

Sterile Compounding Training and Certification

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Disclosure

- There are no relevant financial or non-financial conflicts of interest in relation to this work.



Learning Objectives

- Review some of the regulatory requirements for sterile compounding training
- Outline one way to elevate team members to qualified evaluators of sterile compounding
- Identify an opportunity for team members to showcase their training in and understanding of sterile compounding



Abbreviations

- ACPE: Accreditation Council for Pharmacy Education
- APhA: American Pharmacist Association
- ASHP: American Society of Health-System Pharmacists
- BCSCP: Board Certified Sterile Compounding Pharmacist
- BPS: Board of Pharmacy Specialties
- CE: Continuing Education



Abbreviations

- CPhT: Certified Pharmacy Technician
- CSPT: Certified Compounded Sterile Preparation Technician
- IL: Illinois
- IV: Intravenous
- PPE: Personal Protective Equipment
- PTCB: Pharmacy Technician Certification Board



Abbreviations

- RUMC: Rush University Medical Center
- USP: United States Pharmacopeia
- USP-NF: United States Pharmacopeia-National Formulary



Review some of the regulatory requirements for sterile compounding training



Regulatory Requirements: USP<797> 2008

- “Adequately skilled, educated, instructed and trained”
- Trained by expert personnel
- Formal quality assurance program



USP. <797>. 2008: 36-78.

Regulatory Requirements: USP<797> 2008

- Initial and on-going:
 - Written test
 - Glove fingertip test
 - Media fill test
 - Hand hygiene and garbing
 - Cleaning
- Documentation: initially and annually
 - Remediation, re-test

Regulatory Requirements: IL Pharmacy Practice Act

- Section 1330.640 Pharmaceutical Compounding Standards
 - As of May 1, 2019: USP-NF
- Trained compounding personnel
 - Pharmacists (including pharmacy school students)
 - Pharmacy technicians (certified or not)

Regulatory Requirements: Technician Training Programs (Proposed)

- Proposed upcoming change
 - Required pharmacy technician training
- ASHP/ACPE accreditation standards for training (goals)
 - Understand preparation and process for sterile compounding
 - Prepare compounded sterile preparations

Regulatory Requirement: CSPT

- Eligibility (one or the other)
 - Recognized training program + one year of experience
 - Three years of experience
- Exam
 - Not just on aseptic technique

Regulatory Requirement: CSPT

- Renewal
 - Annually
 - 5 hours of sterile compounding CE



Question #1

The IL Pharmacy Practice Act Pharmaceutical Compounding Standards are governed by:

- A. FDA (Food and Drug Administration)
- B. CMS (Centers for Medicare & Medicaid)
- C. USP-NF (United States Pharmacopeia-National Formulary)
- D. TJC (The Joint Commission)



Outline one way to elevate team members to qualified evaluators of sterile compounding



Why have multiple experts?

- Regulatory visits
- Up to date documents
- Team accountability
- Competencies



Why have multiple experts?

- Quick evaluation and implementation
 - Drug shortages
 - Supply shortages
 - PPE shortages
 - Staffing shortages



RUMC Inpatient IVs Overview

- Adult
- Pediatric
- Chemotherapy
- Operating Room
- RIVA



RUMC IV Super-User Program

- Challenges to overcome
 - Competencies for a large number of team members
 - Staffing for adequate training
 - Growth opportunities within IV specialties
 - Peer to peer accountability
 - In depth understanding of regulatory requirements



RUMC IV Super-User Program

- Overview:
 - Adult IV training
 - Annual competencies



RUMC IV Super-User Program

- Eligibility criteria & expressed interest
- Super-user training and competencies
 - IV training
 - Competencies



RUMC IV Super-User Program

- Dry lab
 - Hand hygiene and garbing
 - Cleaning and material handling
 - IV supplies
 - Resource materials
 - Aseptic technique via practice labels



RUMC IV Super-User Program

- Hands-on training
- Initial competencies
- Annual Competencies
 - Glove fingertip testing
 - Media fill
 - Cleaning



RUMC IV Super-User Program

- Weekly check-ins during training
 - Feedback provided by trainees
- Review of documentation



Question #2

Which of the following is not a benefit to having multiple sterile compounding experts?

- A. Quick evaluation and implementation
- B. Regular team accountability
- C. Timely competency completion
- D. Quick sterile compounding technique

Identify an opportunity for team members to showcase their training in and understanding of sterile compounding

Pharmacist Example: BPS

- BCSCP
- “Validate a pharmacist’s advanced knowledge and experience”
- Offered twice a year

Pharmacist Example: BPS

- Eligibility
 - Graduation
 - License
 - Experience (4,000 hours)
- Exam
- Fees

Pharmacist Example: BPS

- Exam Domains 2021
 - “Standards, regulations, and best practices”
 - “Facilities, equipment, and environmental control”
 - “Compounded sterile preparations”
 - “Patient care”
 - “Quality management”

Pharmacist Example: BPS

- Recertification
 - Every 7 years
 - Fee
 - Either:
 - Exam (100 questions)
 - 100 hours of CE from APhA or ASHP

Pharmacist Example: ASHP

- Training and validation
- Online
- 38 hours of CE
- Comprehensive exam
- Fee

Pharmacist Example: ASHP

- Different learning styles
- 16 modules
 - BPS domains
- No renewal

Pharmacy Technician Example: PTCB

- Expertise, advanced knowledge, commitment
- Eligibility
 - CPhT
 - Either:
 - Education/training program for CSPT program + 1 year experience
 - 3 years of experience
- Fee



Pharmacy Technician Example: PTCB

- Exam
 - 75 questions, multiple choice (60 graded)
 - “Medications and components”
 - “Facilities and equipment”
 - “Sterile compounding procedures”
 - “Handling, packaging, storage and disposal”



Pharmacy Technician Example: PTCB

- Attestation form with qualified supervisor
 - Date of initial training
 - Date of most recent evaluation including:
 - Outcome
 - Feedback received
 - Qualified supervisor statement



Pharmacy Technician Example: PTCB

- Renewal
 - Annually
 - Attestation form
 - 5 hours of sterile compounding CE
 - Fee



Question #3

Which of the following is not a benefit to receiving an external certification/certificate in sterile compounding?

- A. Validate advanced knowledge
- B. Gain licensure
- C. Showcase expertise
- D. Demonstrate commitment

Conclusion

- Training is the foundation of quality and safety
- Impact of more than one expert
- Elevate team members through internal and external strategies

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Questions?

