

MANUFACTURING SINGLE USE SYSTEMS WITH QUALITY IN MIND: HOW TO ASSURE PERFORMANCE, ROBUSTNESS, AND STERILITY OF SINGLE USE SYSTEMS

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Quality control during the manufacturing of single use systems is critical. With traditional stainless-steel systems, the end user has significant control over the design, construction, qualification, validation, and maintenance of the system. When implementing a single-use system, the supplier of the single use product takes responsibility for many of these functions from the user. It is therefore important that the single use supplier has established and uses a robust quality control system. This presentation will highlight the quality systems, processes, facilities, and personnel required to assure the performance, robustness, and sterility of single use systems.

The following topics will be covered:

- Single-use assembly validation
- Qualification of components
- Sterilization qualification
- Manufacturing processes
- Quality control
- Release testing
- Certification
- Risk mitigation practices
- Process particulate control
- Operator training
- Leachables & Extractables
- Patient safety evaluation, study design
- Support by the supplier