

Quality edition

How can biomanufacturers strengthen process control as they scale operations?

Turning disconnected process data into actionable insight

As biomanufacturers scale from process development to commercial production, maintaining process visibility and consistency becomes increasingly difficult. Multiproduct facilities, hybrid manufacturing environments, and growing automation demands often introduce disconnected systems, inconsistent data architectures, and operational silos that can slow scale-up and weaken process control.

From bench-scale development to commercial manufacturing, tech transfer can also become increasingly complex and time-consuming due to different vessel sizes and disparate automation platforms. Manufacturers can encounter several challenges, including:

- Additional manual labor during tech transfer
- Limited continuity of process data across the manufacturing lifecycle
- Increased variability during scale-up

At the same time, manufacturers are under increasing pressure to maintain compliance by quickly identifying and investigating deviations. When alarms, events, audit trails, and process data exist across multiple systems, gaining a clear operational picture becomes more difficult.

To address these challenges, many manufacturers are adopting centralized automation and scalable analytics strategies that help improve process visibility, simplify tech transfer, and support more connected manufacturing operations.

Why is centralized data aggregation important for process control?

Bioprocess data is often spread across multiple equipment platforms, vendors, and software systems. This fragmentation can create data silos and affect compliance readiness, making it harder to identify, trace, and review audit trails.

A centralized data management strategy enables a single source of truth across manufacturing operations, helping to streamline traceability, strengthen data integrity, and provide operators with better visibility into process performance. With centralized access to process data, manufacturers can streamline deviation investigations and make fast operational decisions.

How can distributed control systems (DCS) help improve scale-up and simplify tech transfer?

As biomanufacturing operations scale, many facilities find themselves managing multiple automation platforms across vessel sizes, production lines, and sites. When process development, scale-up, and manufacturing systems operate independently, they can create data silos, increase tech transfer complexity, and reduce visibility across the broader process workflow. Unlike isolated programmable logic controller (PLC)-based systems, DCS allow operators to monitor processes holistically and share data between equipment across upstream and downstream operations.

Additionally, inconsistent naming conventions and data structures across platforms can make it difficult to unify process data across equipment, facilities, and production stages. For example, the same process parameter may be labeled differently between systems, vessels, or automation platforms, creating disconnected data that complicates downstream integration.

Rebuilding process settings manually across scales or facilities can also increase the risk of human error and make process knowledge transfer more difficult to maintain. By using standardized DCS architectures and reusable control strategies, biomanufacturers can reduce variability by enabling operators to apply verified process configurations across production lines and vessel sizes rather than recreating settings manually for each run.

Building a more connected manufacturing strategy

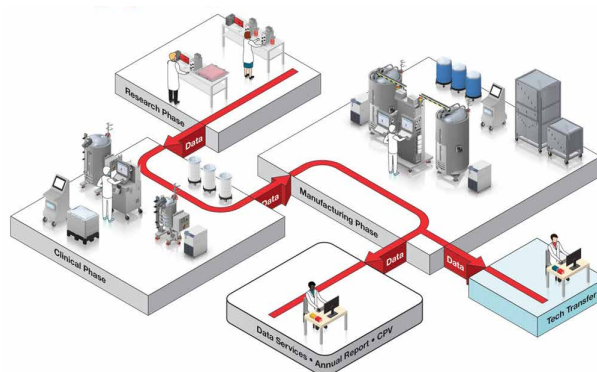
As biomanufacturing operations become more complex, strengthening process control requires more than standalone data systems or isolated automation tools.

Biomanufacturers can help strengthen process control by:

- Centralizing process data to improve traceability and streamline deviation investigations
- Using DCS to connect equipment and improve operational visibility
- Standardizing data models and control strategies across vessel sizes and facilities
- Reducing manual configuration steps during scale-up and tech transfer to help minimize variability

Product spotlight

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