

## **KIMBERLY A COUGHLIN**

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### **PROFESSIONAL EXPERIENCE**

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**B&V Testing, a Cantel Service**  
(formerly B&V Testing, a Stericycle Business)  
Waltham, Massachusetts

**August 2015 – November 2018**

**Manager, Microbiology Services and Technical Reporting** 06/2017 - 11/2018

- Took on responsibility to restructure the microbiology laboratory and its personnel due to ongoing performance issues
- Performed quality and technical assessment of the microbiology laboratory, successfully implemented corrective and preventative actions for continuous improvement initiatives
- Restructured the laboratory reporting process, successfully improved upon accuracy and turnaround times for laboratory reports and client results notifications
- Oversaw compliance with regulatory requirements and industry best practices for the processing of laboratory samples and reporting of results
- Acquired new talent for the laboratory team, increased laboratory technical and regulatory competency and quality of service through continuous technical training, mentoring and coaching
- Responsible for overseeing and directing laboratory management in preparing for ISO 17025 accreditation
- Drafted a business plan for the microbiology laboratory transformation to operate as its own business unit, expand service offerings, increase revenue, develop and promote team members
- Designed a new microbiology laboratory for the company relocation and expansion, prepared relocation plan to avoid disruption of laboratory services
- Monitored departmental productivity and reviewed weekly laboratory metric reports, developed and implemented process improvements to create effective and efficient work flows
- Monitored departmental spending, budgeted for current and future capital equipment needs
- Collaborated with the Technical Services Director to create, revise and restructure quality and technical policies and procedures, prepare technical notifications, improve technical training programs, review regulatory requirements, and provide clients with regulatory support

**Manager, Technical Reporting**

08/2015 – 06/2017

- Responsible for managing the Technical Reporting department operations, development and implementation of report documentation plans for certification and decontamination services to ensure the quality and timely delivery of the final reports in compliance with client expectations and stated deliverables

- Established and successfully accomplished the Technical Reporting departmental goal to eliminate the existing report backlog, exceeded expectations for stated deliverables
- Restructured the organizational flow within the reporting department, created opportunities for team member advancement and development
- Created a positive culture within the reporting department, provided coaching on conflict resolution, developed successful performance improvement plans, coached and mentored employees to develop career and educational goals
- Mentored and promoted a reporting department team member to a supervisory role
- Monitored departmental productivity, reviewed and improved upon weekly metric reports, created measurable and meaningful data, developed and successfully implemented process improvements to create effective and efficient work flows
- Reviewed field documentation forms and report templates for compliance with applicable regulatory requirements
- Performed quality reviews of final certification and decontamination reports
- Worked with clients to resolve engineering control performance issues, provided guidance on remedial efforts, answered technical questions
- Provided field support with environmental monitoring, decontamination and engineering control testing and certification
- Served as the lead technical authority on environmental monitoring, laboratory analysis issues and remediation support
- Worked with top clients to develop meaningful environmental monitoring programs and effective remediation plans
- Restructured the EM training program, effectively increased the competency of field technicians by provided training, evaluations of field staff performance and feedback and recommendations to field staff management
- Performed incubation and laboratory analysis of EM, media fill and BI samples, gram staining and supplemental testing, identification using automated and microscopic methods, performed QC testing of incoming materials, maintained laboratory stock cultures, and performed specialized studies as needed
- Maintained quality system documents and manual, completed client quality audit questionnaires, hosted and led onsite client audits, initiated CAPAs and continuous improvement opportunities, reviewed and approved client quality agreements, educated staff on quality practices
- Authored, reviewed and approved microbiology, quality and technical SOPs
- Participated in business wide initiatives for business development, sales, marketing and acquisition integration
- Evaluated and provided recommendations on potential acquisitions

**Air Systems Technologies, Inc., Avon, Massachusetts  
Documentation and Environmental Monitoring Supervisor**

**01/2014 – 08/2015**

- Performed quality review and approval for client environmental monitoring and certification reports
- Successfully improved upon the accuracy, quality and delivery of client reports
- Provided training and field evaluations for environmental monitoring technicians
- Performed environmental monitoring and engineering control certification
- Developed environmental monitoring sample programs, consulted and developed remediation plans
- Scheduled services for sterile compounding clients, provided technical guidance for quotes and participated in sales efforts

