Workshop Session II: Wednesday, January 29, 3:15 -4:30 pm

Microbiology Topics: Sterilization Validation and Aseptic Topics in Biologics

Workshop Co-Leads

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Topic Summary

This workshop will delve into key microbiological considerations and the evolving landscape of sterile validation and aseptic processing for biologics. Participants will discuss the current expectations for sterile validation data, environmental monitoring, and contamination control, as well as the challenges posed by products under accelerated development programs, newer biologic modalities, and addressing review issues related to sterility assurance. The session will also explore the complexities of validating manufacturing operations, exploring practical strategies for ensuring sterility and quality in flexible, multi-product facilities, as well as explore considerations related to the use of emerging technologies and AI.

Industry and Regulators are encouraged to share perspectives, including how companies are adapting to regulatory changes (particularly Annex 1 of the EU GMP guidelines), and addressing emerging questions in sterile validation. The discussion is intended to focus on how to better navigate the regulatory landscape and manage the risks and complexities of modern aseptic manufacturing.

Health Authority Expectations and Industry Perspectives for Sterilization Validation Data

- What constitutes robust and reliable validation data for aseptic processing and sterilization validation?
  - What is the role of risk management and how is it incorporated into sterilization validation?
- Are there any key differences between Health Authority standards and if so, how do we still achieve global compliance?
- What has been your experience with practical challenges and solutions for meeting the current standards?
- Any lessons learned from sterilization validation failures and successes in biologic product development and commercial production?
- Has there been any impact of Annex 1 of EU GMP guidelines on sterilization validation and aseptic processing?
- Any other recent trends or risks?

Impact of Emerging Technologies and Novel Modalities on Sterilization Validation

- How are we adapting sterilization validation to accommodate novel modalities (e.g., gene therapies, cell-based products, mRNA vaccines) with diverse attributes?
- How to streamline sterilization validation for smaller, more agile manufacturing environments?
- What are risk-based approaches for ensuring sterility and quality in the face of evolving technologies?
- Can AI be used for modeling sterilization validation, etc.? Has Industry started using AI and if so, any lessons learned?