Clarifying Training Requirements of USP <797>

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Disclaimer

“Although I am a member of the USP Sterile Compounding Expert Committee, I am speaking today in my individual capacity and not as a member of the Committee or as a USP representative.

The views and opinions presented are entirely my own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>.”
"For 42 years, I made small, regular deposits of education, training and experience ... and the experience balance was sufficient that on January 15th I could make a sudden, large withdrawal”

Chesley Sullenberger
Agenda

- Why Training?
- Adult Learning
- Foundation of Chapter <797> Training Requirements
- Requirements of the Chapter
- Compliance Framework & Training
- Evaluating Your Training Program
- Critical Elements of Any Training Program
Why Training?

• It is a requirement?
  – State Board of Pharmacy
  – The Joint Commission
  – Hospital policy
• What do your employees need to know to do their job accurately and consistently?
• Who trains new employees?
• What does a pharmacist need to know?
• What does a technician need to know?
• Is there an opportunity to revisit how we educate and train employees?
Training Quality

• On your first day, you brought a high-level of experience and knowledge to the organization.

• In training, we capitalized on your existing skills and began an educational development process to standardize your *compounding skills* and ensure that you were adequately prepared to meet the daily challenges of *aseptic processing*.

• Your participation and preparation prior to any training program is critical to your success. We can only build on the knowledge base you bring to training. Each of us must maintain our own ongoing personal training.

Adapted from Continental Airlines Pilot Training Manual, 2005
Conscious Competence Learning Matrix

- **Awareness:** Learning is occurring
- **Ignorance:**
- **Knowledge:**
  - Ability
  - Competency
  - Proficiency
- **Wisdom:** Knowledge is intuitive
Does Training = Learning?

• We should probably stop using the word training, but just in case, let’s review why it’s inappropriate.

Training is something you do to someone. ≠ Learning is something people do for themselves.

You hope people learn from training, for that is the objective.

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Learning: Making Connections, Integrating Ideas

**Known Information**
Students enter class with their own understandings.

**New Information**

**New Learning**
Learners must make personal connections if new ideas are to be useful and integrated.

Perhaps we should think about the teacher as a facilitator of connection-making?

**Memorized Information**
Memorized information will quickly be forgotten since it is not connected to experience in a meaningful way.
“One only knows something if one can explain it”

Giambatista Vico, 1710, constructivist philosopher

*Adults take knowledge and connect it to other information they hold true, changing their understanding in the process, as in this mock hazardous drug cleanup exercise.*
Constructivist Learning Theory

• Departure from traditional classroom strategies where teacher is information giver to students who play a more passive role

• Constructivism is:
  – student-centered
  – focuses on adaptive learning where students apply what they learn to situations they might encounter in their work lives
  – meaning is closely connected to experience
## Traditional versus Adult-Learning Models

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pedagogy (traditional learning model)</th>
<th>Andragogy (adult learning model)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need to Know</td>
<td>Learner needs to know only what the teacher teaches</td>
<td>Adults need to know <em>why they need to know</em>; how it will apply to their life; what will they gain by learning; what might be negative consequences of not learning it</td>
</tr>
<tr>
<td>Self-concept</td>
<td>Teacher approaches learner as dependent, therefore learner eventually becomes dependent</td>
<td>Adults need to protect self-concept by being <em>seen and treated by others as being capable</em></td>
</tr>
<tr>
<td>Life Experience</td>
<td>Teacher possesses most of valuable experience</td>
<td>Adult has <em>substantial life experience</em> which is a valuable resource</td>
</tr>
<tr>
<td>Readiness to Learn</td>
<td>Learners become ready to learn what the teacher tells them to learn if they want to pass</td>
<td>Adults become ready only when <em>they decide</em> they need to know because info will help them to meet challenges in real-life</td>
</tr>
<tr>
<td>Orientation to Learning</td>
<td>Teacher organizes material according to subject or content areas</td>
<td>Adults <em>prefer task or problem-centered approaches</em> so info presented in context of how it will be applied in real-life situations</td>
</tr>
<tr>
<td>Motivation to Learn</td>
<td>Learner is predominantly motivated by external forces (praise or punishment from parents, teachers, peers)</td>
<td>Adults are motivated by external factors (promotion, increase in pay, prestige), however <em>internal forces are the most powerful motivators</em> (self-esteem, improved job satisfaction)</td>
</tr>
</tbody>
</table>
Computers as Adjunctive Teaching Tools

