# Best Practices for Environmental Monitoring

## Course Information, Goals, and Objectives

This class will immerse participants in the world of Environmental Monitoring (EM). This live training will review everything you need to know to perform EM at your facility. Through engaging lectures and real-life labs and work practices, you will learn how to develop a meaningful EM plan, perform viable air and surface sampling, read results, and analyze and interpret EM reports. Attendees will have the opportunity to receive an Environmental Monitoring Certificate and a Reading Media Certificate.

**Program Dates**

September 13–16, 2021

**Schedule (all times Eastern)**

*Monday*

9:00–10:30 AM **General Concepts of Environmental Monitoring (EM)** *(Faculty: Adam West)*

Objectives:

- Summarize the importance of having a robust environmental monitoring program.
- Discuss the limitations of EM and how those affect program design.
- Identify and source applicable guidance documents.
- Select the appropriate sampling media based on pharmacy needs.
- Critique media manufacturers to identify those that provide reputable products.
- Describe why a pharmacy would need to perform growth promotion testing.

*ACPE UAN: JA0006454-0000-21-3545-L07-P/T; 1.5 credit hours; knowledge-based*

10:45 AM–Noon **Creating an Effective and Compliant Environmental Monitoring Program** *(Faculty: Adam West)*

Objectives:

- List the key elements of an environmental monitoring program.
- Differentiate between required and best practice components of an EM program.
- Identify the standard operating procedures (SOPs) and forms necessary to document the process.

*ACPE UAN: JA0006454-0000-21-3546-L07-P/T; 1.25 credit hours; knowledge-based*

12:45–1:45 PM **Developing a Sampling Plan** *(Faculty: Abby Roth)*

Objectives:

- Select sampling locations that will provide valuable data for making decisions that affect compounding operations.
- Describe why the ability to explain rationale used for determining sampling locations to surveyors and inspectors is essential to the success of the program.
- Discriminate between ad hoc and trended samples.

*ACPE UAN: JA0006454-0000-21-3547-L07-P/T; 1 credit hour; knowledge-based*

1:45–2:45 PM **Interactive Exercise: Developing a Sampling Plan** *(Faculty: Abby Roth, Adam West)*

Objectives:

- Identify a sampling plan that complies with USP 797 and incorporates best practices.
- List the elements of user-friendly documentation used during the sampling session.
- Describe why the development of the sampling plan should be a group effort.

*ACPE UAN: JA0006454-0000-21-3548-L07-P/T; 1 credit hour; application-based*

3:00–3:45 PM **Air and Surface Sampling Technique** *(Faculty: Adam West)*

Objectives:

- Describe how to select the appropriate sampling equipment based on sterile compounding pharmacy's needs.
- Identify aseptic techniques related to the handling, packaging, and use of media.
- Summarize the steps for using a viable air sampler.
- Discuss when and how to reuse opened media.

*ACPE UAN: JA0006454-0000-21-3549-L07-P/T; 0.75 credit hours; knowledge-based*

3:45–4:45 PM **Interactive Exercise: Demonstration and Practice** *(Faculty: Abby Roth, Adam West)*

Objectives:

- Perform all elements of viable air and surface sampling.
- Recognize proper sampling technique to avoid inadvertent contamination of the sampling media.

*ACPE UAN: JA0006454-0000-21-3550-L07-P/T; 1 credit hour; application-based*

*Tuesday*

8:15–9:15 AM **Interactive Exercise: Best Practice Technique for Donning Sterile Gloves** *(Faculty: Abby Roth, Adam West)*

Objectives:

- Determine proper glove sizing.
- List the requirements for sterile gloves and packaging.
- Master the nuances of donning sterile gloves.

*ACPE UAN: JA0006454-0000-21-3551-L07-P/T; 1 credit hour; application-based*

9:15–10:15 AM **Sampling Session Workflow** *(Faculty: Adam West)*

Objectives:

- List and prepare all equipment, materials, and documentation needed for the sampling session.
- List the steps to execute an EM session in the proper order to reduce the risk of contaminating samples and the compounding environment.
- Explain the steps to prepare samples for incubation and laboratory submission.

