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# Process time and cost savings achieved through automation and islands of integration in existing facilities.

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Title

Process time and cost savings achieved through automation and islands of integration in existing facilities.

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Abstract

For most biopharmaceutical manufacturers the cost, time and quality improvements offered by adopting continuous manufacturing operations is, as with any new technology, inhibited by the research and validation costs associated with early adoption. Additional effort is needed to validate the novel technology in-house. There are simple changes that can be made in disposable biomanufacturing , which are necessary for the eventual adoption of full continuous operations, and yet have benefits now. These step changes are shown by economic & scheduling models to offer direct cost savings and improved facility throughput. A road map of these step-wise improvements is provided that leads to fully continuous processing, but minimises the technological risk.

The first step change is a wider adoption of process automation. Automation eliminates operator error, reduces contamination risk and improves batch-batch quality. The higher direct cost of the operating system is offset by improved utilisation of facilities and fewer batch failures.

The next step is to automate the operation of a combination of relatively simple units, such as dead-end filtration, flow-through adsorption, virus filtration, in-line concentration. The aim is to minimise hold steps, QC testing, processing time and maximise the use of disposable manifolds. Incorporating automated integrity testing into the operation further enhances the processing. Examples of such operating systems will be described, either as standard items that require configuration or as customised options, to illustrate the economic risk/benefit analysis.

Additionally, the islands of continuous operation can be extended - for example, perfusion bioreactor operation, capture chromatography integrated with low pH virus inactivation, or flowthrough polishing chromatography integrated with virus filtration and diafiltration. Integrated chromatography and virus inactivation will be reported with the main advantages seen from contracting the process from two working shifts to one and yield increase when producing biotherapeutics sensitive to low pH or sensitive to changes in pH through the isoelectric point.

How each step change compares to envisioned full continuous processing depends on the operating requirements of the facility, with the key variables being the number of biopharmaceutical products manufactured, number of batches per product, titre, bioreactor volume, changeover time and QA release time. As with all facility and operational changes, the value of the benefits discussed depends on the demand being placed on the facilities by products in clinical phases or commercial manufacturing.