• It has been said that people remember:
  – 20% of what they see
  – 30% of what they hear
  – 75% of what they see and hear
  – 80% of what they see, hear, and do

• Some literature indicates that people learn 30% more in 40% less time at 30% less cost by using computer-assisted teaching tools to augment the use of traditional mentors or apprenticeships in business settings
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The intent of the chapter is “to prevent patient harm and fatality from microbial contamination (nonsterility), excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and incorrect ingredients in CSPs.”
Three broad areas contribute to meeting the objectives of USP <797>

<table>
<thead>
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<th>Contamination Control</th>
<th>Training and Documentation</th>
<th>CSP Checks and Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Address particulate sources – people, products, process</td>
<td>• Compounding personnel are skilled, educated and trained</td>
<td>• Reduce occurrence of contamination</td>
</tr>
<tr>
<td>• Create a “clean” environment where aseptic compounding will take place</td>
<td>• Operator testing for proficiency</td>
<td>• Verify the process produced correct CSPs</td>
</tr>
<tr>
<td></td>
<td>• Written policies, procedures</td>
<td>• Use the same process each time</td>
</tr>
<tr>
<td></td>
<td>• Document training</td>
<td>• If contamination or error happens, detect it and take action</td>
</tr>
</tbody>
</table>
Responsibility of Compounding Personnel

Health care professionals who supervise compounding and dispensing of CSPs shall ensure that:

Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:

– Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces.
– Select and appropriately don protective garb;
– Maintain or achieve sterility of CSPs in ISO Class 5 primary engineering devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic drugs.
– Identify, weigh, and measure ingredients.
– Manipulate sterile products aseptically, sterilize high risk level CSPs, and label and quality inspect CSPs.
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What Does the Chapter Require?

• Didactic (what is it, anyway)
• Testing
• Hands on training for media fills
• Significant discretion in the chapter that recognizes the diversity of activities performed, and that every facility is different. The chapter recognizes:
  – Training depends on the job you do
  – Repetition is needed to maintain skills
  – Certain skills are so critical to patient safety that competency must be demonstrated hands-on
• But what does it all mean, and why is it here when it wasn’t at the last revision of the chapter?
Would it be helpful if the USP SCC developed a suggested standardized educational curriculum with the assistance of anyone willing to take the time to comment during the next committee cycle (2010-2015)?
Adjective

1. intended for instruction; instructive: didactic poetry.
2. inclined to teach or lecture others too much: a boring, didactic speaker.
3. teaching or intending to teach a moral lesson.
4. didactics, (used with a singular verb) the art or science of teaching.
What topics need to be covered, and how often?

- One summary slide or bulleted overview of the training requirements seems too generic and high level to provide you with actionable insights.
- Therefore, I am making a four-page “spot check” tool available that you can use to assess your training programs against the requirements in the Chapter.

- CriticalPoint has agreed to provide the PDF to webinar attendees free of charge. In response, here’s what I’m asking:
  - Right now, enter your unmet training needs (pharmacy calculations, calibration procedures, etc.) in the question box in the webinar window
  - Also, share areas you feel need more detailed explanation
  - In the next day or so, we’ll roll them up and send you a survey to rank 5-10 of the most common topics – it’s a 2 minute exercise
  - The ranking will guide future webinar topics
  - When you complete the survey, you get linked directly to the PDF download for free
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Training in the USP <797> Compliance Framework