**Microtest Laboratories, Inc., Agawam, Massachusetts**

**07/2000 - 01/2014**

**Senior Technical Lead, Environmental Sciences (2013-2014)  
Group Leader, Environmental Sciences (2007-2013)  
Environmental Technician/Analyst I-III (2002-2007)  
Laboratory Assistant (2000-2002)**

- Microtest Laboratories was a cGMP, FDA registered, ISO 9001 and 17025 accredited independent contract testing laboratory that provided microbiological testing services of medical devices and pharmaceuticals, analytical chemistry testing, aseptic fill manufacturing and cleanroom testing and certification for medical device, pharmaceutical, and sterile compounding facilities
- Performed and trained field technicians on environmental monitoring, compressed air testing, water collection and engineering control certification.
- Trained laboratory personnel on microbiology practices and sample testing and analysis
- Prepared, organized and developed field testing plans for large environmental monitoring and certification projects
- Authored, revised, reviewed and approved departmental and client testing SOPs
- Authored, reviewed and executed IQ/OQ/PQ protocols
- Provided remediation and engineering control consulting, performed investigational and recovery studies
- Served as a multidisciplinary team member for client quality risk assessments
- Worked with clients to develop environmental sampling programs
- Initiated deviations, discrepancies and CAPA's
- Investigated internal environmental excursions, prepared forms and reports
- Prepared quarterly and annual trend reports for internal environmental monitoring of cleanroom suites and laboratory areas
- Participated in specialized studies, internal validations and equipment qualifications
- Served on the internal audit committee
- Participated in efforts to redesign the environmental laboratory and warehouse space as part of a lean manufacturing initiative

- Performed laboratory testing and analysis of EM samples, waters, biological indicators, product bioburden and bioburden recovery, product stability and accelerated aging studies, ship and package testing
- Performed microscopic identification of mold species
- Additional training in sterility and LAL testing

**CERTIFICATIONS AND ACCREDITATIONS**

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CETA National Board of Testing  
Registered Certification Professional – Sterile Compounding Facilities (RCP-SCF)  
January 2014 – Present

NSF International  
NSF Accredited Class II Biosafety Cabinet Field Certifier  
January 2014 – Present

**EDUCATION**

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Bachelor of Science, Environmental Science  
Westfield State College, Westfield, Massachusetts  
2002

Associate of Arts, Liberal Arts and Science  
Holyoke Community College, Holyoke, Massachusetts  
1999

**APPOINTMENTS/ELECTED POSITIONS**

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**Director, CETA Board of Directors**  
Controlled Environment Testing Association (CETA)  
April 2015 – Present

**Chair/Board Liaison, CNBT Executive Committee**  
CETA National Board of Testing (CNBT)  
April 2017 – Present

**Subject Matter Expert, Sterile Compounding Facilities Exam**  
CETA National Board of Testing (CNBT)  
April 2015 – Present

**Examiner/Grader, CNBT RCP-SCF and RCP-FH Exams**  
CETA National Board of Testing (CNBT)  
April 2015 – Present

**Co-Chair, CNBT Executive Committee**  
CETA National Board of Testing (CNBT)  
April 2015 – April 2017

**PUBLICATIONS**

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***ISPE Good Practice Guide: HVAC and Process Equipment Filters (Draft)***

January 2015 – present

- Participated as a subject matter expert (SME) and writer for the filter testing and training chapters, served as the chapter lead for training and served as a technical reviewer for the draft guide

**PRESENTATIONS AND INVITED LECTURES**

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“CETA National Board of Testing Update,” Controlled Environment Testing Association (CETA) Annual Meeting, Las Vegas, Nevada, April 2016

“CETA Series: USP <797> Gowning Requirements,” Controlled Environment Testing Association (CETA) Annual Meeting, Austin, Texas, April 2017

“Environmental Monitoring, Utilizing Risk Assessments”  
Microtest Laboratories, Inc. Seminar, Dedham, Massachusetts, October 2012

“Got a Lot on Your Plate, Cleanroom Environmental Monitoring”  
Microtest Laboratories, Inc. Seminar, “Keeping it Clean, The Building Blocks of Facility Control,” Dedham, Massachusetts, October 2011

**TRAINING AND PROFESSIONAL DEVELOPMENT**

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“Fundamentals of an Environmental Monitoring (EM) Program” Course  
PDA, Bethesda, Maryland, July 2018

“Establishment of a Risk Based Environmental Monitoring Program” Course  
PDA, Bethesda, Maryland, July 2018

