

Single-Use Disposable Technologies Course

- Course Name: Single-Use Disposable Process Technologies in Bioprocessing
- Overview: Single-Use Disposable Bioprocessing products have gained rapid acceptance by biopharmaceutical manufacturer worldwide. Single-Use Disposable products have reduced contamination rates, enhanced production throughput and decreased overall operating costs. Recent collaborations between leading filtration, container /closure, mixing and cell culture companies have resulted in fully integrated Single-Use Disposable Bioprocessing platforms and systems.
- Description: This seminar presentation examines the many facets of disposable bioprocessing systems that incorporate a wide scope of polymeric single-use products and will cover;
- * Single-Use disposable Technologies, from upstream to downstream processes are reviewed as related to the use of polymeric devices.
 - * Specific attention will be given to the related applications used in the production of biopharmaceuticals and pharmaceuticals.
 - * How to increase productivity, reduce or eliminate cleaning and sanitization processes, reduce batch and cross batch contamination.
 - * Compare the significant material cost savings and reduction in operational expenses using disposables vs. hardware.
- OBJECTIVES: At the completion of this lecture course the participant will be able to:
- Identify applications where the use of disposables would be of practical advantage over hardware, e.g., cleaning validation.
 - Understand the concepts of disposable technology to assist in writing change control documentation.
 - Distinguish changes under the new regulatory process improvement guidelines, e.g., minor, moderate and significant filings.
 - Understand which processes and production areas would most benefit from a change to disposable products.
 - Describe the multiple cost saving analysis and plans for implementing and justifying the use of Single-Use Disposable Technology.
 - Use and handle basic S-U components and devices for a practical hands-on learning experience.

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- RATIONAL:** Attendees will learn the latest developments in Single-Use polymeric products, devices and their application in replacement of hardware. Practical illustrations will teach the participants the 'How-to' apply the disposable technologies on their projects and process operations.
- PREREQUISITES:** It is designed for the experienced staff as well as those new to biopharmaceutical processes.
- Who Should Attend:** Process Development Engineers and Scientists, Pilot-Plant Operations, Production Management and operation staff.
- KEY TOPICS:** Practical Application of Single-Use Technology in bioprocess and pharmaceutical process development and manufacturing.
- Change Control and relative risk analysis and assessment to implement a Single-Use program.
- Regulatory requirements and documentation understanding needed in Single-Use applications.
- Benefits and Cost savings realization from Single-Use programs.
- DURATION:** Two (2) days
- Materials and Equipment:**
- Classroom Instruction Area
 - Laboratory Area
 - A/V Equipment:
 - Computer Projector
 - Easel and markers
 - Laser Pointers
 - Bench Scale Bioreactor or TFF/CFF equipment.
 - SS Holding Tank, 5-10 Liters.
 - Aseptic and Quick-type polymeric Connectors
 - Bag and Chamber Samples, e.g., 1L - 5L
 - Assorted Lab Glassware, e.g., beakers, Test Tubes, etc.
 - Personal Protection Equipment
 - Magnetic Stir Mixer,(bottom) or Impellor type