*ACPE UAN: JA0006454-0000-21-3552-L07-P/T; 1 credit hour; knowledge-based*

10:30 AM–12:30 PM **Interactive Exercise: Sampling Session Workflow** *(Faculty: Abby Roth, Adam West)*

Objectives:

- Discuss how to prepare media, equipment, and other components for entry to the controlled environments.
- Describe best practice garbing.
- List sampling session workflow for a sterile compounding pharmacy.
- Identify where to place the air sampler in relation to the direct compounding area (DCA), pass-throughs, equipment, and people.

*ACPE UAN: JA0006454-0000-21-3553-L07-P/T; 2 credit hours; application-based*

1:15–2:45 PM **Incubation and Reading Samples** *(Faculty: Abby Roth)*

Objectives:

- List appropriate times and temperatures for sample incubation.
- Identify a sterile compounding pharmacy's ability to incubate and read samples in-house.
- Distinguish between samples that require further evaluation and identification by a laboratory.
- Request the appropriate testing for samples that require identification to the genus level.
- Discuss the process for counting colonies recovered during the viable sampling session.

*ACPE UAN: JA0006454-0000-21-3554-L07-P/T; 1.5 credit hours; knowledge-based*

3:00–4:30 PM **Interactive Exercise: Reading Media** *(Faculty: Abby Roth)*

Objectives:

- Describe the steps to inspect and read samples correctly.
- Recognize the different colony morphologies of microorganisms commonly found in the sterile compounding environment.
- Determine when a sample's count should be verified by another staff member.

*ACPE UAN: JA0006454-0000-21-3555-L07-P/T; 1.5 credit hours; application-based*

*Wednesday*

8:15– 9:00 AM **Choosing a Laboratory** *(Faculty: Abby Roth)*

Objectives:

- List the characteristics of a laboratory to ensure testing meets USP 797 requirements.
- Identify common microbiology terms that will allow you to confidently discuss testing and results with the laboratory.
- Recognize the essential components of a testing report.

*ACPE UAN: JA0006454-0000-21-3556-L07-P/T; 0.75 credit hours; knowledge-based*

9:00–10:00 AM **Interactive Exercise: Review and Analysis of Laboratory Reports**

*(Faculty: Adam West)*

Objectives:

- Evaluate laboratory reports for missing and incorrect information.
- Interpret laboratory results to determine if they are acceptable, and identify next steps in the event there is an exceeded action level.

*ACPE UAN: JA0006454-0000-21-3557-L07-P/T; 1 credit hour; application-based*

10:15–11:00 AM **Trending Environmental Monitoring Data** *(Faculty: Abby Roth)*

Objectives:

- Define trending as it relates to environmental monitoring in a sterile compounding pharmacy.
- Discuss the importance of analyzing microbial trends over time.
- Identify a meaningful trending program that incorporates a variety of techniques, including the use of recovery rates.

*ACPE UAN: JA0006454-0000-21-3558-L07-P/T; 0.75 credit hours; knowledge-based*

11:00 AM–12:15 PM **Investigation and Remediation** *(Faculty: Abby Roth)*

Objectives:

- Discuss investigation tools and remediation actions that can be applied to the sterile compounding environment.
- Determine the significance of the types of organisms recovered.
- Evaluate the report results to determine the proper remediation actions.

*ACPE UAN: JA0006454-0000-21-3559-L07-P/T; 1.25 credit hours; knowledge-based*

1:00–4:00 PM **Interactive Exercise: Environmental Sampling Practice Session**

*(Faculty: Abby Roth, Adam West)*

Objectives:

- Prepare all equipment, materials, and documentation needed for the session.
- Execute an environmental monitoring session.
- Describe the steps to prepare samples for incubation and laboratory submission.

*ACPE UAN: JA0006454-0000-21-3560-L07-P/T; 1 credit hour; application-based*

*Thursday*

8:15– Noon **Competency Testing (no CE)**

1. **Hand hygiene and garbing with gloved fingertip sampling**
2. **Environmental sampling**
3. **Reading media**

*(Faculty: Abby Roth, Adam West)*

Objectives:

- Successfully perform hand hygiene, garbing, and one instance of "initial" gloved fingertip sampling as well as the hand hygiene and garbing competency.
- Successfully execute an abbreviated environmental monitoring session using proper sampling technique.
- Successfully count environmental monitoring samples.

