

Personnel involved with manufacturing and testing of sterile products should be given thorough, formal training in the principles of aseptic processing and the techniques to be employed. In fact, personnel training should focus on the following subjects:

1. Minimizing and eliminating sources of contamination
  - a. Air quality
  - b. Cleaning/disinfection/sterilization
  - c. Personal factors
    - i. Selection criteria
    - ii. Requirements to control contamination
    - iii. Gowning procedures
    - iv. Aseptic techniques
2. Objective testing
3. Hands-on testing
  - a. Gowning test
  - b. Broth test
  - c. Media fills
4. Remedial training
5. Understanding what the Food and Drug Administration (FDA) evaluates when inspecting for personnel training and aseptic processing

The broth test is a test of aseptic technique while manually filling vials with sterile culture media (broth) and manually stoppering using sterile forceps. The trainee must first be certified on donning sterile gowning correctly. Manual filling involves 250–400 vials at one setting with the exercise repeated one or two more times on separate days. The vials are incubated just like media-filled vials along with positive and negative controls. Also, after each of the three tests the trainee's fingers and chest are sampled with Rodac plates to determine the presence of any contamination while the trainee was performing the test. If any of the 750–1200 vials show contamination after appropriate incubation, the entire broth test must be repeated after remedial training. These tests also are performed in the presence of a trainer who can point out technique errors during the test.

Subsequently, the acquired knowledge and skills should be evaluated to assure that training has been effective, before they are allowed to participate in the preparation of sterile products. Retraining should be performed on a regular schedule to enhance the maintenance of the required level of expertise. An effort should be made to imbue operators with an awareness of the vital role they play in determining the reliability and safety of the final product. This is especially true of supervisors, since they should be individuals who not only understand the unique requirements of aseptic procedures, but are also able to obtain the full participation of other employees in fulfilling these exacting requirements.

Outlines of personnel training curricula are given in Tables 16-4 and 16-5. Table 16-6 provides example test questions. Figures 16-2 and 16-3 are examples of fun exercises to point out some of the "do's" and "don'ts" of aseptic techniques that are listed in Table 16-7.

### **Role of Management**

Management always plays a key role in any organization. Management always needs to be a source of inspiration for all personnel so that every person does his/her best in their job functions. Management should never be a source of problems due to poor leadership, poor decision making, lack of hard work, lack of support, lack of being good examples, incompetent thinking and facilitation, and so forth. So often, employee attitudes about doing the job as best as they can are dictated by attitudes and actions of their management leadership.

With respect to management responsibilities over employees who work in manufacturing and quality environments, there are several points to consider:

- Management themselves must recognize and fully appreciate the need to follow GMPs, including good documentation practices and good aseptic practices.
- Management must hire people who are willing to accept and follow procedures assuring adherence to GMPs.