CETA Series Workshop: “Methods to Evaluate Fume Hood Operation and Challenge Containment Performance”  
CETA Annual Meeting, Coeur d’Alene, Idaho, April 2018

CETA Series Workshop: “Air, How to Hold, How to Monitor and How to Pass it”  
CETA Annual Meeting, Coeur d’Alene, Idaho, April 2018

CETA Series Workshop: “USP <797> Cleanroom Operation, Testing and Training”  
CETA Annual Meeting, Tampa, Florida, April 2017

CETA Series Workshop: “Testing and Certification of Non-Conventional Containment Equipment”  
CETA Annual Meeting, Tampa, Florida, April 2017

CETA Series Workshop: “Certification of Special Containment Devices”  
CETA Annual Meeting, Las Vegas, Nevada, April 2016

CETA Series Workshops: “USP <800> Cleanroom Training, CVE Certification and Chemo  
EM Swabbing”  
CETA Annual Meeting, Las Vegas, Nevada, April 2016

CETA Series Workshop: “Electrical Troubleshooting”  
CETA Annual Meeting, Destin, Florida, April 2015

CETA Series Workshop: “CAG 002”  
CETA Annual Meeting, Destin, Florida, April 2015

“Understanding the Changes to ISO 14644-1 & ISO 14644-2”  
IEST, Wilmington, MA, December 2015

CETA Series Workshop: “Decontamination”  
CETA Annual Meeting, Austin, Texas, 2014

“Engineering Controls for Sterile Compounding Facilities” Seminar  
Eagleson Institute, Waltham, Massachusetts, December 2013

“Certification of Sterile Compounding Facilities and Aseptic Enclosures” Course  
Eagleson Institute, Englewood, Colorado, November 2013

“Advanced Certification” Course  
Eagleson Institute, Sanford, Maine, December 2013

CETA Series Workshop: “CAG-003 Compliance Testing”  
CETA Annual Meeting, Orlando, Florida, April 2013

CETA Series Workshop: “EM in Regulated Environments”  
CETA Annual Meeting, Orlando, Florida, April 2013

“Leadership and Employee Development Course Series”  
National Training Associates, Inc., Agawam, Massachusetts, 2013

CETA Series Workshop: “Electrical Troubleshooting”  
CETA Annual Meeting, San Diego, California, April 2012

CETA Series Workshop: “Pharmacy Isolators”  
CETA Annual Meeting, San Diego, California, April 2012

“Particle College” Course  
Particle Measuring Systems (PMS), Boulder, Colorado, February 2012

Medical Devices: “Working the Bugs Out, A Course on Maintaining Microbiological and Package Control Seminar”

Microtest Laboratories, Dedham, Massachusetts, September 2009

“Cleanroom Regulations and Monitoring” Seminar

Life Sciences User Group (LSUG), Woburn, Massachusetts, March 2012

“Testing Cleanrooms” Course

Eagleson Institute, Sanford, Maine, October 2011

“Advanced Certification” Course

Eagleson Institute, Sanford, Maine, December 2010

“5S, Lean Manufacturing, Putting it to Work in Your Facility”

Greater Boston Manufacturing Partnership (GBMP), Agawam, Massachusetts, 2010

“Leadership in Action, A Mid-Level Management Certificate Program”

Employers Association of the North East, Agawam, Massachusetts, July/August 2010

“ASHRAE 110 Testing” Workshop

Eagleson Institute, Sanford, Maine, November 2009

“Introduction to Certification” Workshop

Eagleson Institute, Sanford, Maine, November 2009

“Safety Cabinet Technology” Course

Eagleson Institute, Sanford, Maine, November 2008

“HVAC Systems and Laboratory Design” Course

Eagleson Institute, Sanford, Maine, November 2008

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#### **PROFESSIONAL AFFILIATIONS/MEMBERSHIPS**

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Controlled Environment Testing Association (CETA)	2012-Present
Parenteral Drug Association (PDA)	2017-Present
American Biological Safety Association (ABSA)	2017-Present
International Society for Pharmaceutical Engineering (ISPE)	2015-Present

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#### **HONORS AND AWARDS**

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Eagleson Institute Honor Society Eagleson Institute, Sanford, Maine	March 2013
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**OTHER INDUSTRY INVOLVEMENT**

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Participated in the CETA Application Guide committees for CAG-008, *Certification Guide for Sterile Compounding Facilities* and CAG-009, *USP <797> Viable Environmental Sampling and Gowning Evaluation*