Current Courses

AZZUR TRAINING CENTER
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Module	Learning Objectives
Aseptic Behavior	• Review key cleanroom behaviors utilized to prevent contamination • Discuss the importance of proper health and hygiene practices for personnel who work in cleanrooms • Review similarities and differences of open vs. closed systems / aseptic processing vs. terminal sterilization • Convey acceptable and unacceptable cleanroom behaviors
Aseptic cGMP Workshop	• Review the origin and importance of cGMPs (and define the “c”) • Overview of cGDocP and data integrity • Learn about contamination control • Review aseptic behavior and techniques
Aseptic Gowning / Gloving Principles: Overview and Demonstration	• Review industry / site gowning expectations • Demonstrate proper gowning / gloving technique • Trainees practice proper gowning / gloving technique with trainer support
Aseptic Gowning / Gloving: Practice and Verification / Qualification	• Practice aseptic gowning / gloving techniques following the checklist of required steps, prior to qualification testing • Move to the cleanroom to gown / glove aseptically without critical technique failures (up to 3 times) • Samples will be collected in an ISO 5 environment • Successful gowning results will meet the expected microbial contamination limits
Aseptic Techniques	• Define aseptic technique • Review key aseptic concepts and techniques • Discuss proper use of aseptic processing systems (rooms, equipment) • Review best material transfer / personnel and material flow / intervention practices • Describe cleanroom operations in relation to manufacturing parenteral products utilizing Aseptic techniques (general processes, interventions, spills, etc.)
Classified Space Cleaning and EM Workshop	• Develop a cleaning program & review cleaning best practices • Environmental monitoring (EM) overview • Identifying & troubleshooting cleanroom contamination
Cleaning: Best Practices	• Review the proper flow of cleaning (cleanest to dirtiest) • Discuss the importance of wiping surfaces with uni-directional strokes or other approved technique • Discuss industry standard / site materials used for cleaning (IPA, non-shedding wipes, wall mops, etc.)
Cleaning: Developing a Program	• Discuss critical considerations when designing a cleaning regimen for a facility, room, or equipment • Discuss the importance of having an approved, effective cleaning regimen combined with an EM program • Describe surfactants, disinfectants, sanitizers, and sporicidal agents and when / where they should be used • Discuss why it is recommended to rotate disinfectants each full clean
Contamination Control	• Explain what contamination is and potential impacts • Review different types of contamination • Describe the methods to minimize the risk of contamination through engineering, procedural, and behavioral controls • Discuss why understanding contamination control principles is important

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Current Courses

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Module	Learning Objectives
Data Integrity (DI) Overview	• Review 21 CFR 11 requirements and their impact on electronic signatures and record keeping requirements • Review and discuss meaning and importance of ALCOA+ • Recognize regulatory expectations for data handling and data integrity assurance • Review potential consequences of poor data integrity practices • Review DI violations and US FDA 483's / Warning Letters pertaining to lack of good handling of data
Environmental Monitoring (EM): Program Development	• Review room classifications and allowable concentration limits for particulates and microbial contaminants • Define regulatory expectations of an EM program • Discuss the necessary components for an effective EM program for controlled environments • Define and discuss HEPA filters and the importance / frequency for HEPA certifications • Use risk analysis to develop a sampling plan to determine the quantity and type of samples required based on room size and room classification
Environmental Monitoring (EM): Sampling and Trending	• Define the different methods of sampling (particulate readers, air samplers, contact/settle plates) • Review requirements for regular trending of EM data • Define what high traffic areas and touchpoints are (i.e. worst case locations) • Demonstrate and practice proper sampling techniques • Review FDA 483's related to insufficient EM programs
Good Documentation Practices (cGDocP)	• Describe the importance and principles of cGDocP • Define and distinguish types of documents found in a cGMP environment • Detail requirements for document creation, control, maintenance, archival, and retention • Identify requirements for record keeping, including entering and correcting data • Review cGDocP violations and US FDA 483's / warning letters pertaining to lack of good practices
Good Manufacturing Practices (cGMP)	• Review the origin of cGMPs (and define the "c") • Understand how cGMPs support the production of safe and efficacious products • Discuss quality systems and how they align with cGMP regulations / requirements • Describe the Code of Federal Regulations (CFR) and its importance • Discuss the benefits of good, and consequences of poor, quality • Review cGMP violations and US FDA 483's / warning letters pertaining to lack of good systems
Investigations: Best Practices for Collecting Information	• Define and examine the critical parts of an investigation with interactive exercises, including but not limited to: -Consistency when developing titles -Aspects of a detailed description -Documentation of immediate actions -Performing historical reviews • Items to review and pathways to explore during data collection • Provide the complete story

