







Our Inspiration

Founder: Dr. T M A Pai, Padmashree awardee



Manipal College of Pharmaceutical Sciences

Centre for cGMP

In Association with IDMA and Pharmexcil

Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2024/02) *THINK cGMP - cGMP is LIFE*

Commitment

Adherence

Creating Quality Culture



Topic: Personnel Hygiene in Pharmaceuticals and Important Do's and Don'ts within the facility



Procedure and general requirements

- It shall be the responsibility of each manufacturer to provide adequate facilities and procedures related to health, hygiene and owning protocol of the employees to maintain personal hygiene within the factory premises.
- Appropriate gowning and hand washing facilities shall be provided in the
- All personnel involved in the manufacturing of pharmaceutical products shall comply with these requirements strictly to avoid contamination of the products.
- As a cGMP requirement, all personnel shall undergo medical examination upon recruitment and thereafter periodically to ensure that health conditions that can impact quality are treated before the employees are permitted to work.
- Eye checkup is critical & mandatory for personnel involved in the inspection activity (especially working in sterile facility).
- No person with infectious disease or having open lesions on the exposed surface of the body shall be engaged in any manufacturing.
- It shall be the responsibility of the employee to inform about any illness to the respective line Manager.

- Every person entering the manufacturing areas shall wear protective garments appropriate to the operations carried out.
- Personnel shall be instructed to use the hand washing facilities before entering production departments.
- The employees will be adequately trained in the authorized SOPs for hygiene and gowning practices
- Any visitors and untrained personnel, if required to enter the manufacturing area, they should be briefed about the SOPs and shall be accompanied by a trained person.
- Direct contact shall be avoided between operator's hands and the exposed product as well as with any part of the equipment that comes into contact with the products. Gloves of appropriate length and type shall be used to prevent contamination of the product as well as to provide protection to the personnel.
- Eating, drinking, chewing or smoking, or the storage of food, drinking materials or personal medication in the production and storage areas shall be strictly prohibited.

Do's

- Make it a strict habit to bath daily, trim the hair periodically and shave regularly. Wash with detergents and sanitize hands after visiting dining areas and wash areas.
- Nails should be kept short and clean.
- Ensure that gowns, masks, gloves are worn all the time correctly.

Don'ts

- Do not squat on the floor in the manufacturing area. Do not wear jewellery in the manufacturing area.
- Do not eat or chew gum, Do not smoke.
- Do not wear soiled or torn gowns/ gloves, change them immediately.
- Do not wash hands, feet, footwear in the manufacturing area. Use only designated ancillary areas.







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Avoid carrying following items to Manufacturing areas:

Personal items such as keys, coins, cigarettes, matches, pencils, handkerchiefs, watches, tissues and combs Note: The points detailed above may vary in detail from company to company. But Do's and Don'ts remains the same practice in all manufacturing areas.