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 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.)
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.

225 JAMES JACKSON AVE, CARY, NC 27513
ATC.INFO@AZZUR.COM | 919.890.8998

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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 should you 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.
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.
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.

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Module	Learning Objectives
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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