# Training Best Practices

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## Personnel Qualification Testing

<table>
<thead>
<tr>
<th>Personnel Qualification Testing</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Visual Observation Hand Hygiene</td>
<td>Every 6 Months</td>
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<tr>
<td>Visual Observation Garbing</td>
<td>Every 6 Months</td>
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<tr>
<td>Gloved Fingertip and Thumb Sampling</td>
<td>Every 6 Months</td>
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<tr>
<td>Media Fill Testing</td>
<td>Every 6 Months</td>
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<tr>
<td>Training in Sterile Compounding Principles and Practice (written or electronic)</td>
<td>Every 12 Months</td>
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Failures in any evaluation/testing:

- Must be documented
- Corrective actions must be documented
- Retest per SOP; document if retest is failed
- Documentation must be maintained to provide a record and long-term assessment of personnel competency
- Maintain documentation for at least 3 years

USP<797> Section 2. Personnel Training and Evaluation

“All personnel involved in the compounding of CSPs must”

- Initial training and qualification
- Retraining, evaluation, and requalification every 12 months
  - Through written testing and hands-on demonstration of skills
  - Hand hygiene and garbing must be evaluated every 6 months
    - Visual audit that must be documented
- Documentation
- Each compounding facility must develop a written training program
  - Required training
  - Frequency of training
  - Process of evaluation for the required skills necessary to perform assigned tasks
Before beginning to prepare CSPs independently, all compounding personnel must complete training and be able to demonstrate knowledge of theoretical principles and proficiency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions.

**Competency must be demonstrated in at least the following:**

- Hand hygiene
- Garbing
- Cleaning and disinfection
- Calculations, measuring, and mixing
- Aseptic technique
- Achieving and/or maintaining sterility and apyrogenicity
- Use of equipment
- Documentation of the compounding process (e.g., master formulation and compounding records)
- Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
- Proper use of primary engineering control (PECs)
- Principles of movement of materials and personnel within the compounding area

Training is

more than

read the SOP and sign
“Read and understood by:…….”
once a year
Training lessons from the golden arches

1. New employees are first trained in safe food handling.
2. Trained on counting discarded food items.
3. Trained on making fries. Make fries for one week.
4. Trained on making fish sandwiches. Add fish sandwiches to the repertoire.
5. Training on subsequent stations only when the previous is mastered.

Training is gradual, allowing time for new employees to master each task.

Contrast this with

School of Pharmacy Orientation

• One day 9-4 pm, a parade of people tell you what they need you to know.
  • And then they expect you to remember it all.

• Information overload
• No context in which to understand all the information
• Goes in one ear and then who knows where.....

How do you do your training?
Important concepts in training

“See one, do one, teach one”

“Amateurs practice until they get it right
Professionals practice until they don’t get it wrong”

The Four Stages of Learning

1. Unconscious incompetence
   • Unaware of how little is known
2. Conscious incompetence
   • Recognize the deficit
3. Conscious competence
   • Requires concentrated thought OR
   • Requires prompting or notecards
4. Unconscious competence
   • Second nature

To what level of learning do you want to train your sterile compounding staff?
Example of Handwashing and Garbing Training at UConn School of Pharmacy

• Video and written information on the proper order and technique for handwashing and garbing
  • With reasoning behind each step

• Online – quiz requiring students to put the various tasks in order
  • Unlimited attempts allowed, but must be completed before next step

• In person – complete the same quiz
  • Must complete before practicing with supplies

• Opportunity to practice

• Order and technique evaluated by 2 peers

• Evaluate the order and technique of 2 peers

• Order and technique evaluated by supervisor

Evaluations

No communication, verbal or non-verbal, during evaluation

• Check (√) each space for which the person being assessed has acceptably completed the described activity
• X if the order was incorrect or the activity was performed incorrectly
• “N/O” if the activity was not observed

Turn in all evaluations, failing and passing.

<table>
<thead>
<tr>
<th>Name of person assessed</th>
<th>Name of facility or location</th>
<th>Pharmacy</th>
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**Hand Hygiene and Garbing Practices:** The qualified evaluator will check (√) each space for which the person being assessed has acceptably completed the described activity in the correct order, an “X” if the order is incorrect or the activity is performed incorrectly and “N/O” if the activity was not observed. During the assessment, no communication (verbal or non-verbal) is allowed.

- Presents in a clean, appropriate attire and manner.
- Wears no cosmetics or jewelry (rings, earrings, etc. piercing jewelry included).
- Lymph nodes into anti-germs,
- Demonstrates awareness of the line of demarcation separating clean and dirty sides by constraining activities to the appropriate side of the anti-room.
- Gown shoe covers one at a time, placing the covered shoe only on the clean side.
- Gowns should cover if necessary.
- Gown face mask to cover the bridge of nose down to and including chin.
- Gown head cover assuring that ears and all hair is covered.
- Gours gloves & sterile packages with sterile 70% isopropanol before entering buffer room.
- Under arm running water, uses nail pick and brush to remove any debris from under nails.
- Washes hands and forearms up to the elbows with soap and water for at least 30 seconds.
- Rinses hands and forearms up to the elbows with warm water, allowing moist water to run from fingertips to elbows only.
- Dries hands and forearms using lint-free towel.
- Dons gowns and ensures full closure.
- Enters the buffer room without touching the door.
- Disinfects hands again using a suitable alcohol-based handrub with sustained antimicrobial activity following the manufacturer’s instructions for application times, and uses a sufficient amount of product to keep the hands wet for the duration of the application time.
- Washes hands to dry thoroughly.
- Dons appropriate size sterile gloves, ensuring that there is a tight fit with no excess glove material at the teguments.
- Does NOT touch the outside of the first sterile glove donned.
- Puts both gloves up to form a seal over the sleeves of the gown/cap coat.
- Examines gloves ensuring that there are no defects, holes, or tears.
- Applies sterile 70% (isopropanol) alcohol to the gloves and allows it to dry.

