

Adam Jason West

Awest@CriticalPointce.com

Professional with over 10 years of experience in facility engineering controls, environmental monitoring and field certification. Accreditations include CETA CNBT (RCCP-SCF) and NSF-49 Bio Safety Cabinets. Extensive experience in the testing of controlled environments, the compendial requirements of USP <797> viable environmental monitoring and remediation.

Areas of Expertise

- Field Certification, Cleanroom Commissioning, and Performance Qualification
- Engineering Controls, Facility Operations and Installation
- Cleanroom Design Consulting
- Remediation and Contamination Control Consulting
- Cleanroom Certification and Viable Environmental Monitoring Training
- Aseptic Technique
- Environmental Monitoring Sample Plan Development

Professional Experience

CriticalPoint, LLC Totowa, NJ

September 2018 to Present

Environmental Monitoring and Training Specialist

- Assists clients in auditing service vendors
- Develops training for environmental monitoring, field certification and USP <797> practices.
- Provides consultation on environmental monitoring, contamination control and remediation.
- Performs gap analysis for 503A and 503B sterile compounding clients in the interest of ensuring compliance with applicable regulatory standards and guidance.
- Assists 503A and 503B sterile compounding clients in addressing regulatory observations and implementing the necessary corrective actions to prevent recurrence.
- Drafts and revises forms and SOPs used by Clinical IQ, LLC and Critical Point, LLC

Key Achievements:

- Developed new eLearning material and course curriculum for field certification technicians.
- Completed a root cause analysis and providing recommendations for remediation for 503a client's efforts to gain and maintain regulatory compliance

STERIS Corporation – Controlled Environment Certification Services Division Mentor, OH

January 2015 to September 2018

Environmental Monitoring Program Training and Technical Service Specialist

- Served a supervisory role for Controlled Environment Certification Service (CECS-STERIS) in Cincinnati Ohio, facilitating the viable environmental monitoring program to ensure field certification technicians provided quality testing and documentation to customers.
- Supervised viable environmental monitoring and other certification projects by obtaining information from the customer and providing the right tools and knowledge to field certification technicians to complete the job with accuracy and satisfaction.

Adam Jason West

Awest@CriticalPointce.com

- Held an integral role with the training and integration department for Controlled Environment Certification Services (CECS) national business offices.
- Created and implemented curriculum training for Field Service Technicians and pharmacy clients who needed continued training in industry practices.

Key Achievements:

- Assisted with the development of a lab analysis protocol for an internal laboratory as well as helped the laboratory become familiar with USP <797> requirements for analysis and reporting.
- Lead instructor for internal team members on environmental monitoring training and performed SOP reviews for a sterility validation laboratory
- Conducted a root cause analysis for environmental monitoring excursions and performed a gap analysis on enzymatic cleaning protocols for a sterile packaging medical device division
- Performed a root cause investigation for a sterile product packaging and plastics casting manufacture providing products to the healthcare division

Agape Instruments Services Inc Cincinnati, OH

July 2008 to January 2015

Advanced Certification Specialist

- Performed routine certification and repairs of cleanrooms and devices that contain HEPA filters. This included: disassembling, replacing, or repairing defective parts; rewiring or reassembling as required; troubleshooting, adjusting/calibrating, and certifying equipment ready for use by using standard and specialized tools and test equipment (i.e., schematics, diagrams, technical manuals, etc.).
- Provided training and coaching to less experienced technicians and was responsible for overseeing work to ensure quality while on customer sites.
- Performed troubleshooting, repair, or modify standard and special purpose equipment and systems components.
- Provided service calls and third-party equipment warranty calls.

Key Achievements:

- Achieved advanced placements and a leadership role for the viable environmental monitoring division

Lecturer/Other Activities

2019

- CriticalPoint Center for Training and Research Faculty Member

2018

- Controlled Environment Testing Association CETA Keynote Speaker – *Adopting or Adapting? Handling Customer Documentation as it Relates to Current Industry Standards*
- Controlled Environment Testing Association CETA Series Presenter – *USP 797 versus GMP Identifying the Differences Between 503A and 503B Environmental Monitoring*

Adam Jason West

Awest@CriticalPointce.com

2014

- Controlled Environment Testing Association (CETA) Application Guide – 009 Working Group Member
- Controlled Environment Testing Association CETA Series Presenter – *Performing Fingertip Gloved Sampling*

Organizations

- Parenteral Drug Association (PDA)
- Controlled Environment Testing Association (CETA)