**Credit for Pharmacists and Pharmacy Technicians**

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, TRC Healthcare is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

**Statement of Participation/Course Completion**

Credit will be awarded to participants who attend the course, submit a course evaluation within 20 days of the date of participation, and have provided an accurate NABP e-Profile ID and DOB. Participants who have successfully completed this course AND have provided accurate NABP e-Profile information, including month and day of birth, will have their CE credits submitted to CPE Monitor.

Florida-licensed pharmacists and pharmacy technicians: Course completions will be reported to CE Broker if the participant has successfully fulfilled all course completion requirements AND has provided the name and license number that matches what is on file with the Florida Board of Pharmacy. If this information is not provided within 20 days of the date of the activity, the participant will be responsible for manually uploading their completion to CE Broker.

It is the participant's responsibility to verify credit is accurately posted to CPE Monitor and CE Broker (if applicable). Participants who have questions about their credit or do not see their credit on CPE Monitor (or CE Broker, if applicable) 20 days after their participation should contact TRC. Requests received after day 30 may not receive credit. Official statements of credit are only available from CPE Monitor.

Credit for a specific course can only be awarded a single time. If you have previously completed a course as part of another program, you will only receive credit the first time the course is completed.

**CriticalPoint/TRC Healthcare Faculty, Editors, & Staff**

**Sarah Andresen**
Director of Marketing & Communications

**Tammie Armeni, RPh, PharmD**
Editor, Senior Director of Continuing Education & Content Management

**Trish Cipoletti**
Quality Control Manager

**Colene West**
Continuing Education Content & Regulatory Affairs Supervisor

### Disclosures

The faculty, reviewers, and editors of this activity and its publisher, TRC Healthcare (TRC), have no relevant financial interests related to the products or services covered by this activity. All relevant financial relationships, when present, have been mitigated. TRC focuses on delivering completely objective, unbiased drug information and advice for the benefit of subscribers.

Users of this activity are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical or legal judgments. Information and internet links in this activity were current as of the date of publication.

### Cost

The fee for this activity is available online. Register at https://www.criticalpoint.info/activities/.

### Software/Hardware Requirements

This activity can be viewed on any device with an internet connection using one of the following browsers:

- Google Chrome, most recent stable version. Google Chrome applies updates automatically; TRC makes every effort to test and support the most recent version. No configuration recommendations.
- Mozilla Firefox, most recent stable version. TRC makes every effort to test and support the most recent version. No configuration recommendations.
- Microsoft Internet Explorer version 11. Apply all Microsoft updates. Outdated versions of Internet Explorer may result in issues with the connection and impact learning.
- Apple Safari versions 5.x, 6.x and 7.x on Mac OS X. No configuration recommendations.

NOTE: For all browsers, you must have JavaScript and cookies enabled. To view PDFs, you will need a PDF-capable browser or standalone PDF viewer.

### Your Privacy

In order to provide you with continuing education, Therapeutic Research obtains information such as your name, address, email address, phone number, payment information, etc. We treat this information as confidential and use it to provide you with the best service possible. Therapeutic Research has NEVER released any of this information to any outside organization for such organization's own commercial or marketing use and has a policy against doing so. We do not engage in renting out, selling, or trading names of subscribers or any information about any subscriber.

To provide you with valuable services, we will occasionally employ third parties to meet your needs. In such cases, only the information needed to meet your need will be shared with the outside organization. Therapeutic Research only employs third parties that have similarly protective privacy policies. We do not allow any other organization to send you unsolicited emails about any products or services. We might send you information about your subscription, your continuing education credits, or our own drug information services. We do not gather data or track your web usage of any websites other than our own. For further information see our Privacy Policy, or submit a request at http://info.therapeuticresearch.com/privacyofficer.

## Faculty Biographies

**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.

Therapeutic Research Center, Tel: (209) 472-2240 Fax: (209) 472-2249
Copyright © 1995-2021 All rights reserved. Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments. Information and internet links in this document were current as of the date of publication.