Training for aseptic processing cleanrooms must be a dynamic process to meet job requirements and industry demands. The author discusses various approaches that may be taken to ensure a successful training session.

**Requirements**

Every employee must have the education, training, and experience to perform the assigned job functions. Three basic training needs exist in today’s healthcare marketplace: initial training, ongoing training, and new skills training.

**Initial training.** Initial training is required for all new employees. The goals must include:

- a general understanding of good manufacturing practices (GMPs)
- a detailed explanation of the GMP regulations that pertain to the job function, including the job’s application of the GMP principles
- written standard operating procedures (SOPs) specific to the job
- specific operations and handling requirements.

**Ongoing training (review).** Ongoing training is a continuous awareness program, which can be held semiannually, quarterly, or monthly. Ongoing training is also known as a refresher course. It should include a short review of the basics with specific emphasis on SOP review, gowning, aseptic techniques, compliance issues, and changes in processing. Personnel should receive training with sufficient frequency to ensure that operations meet required specifications.

**New skills training.** New skills training is job-specific training for employees who will be handling new equipment, using a new process, or changing positions. This training is concurrent with a change in an SOP and/or a change control event. New-equipment training must involve extensive hands-on instruction in addition to the classroom course.

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Classroom training modules
Before they are trained in specific skills, operators should receive a job description as well as background information about the company and its products. The cleanroom classroom training can then be divided into segments or modules. These segments should include:
- Background information about cleanrooms, rules, regulations, and personnel issues. This segment gives the student the fundamentals on which to build his or her education.
- GMPs, product requirements, and overall operational understanding.
- Gowning, aseptic techniques, workstation cleaning, and sanitation.
A higher training level would comprise advanced courses for monitoring and other complex product-related issues.

The five “I”s” of training
- Inspire
- Identify
- Inform
- Implement
- Institutionalize

Hands-on practice
Students should have the opportunity to learn, observe, and practice. Every level of classroom instruction should be followed by hands-on training. In my 27 years of experience in cleanroom training, I have never met anyone who could perfect the art of donning a sterile garment by watching a demonstration or a video. A video or classroom demonstration can introduce the activity, but nothing can replace an actual practice session. After observations and practice, a follow-up classroom session is recommended to ensure that the concepts learned are well understood, questions are answered, and retraining is performed if necessary.

Simulating real conditions
Proper instruction of today’s aseptic techniques requires the use of a training laboratory or a real laboratory. Training in a cleanroom would be a tremendous advantage because operators and technicians could practice aseptic techniques, environmental monitoring, sterility testing, cleaning and sanitization, equipment setup, and filling procedures under actual conditions.

If training in a cleanroom is not possible, the use of a mock cleanroom will still be beneficial. If an area is created to simulate a gownroom, fill suite, or sterility lab, personnel an simulate production activity.

If a cleanroom or laminar-flow hood is available, hand fills could be done there. This would allow a person to have sufficient background in aseptic training before production media-fill qualification.

Competency-based training
Throughout the training process, employees must know their job responsibilities and what is expected. Training programs should be competency based; that is, based on the knowledge and skills that each employee must have to perform his or her specific job function.

Documentation of training only ensures the training department of a person’s presence in a course. It does not necessarily verify the employee’s comprehension nor ability to perform the function. Therefore, verification of the employee’s ability to perform the work required after training is critical.

Testing, although necessary, is not a sufficient verification method and will not qualify employees on for assigned functions. Many companies are especially reluctant to test senior employees. However, human resource departments are concerned about the employee who has been in a position for many years and who then fails written tests.

Certification also should be part of a training program. The certification process involves demonstration of a defined task using a predetermined checklist by an authorized observer. Objectives of any training program must be defined and the outcome assessment understood before specific training is implemented. In many cases, this may require an assessment of the current situation and an understanding of the desired objectives. It must be made clear whether the training session must be conducted as an initial training course or as a retraining course because of a problem or other reason.

The five “I”s” of training
Inspire. Management must inspire employees to improve their performance. Some people have a built-in need to perform and achieve and have a motivated personality. Other people work hard to improve and earn a chance for advancement. However, certain individuals may need the participation and involvement of management to become motivated.
Identify. Identifying a performance improvement helps inspire employees. A poor performance can identify a need for training.
Inform. Information is the training or transfer of skills and experiences.
Implement. Implementation is the result of proper training.
Institutionalize. Institutionalizing is the maintaining of the skill level of the operator work force and is the responsibility of management.

Management’s role
Commitment is key in aseptic training, and the role of management is critical. Management must participate in motivating the work force while investing in training programs, staff, equipment, and time. Remember, “If you think education is expensive, try ignorance.” Because aseptic processing is a high-risk operation, a continuous awareness program must be established.

Management also must support proper supervision. Nonperformance or short-cuts are not acceptable. Proper cleanroom protocols, aseptic techniques, and following SOPs are all part of expected and desired employee performance.