
Joyce Hansen
Vice President, Johnson & Johnson Sterility Assurance
“Connecting the Dots to Foster Innovation & Talent”

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Supply Chain End-to-End
Supply Chain End-to-End

- Manufacturing site
- Suppliers
Supply Chain End-to-End

- Microbial controls
- Raw materials
Supply Chain End-to-End

 Sterilization

- Facility, gowning, env. controls
- Microbial controls maintained
- Packaging
Supply Chain End-to-End

- Maintain sterility
- Temp/RH controls
Supply Chain End-to-End

Sterility Assurance End-to-End
Why focus on only a portion of what we do?
- Currently address validation from being in a “state of control”
- Not easy to see how linked together

Future products:
- May not be capable of withstanding aseptic processing or terminal sterilization
- May not need terminal sterilization

New Talent:
- Need to share “why” we do what we do
Proposal: New AAMI Working Group to address “E2E Sterility Assurance” with the goal of developing a Standard or Technical Report
Thank You