Abby Roth

SENIOR DIRECTOR OF BUSINESS OPERATIONS

CRITICALPOINT, LLC

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PROFESSIONAL EXPERIENCE

Senior Director of Business Operations | CriticalPoint, LLC

May 2020 to Present

- Liaises with the Vice President and Chief Learning Officer to make decisions for operational activities and set strategic goals.
- Plans and monitors the day-to-day running of the business to ensure progress.
- Develops curriculum for CriticalPoint's eLearning modules and live training classes.
- Participates as a faculty member in CriticalPoint's live Sterile Compounding Boot Camp.
- Performs live off-site training on topics including environmental monitoring, contamination control, sanitization and aseptic technique.
- Drafts and revises forms and SOPs used by Kastango Consulting Group, LLC. and Critical Point, LLC.

Director of Learning and Development | CriticalPoint, LLC

January 2019 to May 2020

- Develops curriculum for CriticalPoint's eLearning modules and live training classes.
- Participates as a faculty member in CriticalPoint's live Sterile Compounding Boot Camp.
- Performs live off-site training on topics including environmental monitoring, contamination control, sanitization and aseptic technique.
- Drafts and revises forms and SOPs used by Clinical IQ, LLC. and Critical Point, LLC.

Director of Microbiology | Clinical IQ, LLC

June 2017 to January 2019

- Oversaw and managed the company's involvement in sterile compounding client's environmental monitoring and microbiology testing.
- Provided consultation on environmental monitoring, contamination control and remediation.
- Performed gap analysis for 503A and 503B sterile compounding clients in the interest of ensuring compliance with applicable regulatory standards and guidance.
- Assisted 503A and 503B sterile compounding clients in addressing regulatory observations and implementing the necessary corrective actions to prevent recurrence.
- Engaged in training/teaching of environmental monitoring and USP <797> practices.

- Drafted and revised forms and SOPs used by Clinical IQ, LLC. and Critical Point, LLC.
- Provided auditing services of client vendors.
- Oversaw the successful implementation of a client environmental monitoring program, ensuring it met the expectations of the regulatory body.
- Planned and participated in a large study involving closed system transfer devices.

Director of Quality | Azzur Labs, LLC

February 2014 to August 2014, March 2016 to May 2017

- Oversaw, managed and executed the company's quality systems program.
- Assured laboratory compliance with client specifications, government regulations and ISO requirements.
- Reviewed company methods and protocols for compliance with the policies set forth in the company Quality Manual.
- Responsible for maintaining the vendor quality program, including conducting vendor audits.
- Represented the company at all client, regulatory and accreditation audits of the laboratory.
- Ensured that all laboratory equipment was properly calibrated and validated.
- Performed internal audits of the laboratory systems.
- Ensured proper control of laboratory documentation.
- Maintained the employee training program.
- Oversaw the expansion of the laboratory which included room design and material flow. Updated the necessary documentation to include the changes associated with the expansion.

Laboratory Manager | Azzur Labs, LLC

August 2014 to March 2016

- Ensured that the conditions of the laboratory are appropriate for the testing performed and provided a safe environment in which employees are protected from physical, chemical and biological hazards.
- Assisted the Quality Department in the investigation of deviations.
- Communicated with clients on an ongoing basis to discuss interpretation of test results, trend analysis and matters regarding exceeded concern levels, follow-ups and reports.
- Collaborated in the research and implementation of new testing and technology and all the method validation associated.
- Ensured that the test methodologies selected have the capability of providing the quality of results required; verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; laboratory personnel are performing the test methods as required for accurate and reliable results.
- Managed laboratory personnel.
- Collaborated in the planning, development, organization, implementation, direction and evaluation of the organization's laboratory operations and performance.
- Conducted management reviews.
- Monitored utilization patterns of lab services and advise appropriate staff of developing trends in analytical testing.
- Ensured operational adherence to applicable policies and procedures by all technical and operational staff.
- Developed and implements training methods.

- Assisted customers in the development of environmental monitoring programs and drafted a risk assessment for the selection of sites for an EMPQ.

