AZZUR TRAINING CENTER
An Azzur Group Company

CURRENT COURSES

Jump to:

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Aseptic Manufacturing

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Aseptic Behavior and Techniques	• Explain the basic differences between aseptic processing and terminal sterilization • Distinguish between isolation technologies and open vs. closed systems • Discuss the importance of proper health and hygiene practices for personnel who work in cleanrooms • Review key cleanroom behaviors utilized to prevent contamination • Discuss key principles of aseptic technique including critical areas and surfaces, first air rule, specific connections and working with pipettes
Aseptic Connections	• Define aseptic connections • Review the types of aseptic connections • Discuss the applications for aseptic connections
Aseptic Processing	• Define aseptic processing • Overview of the history of aseptic processing • Review similarities and differences of open vs. closed systems / aseptic processing vs. terminal sterilization • Determine acceptable use of aseptic processing
Aseptic Processing: Systems	• Explain different aseptic processing systems and how those systems are used • Define single-use systems and aseptic connections and discuss the proper implementation of these practices • Review biosafety cabinet use and techniques • Discuss the aspects of operating and isolator and the regulatory need for process simulations and media fills • Explain the basics of process release sampling/testing as it differs between aseptic processing and terminal sterilization
Aseptic Techniques within Biological Safety Cabinets (BSCs)	• Describe the different classes of BSCs and their different uses • Discuss the importance of aseptic technique as it applies to contamination control and maintaining proper airflow • Demonstrate a number of learned techniques critical to aseptic operation, including how to aseptically introduce materials and how to set up your workstation within the BSC • Review the significance of a regular cleaning and maintenance schedule

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Aseptic Manufacturing Cont.

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Media Fill / Aseptic Process Simulation	• Define an Aseptic Process Simulation (APS) • Discuss appropriate protocols for APS • Define interventions and personnel qualification
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
Visual Inspections and Sample Handling	• Review the types of inspections required throughout the manufacturing process • Discuss the common deformities typical to filling • Basic information on handling samples
What is a Cleanroom?	• Basic introduction into cleanrooms, including: o History o Keeping it clean o Classification system for ISO, EU, and FDA

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: cGMP / Regulations

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Annex 1 2022 Revision Overview	• Examine the necessity for updated Annex 1 guidance through the collaborative effort of organizations such as EMA, WHO, PIC/S, and the FDA • Summarize the key updates in each chapter of Annex 1 • Discuss updated requirements for pre-use post sterilization integrity testing (PUPSIT) • Emphasize the role of quality risk management (QRM) and a contamination control strategy (CCS) throughout the framework of sterile drug manufacturing • Understand the key steps to Annex 1 implementation and compliance
Inspection Readiness	• Discuss the reasons for inspections • Explain the potential outcomes from an inspection • Discuss the mindset that leads to ensuring successful inspections • Explain the appropriate behaviors to utilize during an inspection
New Employee Orientation	• Company and Site Overview (specific) • Company History • Mission and Values • Safety Procedures • Site Security / IT • Emergency Procedures
Overview of cGDocP and Data Integrity	• Define GDocP and the importance of compliance • Discuss and distinguish types of documents found in a GMP environment • Identify requirements for record keeping, including entering and correcting data • Review data integrity importance and the data lifecycle • Define ALCOA+ principles and application to both paper and electronic records • Discuss significant data integrity issues • Distinguish electronic signature and records as well as and the importance of audit trails • Review controls to minimize DI issues
The Origin and Importance of cGMP	• Define GMP and review the historical cases that led to current regulations • Discuss the Code of Federal Regulations (CFR) and consequences of non-compliance • Review cGMP violations and US FDA 483's / Warning Letters pertaining to GMP violations • Discuss Quality Systems and how they align with GMP regulations / requirements • Discuss the areas covered in CFR GMP regulations

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Contamination Control

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Cleaning, Disinfection, and Line Clearance	• Defining cleaning and disinfection • Discussing the importance of cleaning and disinfection • Explain what line clearance is and its significance
Contamination Control	• Define contamination and distinguish the different types (i.e., viable, non-viable, cross contamination) • Discuss sources of contamination and factors of microbial growth • Review the history of cleanrooms and classifications • Describe the methods to minimize contamination through engineering, procedural, and behavioral controls
Developing a Cleaning Program & Cleaning Best Practices	• Review critical considerations when designing a cleaning program for a facility, room, or equipment • Discuss the importance of having an approved, effective cleaning program combined with an environmental monitoring (EM) program • Describe surfactants, disinfectants, and sporicidal agents and when they should be used • Describe the proper flow of cleaning • Discuss the importance of wiping surfaces with unidirectional strokes or other approved techniques • Review industry standard materials used for cleaning (non-shedding wipes, wall mops, etc.) • Discuss material transfer in relation to cleaning
General Gowning	• Review the appropriate actions to take prior to gowning into a grade level area • Provide industry standard practices for gowning into CNC, D, C, B areas • Discuss recommended steps for de-gowning out of various grade levels
Identifying & Troubleshooting Contamination	• Discuss the inevitably of some level of contamination if human operators are present • Review common issues in cleaning and environmental monitoring that may contribute to cleanroom contamination • Discuss operator errors, gowning errors, and training deficiencies • Review critical considerations in current cleanroom procedures that could contribute to contamination • Discuss how to review trend data to identify potential root causes to contamination • Discuss how to develop a meaningful corrective and preventative action (CAPA) when necessary

