



# ISPE FOYA award winning project – The next generation of digital manufacturing excellence

### At a Glance

**Company:** Leading Biotech organisation

**Location:** US

#### Project Mission

To create the next generation of biotech manufacturing site – first facility to use continuous intensified biologics production technology

#### Product / Services

Consultancy and implementation of Automation for Continuous Manufacturing

#### Challenges

- Greenfield site building factory of the future
- Digital manufacturing focus
- Greenfield site to ramp up Biotech production capacities
- Goal to be the leading edge of biologic manufacturing
- Paperless and data driven manufacturing technology

### The Challenge

The main goal for this global Biotech customer was to be at the forefront of biologic manufacturing. This greenfield facility was designed to be an inspirational Factory of the Future and ramp-up Biotech production capabilities in the US. As part of this revolutionary new build, the client wanted to reap the benefits of continuous manufacturing.

Compared to batch processing, Continuous downstream bio-manufacturing operates at significantly reduced volumetric rates. This allows large reductions in facility footprint and equipment sizes (~75% reduction). Additionally, continuous bio-processing operates at a faster process cycle time compared to batch, which reduces work in progress inventory and improves product stability. Continuous processing is widely used in other industries but has been slow to be adopted by biotech.

This project aimed to use continuous, intensified biologic production technology to build one of the world's first digital manufacturing facilities. This Factory of the Future design also included single use process trains, which dramatically shorten time to market, reduce capital costs, improve cycle time and reduce energy consumption.

This digital transformation of the company's manufacturing network sought to enable better use of data to optimise manufacturing processes and ultimately speed up the commercialisation of new medicines emerging from the R&D pipeline.

The facility was the first digital transformation initiative of its kind for the company and the plan was to roll out its innovations as standard and establish a gold standard of biologic manufacturing across the network.

There are many challenges to implementing a complex facility of this nature. From complex equipment designs and controls requiring a robust operation for long duration's to be able to compare batch processes to no universal sampling approach or proven methodology for obtaining representative samples across all stages of the continuous process. This does however mean there are opportunities to develop new methodologies and wider scale product portfolios for continuous equipment.

## Our Solution

Zenith Technologies was part of the engineering team from the very beginning and led the automation project, from concept development, through to being the largest engineering team during design, construction and testing. Focused on creating a flexible and continuous manufacturing strategy, the team developed the automation system for equipment monitoring and process tracking, monitoring and control and efficient utilisation of resources and facilities. Zenith delivered:

- Sophisticated process control for single use unit operations, including continuous upstream and downstream processing
- Integrated data collection systems for process measurement, alarming and reporting
- Interconnected, advanced material tracking systems throughout the facility

As the main systems integrator, Zenith engineers developed the software to control every unit operation. The team also developed the software that integrated the sensors, unit operations, and materials management into a cohesive and effective system. At its peak they had a comprehensive team of 20 engineers on the project team, all ensuring this bespoke system was stable and optimised as well as being delivered on time and to budget.

Chosen as their automation partner, Zenith are widely recognised as leaders in automation engineering for Biotech manufacturing. Zenith's reputation of being at the cutting edge of technology development and support, meant they were a reliable choice for implementation.

## Results and Benefits

Working in close collaboration with Zenith, the company successfully opened the new facility and was able to achieve higher levels of productivity, agility and flexibility, which will reduce the time for a product to move from development lab to patient.

The facility leads the way in delivering the next generation of biologic manufacturing by using data to optimise processes. Its success will shape not only the future of the company but also the industry as a whole.

Highlights of what was achieved during this project were:

- Continuous, multi column chromatography for downstream processing
- Plug and play automation integration of mobile process equipment and product totes.
- Continuous buffer manufacturing using in-line dilution
- Advanced process sensors for real time data analysis and reporting for process control

Beyond this initial facility, there are now similar digital transformation initiatives planned for other sites in Europe and The Americas.

This factory will help meet increasing world-wide demand at lower capital and operating expenses, making it economically feasible for the customer to continue to supply the medicine to so many people whose lives depend on it.

## At a Glance

### Solution

- On the core concept team
- Largest engineering team during design, construction and testing
- Delivery of automation for continuous upstream and downstream processes
- Integration of data collection systems for process measurement, alarming and reporting
- Interconnected Material tracking system

### Results

- Next generation Biotech manufacturing facility opened on time and to budget
- First facility to use continuous intensified biologic production technology
- Using data analytics to drive excellence
- Higher level of productivity, agility and flexibility
- ISPE FOYA winner for Facility of the Future