Microbiologist | Azzur Labs, LLC

April 2012 to August 2014

- Responsible for conducting all microbiological testing (USP Microbial Limits Testing, USP Antimicrobial Effectiveness Testing, log reduction of bacterial spores, culture maintenance, USP water testing, environmental monitoring analysis, bacterial endotoxin testing, bioburden testing).
- Researched and evaluated current technologies for implementation into laboratory operations.
- Developed and validated appropriate methodology for testing client products for bacterial endotoxins utilizing kinetic chromogenic methodology.
- Performed bacterial identification using modified conventional, fluorogenic and chromogenic substrates.
- Microscopy, mold identification.
- Cleanroom environmental monitoring compliant with ISO, USP, EU (RCS, RCS Plus, SAS, MAS 100, Climet, and Metone).
- Performed quality control testing on in house prepared and incoming materials.
- Communicated with clients regarding their samples and remediation following an excursion.
- Wrote SOPs and protocols for client and in-house use.
- Trains employees on laboratory methods.
- Researched multiple systems for Bacterial Endotoxin Testing and implemented the best option into laboratory operations.
- Developed the methods and executed of two large cleaning validations for clients.

Microbiologist II | Microbiological Environments

April 2004 to March 2012

- Communicated with clients regarding their samples and remediation following an excursion.
- Wrote Standard Operating Procedures and Protocols for equipment and practices within the lab environment.
- Responsible for conducting all microbiological testing (USP Microbial Limits Testing, USP Antimicrobial Effectiveness Testing, log reduction of bacterial spores, culture maintenance, USP water testing, environmental monitoring analysis, bacterial endotoxin testing, bioburden testing).
- Performed bacterial identification using cellular fatty acid analysis by gas chromatography (FAME) and employed modified conventional, fluorogenic and chromogenic substrates.
- Microscopy, mold identification.
- Cleanroom environmental monitoring (RCS, RCS Plus, SAS, MAS 100, Climet, and Metone).
- Performed quality control testing.

Laboratory Technician | Orchid Biosciences

June 2003 to April 2004

- Received, cataloged and returned evidence
- Prepared evidence for DNA extraction

EDUCATION

York College of Pennsylvania

2003

Bachelor of Science, Biology
Minor, Chemistry

AREAS OF EXPERTISE

- Regulatory Compliance
- Microbial Validation Testing and Method Development
- Environmental Monitoring - <1116>, <797>, ISO 14698, EUPh Annex I, FDA Aseptic Guidelines
- Sample Plan Development
- Protocol Development
- Contamination Control and Remediation
- Aseptic Technique
- Microbial Product Testing
- Gowning Validation
- Sterility Testing
- Bacterial Endotoxin Testing
- Media Fill Analysis
- Microbial Cleaning Validation

LECTURER AND OTHER ACTIVITIES

2020

- Controlled Environment Testing Association (CETA) Application Guide – 009 Working Group Chair
- Controlled Environment Testing Association (CETA) Application Guide – 012 Working Group Member

2019

- USP Expert Committee Member - Compounding
- Controlled Environment Testing Association (CETA) Application Guide – 009 Working Group Chair
- Controlled Environment Testing Association (CETA) Application Guide – 012 Working Group Member
- National Home Infusion Association Main Session Speaker – *Investigating EM Excursions and Certification Failures*
- American Society of Health-System Pharmacists Summer Meeting – *Sterile Compounding Workshop: Active and Proactive Strategies*
- BD National Sales Meeting – Understanding the Needs of a 503A Pharmacy Customer
- Controlled Environment Testing Association (CETA) – 2018 USP <797> Proposed Revisions Frequently Asked Questions

2018

- USP Expert Committee Member – Compounding

- CriticalPoint Center for Training and Research Faculty Member
- National Home Infusion Association Main Session Speaker and Round Table Moderator - *Sterile Compounding Clinic Viable Environmental Monitoring*
- Eagleson Institute Instructor of the EM Portion in April and October – *Certification of Sterile Compounding Facilities and Aseptic Isolators*
- Controlled Environment Testing Association CETA Series Presenter – *USP 797 versus GMP Identifying the Differences Between 503A and 503B Environmental Monitoring*
- Controlled Environment Testing Association CETA Keynote Speaker – *Guiding your 797 Customer through the Investigation and Remediation of Environmental Monitoring Excursions*
- Controlled Environment Testing Association (CETA) Application Guide – 009 Working Group Member

