

Summary - Training system for Aseptic and Preparation for Aseptic Operators and Support Staff

Aseptic processing takes place in a controlled, but non sterile environment where sterilized components are brought together and aseptically assembled. There are four major components of an aseptic processing environment; product, components, facilities and equipment, and operators. Operators, including those that prepare equipment and components for and also those that work in an aseptic processing area, are the greatest potential source of contamination. The operator qualification program, which consists of initial and ongoing training, is crucial to ensure that colleagues are prepared to fulfil their roles.

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 trainer to be able to examine the gowning process and point out areas of improvement or determine contamination sources.

If an APA operator has not worked in the APA nor done sterile gowning for a significant length of time, the site must assess when demonstration of competence of critical job skills or a refresher course on certain classroom topics is required.

[Read More](#)