Automation of Bioreactors

Single Vessel to Vessel Trains

Advantages

- GAMP-4 methodology in design, implementation and testing provides a solution that is easily validated
- Design based on S88 methodology provides process flexibility, repeatability, and accountability
- Enables compliance with 21 CFR Part 11 requirements and by validating production process and auditing, including IND and NDA/BLA approvals
- Improved enterprise and supply chain efficiency with FactoryTalk® Pharma Suite
- Use of standard control modules expedites design and implementation and eliminates the need for repetitive testing of each module
- A variety of hardware options to meet processing and design requirement for control, I/O, and networking

Overview

Automation helps companies using bioreactors or fermenters as the key equipment in a manufacturing process achieve predictable execution of each batch. Whether a single vessel or large train, bench top or production scale, automation reduces project and production risk to achieve dependability in bioreactor operations.

During the implementation phase of a project, importance is placed on how quickly and reliably a bioreactor can be moved into production. Many biotech companies also strive to reduce the I/O footprint of the control devices. Throughout the process, the success of the application is judged by how precisely the process can be controlled, the integrity of each batch, and how easily product consistency can be verified for FDA compliance or system performance.

Rockwell Automation’s bioreactor control solutions adapt to all types of bioreactor environments, providing consistency, repeatability, and tight control. Our latest batch-enabled systems quickly deliver an easy to validate system that provides flexible, recipe-based operations. Pre-engineered control modules and phases reduce design, testing and ongoing maintenance for a lower total cost of ownership.
Challenges

Bioreactor or fermentation processes are the core manufacturing process in the biotech industry. Implementation delays and process upsets can result in the loss of millions of dollars in revenue through lost product and downtime. Because the bioreactor is such a critical component, getting it into production as quickly as possible and keeping it running, are essential to the profitability of a biotech operation.

During implementation, many end users strive to reduce the I/O footprint of their control devices, since bioreactors use a wide-range of varied signals. Analog I/O points measure pressure, temperature and bring in flow rates for buffer and media. Discrete I/O controls peristaltic/ metering pumps and valves. Additionally, analytical probes control pH, dissolved oxygen and conductivity.

Throughout the process, bioreactors need to maintain precise control speed in the agitator to minimize shear. If the agitator creates too much turbulence, the microorganisms being grown may be torn apart. High rates of oxygen flowing through the sparge tube and improper agitator design can add to the problem of shear.

Additionally, system performance and FDA compliance remain high on the list of challenges faced by bioreactor users. Verifying product consistency may quickly become complex. Laboratory vessels may require many manual steps and highly flexible recipes. Larger bioreactors demand automation for consistent and repeatable operation because each batch can hold millions of dollars’ worth of product with each stage adding significant value.

For bioreactor manufacturers, producing customized equipment and getting it quickly to the market is important to success in the biotechnology industry. Moreover, bioreactors link with other systems such as upstream media supply, downstream harvesting and purification, as well as utilities such as high-purity steam, water, air, and clean-in-place sterilization. Easy and predictable integration into a plant-wide installation may set bioreactor manufacturers apart from the competition.

Solutions

To ensure dependable and consistent operation, biotech companies need reliable control solutions that can be installed quickly allowing them to confidently manage the throughput and integrity of each batch. Rockwell Automation is in the unique position to enable OEMs to provide a world class turn-key solution on their own or provide a turn-key bioreactor control solution, leveraging Rockwell Automation’s engineering team, which has vast experience in life sciences implementations and validations, and can help reduce project and production risk while achieving reliability.

Our batch-enabled controllers can quickly be assembled into an easy to validate control system, which supports flexible recipe-based operations. Control schemes are based on a library of standard off-the-shelf control modules supported by our experience in automating biotech/fermentation processes. This provides assurance of operation reliability and can reduce the cost of ownership. We can also help increase production flexibility through a wide spectrum of tools and services, including real-time batch management tools, scheduling tools, consulting, and engineering.

To help overcome the common challenges of biotech companies, our solution specifically offers the following equipment and technology.

- To help reduce the I/O footprint of control devices while meeting the needs of many varied signals, our solution leverages the scalable Logix control platform and the time proven, granular POINT I/O™ platform (in many cases a single reactor requires between 14 and 26 I/O).
- Our Variable Frequency Drives (VFDs) on EtherNet/IP offer more precise speed control than analog, improved diagnostics, faster commissioning, faster time to market and potential energy savings.
- Data collection/tracking offerings bring value by controlling privileges and writes during a batch, documenting who changed what and when, bringing reliability to tracking and storage of process parameters, and knowing immediately when parameters are out of specification and why.

For bioreactor manufacturers, Rockwell Automation can help quickly and easily tailor a standard solution to customers’ specific applications with our Midrange Architecture System. Our midrange system offers:
- Scalability
- Single network EtherNet/IP
- Information-enabled solutions
- Easy distribution with granular I/O
- Add-on instructions (AOI)/faceplates to allow for reusable global objects

Manufacturers can also reduce time to market by taking advantage of our complete product life cycle management solutions and services – from development to clinical supplies, scale-up, and production.
Typical Midrange Architecture System

- HMI decision is based on need for local data collection on each bioreactor/fermenter
- If 21 CFR Part 11 is required, FactoryTalk® View SE and FactoryTalk® Batch are usually required for Electronic Batch Records, driving need for Windows-based computer

PanelView™ Plus 6

Allen-Bradley Industrial Computer

CompactLogix™ S370 L3 or

CompactLogix S370 L1

Stratix

POINT I/O

PowerFlex® 40 on EtherNet/IP for mixer and pumps