

Site Expansion Project

Major expansion project through demolition, new construction, start-up & integration without causing disruption to production.

At a Glance

Company: Top 10 Global Pharmaceutical Company

Location: Ireland

Project Mission: To increase manufacturing capacity and expand a site

Product / Services: Enterprise / System Integration, Verification & Qualification

Challenges:

- Major expansion project through demolition, new construction, start-up and integration
- Build new cleanrooms and expand existing ones
- Standardise to DeltaV™
- Tight schedule and budget
- Minimise impact on production

Solution Delivered:

- Project Design and Development
- Collaboration with all vendors
- Providing and Implementing the new control system

The Challenge

This customer manufactures biopharmaceuticals and vaccines, and currently has 1,000 full time employees on site. The site in question is one of the largest Biotech Operating Units implementing state-of-the-art technology, cutting edge thinking and production expertise. As part of a reorganisation of its manufacturing strategy, the company launched large expansion project to add manufacturing capacity and transfer existing products to another facility.

The work encompassed expanding an existing clean room suite within the product manufacturing building. This included adding new production rooms and equipment, but the work had to be carried out within an existing, functioning facility. It was essential to complete the work without any impact on existing production. The project also included the creation of two entirely new clean rooms. This work involved some demolition on the ground floor area and the removal of an obsolete production suite. One of their key requirements was to integrate the automation control of both the new and existing equipment in the building.

The company also wanted to improve productivity and efficiency by making all the equipment in the main production process use the same software - in this case the DeltaV™ DCS (Distributed Control System). Zenith Technologies was chosen to handle all aspects of the automation software, from collaborating closely with the company and the skid vendors on the design and development stages to writing the software, commissioning it alongside the equipment, all the way through to the verification and demo batch processing stages.

“Zenith was chosen for the task based on its strong capability and a reputation for getting the job done, its capacity for putting enough engineers onto the project to meet exceptionally demanding timescales, and its ability to deliver value over the life of the project.” (Automation & IT Lead) In addition to the DeltaV™ project, Zenith was also awarded the Qualified Building System Management work, which involved automation of a different DCS used in the control of the clean room HVAC (heating, ventilation, air conditioning).

Our Solution

Design & Development:

The bulk of the work revolved around the design and development of the software. Zenith analysed the specifications from the automation and process engineers and used these to draft the software design documents. The teams worked closely through a series of interactive review cycles. The work involved extensive re-use of existing code used in the equipment already on site. This added further complexity to the software development, but allowed a risk-based approach to testing. Zeniths' experience of S88 structural design allowed them to maximise this re-use and ensured efficient qualification.

Innovative Use of the Coding Resources

To keep the costs down for the customer, Zenith used its offshore resources in Pune, India, to create much of the code needed. As a fully integrated part of the ZT engineering capability they were able to integrate remote engineers seamlessly into the team with no risk to the project. But when it came to the commissioning process, Zenith took the unusual step of bringing these expert coders to Dublin to be on hand to help speed through the process.

“We have a very good working relationship between the Zenith Technologies automation engineers and our multiple disciplinary design and development teams. Their project performance was exceptional, as was the knowledge and expertise delivered by the Zenith Team.”

(Automation and IT Lead, Top 10 Pharma Company)

Our Solution Continued

Accelerated Commissioning:

Once written, the software went through standard FATs (factory acceptance tests). To help ensure a seamless and rapid commissioning process, Zenith performed a comprehensive, integrated FAT in the skid vendor’s premises. This stage of the FAT was fully supported by Zenith and executed under our quality control system.

“Normally we would install the equipment and then test the software on it, but doing it this way, testing it at the vendor’s premises, made the process much easier for us. When we took delivery of the equipment, we knew it worked with the software before it even arrived on site. That also meant we needed only one delivery of software, which again was more efficient and accelerated the whole process.” (Automation & IT Lead)

Results & Benefits

Zenith provided the company with fully functioning and tested automation software that allowed it to run all production processes on DeltaV, delivering significant efficiency improvements across the plant.

Software delivery remained ahead of the required timeline throughout and this helped achieve commissioning on time. The completion schedule exceeded the industry benchmark average by 30% compared to benchmark data from other global biotechnology projects.

“The quality of the delivery of the software was exceptional,” says Automation & IT Lead. “We found the deliveries were workable and could run as they were. As with most large projects there were some rewrites required during commissioning but generally the software from Zenith worked out of the box. It meant that by the end of the commissioning and verification period, for the next year and a half there was very little modification required on site to support the start-up of operations.”

The smooth transition from demonstration to verification batches also benefitted the company financially - because the facility was able to produce commercially viable products during those verification stages.

All areas of the plant including the suite expansion and the new suites are now fully operational. They have successfully passed regulatory audits and are manufacturing commercial batches.

An award winning project

In the summer of 2014, ISPE, the International Society for Pharmaceutical Engineers, recognised the success of the project by naming the project the annual award in the Operational Excellence Category.

At a Glance

Results:

- Fully functional and tested automation system
- All processes running on new DeltaV™ system
- Significant efficiencies and improvements across the plant
- Delivery ahead of schedule, and commissioning on time
- Minimal impact on production
- All areas of the plant are operational and passed regulatory audits
- Award winning facility for operational excellence

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