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

Proposed USP<797> Section 2
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 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

Proposed USP<797>

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**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.

Proposed USP<797>
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?**

| McDonald's | Rx |

### 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
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?

PERSONNEL COMPETENCY TESTING | FREQUENCY
--- | ---
HAND HYGIENE AND GARBING (visual audit) | EVERY 6 MONTHS
MEDIA FILL (using most complex manipulation) | EVERY 6 MONTHS
GLOVED FINGERTIP AND THUMB SAMPLING (inside ISO 5 PEC after media fill) | EVERY 6 MONTHS
STERILE COMPOUNDING PRINCIPLES AND PRACTICE (written or electronic) | EVERY 12 MONTHS

Proposed USP<797>
Failures in any evaluation/testing:

- 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

Does your facility’s SOP address what happens when someone fails media fill, fingertip or other testing?

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
- “N/O” if the activity was not observed

Turn in all evaluations, failing and passing.

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**Portfolio of Training and Proficiency**

**Documentation of Handwashing and Garbing Evaluation**

<table>
<thead>
<tr>
<th>Name of Student</th>
<th>Sec #</th>
<th>Hood #</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>To be completed by the student</th>
<th>For TA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written test of Handwashing and Garbing</td>
<td>Pass/Fail (circle one)</td>
</tr>
</tbody>
</table>

**Handwashing and Garbing Evaluated by:**

- Print name of first student evaluator
- Print name of second student evaluator

**Evaluated Handwashing and Garbing for:**

- Print name of first student that you evaluated
- Print name of second student that you evaluated

**Passed Final Evaluation by teaching assistant:**

- Print name of teaching assistant

Fingertip Test Results
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 x 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)
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.

EVERY 6 MONTHS along with fingertip and thumb testing. Proposed USP<797>

Media Fill Testing – Required to Demonstrate Competency in Aseptic Manipulation

- Incubate 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.

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

Versus

Developing 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
Like LIFE-LONG Learning

Cleanroom training never stops.