Live vCourse: Best Practices for Handling Hazardous Drugs

This program teaches requirements of USP Chapter 800 as well as CriticalPoint Best Practices that are relevant to all aspects of handling hazardous drugs (HDs). Attending this class will help participants, including pharmacists and pharmacy technicians, develop and implement best work practices while they work to future-proof their facility for performing both nonsterile and sterile HD handling. Of particular note is the focus on the integration of USP 797 microbial-risk-reduction work practices with the additional requirements for containment of hazardous drugs. Participants must successfully complete selected eLessons prior to attending the live virtual training, which is presented in a fun and dynamic way by faculty with demonstrated expertise in handling hazardous drugs.

Program Dates (virtual)

February 16 – 18, 2021
May 11 – 13, 2021

Schedule (all times Eastern)

Tuesday

10:30 AM – 11:30 AM ***Overview of USP 800 and HD Handling*** (Faculty: Patricia Kienle)

Objectives:

- Cite examples of HD-exposure effects on persons who handle HDs.
- Describe the location of resources regarding HD practice.
- Recall common HD guidelines, standards, and regulatory and best practice events.
- List the major elements of USP 800.
- Differentiate between the scope of USP Chapters 795, 797, and 800.
- Describe current issues related to USP Compounding Chapter enforceability and compendial applicability.

ACPE UAN: JA0006454-0000-21-3517-L07-P/T; 1 credit hour; knowledge-based

11:45 AM – 1:00 PM ***Containment Secondary Engineering Controls (C-SECs): Cleanroom Suites and C-SCAs*** (Faculty: Adam West)

Objectives:

- Describe the types of compliant C-SECs for nonsterile and sterile HD compounding.
- Discuss considerations relevant to the use of pass-throughs in HD applications.
- Analyze the allowable but suboptimal design of C-SECs and strategies used to compensate for such.
- Describe the tests required for certification of C-SECs.

ACPE UAN: JA0006454-0000-21-3518-L07-P/T; 1.25 credit hours; application-based

1:30 PM – 2:30 PM ***Containment Primary Engineering Controls (C-PECs)*** (Faculty: Adam West)

Objectives:

- Describe the types of compliant C-PECs for nonsterile and sterile HD compounding.
- Describe the tests required for certification of C-PECs.

ACPE UAN: JA0006454-0000-21-3519-L07-P/T; 1 credit hour; knowledge-based

Wednesday

10:15 AM – 11:15 AM ***Donning, Doffing, and Types of Personal Protective Equipment (PPE)*** (Faculty: Melanie Dorey)

Objectives:

- List the best sequence in which to perform donning and doffing of HD PPE resulting in microbial protection of CSPs, HD containment, and protection of the worker.
- Differentiate between USP 800 requirements and CriticalPoint best practice recommendations.
- Evaluate proper donning and doffing practices.
- Identify garbing-technique best practices to reduce HD contamination.

ACPE UAN: JA0006454-0000-21-3520-L07-P/T; 1 credit hour; knowledge-based

11:30 AM – 12:15 PM ***Interactive Doffing Exercise*** (Faculty: Melanie Dorey)

Objectives:

- Compare doffing practices at your facility to presented best practices.
- Identify a best practice doffing sequence.

ACPE UAN: JA0006454-0000-21-3521-L07-P/T; 0.75 credit hours; knowledge-based

12:45 PM – 2:00 PM ***Work Practice Strategies for Receiving, Storing, Compounding, and Transporting HDs and HD CSPs*** (Faculty: Melanie Dorey)

Objectives:

- List the practice elements essential to reducing the generation of HD contamination and risk of exposure throughout the HD-use lifespan.
- Differentiate between USP 800 requirements and CriticalPoint best practice recommendations.
- Describe effective handling during compounding to ensure the final HD CSP container and packaging are free from HD contamination.
- Evaluate safe transport procedures for HD inventory and final CSPs.

ACPE UAN: JA0006454-0000-21-3522-L07-P/T; 1.25 credit hours; knowledge-based

2:15 PM – 3:15 PM ***Decontamination, Cleaning and Disinfection, and Residue Removal in HD Compounding Environments*** (Faculty: Abby Roth)

Objectives:

- Define and differentiate the terms deactivation, decontamination, cleaning, disinfection, and sanitization.
- Identify agents that may be used for decontamination of hazardous drugs.
- Properly sequence decontamination, cleaning and disinfection, and application of sterile IPA in HD environments.
- identify opportunities to modify decontamination, cleaning, and disinfection practices to ensure removal/containment of HD residue without compromising the state of microbial control.