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Module	Learning Objectives
Investigations: CAPA (Corrective / Preventative Actions) and Effectiveness Checks	• When you should initiate a CAPA • Tying repeated issues to an on-going CAPA • Provide guidance on when to implement a CAPA • Review of elements that make up an effective CAPA • Discuss effectiveness checks and their importance
Investigations: Overview	• Review the importance of conducting thorough investigations • Discuss the different activities that investigations support • Review the key components required for a complete investigation • Discuss effective investigation programs
Investigations: Regulatory Requirements	• Identify the regulations governing investigations • Review consequences of performing inadequate investigations • Review examples of FDA citations (483's / warning letters) pertaining to lack of or inadequate investigations
Investigations: Root Cause Analysis (RCA) Overview	• Define root cause • Identify and review common RCA tools • Root cause vs. contributing cause • How to tell that you've found true root cause • Determining "repeat" events
Investigation Writing Workshop	• Why we investigate & regulatory requirements for investigations • Conducting an investigation • Goals and principles of RCA, choosing the correct RCA tool, & RCA activity • Title, detailed description, immediate actions, & historical review activity • Data collection activity • Investigation activity • Root cause analysis activity • Deviation conclusion activity
Isolators: Cleaning and Disinfecting	• Discuss methodologies for cleaning and disinfecting the interiors of isolators • Discuss current decontamination options and proper decontamination techniques • Describe what configurations need to be set on the isolator when performing a decontamination process • Discuss considerations when working with products sensitive to oxidation by H^2O^2
Isolators: Design Principles	• Discuss isolator design to minimize contamination risk • Discuss pressure differential and what it should be between the isolator interior and the surrounding area • Design and maintenance considerations for gloves and glove ports • Review cleaning/sanitization options • Discuss ergonomic considerations • Review glove ports
Isolators: Maintenance and Integrity Testing of Isolators and Gloves	• Describe an effective maintenance plan for gloves • Review common issues with gloves, glove ports, and isolators • Discuss methods that should be used for integrity testing of isolators and gloves • Discuss how to handle a glove integrity failure

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Module	Learning Objectives
Isolators: Proper Aseptic Behaviors	• Discuss proper gowning requirements for working with an isolator and the surrounding room • Discuss the importance of disinfecting gloves prior to entering the isolator gloves • Discuss proper aseptic techniques utilized when working with isolators • Discuss proper techniques for performing media fills inside the isolator • Describe material transfer methodology related to isolators • Review tips and tricks based on years of experience
New Employee Orientation	• Company and site overview (specific) • Company history • Mission and values • Safety procedures • Site security / IT • Emergency procedures
Regulations and Regulatory Authorities	• Understanding the Code of Federal Regulations (CFR) • Review the history and scope of regulatory bodies • Explain the function of regulatory authorities • Overview of the different regulatory agencies • Describe the impact of noncompliance with regulations
Quality Systems Introduction	• Describe the role of the quality system and its importance in the industry • Discuss entities and associated guidances that provide expectations for quality systems • Review the different aspects that comprise the quality system • Describe the importance of continuous improvement • Review quality system violations and US FDA 483's / warning letters / consent decrees pertaining to lack of a quality system
Train the Trainer: Adult Learning Styles	• Review main learning styles - auditory, visual, and kinesthetic • Look at how adults learn and retain knowledge • Discuss approaches to increasing knowledge retention • How much repetition is necessary for adults
Train the Trainer: Coaching and Mentoring Real Time	• Discuss the difference between coaching and mentoring • Real time strategies to highlight and lock in desired behaviors • Provide immediate feedback whenever possible • Review conflict management strategies
Train the Trainer: How to Effectively Train Adults	• Recognizing the learning styles of your team • Utilizing more than one style at a time to improve knowledge retention in the class • Respect what adult students bring to the class (prior experience) • Learning goes both ways

Courses in Development

1) Technical Writing
2) Quality Risk Management / Performing Risk Assessments
3) Validation Principles
4) Complaint Management
5) Strategies for Continuous Improvement
6) Leadership Principles
7) Auditing (Internal and External)

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