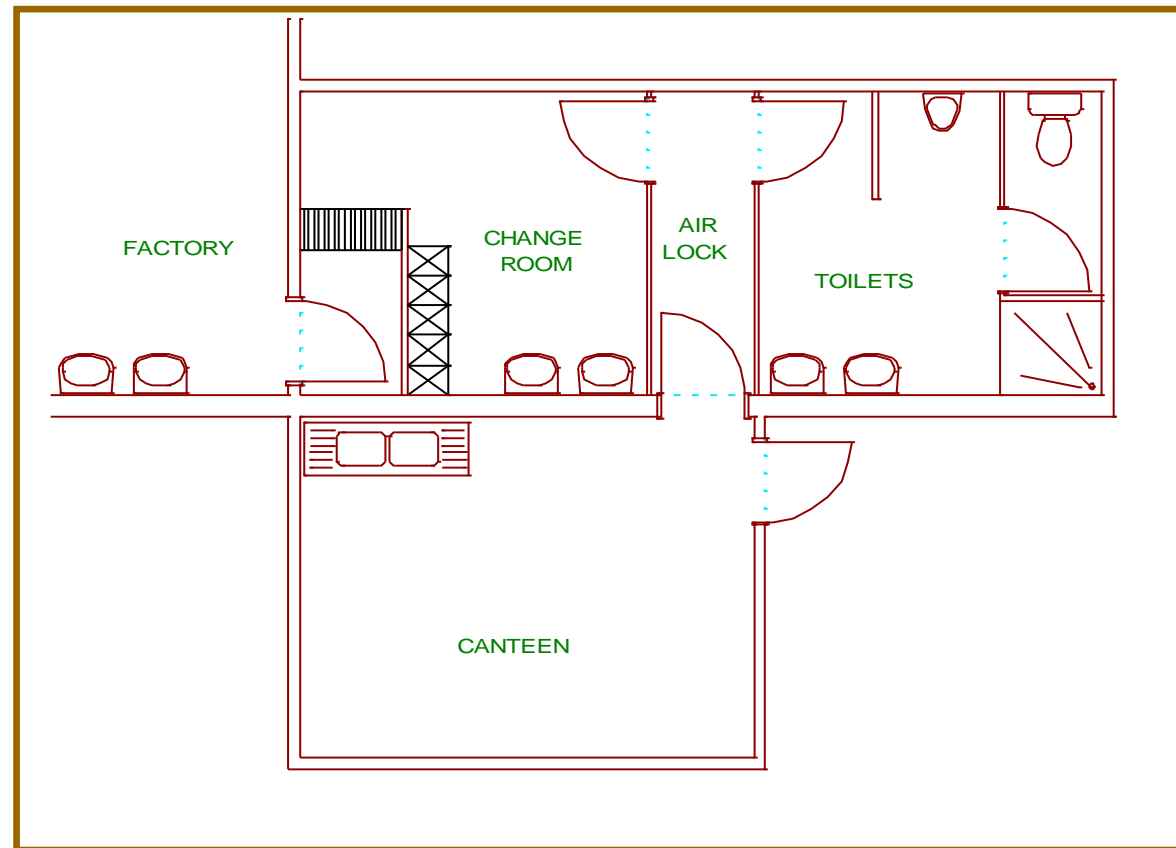
**11.7, 12.11**



# Basic Principles of GMP

- Toilets should not open directly into production or storage areas

12.12



# Sanitation and Hygiene

## Personnel Hygiene (5)

- Personal hygiene procedures including wearing protective clothing apply to all persons entering into production areas:
  - *Full-time employees*
  - *Temporary and contract workers*
  - *Contractor's employees*
  - *Visitors*
  - *Managers*
  - *Inspectors*

11.8



# 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 – prevent backflow

12.2, 12.3, 12.7, 12.9, 12.29



# *Basic Principles of GMP*

- Protection from insects, birds, vermin and weather
  - from receipt of raw materials to dispatch of released product

12.9



# Sanitation and Hygiene

## Production Operations – Sanitation (1)

- 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 (2)**

- Full records kept
- Water systems
- Water - major constituent of most products
- SOP for cleaning and sanitization of the water purification system should include distribution line
- Validation and removal of disinfectant before reuse



# Sanitation and Hygiene

## Production Operations – Sanitation (3)

- 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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# ***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***

## ***Possible Issues – II Hygiene***

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

