Live vCourse: Best Practices for Nonhazardous Sterile-to-Sterile Compounding

The program is intended as the fundamental and initial offering of the CriticalPoint Sterile Boot Camp® Live Onsite and Live Virtual Training Series. This course is suitable for pharmacists, pharmacy technicians, and those who manage or perform sterile compounding as well as for others who may be involved with the sterile compounding industry. The Best Practices class builds a comprehensive understanding of regulatory requirements as well as best practices for nonhazardous sterile-to-sterile pharmacy compounding. Though the emphasis is on sterile compounding best practices, it covers the current USP 797 requirements (2008 version) as well as the version of the chapter published June 1, 2019.

Program Dates (virtual)

January 25 – 29, 2021
April 12 – 16, 2021
June 14 – 18, 2021

Schedule (all times Eastern)

Monday

11:00 AM – Noon ***Contamination Control: Engineering and Work Practice Principles***
(Faculty: Melanie Dorey, Mary Nazzal, Abby Roth, Adam West)

Objectives:

- Define microbial state of control as the overall goal of facility maintenance in sterile compounding practice.
- List engineering-related contamination-control principles of cleanroom suites and segregated compounding areas (SCAs).
- List the three categories of work practices fundamental to contamination control.

ACPE UAN: JA0006454-0000-21-3501-L07-P/T; 1 credit hour; knowledge-based

12:30 PM – 2:30 PM ***Sterile-to-Sterile Compounding*** (Faculty: Eric Kastango)

Objectives:

- Identify situations that are "not compounding" and the new immediate-use category defined in USP 797 (2019), and contrast them with the 2008 requirements.
- Differentiate between Category 1 and 2 BUDs described in USP 797 (2019) from the risk levels in the 2008 USP 797 (currently enforceable).
- Compare and contrast the 2008 versus 2019 requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages.
- Contrast drug-strength testing with stability-indicating methods for drug stability.
- Define compounding records versus master formulation records, and describe CriticalPoint best practices for their implementation.
- Describe quality release testing for nonhazardous sterile-to-sterile compounding.

ACPE UAN: JA0006454-0000-21-3502-L07-P/T; 2 credit hours; knowledge-based

Tuesday

10:15 AM – 12:30 PM (includes a 15-minute break at 11:15 AM)

Secondary Engineering Controls for Nonhazardous Sterile Compounding (Faculty: Adam West)

Objectives:

- Describe the functions of SECs used for nonhazardous sterile compounding, and list the USP 797 requirements of each.
- Explain how proper facility design facilitates the maintenance of a state of control.
- Differentiate between ISO 5, 7, and 8 area cleanliness and particulate counts.
- Explain the rationale for and describe how to apply best practice design elements to your compounding facility.

ACPE UAN: JA0006454-0000-21-3503-L07-P/T; 2 credit hours; knowledge-based

1:00 PM – 2:15 PM ***Contamination Control: Hand Hygiene and Garbing*** (Faculty: Melanie Dorey)

Objectives:

- Properly sequence the activities of hand hygiene and garbing for nonhazardous sterile compounding based on the location of the sink.
- Differentiate between the garbing requirements of USP 797 2008, USP 797 2019, and best practice recommendations.

ACPE UAN: JA0006454-0000-21-3504-L07-P/T; 1.25 credit hours; knowledge-based

2:30 PM – 3:00 PM ***Contamination Control: Material Handling*** (Faculty: Melanie Dorey)

Objectives:

- Differentiate between the USP 797 2008, USP 797 2019, and best practice material-handling recommendations.
- Identify contamination-control best practices to integrate into your own facility SOPs and work practices.
- Describe strategies for staging batches and patient preps not addressed by USP 797.

ACPE UAN: JA0006454-0000-21-3505-L07-P/T; 0.5 credit hours; knowledge-based

3:00 PM – 3:30 PM ***Initial Gloved Fingertip Sampling*** (Faculty: Abby Roth)

Objectives:

- Describe the difference between solid and liquid media, and identify what each is used for by sterile compounding organizations.
- Identify and explain the critical components of a certificate of analysis.
- List the conditions and steps to successful initial GFS.
- Differentiate between the minimum requirements and best practice recommendations for personnel sampling.
- Explain necessary corrective actions and additional training in the event of initial GFS failures.

ACPE UAN: JA0006454-0000-21-3506-L07-P/T; 0.5 credit hours; knowledge-based

Wednesday

10:15 AM – 11:30 AM ***Primary Engineering Controls for Nonhazardous Sterile Compounding*** (Faculty: Adam West)

Objectives:

- Differentiate between nonhazardous PECs, and identify airflow characteristics of each.
- Differentiate between unidirectional and turbulent airflow, and describe how to determine whether a PEC is appropriate for sterile compounding.
- Describe factors important for proper integration of PECs into facilities to ensure optimum workflow and equipment functionality.
- Discuss appropriate applications and limitations of the PECs used for sterile compounding.
- Explain HEPA filtration and how it applies to the principles of airflow.
- Correlate airflow principles to compounding, and describe how proper aseptic technique relates to first air.

