

16 | Personnel requirements for sterile manufacturing

Of all the potential sources of microbiological and particle contamination in a sterile product manufacturing facility, people are the worst offenders. Therefore, anything that can be done to reduce contamination levels from people will improve the assurance of sterility of dosage forms prepared in the presence of people. Of course, the ultimate solution to eliminate this major source of contamination is to completely remove any contact of people with product being manufactured. Indeed, the advent of barrier isolators aims to do just that (chap. 23). Perhaps someday all sterile product filling will be accomplished using isolator systems, but until then, control of contamination from people will continue to be the greatest challenge in assuring product sterility.

PERSONNEL CHARACTERISTICS TO WORK IN CLASSIFIED ENVIRONMENTS

Personnel selected to work on the preparation of a sterile product must be neat, orderly, and reliable. They should be in a good health and free from dermatological conditions that might increase the microbial load. If they show symptoms of a head cold, allergies, or similar illness, they should not be permitted in the aseptic area until their recovery is complete. However, a healthy person with the best personal hygiene will still shed large numbers of viable and nonviable particles from body surfaces. This natural phenomenon creates continuing problems when personnel are present in clean rooms; effective training and proper gowning can reduce, but not eliminate, the problem of particle shedding from personnel.

Studies have been published (1–4) showing the huge number of particles emitted from the human body, depending on the type of activity (Tables 16-1 and 16-2). Each adult loses approximately 6–14 grams of dead skin material every day and a complete layer of skin is shed about every 4 days. When these huge numbers are compared against what defines a Class 100/Grade A clean room, it is a small wonder that the presence of human beings in the clean room presents a formidable challenge in maintaining high-quality particle standards. Table 16-3 provides other data on the relative number of particles shed from people and surfaces.

Personnel training is one of three important components that good manufacturing practice (GMP) regulations use to define qualified personnel involved in the preparation and testing of pharmaceutical products. The other two components are education and experience. There might be a fourth component, especially concerning personnel involved in aseptic manufacturing, and that fourth component is attitude. Indeed, in most job functions, personnel are adequately educated, experienced, and trained, but mistakes are still made and such mistakes most of the time can be traced to poor attitudes (lack of discipline, carelessness, apathy) about doing the job right.

There are at least six personnel factors that influence the degree of potential contamination from an individual working in a clean room (2). These are discussed below.

Bathing

Bathing will remove microorganisms, but will increase the number of particles emitted from the body. The washing process removes the outer oily sebum layer of the skin, causing skin scales to dry, curl, and peel off the body. Within 2 hours after bathing, the skin surface will resume its original pattern of microcolonization. Employees working in clean rooms should bathe at least 2 hours before they enter the clean room environment to minimize the extent of skin particle shedding resulting from the bathing process.

Suntan

Suntan dries the skin, causing it to flake and peel more easily. Incidents of contamination occur more frequently during the summer months, partly due to suntan issues. Creams help to reduce