

Basic Principles of Safety – Gowning

Your Objectives:

At the end of the lesson, you should be able to explain the ins and outs of gowning and so that you may apply these appropriately.

Gowning

Our bodies are constantly shedding particles (follicles) from our skin (derma), and these can contain bacteria—common ones are impetigo, folliculitis, and furuncle, which have usually entered through skin abrasions—not to mention possible pathogens such as *S aureus*, β -hemolytic streptococci, and coryneform bacteria.

Without special attire to contain these, the clean-room environment would easily fall short of the specified requirements for cleanliness. As such, Biogen ~~the~~ supplies its manufacturing personnel with gowning materials and special protective apparel, which must be donned prior to entering a cleanroom.

The details below outline gowning responsibilities and guidelines. Consult SOPs (standard operating procedures) for your area, as these will detail gowning requirements.

Gowning areas

Different manufacturing areas have one or more adjoining gowning areas, generally equipped with personal lockers. There are separate locker-rooms designated for women and for men. Each gowning area allows for a limited number of persons to gown at any one time.

A gowning bench divides the room into a “clean” gowning level and a “dirty” gowning level. This bench provides a line of demarcation so that an employee will either don or remove the proper garments before crossing the marker (bench).

Regular dress

Certain employees are to wear a plant uniform on the job (instead of their regular clothes) until the end of their shift.

Footwear

Almost all manufacturing personnel are required to wear dedicated plant safety shoes. These shoes are provided for by Biogen and are used only in manufacturing areas. Dedicated plant safety shoes are kept and to be left in the lockers. At the start of a shift, the employee dons the designated shoes. And at the shift’s end, employees will return the designated shoes to their locker before changing back into regular footwear.

Gowning apparel

Each work area at Biogen requires different types of gowning apparel.

The following list, though not exhaustive, includes most types of gowning apparel used at Biogen:

- Head / Hair covers
- Safety glasses / goggles
- Beard covers
- Protective / working & cleanroom gloves
- Masks
- Safety shoes
- Booties, or shoe coverings
- Under-suit
- Single-use gowns
- Reusable gowns
- Everyday-use gowns
- Scrubs
- Lab coats
- Cleanroom jumpsuits
- Cleanroom coveralls

SOPs describe gowning requirements for each area, as well as gowning stipulations for moving from one area to another.

Gowning practice

Basically, gowning procedures include the following steps (though not all areas require all steps).

1. At the start of a shift, enter the designated locker-room to don the minimum required gowning:
 - bespoke plant safety-shoes
 - everyday-use plant uniform
2. Enter the appurtenant gowning area. Allow any personnel de-gowning to finish before gowning yourself. Do not enter a room if someone with a different than required gowning is present. Wait for them to exit, then enter.
3. Begin your gowning on the correct side of the bench.
4. Cover your head/hair first.
5. Put on a beard cover (if needed).

6. Wear an under-suit (if required).
7. Wash hands thoroughly before putting on changing gloves (if required)
8. Put on a facemask.
9. Put on a coverall/body garment. Do not allow garments to ever touch the floor.
10. Put on booties/shoe covers. As you put a shoe cover on one foot, swing that leg over the bench to the “clean” side. Seated across the bench, follow the same process with the second shoe cover, before revolving your torso over fully to the clean side, when done.
11. Inspect yourself in a mirror or ask a co-worker to inspect your apparel to ensure your garments are properly fitted and are unblemished.
12. Remove changing gloves and put on working gloves (if required).
13. Put on safety glasses and/or other facial protection.
14. Disinfect hands or gloves (if required).

De-gowning

De-gowning is essentially the reverse process: Remove all gowning materials. Place reusable materials in the appropriate bins. Discard disposable gowns, shoe covers, head covers, masks, beard covers, and gloves. Allow personnel who are gowning to finish before you begin de-gowning. Do not enter a room with a different than required gowning if someone with a different gowning is present. Wait for them to exit, then enter.

In emergencies

In the event of an emergency or unanticipated incident, do take a minute to de-gown immediately after exiting the cleanroom.

Upon returning to manufacturing areas, gown appropriately. Remove dedicated shoes and clean them thoroughly. Re-gown when entering again the cleanroom.

Movement

The ways in which we move—our postures, gestures, our positions, our speed, — inevitably disturb the **laminar airflow** coming downward (from the ceiling), which will produce turbulence, and therefore factor into the equation when moving about in a cleanroom. Standing or sitting, moreover, will cause a different **particle dispersion level** from those personnel moving about. What follows are a few general considerations/ rules when occupying a space within a cleanroom:

- Move slowly and deliberately, with economy of movement
- Always sit correctly at a workspace

- Approach other technicians from behind; avoid talking to someone from across the workspace
- When carrying materials, have your hands at the base of the container
- Hold materials you carry at or above waist level
- Ensure that your hands touch and handle and manoeuvre only the tools and materials necessary to perform a given task

Code of norms

Besides observing appropriate gowning and moving practices, the following customs are strictly prohibited in the cleanroom:

- No consuming food and drink
- No smoking, chewing gum or tobacco, etc.
- No bringing any personal reading materials (e.g. no magazines, newspapers, etc.)

Additional information: <https://blog.gotopac.com/2018/01/26/cleanroom-cleaning-procedure-contamination-control-iso-14644-1-protocol/>