

Contamination & Personal Hygiene

By:
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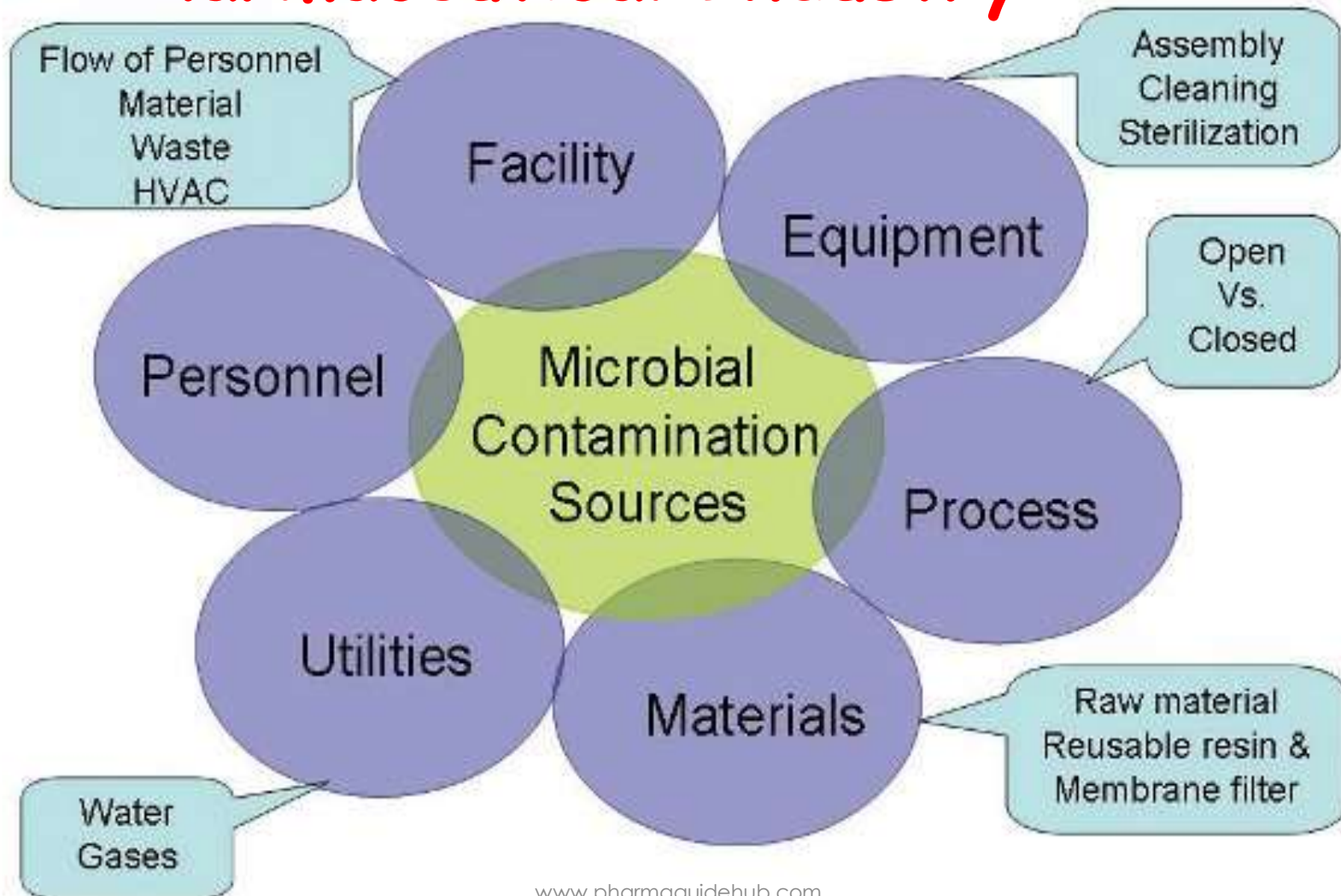
A red arrow graphic pointing to the right, located in the top left corner of the slide.

The presence of unwanted materials such as dust and particles during the manufacturing and transportation time is called contamination.



The term contaminants includes any unwanted matter that is found in the product. These contaminants affect the quality of the product or the process.