ACPE UAN: JA0006454-0000-21-3523-L07-P/T; 1 credit hour; knowledge-based

Thursday

10:15 AM – 10:45 AM ***Interactive Exercise: Negative-Pressure Compounding Versus the Use of a CSTD*** (Faculty: Melanie Dorey)

Objectives:

- Differentiate simple syringe manipulations based on positive, negative, and CSTD strategies.
- Evaluate the time necessary to correctly perform negative-pressure compounding against the performance of potential supplemental engineering controls (ECs) at your location.
- Identify negative-pressure compounding-practice changes that may be needed at your location.

ACPE UAN: JA0006454-0000-21-3524-L07-P/T; 0.5 credit hours; knowledge-based

11:00 AM – Noon ***Elements and Practical Examples of Performing an Assessment of Risk (AoR)*** (Faculty: Patricia Kienle)

Objectives:

- List which drugs may be exempted from full containment and work practices of USP 800.
- Define the components required in an AoR.
- Evaluate different approaches to the creation and maintenance of an AoR.
- Discuss specific examples of AoR strategies from actual practice.

ACPE UAN: JA0006454-0000-21-3525-L07-P/T; 1 credit hour; knowledge-based

12:30 PM – 1:00 PM ***Response to HD Exposure and Spills*** (Faculty: Patricia Kienle)

Objectives:

- List the required elements of an exposure control and response plan.
- Discuss the requirements for HD spill cleanup.

- Describe the logistical and practical hurdles that can be encountered in implementing an effective spill management program.
- List potential strategies for effective spill management.

ACPE UAN: JA0006454-0000-21-3526-L07-P/T; 0.5 credit hours; knowledge-based

1:00 PM – 1:45 PM ***Interactive Exercise: Design and Build Evaluation of Facilities Intended for HD Compounding***
(Faculty: Abby Roth, Adam West)

Objectives:

- Evaluate sample layouts, and identify areas of concern relative to USP 797 and 800 compliance, efficiency of workflow, and best practice considerations.
- Revise sample layouts to ensure improved compliance, efficiency, and achievement of best practices.

ACPE UAN: JA0006454-0000-21-3527-L07-P/T; 0.75 credit hours; knowledge-based

Credit for Pharmacists and Pharmacy Technicians

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Faculty Biographies

Joe Coyne, RPh, currently serves as the Director of Field Operations for Kastango Consulting Group LLC where he has been since 2017. Before joining forces with the KCG team, Joe served as President and CEO of Coyne Consulting. Joe has practiced pharmacy in many different capacities and settings, including hospitals, community-based retail, long-term care, hospice, and home care. Joe is a trusted speaker who has presented nationally and internationally on various pharmacy-practice topics, such as pharmacy compounding, hazardous drug handling, and quality standards. He is also currently serving as a faculty member at the CriticalPoint Center for Training and Research® (CCTR). Joe continues to contribute to numerous industry publications. He is also an active member of the American Society of Health-System Pharmacists (ASHP). Joe received his Bachelor of Science degree in Pharmacy from the Philadelphia College of Pharmacy and Science where he served as Clinical Preceptor and an Adjunct Senior Clinical Professor of the Department of Pharmacy Practice. Joe received his Compounded Sterile Preparations Certification from the Board of Pharmacy Specialties in the fall of 2019 as a member of its inaugural class.

Kimberly Coughlin, B.S., RCP-SCF, NSF-49, currently serves as the Director of Microbiology for KCG, joining in early 2019. In her role, she provides consultation on environmental monitoring, remediation, and facility design performance. Kimberly is also responsible for reviewing regulatory compliance and performing onsite gap analysis at client facilities and audits of client vendors. Kimberly has over 20 years of experience in microbiology laboratory testing, environmental monitoring, field testing, and certification of engineering controls in the pharmaceutical, medical device, research, and sterile compounding industries. Since 2015, Kimberly has served as a Director on the Controlled Environment Testing Association (CETA) Board of Directors. She is the 2019–2021 President-elect for CETA and Program Chair for the 2020 and 2021 annual meetings. Kimberly also serves as a subject matter expert (SME) for the CETA National Board of Testing's (CNBT) Registered Certification Professional — Sterile Compounding Facilities (RCP-SCF) accreditation program. Kimberly received her Bachelor of Science degree in Environmental Science from Westfield State College. She received NSF Accreditation for the Field Certification of Class II Biosafety Cabinets and CETA accreditation as a Registered Certification Professional — Sterile Compounding Facilities.

