

## Case Study

# Advent Enables Manufacturing Flexibility for Biopharma Leader



A biopharmaceutical and medicine manufacturing company driven to revolutionize the manufacture of novel medicines was expanding. With an eye toward pandemic preparedness following the COVID-19 pandemic, the organization had purchased two single-use fermentation process lines instead of traditional stainless-steel equipment to allow for greater production flexibility.

The equipment, which ranged from biorockers to a bioreactor train, was the first of its kind to be installed at the facility, and the company turned to Advent Engineering for commissioning and qualification.



### Challenge

A biopharma leader wanted to position its manufacturing lines for greater flexibility in producing different types of vaccines.



### Solution

Advent identified opportunities to streamline in order to complete testing, commissioning, and qualifying processes in one month.



### Result

Advent enabled the client to move to process validation for the line, enabling production flexibility and reducing risk.



## Challenge

Looking to adopt the flexibility needed to manufacture different vaccines, the client had chosen single-use equipment, which uses plastics, rather than the stainless-steel materials typically used in a pharmaceutical manufacturing facility. Single-use equipment decreases the amount of time required for cleaning and line clearance in between campaigns, but it also introduces new concerns about leachables and extractables. The client's quest for flexibility and the tight schedule meant that Advent needed to evaluate equipment and component capabilities to determine the best ranges to test.

The client was operating on an extremely tight timeline, which was complicated by the need to stagger how and when teams worked in accordance with World Health Organization guidelines during the COVID-19 pandemic. Advent had just over a month—about half the time typically required—to complete execution and qualify multiple pieces of equipment.

## Solution

The Advent team began by evaluating the equipment and determining the level of qualification required for each piece based on its criticality, or impact on product quality or patient safety. The team then reviewed the major functions of the equipment to determine the level of functional testing required during validation. Because there was also a large amount of automation on the equipment, Advent also performed a Data Integrity and Electronic Records Assessment to ensure compliance with the U.S. Food and Drug Administration's 21 CFR Part 11. Advent used the results of these assessments to create commissioning and qualification protocols for the process equipment.

The Advent team leveraged its extensive experience in the process equipment being installed and the manufacturing processes involved to streamline qualification efforts on site. Advent reviewed vendor factory acceptance tests (FAT) and site acceptance tests (SAT) to determine cases where the level of details provided were appropriate and could be leveraged to reduce the amount of testing required. In addition, because there was a wide range of hose sizes to be used in the peristaltic pumps, Advent took a bracketing approach to testing. Instead of testing 5 or 6 different hose sizes per pump, which could take a significant amount of time, Advent determined the minimum and maximum flows required for manufacturing and ensured that all required flow rates were available with the various hoses.

Once testing was complete, Advent compiled all of its findings and recommendations for future use of equipment. A Requirements Traceability Matrix was also completed, confirming the testing and documentation of all user requirements.

## Result

Using a risk-based validation approach and bracketing to streamline and minimize testing, Advent successfully completed all qualification execution activities in one month, enabling the client to move to process validation for the line. By identifying possible failures and mitigation measures, such as monitoring and alarms, Advent also helped the client successfully reduce risk and position the facility for greater flexibility in production.

### About Trinity

Founded in 1974, Trinity Consultants helps organizations overcome complex, mission-critical challenges in EHS, engineering, and science through expertise in consulting, technology, training, and staffing. We support clients in geographies worldwide and across a broad range of sectors including industrial, energy, manufacturing, mining, life sciences, and commercial/institutional.