

Biologics facility upgrade ensures capacity demands are met for new cancer fighting immunotherapy

At a Glance

Company

Top 10 Biopharmaceutical manufacturer

Project Mission

Repurposing an existing facility into a new state of the art biologics facility to produce immunotherapies for the treatment of cancer

Location

Existing site in Ireland

Technology

Emerson DeltaV™ DCS

Services Delivered

- Front End Engineering Design
- Systems Integration
- Software Engineering
- Commissioning of the control system software
- Support for Qualification and Conformance Runs
- Computer System Validation
- Document Control
- Managed Service

Delivering engineering design, system integration, commissioning, and CSV to upgrade an existing facility in order to manufacture top cancer immunotherapies, and all executed during the Covid-19 pandemic. Support provided for system and equipment qualification, and start-up of manufacturing operations.

Introduction

A global biopharmaceutical company decided to renovate an existing facility in Ireland and transform it into a state-of-the-art biologic's facility, to manufacture treatments of a wide range of cancers.

Zenith Technologies, A Cognizant Company, provided the design methodology, technology expertise, and resources to deliver a new manufacturing system that would transform the original site beyond recognition.

The project team provided front end engineering design, system integration, commissioning and qualification that resulted in a facility able to manufacture the immunotherapy oncology biologics like never before. A managed services team was also set up to support the operational start-up of PAS, OEM and MES systems within the facility.

COVID-19 complicated the delivery of the project since it meant adapting schedules and organisation of personnel to take restrictions into account.

Collaboration between all global teams

Zenith Technologies' global teams, from 6 offices, collaborated tirelessly to design, implement, and support the development of this project. Operations, software engineering, quality/validation, and sales teams began work in 2018 to proceed through four consecutive phases within an accelerated timeframe:

- Front end engineering design (FEED)
- Systems integration (SI)
- Commissioning and qualification (C&Q)
- Managed services agreement (MSA)

Complex coordination and fast-tracking during lockdowns

The fast-track schedule of the SI project, combined with the need to coordinate a large number of engineers in offices around the world, made this an ambitious project. Engineering expertise over a wide range of roles allowed flexibility for individuals to take on design, coding, testing, commissioning, changes, or support as needed to deliver to the tight schedule.

The COVID-19 pandemic and lockdowns further complicated this and required creative approaches to overcome this significant hurdle.

The integrated factory acceptance testing (iFAT) that occurred pre COVID-19 at vendor sites in numerous countries required organizing the movement of engineers and the shipping of DCS controller flight cases used to connect hardware and software to test the equipment on vendor skids.

The coordination of the site teams involved in each workstream of C&Q was also complex and was led by a project manager and lead engineers.

Six months from the start of the commissioning process, Ireland went into a COVID-19 lockdown. The team worked from home for two weeks while the customer prepared the facility for physical distancing, enhanced cleaning, and altered work practices. Reintroduction of the team to the facility then occurred in phases.

Client benefits

The engineering team delivered a one-stop solution with a single point of responsibility for the DeltaV™ integration, C&Q, and support which included:

- Continuity of resources through each project phase meaning the same engineers were involved throughout.
- Device and instrument testing at iFAT was leveraged to make on-site loop testing more efficient.
- iFAT and SFAT results were leveraged, where possible, to speed up physical and procedural layer testing.
- A comprehensive understanding of the DeltaV™ software since most of the site team was involved in the design, coding, or testing stages of SI.

This project was delivered on time and to budget. The introduction of the new systems to a very high quality, and the output was a fully qualified control system providing the facility with the capacity and technology required to make the immunotherapy.

Additional services that Zenith delivered included DeltaV™ eLearning support, MES project support, Laboratory Systems validation support, and the integration of Cytiva Wave Rockers to DeltaV™.

Managed Service for biologics manufacturing and New Product Introduction

The team successfully closed out the initial three phases (FEED, SI, and C&Q), ensuring the pharmaceutical client has the manufacturing capacity to make the cancer fighting immunotherapy biologics in 2021.

The Zenith Technologies team continues to deliver manufacturing support. Through the managed services agreement the team is responsible to support the operational start-up, ensuring the manufacturing IT systems remain in a validated state and continuous improvement is delivered. The Zenith team has also been tasked with a Front-End Study (FES) for a new product introduction (NPI) into the facility.

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Project Challenges

- Demanding fast tracked schedule
- Co-ordination of global engineering teams across 6 offices
- Overcame the significant hurdle of the Covid -19 pandemic

Results

- One stop solution for integration and support
- Complete project life cycle management
- Fully qualified control system providing the facility with capacity and technology requirements
- Project delivered on time and to budget
- Continuing to deliver manufacturing IT systems support through managed services
- Ensuring systems retain valid state
- Continuous improvement initiatives delivery

