

Who is Qualified to Perform Sterile Compounding Competency Evaluations (Visual Observation)



Critical Compounding Resources

Consistently flawless aseptic technique is unique to sterile compounding and therefore operations require a skilled and capable individual to perform visual observation and competency assessments.

In a hospital setting, it's common to see pharmacists and pharmacy technicians performing aseptic technique evaluations. These professionals boast ample experience in implementing and monitoring sterile compounding activities. They have a keen eye for identifying areas that warrant improvement and can provide the training to address them.

In other sterile compounding institutions, pharmacy staff may also be responsible for evaluating aseptic technique. Supervising pharmacists or pharmacy managers oversee evaluations to ensure their team is adept in maintaining a sterile environment and are proficient in the preparation of compounded sterile products.

Cleanroom certification technicians have also provided these evaluations. CCR recommends vetting the certifier's experience in sterile compounding before allowing them to perform competency evaluations. While certifiers are experts in engineering controls and first air, they often lack formal training, understanding, and experience in compounding-related aseptic technique and operator conduct. Evaluators should be seasoned compounders with extensive knowledge of the sterile compounding environment, related tasks, desired operator conduct, aseptic technique, contamination control strategies, as well as the inner workings of the sterile compounding operations.

Whether a pharmacy employee or third-party evaluator, those performing competency evaluations should have expertise and experience in the activities they are evaluating. Third-party evaluators must be independent and free of any real or perceived conflict with the individuals(s) being evaluated. These unbiased experts must undergo their own annual competency assessment. They may be evaluated at the workplace or at an alternate location (if state/province/territories allow) and there must be specific procedures in place to define the requirements for training and evaluation. Aseptic technique evaluation is essential to facilitate patient safety, as well as enhance illness prevention and adverse events.

CCR recommends:

- Visual observation be performed not only during media fill testing but also randomly during the compounding day to truly measure the compounders' abilities.
- That the person performing visual observations receive additional training on the nuances of the activities they are tasked with observing and how to best observe. Though sterile compounding training options are numerous, CCR recommends an in-person, live instruction on contamination control strategies, first air dynamics, primary engineering control designs, airflow and aseptic technique and conduct in the compounding area.
- A policy and procedure is in place that describes how to perform competency evaluations.
- Having proper documentation, such as forms, to perform the observations and document the results.
- Communication of the results to staff to highlight areas of mastery as well as describe items that require improvement. If a failure occurs, discuss the plan of action to get the compounder back on track.



Some healthcare professionals seek supplementary certifications to develop and measure their expertise in aseptic technique. These certifications are sometimes offered virtually through eLessons. CCR recommends taking in-person, live training conducted by vetted faculty who are experts in their field of work. These certifications should have a cleanroom component to provide real workplace simulation as well as objective testing that closely simulates the work setting.

To summarize, aseptic technique competency evaluations are best conducted by individuals with extensive knowledge of sterile compounding operations, contamination control strategies, and engineering controls. Healthcare professionals such as experienced pharmacy staff are ideal candidates for this essential role. After all, patient safety hinges on the proficiency of those ensuring aseptic standards are maintained – and, as Florence Nightingale aptly said, "there is no greater duty than protecting the health and lives of others."