

## Case Study

# Interim CIO Transforms Biotech, Meets Aggressive Regulatory Timelines, and Achieves Operational Excellence

## The Challenges

- **Aggressive Timelines:** Setting an 18-month deadline was highly ambitious for establishing a cGMP-compliant plant with the necessary equipment, processes, technology, and resources to support future growth.
- **Resource Constraints:** At the project's outset, one site's executive team was primarily composed of consultants, with only three permanent employees and minimal support staff. These limitations hindered swift decision-making and execution, which were crucial for meeting the tight deadline.
- **System Adoption Limitations by the Client:** After implementing and validating critical systems in their newest manufacturing site, the team's next challenge was ensuring effective use. As new hires, the executives and their teams had yet to develop the necessary processes to run the plant and lacked a full understanding of their data.

## The Solutions:

The Interim CIO's expertise in pharma's regulatory requirements met the client's immediate and long-term needs, as well as the 18-month deadline.

**Build a 5-Year IT Strategic Plan:** Developed a comprehensive IT Strategic Plan with a 5-year budget and forecast for all sites. This created a central IT budget for the main site and tracked historical IT spending to ensure a solid foundation for future financial planning.

**Develop a Business-Aligned IT Roadmap and Project Plan:** Created an IT roadmap and project plan that integrated with the new site's overall startup project plan. Systems and technologies were implemented and validated in a specific sequence to meet regulatory requirements.

**Establish a Data Classification Schema:** Formed a team to define a product data schema and hierarchy for BatchMaster ERP. The team classified 1600 items, improved data accessibility and enables efficient product release and distribution.

## Client Profile

- Global biotech company
- Founded in 2006
- ~100 employees
- Funding: PE firm (2019)



## Execute the 18-Month Project Plan:

- **Network and Infrastructure:** Prepared an RFP and selected a Managed Services and Security Provider (MSSP) within four weeks to build the plant's foundational infrastructure to ensure enterprise and operational network support.
- **eQMS Implementation:** Partnered with the client and supplier to implement and validate an electronic Quality Management System (TrackWise Digital) for managing SOPs, work instructions, and validation documents.
- **CMMS Installation:** Collaborated with the supplier and plant engineer to install and validate a Computerized Maintenance Management System (Blue Mountain) for equipment calibration and maintenance.
- **ERP (Enterprise Resource Planning) Selection:** Led the evaluation and selection of the BatchMaster Manufacturing add-on to SAP Business One for enterprise-level budget and finance management that enabled timely implementation and validation within the 18-month timeline.

## The Results:

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All the systems required for the new site to operate the plant were implemented and validated within 18 months. This achievement positioned the company to meet the pharmaceutical industry's quality and regulatory standards, which were crucial for the company's success and future growth.

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**The Fortium CIO was a strong business partner at a biotech company under PE ownership; I was COO with a Fortium CIO as my partner. The CIO's IT skill set was broad & flexible; she presented a strategic conceptual systems perspective to both architecture & implementation work, understood both IT and OT roles & could manage at the Board level as capably as resolving a field-level data issue. The CIO brought dedication & focus to the task & drive to closure. She was a pleasure to work with & get to know." ~Biotech COO**