If there are any deficiencies, the person must be reassessed after this study and practice.

<table>
<thead>
<tr>
<th>Signature of Person Assessed</th>
<th>Printed Name</th>
<th>Date</th>
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<tr>
<td>Signature of Qualified Evaluator</td>
<td>Printed Name</td>
<td>Time</td>
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Portfolio of Training and Proficiency

Training Program includes Proficiency Testing

Gloved Fingertip and Thumb Evaluation

To assess proficiency in preparing to enter the buffer room to compound.

Media Fill Testing

To assess proficiency in aseptic technique.
Gloved Fingertip and Thumb Evaluation

• Before being allowed to compound independently
  • Fingertip and thumb sampling on 3 after full handwashing and garbing procedure each time.
  • Performed in a classified area
  • Success = ZERO cfu

• Every 6 months
  • Fingertip and thumb sampling after full handwashing and garbing and media fill testing
  • Performed in ISO 5 PEC
  • Success ≤ 3 cfu total for both hands

• Do not disinfect gloves immediately before touching the plate.
• One plate per hand (labeled R or L)
  • Roll fingertips as if you are getting fingerprinted at police station
  • SCDA (i.e., TSA) supplemented with neutralizing additives (e.g., lecithin & polysorbate 80)

Media Fill Testing – Required to Demonstrate Competency in Aseptic Manipulation

When performing a media-fill test, use the most difficult and challenging compounding procedures and processing conditions encountered by the person during a work shift (e.g., the most manipulations, most complex flow of materials, longest time to compound, size of batch), replacing all the components used in the CSPs with soybean–casein digest media.

Evaluation results must be documented, and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including expiration date and lot number, the results, and the signatures of the person evaluated and the observer. EVERY 6 MONTHS along with fingertip and thumb testing.

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Media Fill Testing – Required to Demonstrate Competency in Aseptic Manipulation

• Incubate SCDM in final containers for **7 days** at 20°–25° followed by **7 days** at 30°–35° to detect a broad spectrum of microorganisms.

• Failure is indicated by visible turbidity or other visual manifestations of growth in one or more container–closure unit(s) on or before 14 days.

Developing and Maintaining a Culture of Clean
Developing a Culture of Clean

Culture
• Reflects
  • Actions
  • Attitudes
  • Behaviors
• Of all members of the team
  • Managers
  • Supervisors
  • Staff

How do I get buy-in from all staff?

A strong, positive “culture of clean”
• “Clean” is a positive value that helps prevent contamination of the parenteral products, thereby ensuring safety of the patient.
• “Clean” must be regarded as a core value by all cleanroom staff and management.
• A “culture of clean” emanates from
  • Ethical, caring, and practical motivations
  • NOT from compliance with regulatory requirements
• A “culture of clean”
  • Requires that every level of staff has the
    • knowledge, skills and motivation
    • to identify and report potential problems and improvements.
Developing and Maintaining the “Clean Culture”

• Starts with thorough and effective training
• Long-term effort
• Partner with other departments with similar need for “culture of clean”
• Continuous education
  • Use incidents at other institutions as relevant examples for teaching
• Continuous improvement
• Continuous communication
• Assess the weak points (administrative, engineering) in the system
• Continuous awareness
• Periodically solicit feedback from staff
• Requires support (time and $$) from management
• Track progress and celebrate positive results and success stories

OBSERVATION 1
The ISO 5 classified aseptic processing areas had visibly dirty equipment or surface. Specifically,
On 04/18/2018 during aseptic processing of TPN Prescription Number (b) (6), a large area of brown residue was observed on the HEPA filter grate of an ISO 5 hood being used. Firm management could not identify the nature or source of the residue.

OBSERVATION 2
Personnel moved rapidly in the vicinity of instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area. Specifically,
On 04/17/2018, a pharmacy technician performing sterile production of Ertaopenem 1 gm/100 ml 45% NaCl for Prescription Number (b) (6), Rifampin 300 mg/400 ml D5W eclipse for Prescription Number (b) (6), Methylprednisolone 1 gram/100 ml NS HP for Prescription Number (b) (6), and Azithromycin 500 mg/100 ml NS Eclipse for Prescription Number (b) (6), in hood (b) (6) continuously demonstrated rapid hand movements including opening instruments, picking up syringes, picking up vials, moving trash around the table, and repeatedly waving hands around inside the hood after sanitizing.

OBSERVATION 3
Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product. Specifically,
On 04/18/2018, during sterile production of TPN Prescription Number (b) (6), in Hood (b) (4), a pharmacy technician manipulated sterile connections (b) (4) such that (b) (4) in the ISO5 space blocked the exposed sterile connections from first pass air.
Like LIFE-LONG Learning

Cleanroom training never stops.