

## Example – Media Fill Assessment Competency

### Train the Trainer Media Fill/GFS Direct Observation Assessment

Employee: \_\_\_\_\_

Position: \_\_\_\_\_

Evaluator: \_\_\_\_\_

Position: \_\_\_\_\_

Type: ☐ Initial Assessment

☐ Annual Assessment

☐ Other (please specify): \_\_\_\_\_

Testee or another qualified designated member of the pharmacy staff will complete this Direct Observation Assessment. “Trainers” will utilize the standard observational competencies: Hand Hygiene/Garbing, Cleaning and Disinfection, Aseptic Technique. Trainers will observe *testee* completed each discrete skill. *Testee* will complete incorrectly or not complete at all 5 items on the list below. A = acceptable, I = incomplete, N/O = not observed, and N/A = not applicable. The “trainers” need to observe/correct 4 of the 5 incorrect/incomplete actions to pass. Additional comment is required for all activities marked as I or N/O and a specific plan for correction must be documented in the Remedial Action Plan section.

Prior to Entry into Cleanroom:	Observation	Comments
Assesses individual is appropriately dressed in freshly laundered scrub top, scrub pants, and closed toe shoes worn with socks.		
Assesses individual removes all jewelry, piercings, ear buds, headphones, cosmetics, artificial nails, nail polish, and outer garments (i.e. sweatshirts) prior to entering classified areas. Closed toe shoes and socks are worn. <i>Testee shows up wearing one of these items, jewelry, earbuds, cosmetics.</i>		
Gowning and Garbing:	Observation	Comments
Ensures individual dons garb in following order 1. Head Cover 2. Face mask 3. Facial Hair cover (if applicable)		
Assesses individual understands purpose of line of demarcation and can identify it in the anteroom.		
While crossing line of demarcation, ensures individual dons pair of shoe covers before stepping on “clean” side. <i>Testee dons pair of shoe covers on dirty side and does not cross over line of demarcation.</i>		
Observes individual rinses fingertips before removing debris from under nails with nailpick. <i>Testee skips using nailpick and begins handwashing.</i>		
Observes handwashing from fingertip to elbow with soap and water for at least 30 seconds.		
Observes individual pat dries hands and arms with low lint disposable wipe. <i>Testee wipes forearms and hands.</i>		
Cleaning and Disinfection:	Observation	Comments
Identifies appropriate cleaning tool, cleaning consumables		
Can identify appropriate cleaning solution and disinfecting solution		
States dwell times of each cleaning solution (daily cleaning, monthly cleaning, disinfection solutions).		

## Example – Media Fill Assessment Competency

Cleans PEC with cleaning tool (if needed) and appropriate cleaning consumable and cleaning solution.		
Wipes using unidirectional/overlapping strokes.		
For Daily clean, cleans in following order <ol style="list-style-type: none"> <li>1. Ceiling</li> <li>2. Back Wall</li> <li>3. Side Walls</li> <li>4. IV Bar</li> <li>5. Inside Sash (Vertical BSC)</li> <li>6. Deck</li> </ol> <i>Testee cleans in an incorrect order.</i>		
<b>Media Fill:</b>	<b>Observation</b>	<b>Comments</b>
All supplies introduced into clean room environment are wiped down with Sterile Isopropyl Alcohol (sIPA) prior to transfer into classified space (ISO 7 or 8).		
Sterile gloves are disinfected with sIPA 1) before placing gloved hands into the Primary Engineering Control (PEC), 2) anytime gloved hands leave the PEC, 3) anytime gloved hands touch non-sterile surfaces. <i>Testee has gloved hands leave ISO 5 at least once to perform an action without disinfecting gloves.</i>		
Supplies for use in the PEC are wiped down with sIPA prior to placing them inside the PEC (note- when sterile supplies are received in sealed pouches designed to keep them sterile until opening, the supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 PEC without the need to disinfect the individual sterile supply items).		
Ensures syringes, needles, and tubing remain in their individual packaging and are only opened after being placed in the ISO Class 5 PEC.		
All containers (fluids, vials, and ampules) are examined prior to use to determine they are in date and free from particulate.		
Prior to entry into a critical site (vial septum, injection port, ampule neck, etc.) locations are vigorously wiped with a sterile single use alcohol prep pad three times in one direction and allowed to dry before entry. <i>Testee does not wipe the septum of a vial prior to entry.</i>		
Demonstrates understanding of how to utilize unidirectional airflow to maintain first air in the direct compounding area.		
Items in the DCA must be placed 6 inches from all sides of the hood including the front. <i>Testee places items at front edge of hood and within 6 inches of sides.</i>		
Avoids contact contamination by never touching; 1) any part of the needle, 2) the septum of the vial, 3) the sides of the plunger of the syringe. <i>Testee grasps hub of needle when removing from package.</i>		
Performs all aseptic manipulations in areas of uninterrupted first air and placement of hands does not block the flow of first air to		

## Example – Media Fill Assessment Competency

critical sites. <i>Testee makes an aseptic break during manipulations.</i>		
Spikes infusion ports without contact contamination.		
Affixes needles to syringes without contact contamination.		
Punctures vial stoppers without contact contamination.		
Transfers solutions from a vial to a syringe without contact contamination.		
Removes air bubbles to ensure accurate measurement of solutions.		
Directs opening of ampules away from the HEPA filter of the Primary Engineering Control.		
Uses a filter needle to withdraw or inject solution from an ampule. <i>Testee does not use filter needle.</i>		
Reconstitutes powders without contact contamination.		
Disposes of sharps and waste per institutional policy.		
<b>Remedial Action Plan:</b>		

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date