

Guidance 065 Training system for Aseptic and Preparation for Aseptic Operators and Support Staff

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

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Re-qualification due to monitoring failure – Re-qualification should be conducted when an investigation shows that operator error due to lack of understanding or competence is the source of the EM excursions. There are many reasons that an environmental excursion could occur—changes in procedures, disinfectants, new equipment for example—that would not indicate that operator training would be needed.

The structure of this training should be handled on a case by case basis as determined by the investigation. All knowledge and skills based training must be documented.

Training Effectiveness Assessments

Assessment should be made of the operators understanding of the knowledge based training and competence in any job skills. Methods for assessing training effectiveness should be approved by the Site Quality Team and Site Production Team prior to use.

Typically, written or oral assessments or classroom activities that cover key objectives are appropriate for knowledge based training while actual documented physical demonstration of job skills is appropriate for Skill Based

Identifying Trainers

An internal site trainer, who has expertise in this area/topic, should perform the training.

These individuals should be evaluated or trained to perform training to ensure that they have the appropriate skills and knowledge to ensure training is effective. Aseptic Qualification training is very similar to Structured On-the-Job training for any other production related process.

Therefore the evaluation/training of the trainer can be similar if not the same.

Documentation of Qualification Process

The site qualification program for APA/APA Support and PAA/PAA Support personnel should be formalized in an SOP. The SOP should include details about the Initial Qualification, Annual Re-Qualification and Re-Qualification after an absence or deviation, who is responsible for carrying out the training and approximately how long the training is expected to take.

All materials used during the Qualification/Re-Qualification process; i.e. SOP, checklist, training form, equipment manual; should be defined in the SOP process.