GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

Aseptic Processing Overview and Validation

Learning Objectives

- *Basic Micro Review*
  Definition of Human Factors Categories (HFC)
- *Review of Aseptic Processing Basics*
- *Review of Clean Area Behaviors*
- *Aseptic Validation*

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

This course will provide an overview of the requirements for aseptic and bulk manufacturing operations, including facility design, contamination controls, and acceptable personnel behaviors.

PRESENTED BY:

Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems; as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

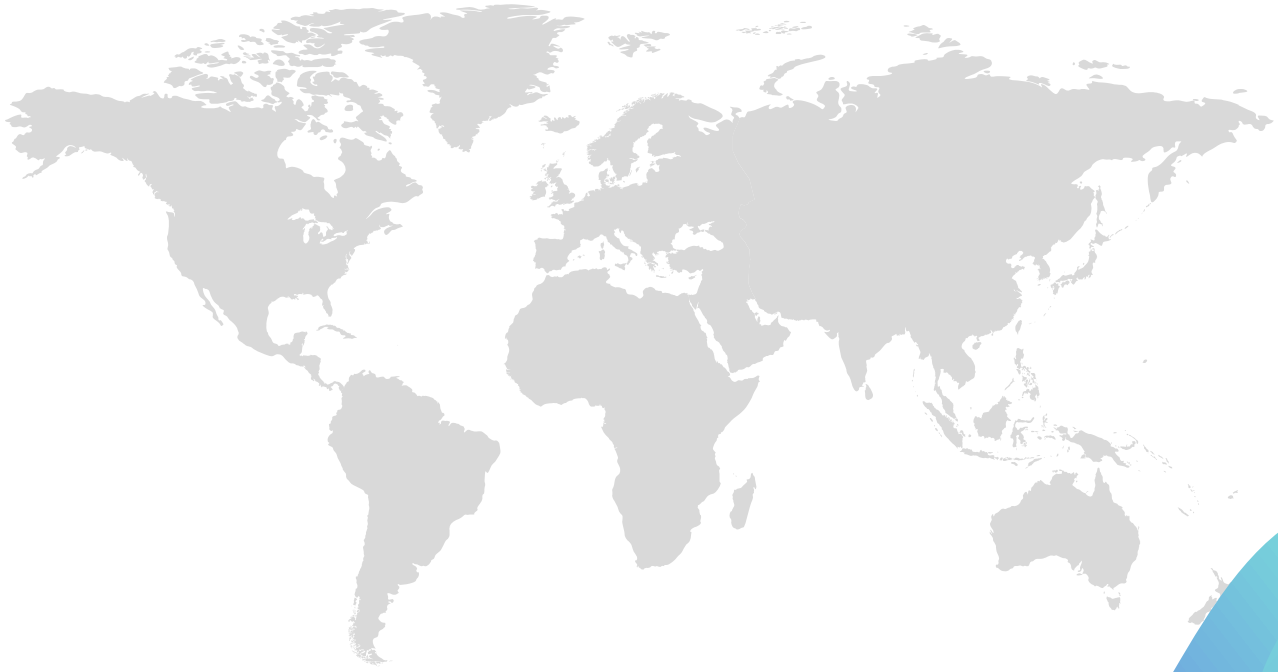
This course will provide an overview of the requirements for aseptic and bulk manufacturing operations, including facility design, contamination controls, and acceptable personnel behaviors.

Cleanroom classifications and the techniques for proper cleaning and disinfection are presented; along with a high-level overview of microbiology in regards to cleanroom environmental monitoring and the associated impact to product and patient health and safety. This course will also review the guidance provided in USP <1116> to ensure compliance with regulatory expectations are met.

Who Should Attend ?

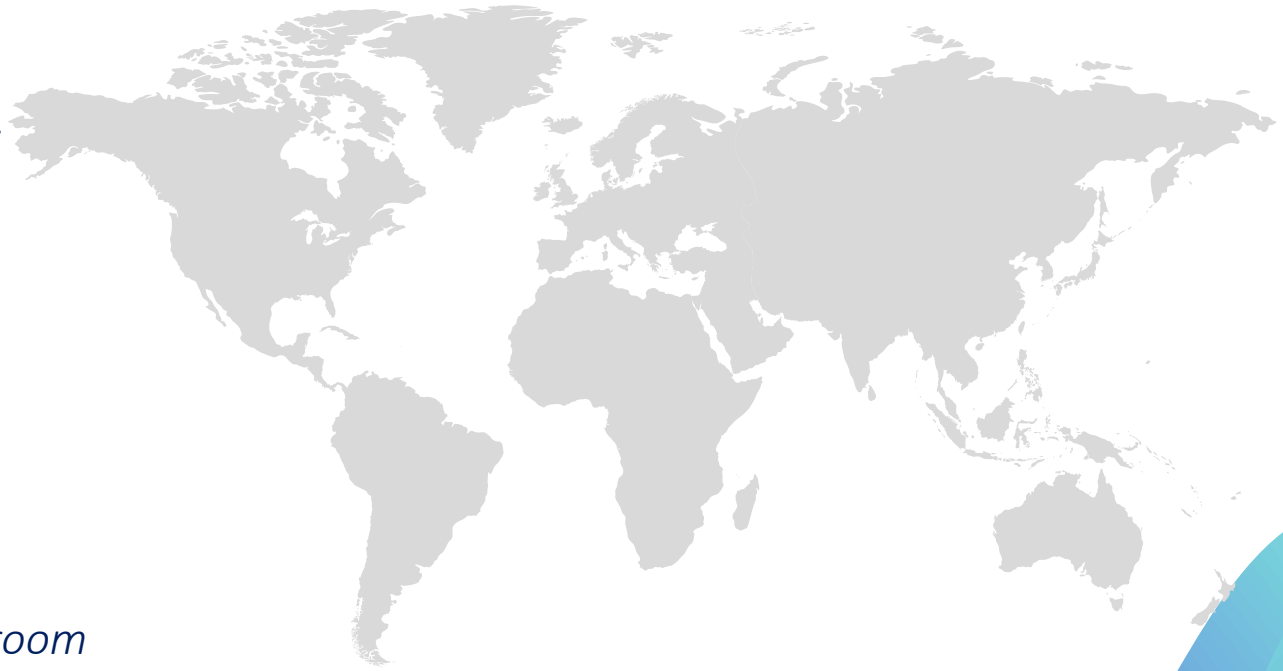
Target Audience: Operations employees who are required to enter controlled environments as part of their job function – includes some or all of the employees in the following departments:

- *Production*
- *QC Micro*
- *Engineering & Validation*
- *Facilities / Maintenance*
- *Quality Assurance*



GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

Why Should Attend ?

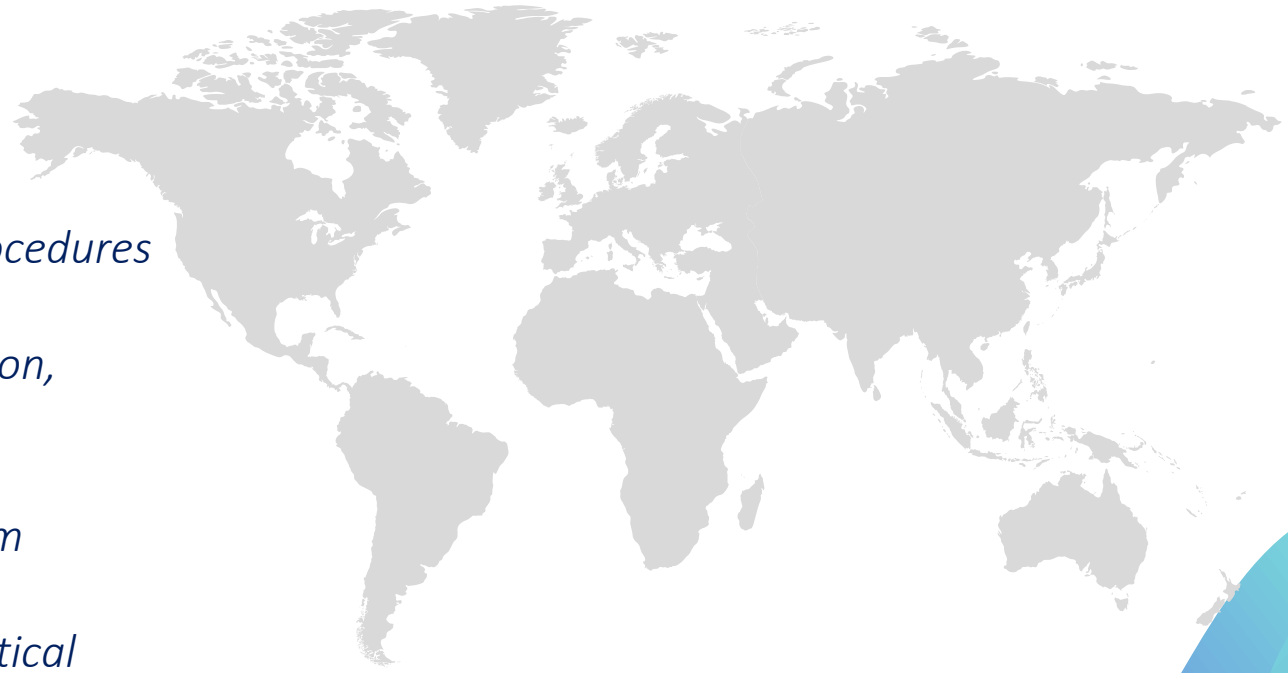


Course Objectives: At the completion of this course, attendees will be able to:

- *Explain the difference between Aseptic and Bulk processing*
- *Understand the facility and personnel requirements necessary to maintain microbial control*
- *Explain basic principles of microbiology and microorganism recovery in relation to clean room environmental monitoring (EM) and impact on product*
- *Understand the gowning requirements associated with different clean room classifications*

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

- *Explain basic principles of aseptic processing, including:*
  - *Cleanliness classifications*
  - *Proper Engineering controls*
  - *Process differences between aseptically produced and terminally sterilized product*
  - *Relation of manufacturing and handling procedures to sources of product contamination*
  - *The differences between cleaning, disinfection, and sanitization*
  - *Proper cleaning/disinfectant technique*
  - *Elements of a robust environmental program and why EM is important*
  - *The purpose of media fills, and elements critical to their success*
  - *The role of isolator technology*
- *Identify behaviors that are or are not appropriate when working in controlled areas, and why*
- *Identify ways that they can impact/improve site-specific EM and aseptic behavior issues*



GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321