

Basic Principles of Safety – Hygiene

Your Objectives:

At the end of the lesson, you should be able to explain why hygiene is so important.

Since pharmaceutical products are sold for human (and **animal**) consumption, it is the manufacturer's **responsibility** to ensure first and foremost that its products are free of **contamination**.

Mostly, contaminations, by such microbial agents as bacteria, moulds, and **viruses**, are caused by operators themselves or by poor **manipulations**. This is because the average person is literally covered in a whole slew of microorganisms, which may include viruses, bacteria, **yeasts**, fungi, mammalian cells and even **spores**. Noteworthy dangerous contaminants are Mycoplasma spp.

The best preventative is, therefore, **personal** hygiene. Hygiene greatly reduces the transfer of these organisms from the worker to the process and product.

Defence against product contamination is achieved through the following:

1. Good **hygiene**: All personnel must have a good personnel hygiene, trim hair, beards (etc.), wear suitable clean **clothes**, avoid wearing jewellery
2. SAS (Safety Access System or Special Airlock System) between areas of different containment level. Differential pressure so that **contaminants** do not access higher containment level
3. Gowning: SAS workers must put on **overshoes** (or change into special shoes), wear hair and beard **masks**, disposable gloves, white coats, overalls, or then special combinations with respirators.
4. **Washing** hands before and after gowning, and at different SAS levels
5. Avoid touching hair, face, skin—if this occurs, wash hands.

Personal hygiene

Cleanroom workers must first ensure personal hygiene is at a high level. This means that personal hygiene practices must begin prior to coming to work. This includes:

- daily showering
- clean hair
- oral hygiene
- clean clothing: apparels, cosmetics, and accessories

Nail polish and make-up must be removed prior to gowning for cleanroom operations as these may flake off in the cleanroom environment. Apart from a plain wedding band, jewellery (including watches) must also be removed prior to cleanroom work. Because jewellery has sharp edges and points, it may tear gloves, hair cover or face mask. Beard covers are available, but they don't always completely cover beards and may be uncomfortable, which is why beard trimming is important.

Personal health

In addition to personal cleanliness, it is important to be aware of the state of your health. Infections, coughs and sneezes increase the risk of product contamination, as well as the spread of illness to co-workers. If you should have any type of infection or health problem, report it to your supervisor. In many cases, your supervisor can assign work in an area where you will not pose a contamination risk.