6 Case studies

Numerous unit operations in a biopharmaceutical production process can take advantage of single-use technology (SUT), from bioreactors, filtration, centrifugation chromatography and filling operations through to mixing, connection/disconnection, sampling, product transfer, hold and storage. Even though one unit operation may involve a single application, several types of SUT (e.g., bags, filters, tubing, tubing, fittings, sensors, valves) may be involved, all of which are composed of materials and properties that may differ.

Implementation of a SUT system starts with selection of the appropriate technology for the intended use, followed by a detailed definition of the intended application of the equipment and all related requirements. This information should be captured in a user requirement specification (URS). Based on the URS, the design phase and material selection of the SUT is initiated. System design of the SUT will be draft versions until a feasibility trial or verification is conducted before selection. During this stage, relevant component- and product-based tests can be established. At this point, understanding of the requirements and preferred options should be sufficient to reassess capital sanctions.

Once capital approval is assessed to acquire the technology, then the URS, SUT design and material selection are revisited and completed. The final stage is qualification of the process equipment parameters and procedures, followed by a final process performance qualification (PQ). This chapter presents a general overview and examples of particular attributes and considerations during the selection, specification, design and qualification of SUT used for:

- Storage and preparation of solutions using bag systems;
- Cell culture using single-use bioreactor (SUB) technology;
- Tangential-flow filtration (TFF); and
- Formulation, sterile filtration and filling operations.

Considerations during implementation of off-the-shelf and custom-designed SUT systems are presented.

A risk-based approach is presented throughout case studies, with examples of more formalised versions of risk assessments, such as failure mode and effect analysis (FMEA) applied to design, operation and quality attributes of the product.

All examples shown are for demonstration only because each organisation will have their own methodology and approach to assess risk.

All sections within the case-study chapter must be read to elicit good understanding of overall considerations of SUT implementation because different examples are presented in different sections, which can be applied readily to a given SUT system.

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