WCBP 2025
Workshop Session 3

Bridging the Gap: Harmonizing Annex I and FDA Guidance While Understanding the Differences

Workshop Co-chairs

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Discussion Questions

- How do the new requirements in Annex 1 impact the manufacture of sterile medicinal products at your company?
- What are the main areas of harmonization between the revised Annex 1 and the FDA's 2004 guideline on Sterile Drug Products Produced by Aseptic Processing?
- Examples of how the revised Annex 1 and FDA guidelines differ in their approach to aseptic process design.
- How can manufacturers ensure compliance with both the revised Annex 1 and FDA guidelines in their aseptic processes?
- What challenges might arise from the new sterilization requirements for manually loaded lyophilizers in Annex 1?
- What strategies can be employed to manage the transition from internal production to contract manufacturing in light of the new guidelines?

Discussion Questions

- What best practices can be shared from your experiences in designing aseptic processes that comply with both EMEA Annex 1 and FDA guidelines?
- Has your company developed a contamination control strategy and if so, what have been the benefits of that development?

Discussion Questions

- How do the new requirements in Annex 1 impact the manufacture of sterile medicinal products at your company?
  - Enhanced contamination control
  - Stricter environmental monitoring
  - Risk-based approach – mandate application of Quality risk management
  - Reinforcement of quality system
  - Personnel training
  - Encourage use of advanced technologies i.e., barrier systems and isolators

Discussion Questions

- **Main areas of harmonization between the revised Annex 1 and the FDA's 2004 guideline on Sterile Drug Products Produced by Aseptic Processing?**
  - **Contamination Control Strategy (CCS)**
  - **Environmental monitoring**
  - **Quality risk management**
  - **Personnel training and qualification**
  - **Facility design to consider room classification levels depending on nature of operations; importance of pressure differentials**

Discussion Questions

- Examples of how the revised Annex 1 and FDA guidelines differ in their approach to aseptic process design.
  - Annex I integrates risk management and contamination control throughout the manufacturing process while FDA guidance focuses more on specific practices and procedures within aseptic processing
  - Annex I requires defines environmental monitoring both at rest and during production while FDA focus is on environmental monitoring during production
  - Annex I has significant emphasis on aseptic process simulation, FDA has less frequent simulations

Discussion Questions

- How can manufacturers ensure compliance with both the revised Annex 1 and FDA guidelines in their aseptic processes?
  - Comprehensive contamination control strategy
  - Implement robust environmental monitoring program
  - Apply quality risk management
  - Enhance personnel training
  - Utilize advanced technologies like PUPSIT
  - Any examples where details of differences mattered (e.g. headspace in simulation vs. no headspace).

Discussion Questions

- What challenges might arise from the new sterilization requirements for manually loaded lyophilizers in Annex 1?
  - Annex 1 can present several challenges for manufacturers
    - Increased Sterilization Frequency
    - Operational Downtime
    - Validation and Documentation
    - Equipment Wear and Tear
    - Contamination Risk Management

Discussion Questions

- What best practices can be shared from your experiences in designing aseptic processes that comply with both EMEA Annex 1 and FDA guidelines?
  - Comprehensive Contamination Control Strategy (CCS)
  - Robust Environmental Monitoring
  - Quality Risk Management (QRM)
  - Advanced Technologies
  - Personnel Training and Qualification
  - Process Validation and Aseptic Process Simulation (APS)
  - Continuous Audits and Inspections

Discussion Questions

- Has your company developed a contamination control strategy and if so, what have been the benefits of that development?
  - Benefits of developing a contamination control strategy
    - Enhanced Product Quality and Safety
    - Improved Process Efficiency
    - Cost Savings
    - Enhanced Reputation and Trust
    - Continuous Improvement
    - Risk Mitigation