Modern Aseptic Processing

What are you validating and why?

03Jun2020

Background

Aseptic Processing

Asepsis: the absence of microorganisms

Aseptic ≠ Sterile

Validation

A regulatory requirement

Establishing evidence of compliance for an activity or process

Validation

Requires a thorough understanding of the process

- A “black box” approach is not acceptable

Typical path to a validated state

- Installation Qualification → Operational Qualification → Performance Qualification / Process Validation

Aseptic Filling PQ / PV

Two key areas of focus

- Aseptic Process Simulation (APS)
- Environmental Monitoring Program (EM)

Why?

- Contamination is the #1 risk

Contamination

Two types
- Viable
- Non-viable

Two locations
- Surfaces
- Airborne

Effective management
- Prevent
- Eliminate
- Control
- Monitor

Contamination

Source?

- Interventions by ***people***!

Solution?

- Get the operators out of the environment
- Get the operators out of the process

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Priority #1: Eliminate the interventions

- Design a robust, automated process

Priority #2: Separate the operator from the environment

- Locate the process in an isolator

Result: The introduction of the

- gloveless
  - robotic
    - isolator

aseptic filling workcell

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The gloveless, robotic, ***isolator*** aseptic filling workcell

ISO5 / Grade A Environment in an Isolator

- Allows effective decontamination
- Separates the less clean areas from the critical filling zone
- Removes the operator from the environment

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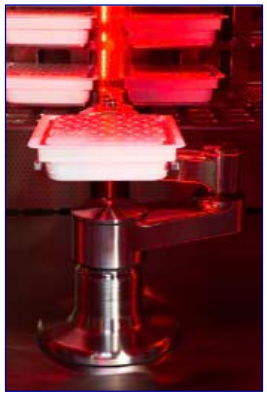
The gloveless, ***robotic***, isolator aseptic filling workcell

Robotic (or automated) Process Handling

- Possible due to use of nested RTU components
- Eliminates container to container contact
- Removes the need for human intervention
- Minimizes the amount of process-specific tooling



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The ***gloveless***, robotic, isolator aseptic filling workcell

No gauntlet gloves on the isolator

- Removes the operator from the *process*
- Eliminates a source of isolator integrity failure
- Shortens decontamination aeration times

Implementation

Positive developments

- More and more regulatory guidance documents specifically addressing isolator use
- Some excellent industry evaluations and publications
- The innovation directly addresses the key focus areas of aseptic process validation
  - APS
  - EM

Barriers to Implementation

Deeply established validation approaches to:

- APS
- EM

A couple examples

- Mandating APS for every container/closure/fill volume/batch size combination
  - Use matrix (“family”) approach to simplify
- Requiring extensive EM when operators are no longer part of the process
  - Use well-supported risk assessment to design EM

When it comes to innovation, we can be our own worst enemy.

Discussion/Questions

Thank you