ACPE UAN: JA0006454-0000-21-3507-L07-P/T; 1.25 credit hours; knowledge-based

11:45 AM – 12:45 PM ***Aseptic Work Practice Review*** (Faculty: Melanie Dorey)

Objectives:

- Define segregation and area clearance and how these concepts improve patient safety and reduce the potential for error.
- List the “dos and don’ts” of worker conduct both inside the perimeter of the SCA and inside of the cleanroom suite.
- Describe the care/maintenance of the staging cart and the proper way to move items from the staging cart into the PEC.
- List the influences on first air and how proper ergonomics, setup of supplies, and aseptic work practices reduce the risk of contamination.
- Describe a best practice strategy for removing finished CSPs from the compounding area.

ACPE UAN: JA0006454-0000-21-3508-L07-P/T; 1 credit hour; knowledge-based

1:15 PM – 2:15 PM ***PEC, SEC, and Aseptic Work Practices Lab*** (Faculty: Melanie Dorey, Adam West)

Objectives:

- Analyze the ideal sterile compounding facility design and workflow to ensure efficiency and compliant material transfer into the SEC.
- Evaluate dynamic airflow smoke-pattern test results and use the results to improve compounding technique and work practices.
- Identify proper hand positioning during compounding for both vertical and horizontal airflow PECs.
- Discuss proper transfer of components and supplies into the PEC.

ACPE UAN: JA0006454-0000-21-3509-L07-P/T; 1 credit hour; application-based

2:15 PM – 3:00 PM ***Media-Fill Testing and Subsequent Gloved Fingertip Sampling*** (Faculty: Abby Roth)

Objectives:

- Describe under what conditions surface sampling becomes a personnel metric rather than an environmental metric.
- Differentiate between the minimum requirements and best practice recommendations for personnel sampling.
- Summarize the importance of personnel and process media-fill testing as verification of the aseptic-technique skills of staff and the compounding process.
- Define the design requirements of a personnel aseptic media-fill and media-process verification.
- Describe the best practice integration of media-fill testing, surface sampling, and subsequent GFS.
- Explain necessary corrective actions and additional training in the event of media-fill or GFS failures.

ACPE UAN: JA0006454-0000-21-3510-L07-P/T; 0.75 credit hours; knowledge-based

Thursday

10:15 AM – 11:45 AM ***Testing and Certification of PECs and SECs*** (Faculty: Adam West)

Objectives:

- Describe the role certification plays in ensuring patient safety.
- Summarize documentation requirements of applicable certification tests.
- List required best practice reporting components to ensure your facility receives a comprehensive certification report.
- Discuss certification testing so that you can confidently communicate with the certification technician and facilities personnel.

ACPE UAN: JA0006454-0000-21-3511-L07-P/T; 1.5 credit hours; knowledge-based

12:15 PM – 1:30 PM ***Sterility and Bacterial Endotoxin Testing and Overview of Rapid Microbial Testing*** (Faculty: Adam West)

Objectives:

- Describe the difference between direct inoculation and membrane filtration USP 71 sterility testing, and list the benefits of using membrane filtration.
- Identify the user-requirement specifications of rapid testing and how they relate to taking a risk-based approach to rapid sterility testing.
- Explain the need to perform bacterial endotoxin testing on CSPs prepared in your organization.

ACPE UAN: JA0006454-0000-21-3512-L07-P/T; 1.25 credit hours; knowledge-based

1:45 PM – 3:15 PM ***Sanitization of Sterile Compounding Primary and Secondary Engineering Controls*** (Faculty: Melanie Dorey)

Objectives:

- Differentiate between the requirements of USP 797 2008, USP 797 2019, and best practices for sanitization.
- Discuss principles related to the selection and use of cleaning agents and supplies.

- Properly sequence critical activities of daily and monthly cleaning.
- List personnel safety, training, and competency considerations.
- Describe SOP and documentation requirements.

ACPE UAN: JA0006454-0000-21-3513-L07-P/T; 1.5 credit hours; knowledge-based

Friday

10:15 AM – 11:30 AM ***Environmental Monitoring*** (Faculty: Abby Roth)

Objectives:

- Outline a model ongoing-EM program, including the identification of baseline and action levels of microbial growth.
- List the conditions and steps to conduct viable air and surface sampling.
- Explain the proper use of equipment and supplies for air and surface sampling.
- Identify the chapter requirements for investigating an exceeded action level.

ACPE UAN: JA0006454-0000-21-3514-L07-P/T; 1.25 credit hours; knowledge-based

11:45 AM – 12:45 PM ***Quality Systems for Sterile Compounding*** (Faculty: Abby Roth, Mary Nazzal)

Objectives:

- Define quality assurance and quality control, including essential elements of a formal QA/QC system for your organization.
- List steps for notification and recall of out-of-specification dispensed CSPs.
- Develop a comprehensive, systematic, and written complaint-handling system.
- Describe the role of personnel training as it relates to quality assurance.
- Summarize how SOPs, documentation, and a change control system are critical to USP 797 compliance.

ACPE UAN: JA0006454-0000-21-3515-L07-P/T; 1 credit hour; knowledge-based

1:15 PM – 2:15 PM ***Case Study Lab*** (Faculty: Melanie Dorey, Abby Roth, Adam West)

Objectives:

- Apply USP 797 standards and CriticalPoint best practice recommendations to determine appropriate work practices and facility design.
- Identify possible hand hygiene and garbing procedures based on the location of the sink.
- Develop a robust material handling and sanitization program to ensure a microbial state of control.
- Propose the certification testing required for a cleanroom suite and LAFW.

ACPE UAN: JA0006454-0000-21-3516-L07-P/T; 1 credit hour; application-based

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Course Information, Goals and Objectives

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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.