

Real Time Environmental Monitoring

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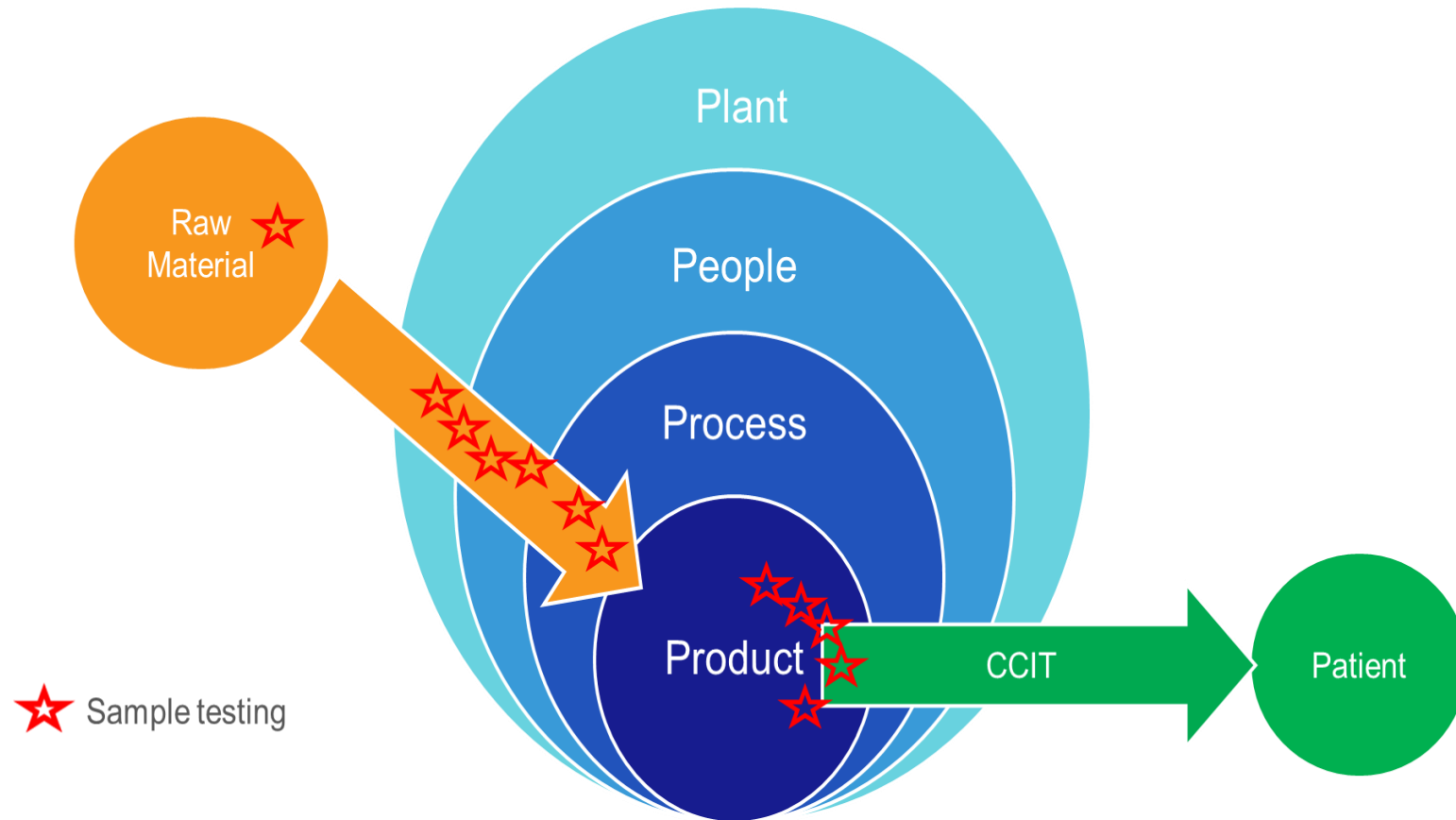
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Agenda