- Training can help:
  - Assimilate new staff: get into control, educate on a facility’s practices, build baseline knowledge to become compliant with the “way we do things”
  - Make sure everybody does it the same way according to policy and procedure.
  - Maintain competency: remain in a state of compliance by demonstrating continued competency
- This is reflected in the compliance framework: get into control, then stay in control.
- Training and education is a key component of the compliance process: not a one-time event, but a continuing cycle of training, assessment, and improvement.
Considerations for Training Program Development

• Recognize that USP <797> Changes Ingrained Behavior
  – Research shows that training plays a big role in changing ingrained behaviors, particularly if new practices are different from what people “know” from their experience

• Some compounding processes have critical steps or precise order. Training does two things: explain why it needs to be done correctly (rationale), and how to do it (process)

• Opportunity to emphasize professional skills development
  – “Enlightened” facilities view training as an opportunity to improve skills, morale, and engagement vs. a simple requirement.

• Supported by the literature
  – Studies show that using multiple training techniques increases retention and competency (therefore didactic and hands on requirements for critical compounding steps)
  – Addition of other methods (such as simulation) can be expected to yield further improvements
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Evaluating Your Training Program

Compliance to the standard is a process. In that light:

• Does the training reflect what the facility actually does, and the equipment used?

• Does your staff understand why training is so important on sterile compounding?

• Does training emphasize the link behind the quality of CSPs made in the pharmacy and patient safety (their friends/family)?

• Does training address areas you’ve identified for improvement as a result of employee review, gap analysis, compliance audits and patient incident?

PPP State of Pharmacy Compounding Survey (2009)
Would your employee be able to identify a gross error?

October 2006, Nevada
Hospital Pharmacy involved in fatal 1,000-fold Zinc overdose in TPN

- Scenario
  - Neonate TPN order for 330 mcg/100 mL of Zinc
  - RPh entered order in computer as 330mg/100mL
  - Tech prepares 500mL bag and changes zinc source container 11 times!
  - Bag checked by RPh
  - TPN bag hung @ 3am
  - Tech explained to oncoming tech # of Zinc syringes who checked the order and notified RPh

- Result/Outcome
  - Unit notified and Poison Control called
  - Calcium EDTA ordered but unsuccessful
  - Baby died from cardiac failure caused by zinc intoxication

- Root Cause:
  - Lack of employee training

http://www.ismp.org/newsletters/acutecare/articles/20070906.asp?ptr=y
Ways to evaluate your training

Consider evaluating your training activities in four key areas:

- **Is it appealing?**
  - Will staff want to engage in the training program, or view it as a “check the box” exercise? What can be done to improve appeal? Introducing new learning methods?

- **Is it dynamic?**
  - Is it updated to include recent changes (like the new chapter requirements!) or to reflect literature that has been published with best practices?

- **Is it practical and job related?**
  - Is there a clear linkage between what people need to do in their job, and the training they receive? Do staff receive feedback based on observations before and after training takes place?

- **Is it authoritative?**
  - Does the training reflect processes that take place at the facility, and do they accurately communicate the concepts and requirements of the chapter?
Common mistakes

- Identification based on what may appear to be important tasks
- Identification of excessive numbers of targeted competencies
- Not involving staff and making them responsible for their own competency verification
- Misconception: that it is required to check every behavioral and cognitive component required to do every job every year
- Plans demonstrating careful planning and result in limited number of targeted competencies are actually encouraged
Mythical Processes

• Does your organization have processes and practices that have mythical origins and leave current employees scratching their heads on why you do them?
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Components of successful program

- Consistent approach
- Flexibility to address individual and group needs
- Initial assessment and ongoing monitoring is appropriate to situation
  - Orientation for new staff
  - Initial staff
  - Tenured staff
- Expectations that employees will increase proficiencies in identified areas relative to job description
- Competencies identified and applied
  - Across entire organization (customer service)
  - For each specific job description (i.e., pharmacy tech and cleaning)
Excellence is an art won by training and habituation. We do not act rightly because we have virtue or excellence, but we rather have those because we have acted rightly. We are what we repeatedly do. Excellence, then, is not an act but a habit.

Aristotle
THANK YOU