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Contamination Control Cont.

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Isolator 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 H2O2
Microlearnings	• Pre-recorded 1-5 minute courses with audio covering a refresher of basic contamination control topics, including: o What is contamination? o Contamination Sources o Modes of Contamination o Cleanroom History o Cleanroom Classifications o Methods of Controlling Contamination o Basic Environmental Monitoring o Contamination Regulations and Impacts o Contamination Growth o Cleanroom Subclassification o Controlling Contamination – Aseptic Gowning o Controlling Contamination – Cleaning, Sanitization, and Sterilization o Environmental Monitoring – Air Sampling o Environmental Monitoring – Personnel and Surface Monitoring o Re-Establishing a State of Control o Contamination Control Design o Environmental Monitoring – Program Design o CAPA Management

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Equipment

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Analytical Balances and Micropipettes	• Review important safety considerations when handling sensitive equipment • Discuss best practices for use, calibration, and maintenance • Highlight small equipment cleaning methods that help maintain the longevity of balances and micropipettes • Demonstrate proper technique when using micropipettes to ensure accurate liquid transfer volume
Isolator 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
Lab Equipment and Safety Overview	• Introduces Biosafety and Chemical Safety • Reviews General Safety Requirements • Details common laboratory equipment
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

Current Courses: Leadership

Course	Learning Objectives
Management in an Aseptic Environment	• Review the restraints an aseptic environment places on effective management techniques • Define the traits of an effective manager or potential manager • Discuss the importance of sharing your vision

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Microbiology

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Cellular Processes	• Provides an overview of cell processes, including: o Cell collection o Cell differentiation and purification o Cell expansion and harvesting o Cryopreservation
Environmental Monitoring (EM) Overview	• Review room classifications and allowable concentration limits for particulates and microbial contaminants • Define regulatory expectations of an EM program • Discuss the development of a sampling plan (i.e., number of samples required based on room size and room classification) beginning with Environmental Monitoring Performance Qualifications (EMPQ) • Review considerations for selecting media, defining incubation parameters, and performing growth proficiency testing (GPT) • Discuss the importance of a robust data set in an EM program and the expectations for data trending • Review and demonstrate different methods of sampling (particulate readers, air samplers, contact/ settle plates) and sampling best practices

Current Courses: Quality Systems

Course	Learning Objectives
Auditing Aseptic Areas	• Discuss the principles around audits • Define audit types • Explain areas of interest in an aseptic audit
Change Control Management	• Define change control and the managing of change control • Discuss the importance of controlling changes • Review the regulations regarding change control • Define the responsible personnel for change control

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Quality Systems Cont.

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Conducting Investigations	• Define and examine the critical parts of an investigation with interactive exercises, including: o Consistency when developing titles o Aspects of a detailed description o Documentation of immediate actions o Performing historical reviews • Define root cause • Provide guidance on when to implement CAPA • Review of elements that make up effective CAPA • Items to review and pathways to explore during data collection section with interactive exercise: o Writing a problem statement o Collecting background information o Defining scope o Asking the right questions and brainstorming during investigation
Deviation and CAPAs Overview	• Discuss the basics of a deviation • Explain the impact of deviations on the site and the patient • Discuss the basics of CAPA and effectively writing CAPAs • Review how to conduct or improve investigations • Provide solutions on reducing deviation recurrence
Quality Risk Management	• Define Quality Risk Management (QRM) • Discuss the lifecycle of QRM • Determine the QRM Process
Root Cause Analysis	• Goals and principles of root cause analysis • Review common RCA tools • When to choose a specific RCA tool • Define human error and strategies to reduce it
Why We Investigate & Regulatory Requirements for Investigations	• Review the importance of conducting thorough investigations • Discuss the different activities that investigations support • Discuss effective investigation programs • 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

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Train the Trainer

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
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?
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
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

Current Courses: Validation

Course	Learning Objectives	
Analytical Instrument Qualification	• Overview • Regulatory requirements • Qualification Phases	• 4-Q Model • Risk categorization • Wrapper protocols
Cleaning Validation (CV)	• What is Cleaning Validation / Verification? • What does it accomplish? • Common criteria to evaluate • Types of cleaning (manual vs automated) • Determining a cleaning process • CIP / SIP overview	

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Validation Cont.

