



Compounding CE Event

Saturday September 19, 2015 10:00 AM – 3:00 PM

Topics/Speakers

2015 Sterile Compounding Law Update

David Seaver, JD, R.Ph.
Risk Manager
Brigham and Women's Hospital

Practical Pearls on USP <797> and Sterile Compounding

Denise A. Arena R.Ph.
Clinical Pharmacist Supervisor
Beth Israel Deaconess Medical Center

Peggy Stephan, M.S., R.Ph.
Clinical Pharmacist Supervisor
Beth Israel Deaconess Medical Center

Enhancing Sterile Compounding Services: A systems approach to practice transformations

Paul Baker Pharm.D., R.Ph.
Pharmacy Operations Specialist
Tufts Medical Center

Melissa Ortega, M.S., Pharm.D., R.Ph.
Assistant Director of Pharmacy
Tufts Medical Center

Pharmacy Sterile Compounding: Quality, Technology and Robots..... oh my!

Caryn Belisle MBA, R.Ph.
Director of Pharmacy Regulatory Compliance, Quality and Safety
Brigham and Women's Hospital



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Learning Objectives

At the end of this program, participants should be able to:

2015 Sterile Compounding Law Update

- Discuss timeline of NECC tragedy
- Review BoP regulations passed in November 2012
- Review Chapter 159 of Acts of 2014
- Discuss potential changes in regulation for both hospital pharmacies and hospital pharmacists
- Review federal legislation in wake of NECC

(1.0 contact hour – pharmacists and technicians)

ACPE # 0837-9999-15-085-L03-P/T

Practical Pearls on USP <797> and Sterile Compounding

- Provide a history on sterile compounding from the 1930's to present, including the inception of USP <797> and other regulatory chapters
- Review relevant USP <797> regulations and how to meet the standards
- Review risk levels and extended beyond-use dating
- Discuss environmental monitoring programs and remediation scenarios
- Review personnel training requirements and competency assessments
- Discuss the optimal use of policies, procedures and sterility/stability charts

(2.0 contact hours – pharmacists and technicians)

ACPE# 0837-9999-15-086-L01-P/T

Enhancing Sterile Compounding Services: A systems approach to practice transformations

- List the basic considerations of a high performing sterile compounding area
- Define the three key fundamentals of the systems approach to identify opportunities for improvement Describe the process of transition from current state to an ideal state
- Propose how to utilize insourcing as a business model to reach a high performing sterile products area

(1.0 contact hour – pharmacists and technicians)

ACPE# 0837-9999-15-087-L01-P/T

Pharmacy Sterile Compounding: Quality, Technology and Robots.....oh my!

- Describe the current state of compounding sterile products
- Demonstrate the use and need for an ongoing Quality Assurance Program
- Identify the current metrics of compounding sterile products in the pharmacy department
- Evaluate the use of technology to assist with upholding USP regulations

(1.0 contact hour – pharmacists and technicians)

ACPE# 0837-9999-15-088-L01-P/T



College of Pharmacy
Office of Continuing Education

Requirements for Receiving CE Credit:

- Successful completion of post-presentation questions
- Participation at live program
- Complete program evaluation form

Note: The process on how to claim credit will be made on the day of the program

Statement of disclosure: Disclosure will be made on the day of the program regarding any interest or affiliation a speaker may have with a supporting organization.



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