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

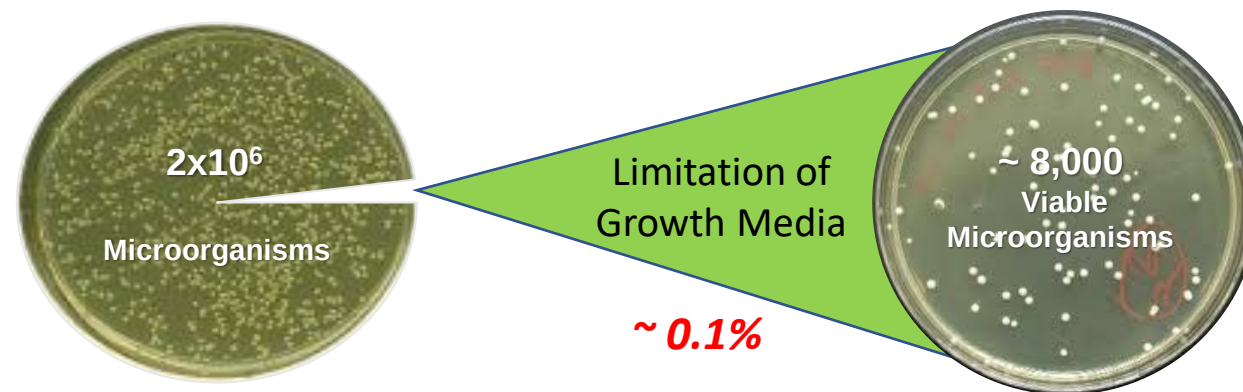
Environmental Control Strategy

- 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

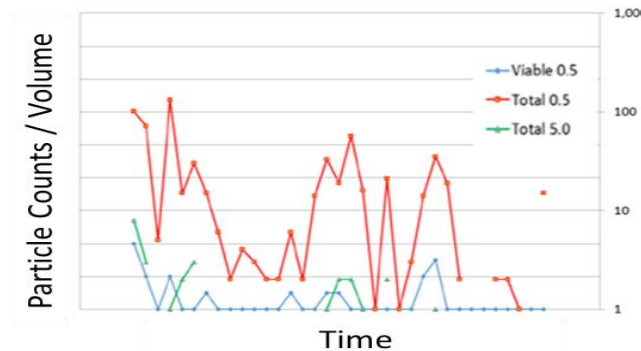
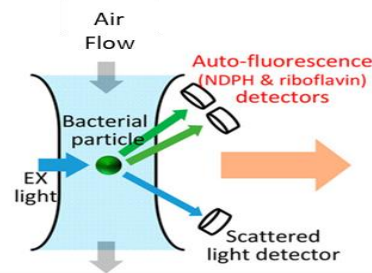
- Settle Plates capture challenges
 - Small portion of surface area / air flow challenges
 - Introduction of media into aseptic area
- Limited sample context
 - When did the microorganism event occur?
 - All or Nothing
- “Viable But Not Culturable” (VBNC) microorganisms.



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



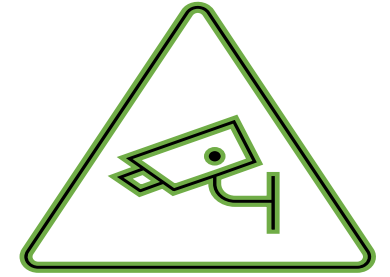
Sample Capture for Identification Video Cameras