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Commissioning 101	• Overview of Commissioning principles • URS and trace Matrix • FAT (Factory Acceptance Test)/ SAT (Site Acceptance Test) • Discuss the importance of documentation, data, and storage. • Review how change control can be applied / tracked through the Commissioning process. • Decommissioning overview
Computer System Validation – CSV / CSA	• What is CSV – Computer System Validation? • Brief History • Requirements per 21 CFR Part 11 • Requirements from Annex 11 • Testing Strategies • CSA – Computer Software Assurance
Intro to Temperature Mapping	• Overview of Temperature Mapping • Discuss the lifecycle of a validated system • Review the execution of temperature mapping
Introduction to CQV Principles	• Overview of Commissioning, Qualification, and Validation • Review regulations for validation • Discuss general CQV Process
Maintaining a Validated Cleanroom	• Discuss how to establish and maintain control of a validated state • Explain the causes and potential impacts of losing control • Discuss how to reduce deviation and events • Review training strategies • Review case studies regarding validated cleanroom gowning
Process Validation	• Review current Guidance / Regulatory requirements • Process Control and Validation • Process Validation Stages • Types of Process Validation • Key points for Process Validation

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Validation Cont.

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Qualification 101 (FUSE)	• Overview of Qualification Principles with focus on FUSE (Facilities, Utilities, Systems, and Equipment) • Discuss IQ, OQ, PQ, and other acronyms • Utilizing Vendor Protocols • Stakeholders
Shipping Validation	• Definition and Regulatory requirements • Good Distribution Practice review • Risks involved with shipping and distribution • Risks involved with Transportation
Validation 101 (process, cleaning, computers) – history and context	• What is Validation? • Why is it necessary? • Typical Strategies • Document types and testing associated
Validation discrepancies – writing and resolving	• Discrepancies / PGE's / Investigations… • Types of Discrepancies • Example Discrepancy Process • Root Cause Analysis Tools • Example of a well-written Discrepancy
Writing Protocols and final reports	• Regulatory framework • Different protocol / report types • Review protocol / report content • Review standard protocol TOC • Writing Final Reports – basic expectations
Writing VMP / VPP	• Purpose and Use of both • What sections are typically found in each • Writing Tips • Share examples • Writing activity

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Activities / Workshops

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Conducting EM/ PM Sampling (Viable / Non-Viable)	• Gown up to enter a cleanroom • Overview of different types of sampling equipment and strategies • Practice using sampling equipment typically used to collect environmental samples (viable / non-viable) • Practice collecting personnel samples using a plating technique • Review best practices when collecting samples
Gowning / Gloving Practice	• 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
Investigations: Data Collection	• Utilize the information from initiation and immediate actions to perform data collection: o Write the problem statement o Record all background information about the process and/or product (i.e., what usually happens when the procedure is executed) • Define the scope
Investigations: Deviation Conclusion	• Review additional actions and remaining sections of the deviation as a class. • Write a concise summary of your entire investigation, starting with the detailed description, then a bit of background info, investigation findings, RCA, and conclusion of the entire deviation. • Determine the final impact to the product SQuIPP and if CAPA are required
Investigations: Choosing the Correct RCA Tool & RCA	• Identify and review common RCA tools • Use fishbone diagram to analyze the 6Ms and determine a root cause for the issue given • Discuss finding as a class

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

INFO@AZZUR.COM | AZZUR.COM

Current Courses: Activities / Workshops Cont.

AZZUR TRAINING CENTER
An Azzur Group Company

Course	Learning Objectives
Investigation Activity	• Brainstorm and determine questions you should be asking as an investigator in the “Investigation” section. o What could have caused the pressing issue? o Think about all the criteria you want to look at and evaluate each of them. • Reinforce this section is the “meat” of your entire investigation. It should be the longest section of your entire deviation. All new information should be introduced in this section.
Investigations: Root Cause Analysis	• Determine the root cause by using one of the RCA tools discussed • Use information gathered in the investigation section to categorize causes into one of the 6M categories • Analyze all possible causes to determine the true root cause
Investigations: Title, Detailed Description, Immediate Actions & Historical Review	• Read the prompt of the investigation and individually come up with: o Title: object, location, and the problem o Detailed description: who, what, when, where how and why o Immediate actions/initial impact: who was notified and determine severity of the issue, etc. • Historical review: identify any repeat occurrences and/or trends

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

INFO@AZZUR.COM | AZZUR.COM