

FDA's Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing, calls for knowledge and/or skill based training on aseptic technique and clean-room behavior, basic microbiology, gowning techniques, personal hygiene, and job specific training. A critical aspect of training not specified by either of these documents is education on the overall process for producing aseptic products. Knowledge based training is critical so that operators have an understanding of the overall production process, the critical role they specifically play, and the special considerations that need to be given to any sterile drug administered through injection or IV. Skill based training develops specific job skills so that operators can carry out tasks to required specifications each and every time.

Implementation of Aseptic Training System

An Aseptic Training System is very similar in form to a GMP Training System.

System Component Requirements

Knowledge Based Training

Curriculum list: (see appendix 1)

- A. Aseptic technique and clean room behavior
- B. Clean Room Design
- C. Disinfection, Sanitization, and Sterilization Practices
- D. Basic Microbiology
- E. Environmental Monitoring
- F. Gowning (tutorial and practical training)
- G. Airlock/Pass through Practices
- H. Overview of Manufacturing Process including job functions and their impact

The training concepts discussed above need to be understood by the operator *prior* to working in the aseptic area. The exceptions would include complete job specific training which may need to be observed in the aseptic area itself as well as participation in aseptic process simulations or media fills. Retraining needs to be accomplished **minimally** on an annual basis, when new technology, equipment, or processes are employed, as needed for refresher training, when identify as a corrective/preventative action for a deviation, or when an operator has been absent from the aseptic work environment for a specified time as covered by site policy. Opportunity for *continuous* learning cannot be overemphasized.

While training is a key component, the criticality of the clean room environment necessitates the routine presence of management, or designates, to routinely assess the operators' activity in the aseptic core, looking for opportunities for continuous improvement.

Training is more effective when the trainee can do and see as opposed to simply hearing the information. For example, simulations of unidirectional airflow using smoke generators or smoke sticks can provide a clear picture the difference quick vs. slow and deliberate movements can have on unidirectional airflow. It also demonstrates how placement of objects and equipment on and around the filling line affects the airflow patterns. Another example is videotaping operator gowning practice which can enhance gowning training as it provides a tool to the operator and