

Clean Room Garment

The garment—including the body gown, hood, gloves, booties, masks—must be clean, sterile, and non-shedding. Almost equally important is how the entire garment is put on prior to entering a classified environment.

Traffic Movement and Control

Airborne contamination is directly related to the number of people working in a given area of clean room space and the types of activities they are doing. Therefore, number of personnel and degree of activities must be kept to a minimum. Activities that produce turbulence and increase particle contamination include talking, bodily movements, and anything that interrupts the flow of laminar air.

Human Skin Contamination

Ljungqvist and Reinmueller have published many research articles and books on clean room contamination and the problem of people being the main contamination source [(7–9) and references therein]. They have reported that there are >1.2 million/m² aerobic bacteria in head and neck regions of both male and female subjects and 0.9–3 million/m² in human hands and arms (10). There are even higher numbers of viable anaerobes, primarily *Propionibacterium acnes*. A fully gowned person sitting in clean room releases approximately 15,000 particles per minute, > 0.5 μm , and a walking person releases approximately 157,000 particles per minute, > 0.5 μm . Therefore, the ratio of total particles > 0.5 μm and viable aerobic organisms encompass a broad range of 600–7000 to 1. People release 600–1300 total particles per hour in > 0.5 μm size range, with approximately 40 colony-forming units (CFUs) of viable aerobic organisms among these. The typical, properly gowned clean room worker will contribute 10–100 CFUs of viable aerobic organisms to the environment per hour (9).

What this reveals is that even the best classified environments and clean rooms with people in them will not approach “sterility.” Since release of organisms by gowned personnel is quite normal, it should never be surprising to recover organisms at any location in the clean room. Clean room environments are not sterile as long as people populate them. The only viable approach is to have people gowned properly and strictly adhere to good aseptic practices and techniques.

Gowning

The uniform worn is designed to confine the contaminants discharged from the body of the operator, thereby preventing their entry into the production environment. For use in the aseptic area, uniforms should be sterile. Fresh, sterile uniforms should be used after every break period or whenever the individual returns to the aseptic area. In some plants this is not required if the product is to be sterilized in its final container. The uniform usually consists of coveralls for both men and women, hoods to cover the hair completely, face masks, and Dacron or plastic boots (Fig. 16-1). Sterile rubber or latex-free gloves are also required for aseptic operations, preceded by thorough scrubbing of the hands with a disinfectant soap. Most companies require two pairs of gloves, one pair put on at the beginning of the gowning procedure and the other pair put on after all other apparel has been donned. In addition, goggles are required to complete the coverage of all skin areas.

Dacron or Tyvek[®] uniforms are usually worn, are effective barriers to discharged body particles (viable and nonviable), are essentially lint-free, and are reasonably comfortable. Air showers are sometimes directed on personnel entering the processing area to blow loose lint from the uniforms.

Gowning rooms should be designed to enhance pre-gowning and gowning procedures by trained operators so that it is possible to ensure the continued sterility of the exterior surfaces of the sterile gowning components. De-gowning should be performed in a separate exit room.

While gowning heroically prevents human particles from grossly contaminating the controlled areas where they work, there are also certain issues with the gown and gowning process. There is no universally accepted procedure for the sequence of gowning steps. Some manufacturers put on boots before masks or hoods; others use the opposite sequence. The use of single versus double gloves still differs among manufacturers, although the great majority of