Melanie Dorey, RPhT, QP503A, is the Compounding Learning and Product Specialist at CriticalPoint LLC and is licensed in Canada as a Pharmacy Technician. She graduated in 2006 from La Cite Collegiale from a two-year Pharmacy Technician program specializing in sterile compounding and has been continuously employed as a technician at a pediatric hospital since that time. Melanie has served as an aseptic teacher (practical and theory) at an accredited pharmacy technician college in Ottawa since 2010. She has been working with CriticalPoint since 2015, where she is currently the lead faculty for sterile compounding aseptics and serves as the lead SME in nonsterile compounding. Melanie develops SOPs and eLessons as well as virtual and live face-to-face training curricula.

Eric S. Kastango, M.B.A., B.S.Pharm., FASHP, is president of Kastango Consulting Group LLC, a health-care consulting firm, and CriticalPoint, LLC, a web-based education company. Mr. Kastango received his Bachelor of Science degree in pharmacy from the Massachusetts College of Pharmacy and Allied Health Sciences and his Master of Business Administration degree from the University of Phoenix. He completed 65 hours of training in nuclear pharmacy at Purdue University and 80 hours of didactic training for the Six Sigma Green Belt certification that he started with BD Medical Systems. Since 1980, he has practiced pharmacy in a number of practice settings, including hospitals, community, and home care, and in a number of different of roles, including the Corporate Vice President of Pharmacy Services for Coram Healthcare Corporation. He has also managed an FDA-registered cGMP manufacturing operation for Baxter Healthcare Corporation. He is an active member and Fellow of the American Society of Health-System Pharmacists and served on the USP Sterile Compounding Committee from 2005–2010, and 2010–2015 USP Council of Experts, Compounding Expert Committee until April 2013. In May 2013, USP recognized Eric and the members of Compounding Expert Committee with an Award for Outstanding Contribution to the USP standards-setting process. He has served on the USP Hazardous Drug Expert Panel since 2010 and is actively working with NABP and state boards of pharmacy to provide training to their sterile compounding inspectors. Eric also served on the Expert Panel for ASHP Research & Education Foundation in the development of the 2015 Outsourcing Sterile Products Preparation Vendor Assessment Tool and ASHP's Insourcing Readiness Assessment Tool.

Patricia Kienle, RPh, MPA, BCSCP, FASHP, is the Director of Accreditation and Medication Safety for Cardinal Health. Patti has presented over 500 talks on medication safety, compounding, regulatory, and accreditation issues. She is the author of *The Chapter <795> Answer Book, The Chapter <797> Answer Book*, and *The Chapter <800> Answer Book* and co-author of *Meeting Accreditation Standards: A Pharmacy Preparation Guide*. Patti is a member of the USP Compounding Expert Committee and chairs the subcommittee on hazardous drugs. Patti has been a valued part of the CriticalPoint live training faculty for over a decade.

Mary Nazzal, Pharm.D., BCSCP., is the Associate Director of Field Operations for Kastango Consulting Group. She received her PharmD degree from Butler University of Indianapolis and has completed the Nuclear Pharmacy Certificate Program at Purdue University. Mary received her Compounded Sterile Preparations Certification from the Board of Pharmacy Specialties in the fall of 2019 as a member of its inaugural class. She has over 14 years of progressive and diverse hospital pharmacist experience, including administrative, inpatient pharmacy, de-centralized pharmacy, and operating room, with a focus in sterile compounding. She performs gap analysis, facility design development, and review of construction documents for clients to ensure regulatory compliance as well as provide best practice recommendations regarding sterile compounding.

Abby Roth, CMQ/CO, QP503A qualified, is the Senior Director of Business Operations at CriticalPoint. In addition to operational responsibilities, she develops content for CriticalPoint's eCurriculum and live onsite and live virtual training classes. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring, including program development, sampling technique, sample analysis, and data trending. Abby also has experience in consulting on microbial contamination sources and remediation. She served on the USP Compounding Expert Committee during the 2015–2020 cycle.

Adam West, RCP-SCF, NSF-49, is the Environmental Monitoring and Training Specialist at CriticalPoint, where he is responsible for the development and delivery of live onsite, virtual, and eLesson curricula related to aspects of primary and secondary engineering controls and certification. Adam has over ten years of experience in the certification industry providing Field Certification Services for 503A and 503B sterile compounding facilities and pharmaceutical and medical device manufacturers. Adam also has expertise in viable environmental monitoring, including sampling plan development and remediation. Adam holds the Registered Cleanroom Certification Professional – Sterile Compounding Facilities (RCCP-SCF) certification and NSF-49 accreditation.