Abby Roth
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Professional with thirteen years of experience in environmental monitoring, laboratory testing and analysis with expertise in microbiological testing which complies with regulatory specifications. Certifications though ASQ as a Certified Manager of Quality / Organizational Excellence and Quality Improvement Associate have been vital in performing gap analysis for clients.

Areas of Expertise

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

Technical Proficiencies

- Laboratory Information Management Systems
- Sievers 900 Laboratory Total Organic Carbon (TOC) Analyzer
- EndoSafe MCS Bacterial Endotoxin Detection System
- BD BBL Crystal MIND
- API Identification Panels
- Sherlock Microbial Identification System

Professional Experience

Clinical IQ, LLC Wayne, NJ *June 2017 to Present*
Director of Microbiology

- Provides consultation on environmental monitoring, contamination control and remediation.
- Performs gap analysis for clients in the interest of ensuring compliance with applicable regulatory guidelines.
- Engages in training/teaching of environmental monitoring and USP <797> practices.
- Drafts and revises forms and SOPs used by Clinical IQ, LLC. and Critical Point, LLC.
- Provides auditing services of client vendors.

Azzur Labs, LLC Schnecksville, PA *February 2014 to August 2014, March 2016 to May 2017*
Quality Director/Safety Coordinator

- Oversees, manages and executes the company's quality systems program.
- Assures laboratory compliance with client specifications, government regulations and ISO requirements.
- Reviews company methods and protocols for compliance with the policies set forth in the company Quality Manual.
- Oversees the CAPA and Change Control programs.
- Responsible for maintaining the vendor quality program, including conducting vendor audits.
- Represents the company at all client, regulatory and accreditation audits of the laboratory.
- Ensures that all laboratory equipment was properly calibrated and validated.

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- Reviews equipment installation, operational and performance qualifications.
- Performs internal audits of the laboratory systems.
- Ensures proper control of laboratory documentation.
- Maintains the employee training program.
- Tracks laboratory observations and deviations and develops corrective and preventative actions.
- Completes investigations of laboratory deviations and testing with client exceeded levels.

Key Achievements:

- 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.

Azzur Labs, LLC Schnecksville, PA *August 2014 to March 2016*
Laboratory Manager

- Ensures that the conditions of the laboratory are appropriate for the testing performed and provides a safe environment in which employees are protected from physical, chemical and biological hazards.
- Understand the significance of deviations found with regard to the normal use of materials tested and assist the Quality Department in the investigation of deviations.
- Communicates with clients on an ongoing basis to discuss interpretation of test results, trend analysis and matters regarding exceeded concern levels, follow-ups and reports.
- Reviews opinions and interpretations expressed by testing personnel.
- Collaborate in the research and implementation of new testing and technology and all of the method validation associated.
- Ensure 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.
- Responsible for drafting and revision of documents
- Manages laboratory personnel.
- Collaborate in the planning, development, organization, implementation, direction and evaluation of the organization's laboratory operations and performance.
- Conduct management reviews.
- Monitor utilization patterns of lab services and advise appropriate staff of developing trends in analytical testing.
- Ensure operational adherence to applicable policies and procedures by all technical and operational staff.
- Acknowledges investigations of laboratory deviations and client exceeded concern levels.
- Develops and implements training methods.
- Oversees the training program.
- Oversees the scheduling and conduct laboratory operations.

Key Achievements:

- Revised the controlled training forms to be more comprehensive.
- Assisted customers in the development of environmental monitoring programs and drafted a risk assessment for the selection of sites for an EMPQ.

Azzur Labs, LLC Schnecksville, PA *2012 to 2014*
Microbiologist/Safety Coordinator

- Responsible for conducting all microbiological testing, including - Microbial limit testing (USP; CTFA.), antimicrobial effectiveness testing (USP; CTFA), log reduction of bacterial spores, culture maintenance, water testing (USP/EuPh), environmental monitoring analysis, bacterial endotoxin detection, bioburden testing
- Researches & evaluates current technologies for implementation into laboratory operations.
- Develops and validates appropriate methodology for testing client products for bacterial endotoxins utilizing kinetic chromogenic methodology
- Conducts analysis for Total Organic Carbon in water and cleaning validation studies
- Bacterial Identification - employs modified conventional, fluorogenic and chromogenic substrates.
- Microscopy - Mold identification, microphotography.
- Cleanroom environmental monitoring compliant with ISO, USP, EU (RCS, RCS Plus, SAS, MAS 100, Climet, and Metone).
- Performs quality control testing on in house prepared and incoming materials.
- Communicates with clients regarding their samples and remediation following an excursion.
- Writes SOP's and protocols for client and in house use.
- Trains employees on laboratory methods.
- Drafts, reviews and maintains the safety program.
- Trains employees in proper safety procedures.
- Maintains hazardous chemicals and their MSDS
- Assists in attainment of new laboratory clients by attending tradeshows and contacting potential clients by phone and through email.

Key Achievements:

- Developed and maintained all company health and safety systems, including the Biological Safety Plan, Chemical Safety Plan, Ergonomic Safety Plan, Blood Borne Pathogen Plan.
- Researched multiple systems for Bacterial Endotoxin Testing Methodology and implemented the best option into laboratory operations.
- Developed the methods and executed of two large cleaning validations for clients.

Microbiological Environments, Bethlehem, PA *2004 to 2012*
Microbiologist II/ Safety Coordinator

- Communicated with clients regarding their samples and remediation following an excursion.
- Trained employees in proper safety procedures.
- Maintained hazardous chemicals and their MSDS.
- Write Standard Operating Procedures and Protocols for equipment and practices within the lab environment.
- Observe / comply with CGXP and procedures.
- Responsible for conducting all microbiological testing, including - Microbial limit testing (USP; CTFA.), antimicrobial effectiveness testing (USP; CTFA), log reduction of bacterial spores, culture maintenance, water testing (USP), environmental monitoring analysis, bacterial endotoxin detection, bioburden testing
- Bacterial Identification - Cellular fatty acid analysis by Gas Chromatography (FAME) and employed modified conventional, fluorogenic and chromogenic substrates.
- Microscopy - Mold identification; Identification of starch particles through polarized light microscope, microphotography.
- Cleanroom environmental monitoring (RCS, RCS Plus, SAS, MAS 100, Climet, and Metone).
- Performed quality control testing.

Key Achievements:

- Advanced from Microbiological Technician to Microbiologist II

- Developed and maintained all company health and safety systems, including the Biological Safety Plan, Chemical Safety Plan, Ergonomic Safety Plan, Blood Borne Pathogen Plan.

Orchid Biosciences, Germantown, MD *2003 to 2004*
Laboratory Technician

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

Recent Publications

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

Lecturer/Other Activities

2017 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 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 to Present USP Expert Committee Member – Compounding

2014 CETA National Board of Testing (CNBT) Subject Matter Expert – Develop multiple choice questions for the exam which is part of the certification program for professionals who certify sterile compounding facilities.

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*

Education and Certifications

- EMD Millipore & Associates of Cape Cod - BEST QC Microbiology Training
- American Society for Quality-CQIA Certified Quality Improvement Associate
- High Peaks Associates – Validation of Microbiological Methods
- Charles River – LAL Testing Seminar and Workshop
- York College of PA - BS, Biology
- York College of PA - Minor, Chemistry

Organizations

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