The Main Sources of Contamination in the Pharmaceutical Industry



Personnel

- ✓ Supervising or performing drug manufacturing or control
- ✓ Can be a potential source of microbiological contamination and a vector for other contaminants.

Main reasons for contamination from the personnel:

- Lack of training
- Direct contact
- Inadequate cleanliness
- Access of unauthorized personnel
- Inadequate gowning and personnel protective equipment
- Malpractices



PEOPLE



CAUSE

CONTAMINATION



HEH!
HEH!
HEH!



- IMPURE
- UNCLEAN
- UNFIT FOR USE

CONTAMINATION

Buildings and Facility

- Insufficient size and inadequate organization of the space
- Inadequate pest controls
- Rough floors, walls, and ceilings
- Lack of air filtration systems
- Improper lighting and ventilation
- Inadequate washing, cleaning, toilet, and locker facilities to allow for sanitary operation, cleaning of facilities, equipment, and utensils; and personal cleanliness

Equipment

- Inappropriate design, size, material leading to corrosion
- Design preventing proper cleaning and maintenance
- Improper calibration and irregular service
- Deliberate use of defective equipment

Materials

- Mix-ups or selection errors
- Contamination with microorganisms or other chemicals
- Degradation from environmental conditions
- Improper labeling
- Improper sampling and testing
- Use of materials that fail to meet acceptance specifications.

Manufacturing Process

- Lack of dedicated facilities to manufacture a single product
- Inappropriate cleaning in-between batches
- Use of an open manufacturing system exposing the product to the immediate room environment
- Inappropriate zoning
- Lack of cleaning status labeling

HVAC System

A poor HVAC system can be a potential source of microbes growth and a transportation mode for dispersing contaminants throughout the manufacturing facility.

The main reasons of contamination:

Accumulations of organic material in or near HVAC air intakes

Ineffective filtration of the supply air

Insufficient magnitude of pressure differentials causing flow of reversal

Erroneous ratio of fresh air to recirculated air

Inability to access ventilation dampers and filters from outside the manufacturing areas, and

Non-directional airflow within production or primary packing areas

WHY IS HYGIENE AND SANITATION IMPORTANT?

**Man is a natural carrier of microorganisms.
These are expelled when we**



SNEEZE



COUGH



YAWN



TALK

TRAINED PERSONNEL=QUALITY PERFORMANCE
=CONTINUAL IMPROVEMENT

LESS PRONE TO ERRORS

LESS DEVIATIONS FROM STANDARDS

REDUCE AMOUNT OF REWORK

REDUCE AMOUNT OF REJECTS

CGMP REGULATION



**Report any injury or illness immediately to
your supervisor.**

Staff who have an illness or open lesions that are likely to present a risk to the product, should not be allowed to carry out operations that involve handling of starting materials, intermediates or finished products until the condition has cleared up.



HYGIENE AND SANITATION PRACTICES

Wash hands with soap and water

- After using the toilet
- Before starting to work
- After blowing your nose
- After handling dirty things
- After touching body surface
- After eating







STREET SHOES



PLANT SHOES



Street shoes contain germs from the soil and dirt we stepped on, so it must not be worn inside the plant, plant shoes must be used instead.

Cover finger nails and hands which have germs.

PLANT UNIFORM



Cover street clothes that contain contaminants, organisms you collect on your way to the plant. Cover your exposed skin which sheds particles with germs.



Cover your hair which have dust & germs. Prevent hair from falling into the product.

Cover the nose and mouth which are natural reservoir of germs. Trap particles or droplets from the nose and mouth.

HANDLING OF GLOVES

- 1) Place gloves in a clean plastic bag during break time.



- 2) Wash gloves with soap and water after use. Dry and sanitize.



Recommendations

- The company must be able to ensure that operators not only understand hygiene requirements, but also fulfil them.
- Health checks should be carried out on all new operators and periodically on all staff during employment. This could be a problem if the managers are reluctant to carry the expense.
- The operators must feel that they can report these problems in confidence without risking their jobs.
- The final quality of the product depends, to a large extent, on the willingness of the operators to take personal responsibility for such issues as hygiene.
- Training should include references to procedures for cleaning and hygiene requirements, which should be included in written training records.



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