

# USP <800> – Deconstructed



## Course Details

**What:** USP <800> Deconstructed

**Where:** Hyatt Place St Paul/Downtown  
180 Kellogg Blvd. East  
Saint Paul, Minnesota,  
United States, 55101-1406

**When:** April 11 & 12 2019

**Tuition:** \$900.00

## Speakers and Featured Lectures:

### L. R. Dillon RPh

- Contamination Control in the Compounding
- Proper Usage of Engineering Controls and PPEs in the Compounding Pharmacy
- Documentation and Risk Assessment
- SOP Writing Workshop

### Shawn Valandra

- Facility Design

### Fagron Academy Staff

- Laboratory Cleaning Workshop

## USP <800> – Deconstructed

If you have questions about how to implement USP <800> in your practice, join Fagron Academy for a two-day course where you will learn from experts in the fields of cleanroom design, contamination control, ventilation technology and documentation writing to include an SOP writing workshop. We will break down the

chapter into manageable sections in which the experts can clarify the standard, answer your questions and help you make informed decisions. Included in this coursework, We are going to offer hands on training guided by our knowledgeable speakers in a simulated work environment.

This will demonstrate and give you a better understanding on how this standard will affect daily compounding processes from beginning to end. At the completion of this course you will have an increased understanding of how to implement and become compliant with USP <800>.



USP <800> Deconstructed – has been approved for 12 contact hours (1.2 CEUs) of continuing education credit. Attendees will be required to complete an online evaluation for each CE session they attend to verify attendance and acquire their CE. Attendees must provide their NABP e-Profile ID and birthdate (MMDD) to receive credit for any ACPE-accredited CPE session.

It is the responsibility of the CPE taker to give correct information. If incorrect information is provided, the record will be rejected by the CPE Monitor and the CPE credit will not be awarded. If you complete an online evaluation for each CE session you attend at the conclusion of the conference, your CPE credits will be uploaded to the CPE Monitor System within 60 days of completion. If you do not see CPE activity displayed for a session that you attended and it has been more than 60 days since you submitted the CPE to the provider, please contact your CPE provider.

All sessions carrying the ACPE program number are approved for continuing education credit. The American College of Apothecaries, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. USP <800> Deconstructed is co-sponsored by the American College of Apothecaries.



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## Presentations

Contamination Control in the Compounding Pharmacy		
Speaker: L.R. Dillon	UAN: 0201-9999-17-033-L04-P/T	Contact Hours (CEU): 1.5 (0.15)
Goals and Learning Objectives - Discuss training techniques for the proper cleaning of HD and Non-HD compounding areas - Recognize the importance of decontamination in the compounding laboratory - Identify products that best meet cleaning processes relevant to USP guidelines - Develop a plan to put cleaning and decontamination processes into practice in the HD environment		
Proper Usage of Engineering Controls and PPEs in the Compounding Pharmacy		
Speaker: L.R. Dillon	UAN: 0201-9999-17-031-L04-P/T	Contact Hours (CEU): 2.0 (0.2)
Goals and Learning Objectives - Provide basic understanding of engineering controls and their classifications in conjunction with USP <800> - Recognize and understand the role and functionality of engineering controls in the compounding laboratory - Discussion of PPEs and the requirements per USP <800>		
Documentation and Risk Assessment		
Speaker: L.R. Dillon	UAN: 0201-9999-17-035-L04-P/T	Contact Hours (CEU): 2.0 (0.2)
Goals and Learning Objectives - Discuss and recognize skills required for good documentation practices - Understand what should be included in personnel training - Identify risk and learn assessment tools		
Validating a Reusable and Disposable Garment Program Compliant with USP <797>/<795> and USP <800>		
Speaker: L.R. Dillon	UAN: 0201-9999-17-034-L04-P/T	Contact Hours (CEU): 1.0 (0.1)
Goals and Learning Objectives - Review and understand Section Seven of USP <800> - Discuss the process of selecting the correct garment systems for working in an ISO Class 5 compounding environment and a non-sterile compounding environment - Discuss how to integrate USP <800> garbing and SOP requirements		
SOP Writing Workshop		
Speaker: L.R. Dillon	UAN: 0201-9999-17-036-L04-P/T	Contact Hours (CEU): 1.0 (0.1)
Goals and Learning Objectives - Discuss the importance of writing, maintaining and updating Standard Operating Procedures (SOP) - Review and understand the necessary sections to include in an SOP - Create a sample SOP		
Facility Design		
Speaker: Shawn Valandra	UAN: 0201-9999-17-032-L04-P/T	Contact Hours (CEU): 2.0 (0.2)
Goals and Learning Objectives - Discuss and understand facility design - Review environmental quality and control - Discuss the appropriate selection of testing agencies - Recognize the challenges, training, equipment, and validation needed for in house testing - Examine and understand environmental contamination control and validation		
Laboratory Cleaning Workshop		
Speaker: Fagron Academy Staff	UAN: 0201-9999-17-037-L04-P/T	Contact Hours (CEU): 2.5 (0.25)
Goals and Learning Objectives - Review laboratory best practices, appropriate garbing and API containment guidelines as it relates to the NIOSH list - Demonstrate proper cleaning and decontamination procedures - Demonstrate using sensory techniques of contamination venues in the lab - Review and demonstrate proper use of engineering controls and the supporting logic		

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## Speakers

### L. R. Dillon RPh

L. Rad Dillon, R.Ph., ASQ CMQ/OE, ASQ CQA, ACHC/PCAB CAC. Rad has decades of experience in sterile and nonsterile hazardous drug compounding, including the development of SOPs and audit tools to monitor compliance with best practices and regulatory requirements regarding these drugs. He is an American Society for Quality (ASQ) Certified Manager of Quality and Organizational Excellence and an ASQ Certified Quality Auditor, and is also an ASQ Certified Six Sigma Green Belt. Rad is a Certified Accreditation Consultant for ACHC/PCAB. In the last five years, he has averaged one ACHC/PCAB surveying or consulting assignment per week involving hazardous drugs. He is the primary author of the PCAB Standard Operating Procedures for Non-Sterile & Sterile Compounding sold by ACHC/PCAB. He is also the informal chairperson for the Hazardous Drug, Nonsterile Compounding and Sterile Compounding Consensus Groups. He is the author of Accreditation University's Hazardous Drug Designated Person Certification offering. He is currently heavily involved in assisting pharmacies seeking compliance with the new revisions of USP chapters 795, 797 and 800, and delivering presentations on these topics to various audiences.

### Shawn Valandra

Shawn Valandra is the owner of SV Environmental Consulting (SVE) that specializes in industrial air filtration systems and USP <800> engineering compliance. Shawn's career as a filtration specialist in large industrial companies has spanned over two decades. He established SVE as a single-source provider to underserved and specialty niches such as nutraceuticals and compounding pharmacies. SVE's unique advantage is building a strong working knowledge of regulatory standards which serves as a valuable resource to their clients.

### Tom Wynn RPh

Tom Wynn is a graduate of the University of Cincinnati and began his career in compounding pharmacy as the pharmacist in charge at an independent compounding pharmacy in Ohio. As a Fagron Academy Consultant, Tom brings over 14 years of compounding experience to the consulting team. He is currently on faculty at the University of Cincinnati College of Pharmacy. Tom has a compounding focus in HRT, veterinary, and wound care. He has published multiple case studies in areas of wound, pain, and pediatrics. Tom has worked in community pharmacy practice setting the majority of his pharmacy career. He brings insight into common problems faced by compounders today. Tom is currently the director of Fagron Academy.

