Training Best Practices

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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 every 12 months in at least the following:**

- Hand hygiene
- Garbing
- Cleaning and disinfection
- Calculations, measuring, and mixing
- Aseptic technique
- Achieving and/or maintaining sterility and asepsis
- 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

If you are the only person involved in compounding at your facility, who trains and tests you?

If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.

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.

Training is more than

read the SOP and sign
“Read and understood by:…….”
once a year
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

Categorization of Personnel Competency Testing:

<table>
<thead>
<tr>
<th>Personnel Competency Testing</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Hygiene and Garbing</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Media Fill (using most complex manipulation)</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Gloved Fingertip and Thumb Sampling</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Sterile Compounding Principles and Practice</td>
<td>Every 12 months</td>
</tr>
</tbody>
</table>

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

Repetition is key
Evaluation/Audit

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
- "no" if the activity was not observed

Turn in all evaluations, failing and passing.

Training Program includes Proficiency Testing

Gloved Fingertip and Thumb Sampling
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 Sampling

- Before being allowed to compound independently
- 3 × Fingertip and thumb sampling after full handwashing and garbing procedure each time
- Performed in a classified area (but not ISO 5 PEC)
- Success = ZERO cfu

- Every 6 months
- Fingertip and thumb sampling after 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)

Portfolio of Training and Proficiency

Documentation of Handwashing and Garbing Evaluation

<table>
<thead>
<tr>
<th>Name of Student</th>
<th>Date</th>
<th>Educator</th>
<th>Result</th>
<th>Failure</th>
<th>Retest</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>1/13/2020</td>
<td>Jane Smith</td>
<td>Passed</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Gloved Fingertip and Thumb Sampling

- Incubate final containers for 7 days at 20°C–25°C followed by 7 days at 30°C–35°C 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.

- Document the failure.
- Retrain and document.
- Retest.
Training and Testing Periodically

Versus

Developing a Culture of Clean

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
• Periodically solicit feedback from staff
• Requires support (time and $$) from management
• Track progress and celebrate positive results and success stories

Like LIFE-LONG Learning

Cleanroom training never stops.