

Antibiotic Production Benefits from Modernisation Project

Agile software development delivered to tight budgets

At a Glance

Company:

Large Pharmaceutical Manufacturer

Location:

South East, USA

Project Mission:

Develop software for a new, modern facility for the production of an antibiotic

Product / Services:

Emerson, DeltaV™

Challenges:

- Modernisation of plant and processes
- Generic drug manufacturing
- Need for an agile development method
- Integration with their own QMS

Solution Delivered:

- Effective Project Management
- Process prototype, and efficient CIP software process
- Accurate cost and schedule performance
- Incremental build approach

The Challenge

One of the world's largest pharmaceutical companies, needed to modernise its antibiotic production in the South East, USA. Since the antibiotic is no longer under patent, they needed to bring the new facility online while rigorously controlling costs in order to successfully compete with generic drug manufacturers.


They were also looking for a software development partner that could provide exceptional levels of flexibility and expertise. The company uses an iterative (agile) software development process and needed to create a development team comfortable and experienced with these methods. They also needed to use their own quality management system for the entire project. These presented significant challenges, especially around cost control, as any outside software providers would have to work to their methods and standards rather than their own.

The company chose Zenith because of the company's expertise and its extensive experience of working with pharmaceutical companies worldwide. The knowledge of the Zenith teams meant they would be able to work according to the companies' own software object library standards. Additional factors included Zenith's ability to put a team in place in Philadelphia for the design phase and on site in Virginia for implementation.

Our Solution

Effective project management was key to the success of the project. The Zenith team began by creating a 'vertical slice' prototype of one production unit to show how we would develop the software and investigate new and more efficient ways of doing Clean in Place (CIP).

The team was then able to choose a more efficient CIP software process from the proposed solutions. The prototype was also used to generate highly detailed and accurate cost and schedule performance indices. This was a vital component of project delivery because iterative software development involves an incremental build approach, rather than creating a complete design at the start and then simply writing the necessary code. As the iterative approach makes it harder to define costs and schedules in advance, the prototyping process mitigated these risks and helped to ensure tight cost controls.



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Solution Cont.

The Zenith team further reduced costs through a range of innovative methods, including:

- Development of macros specific to the client’s existing Equipment Module library which could then be used for all future projects.
- Use of the client’s own document generation tools to create the necessary documents.
- Use of a GAMP 5 risk-based approach to testing. This ensured testing only of those elements that had changed and needed to be verified.

Results and Benefits

The software development work for the updated facility was successfully completed on time and on budget – an impressive achievement considering the challenges around adapting to the companies own methodologies and processes and the use of an iterative software development process.

They now benefits from high quality, cost-effective software, enabling the company to compete with generic providers and retain market share. The company also benefits from a thoroughly modern facility which meets compliance requirements, operated by a modern control system. Our client has also benefited from long-term improvements to its software library delivered as part of the overall development process along with innovative approaches to CIP.

At a Glance

Solution Continued:

- Tight cost controls
- Module library for use on future projects
- Document generation tool
- Gamp5 risk-based approach to testing

Results and Benefits:

- Modern control system delivered on time and to budget
- High quality, cost effective software
- Competitive advantage and increased market share
- Meet compliance requirements
- Software library improvements with long term benefits
- Innovative approaches to CIP

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