2017

- USP Expert Committee Member – Compounding
- American Society of Health-System Pharmacists 2017 Midyear Clinical Meeting – *Investigation and Remediation of Environmental and Personnel Sampling Excursions*
- Eagleson Institute Instructor of the EM Portion in April and October – *Certification of Sterile Compounding Facilities and Aseptic Isolators*
- Controlled Environment Testing Association CETA Series Presenter – *Where do I Sample? Developing a Sample Plan for USP <797> Compliance*
- Controlled Environment Testing Association CETA Keynote Speaker – *USP <797> and Beyond: The Importance of USP Chapters 1000-1999*
- Institute of Environmental Sciences and Technology (IEST) Upstate New York Chapter Spring 2017 Contamination Control Technical Seminar - *Complying with USP Chapter Pharmaceutical Compounding – Sterile Preparations: Understanding the Sampling Plan, the Sampling Process and the Remediation Plan*

2016

- USP Expert Committee Member – Compounding
- Eagleson Institute Instructor of the EM Portion in October – *Certification of Sterile Compounding Facilities and Aseptic Isolators*
- Controlled Environment Testing Association CETA Series Presenter – *Chemo EM Swabbing*
- Controlled Environment Testing Association CETA Keynote Speaker – *Update on USP Chapters 797 and 800*

2015

- USP Expert Committee Member – Compounding

2014

- CETA National Board of Testing (CNBT) Subject Matter Expert – Develop multiple choice questions for the Registered Certification Cleanroom Professional exam.

- Controlled Environment Testing Association CETA Series Presenter – *Performing Air and Surface Environmental Monitoring in an Isolator*

2013

- Guest Expert for WG02 Committee for ISO 14698

2012

- Parenteral Drug Association Lecturer - Global Microbiology Conference Session B3: Contamination Control - *Contributing Factors to Microbial Contamination Frequently Observed in Pharmaceutical Manufacturing Environments*

PUBLICATIONS

- *Part 1 – Principles that Drive Effective Cleaning* Pharmacy Purchasing & Products March 2020 – Vol. 17 No. 3
- *Environmental Monitoring in the Clean Room Microbiological Clues to Improving Your Practice* Infusion: Official Publication of the National Home Infusion Association (NHIA) September/October 2017.
- *Microbiological Testing for 503A Sterile-Compounding Pharmacies* International Journal of Pharmaceutical Compounding Issue: May/Jun 2017 - Volume 21, Number 3
- *USP General Chapter <797> Revision: Where are we now?* CETA Performance Review; The Journal of the Controlled Environment Testing Association Vol. Winter 2016
- *The United States Pharmacopeia: Beyond <797>* CETA Performance Review; The Journal of the Controlled Environment Testing Association Vol. Winter 2016
- *Your Comments Matter: The Role of USP's Public Review and Comment Process in the Revision of Standards* CETA Performance Review; The Journal of the Controlled Environment Testing Association Vol. Fall 2015
- *Important Aspects to Consider When Performing a Microbial Cleaning Validation According to USP <1072>* PDA Southern California Chapter Nexus Vol. 2 July 2015
- *Taking the Mystery Out of the Chain of Custody* CETA Performance Review; The Journal of the Controlled Environment Testing Association Vol. Summer 2014
- *Environmental Monitoring in the Cleanroom* Pharmacy Purchasing & Products Vol. 9 No. 3

CERTIFICATIONS AND TRAINING

- QP503A Qualified - CriticalPoint
- EMD Millipore and Associates of Cape Cod - BEST QC Microbiology Training
- American Society for Quality - CQIA Certified Quality Improvement Associate
- American Society for Quality - CMQ/OE Certified Manager of Quality / Organizational Excellence
- High Peaks Associates – Validation of Microbiological Methods
- Charles River – LAL Testing Seminar and Workshop

ORGANIZATIONS

- Parenteral Drug Association
- American Society for Quality - Senior Member
- Controlled Environment Testing Association