Real Time Environmental Monitoring

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Agenda

• Challenges of growth-based environmental monitoring
• Next-Gen Environmental Monitoring
• Qualification
• Implementation Concept
• Q&A
Environmental Control Strategy

- Multi-layered risk assessment
  - Increased controls closer to product
- “Victim of Success”
  - Isolators are effective
  - Testing is source of risk – appropriate responses
Challenges of Growth Based EM

• Settle Plates capture challenges
  • Small portion of surface area / air flow challenges
  • Introduction of media into aseptic area

• Limited sample context
  • When did the microorganism event occur?
  • All or Nothing

• “Viable But Not Culturable” (VBNC) microorganisms.

2x10^6 Microorganisms

~ 0.1% Limitation of Growth Media

~ 8,000 Viable Microorganisms
Next-Gen Environmental Monitoring

Biofluorescent Particle Counters
• Real-time continuous active air particle counting that provide **bio-fluorescence, size, and count data** for environmental monitoring

Sample Capture for Identification
Video Cameras
• Trucking Industry – driver coaching and training
• Limited recording: **7 sec buffer + 8 sec event based**
Limitation of Airborne Monitoring

• Airborne bioburden analyzers measure airborne particles, inert or biological; it is not an indication of surface cleanliness.
  • *The air can be very clean even when floors or surfaces are not.*

• “Biologics” are not equivalent to CFU (colony-forming units). They include organic particles, Viable But Not Culturable (VBNC), stressed organisms, some interferents.

• The system does not replace a compendia test. The data cannot be used for QA/QC release purposes.
  • *The airborne bioburden analyzers enable risk reduction and source identification*
Video Camera Considerations

**Benefits**

- **“Electronic Window”** Enables remote observation without entering classified areas
- **Training** Identifying best practices for aseptic manufacturing
- **Investigations** Identify sources of variability and decrease the scope
- **Transfer troubleshooting** Objective evaluation of process upset or variability

**Challenges**

- **Background Activities** Ensure the field of view is appropriate for need
- **Data Archival and Review** Viewing versus archiving, local machines, +/- seconds of information.
- **Privacy & Legal** Ensure there is a written policy about video cameras usage
Process Qualification

- Demonstrated area & activity are “fit for purpose” at three levels:
  - As built
  - At rest
  - In operation

- Qualification of hardware and practical risk assessments
  - Filter integrity
  - Air pressure differentials
  - Temperature and relative humidity controls
Real-Time EM Implementation

Points to consider:
- Sample capture
- Parallel systems
- Identification limitations
- VBNC
  *Vial Tracking*

Post Production Decisions