- 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

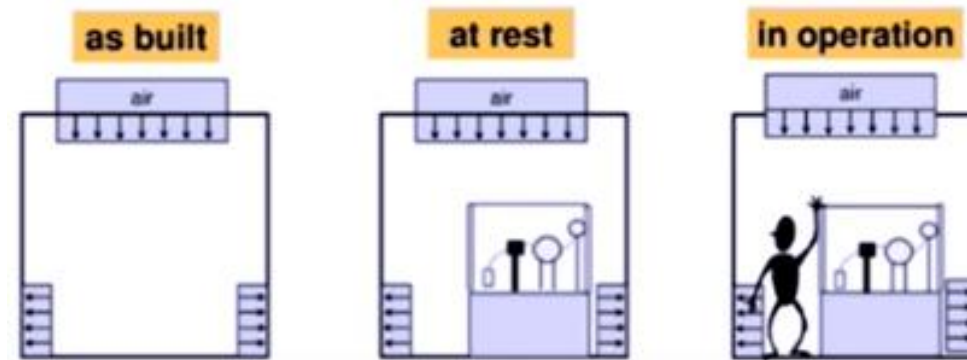
Challenges

- 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

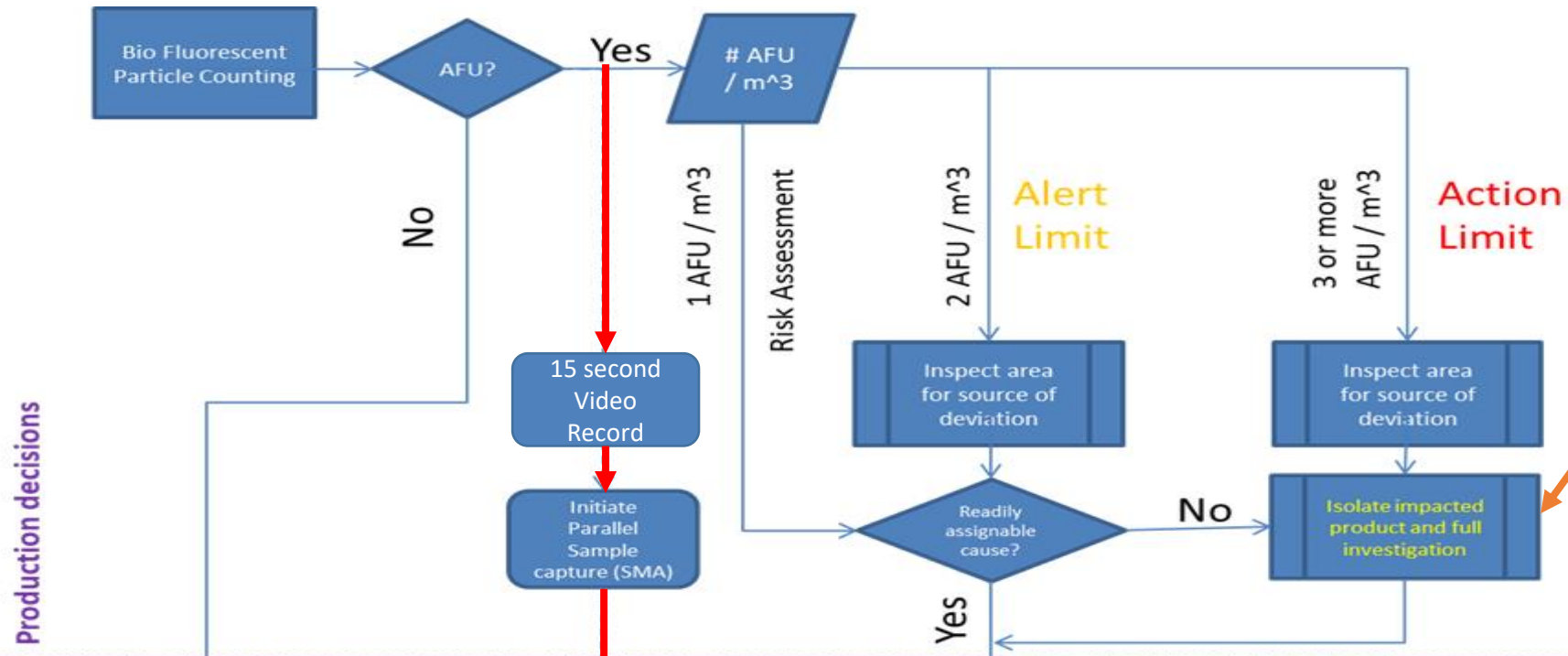
- Demonstrated area & activity are “fit for purpose” at three levels:

- 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

