

Preparing for Growth

Ultra Consultants Guides A Pre-Commercial Biopharmaceutical Company in Technology Selection and Business Process Transformation

At a Glance

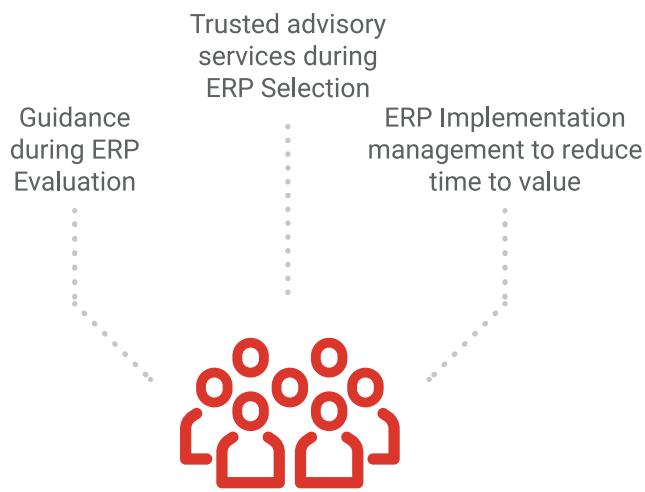
A biopharmaceutical company needed to replace its outdated and unsupported ERP solution to enable its rapid growth and to automate key business processes. Ultra Consultants guided the company through business process definition and improvement, technology selection and implementation.

Project Highlights:

- The existing ERP solution was no longer supported and needed to be replaced.
- The new system had to be validated and able to support Sarbanes-Oxley, Sunshine Act and FDA compliance.
- The company expected extreme growth with both dynamic and rapid change.
- Business processes needing more formal definition included accounts payable processing, approval processes and more.
- A key goal was to improve forecasting and inventory planning.
- The company required more timely reporting capabilities.

Ultra Value

The Ultra team supported the core project team with IT and enterprise solution expertise, business process transformation strategies and solution selection/implementation.



As it moved through stage 3 trials for a new drug, a biopharmaceutical company needed to replace its outdated and unsupported ERP solution to enable its rapid growth and to automate key business processes. Ultra Consultants guided the company through business process definition and improvement, technology selection and implementation, and the development of a comprehensive IT strategy.

Project drivers focused on the commercial launch of the company's new drug and its expectations to sell it globally:

- The existing ERP solution was no longer supported and needed to be replaced.
- The new system had to be validated and able to support Sarbanes-Oxley, Sunshine Act and FDA compliance and regulatory requirements, including FDA regulations on electronic records/signatures, inventory and production tracking, lot control and serialization.
- The company expected extreme growth with both dynamic and rapid change. It needed an enterprise technology solution coupled with mature business processes that would scale with the expected growth.
- Business processes needing more formal definition included accounts payable processing, approval processes to support purchase requisitions and POs, order-to-cash, supply chain, operations with contract manufacturers, third party logistics for sales order entry/distribution/receivables, serialization and revenue recognition. Better forecasting and inventory planning were also project goals.
- The company required more timely reporting capabilities.



Ultra was effective at assessing the existing capabilities within our team and offering guidance. We met overall project objectives with minimal risk.

The Starting Point

When the organization first engaged Ultra Consultants, the company was in the pre-commercial phase to bring its first drug to market. The company's legacy enterprise solution was no longer supported. The company expected significant growth and expansion and realized the need for a new, scalable ERP solution and associated improvements in key business processes.

Using its established methodology, Ultra began with a business process analysis to identify the key drivers for project success and value to the organization. The project was multi-faceted with a focus on:

- Business process definition and improvement to include a maturing of business processes as the company grew from 20 employees to 500 as a commercial entity
- Overall IT infrastructure evaluation and strategy development
- Technology selection and implementation management

Working closely with company management, Ultra established a steering committee and core project team. The team conducted interviews resulting in a clearly defined set of solution requirements and criteria, including inventory and production control and project-based manufacturing. Other future drivers were also identified, including human resources and financial operations.

"With strong business partnering, Dave Saunders of Ultra Consultants was very effective at assessing the existing capabilities within our team and offering guidance on how to both augment and adjust skills to ensure the overall project objectives were met with minimal risk," commented the Head of IT.

ERP Selection

The Ultra team documented a future state scenario for the team that included new strategies, business processes and solutions. Because the company had limited IT staff, the Ultra team developed an overall IT strategy that started with the hiring of a CIO who then hired heads of ERP, commercial, R&D and infrastructure to fully build out the IT department.

The Ultra team managed the ERP selection process, using their knowledge of the solutions and partners that would meet the company's specific criteria. Ultra created an RFQ, cast a wide net and narrowed the contenders to a few solutions for review by the core team. The consultants crafted vendor scripts and demo processes. The team scrutinized the functionality of each solution, the implementation partner, the technology itself and the costs/ROI. The team made its final selection and Ultra worked with leadership to negotiate pricing with the vendor and the implementation partner.

Management indicated that the process from start to finish was very intentional, helping them make an informed decision about the right choice in a partner and software vendor.



Ultra organized multiple vendors, kept the project focused and on schedule while the internal team was onboarded.

ERP Implementation

The Ultra team worked to oversee the implementation of the solution. They used Ultra's project management methodology to coordinate all aspects of the implementation, which was completed on time and under budget.

Management at the biopharmaceutical company acknowledged that "there was no way we could have done it on our own. Ultra saved us both time and money."

Ultra provided project management consulting throughout the implementation, which included managing the overall project plan, budget, and risk register and by leading weekly PMO meetings.

The Head of IT remarked, "The Ultra Consulting team brought a deep knowledge and practical experience with both Project and PMO management. They were a key player organizing multiple vendors, keeping the project focused and on schedule while the internal team was onboarded."

The project team arrived at an appropriate project scope based on existing staffing levels and progress of product in the pipeline. For example, during the pre-commercial phase, the company did not require a full-blown inventory management system.

A Trusted Advisor

The 11-month timeline from the initial business process mapping to the go-live date for the first stage of the implementation plan went smoothly, with the Ultra team supporting the core project team with IT and enterprise solution expertise, business process transformation strategies and solution selection/implementation.

Overtime, the Ultra team members coordinated additional functionality and consulting requests and have served as trusted advisors. The team assisted the company with related IT and project strategies, including staffing, outsourcing support/hosting, and financial operations.

At the conclusion of the first release, the members of the project team were surveyed about lessons learned. The biggest project successes were classified as:

- Core financial functional requirements were delivered on time and under budget. Despite limited resources, this was accomplished due to the intensive effort put forth by everyone on the project team in combination with a continual focus on risk management, scope control, and effective phasing of the project implementation.
- Supply chain future state was established.
- First qualified environment was implemented.

As the first phase for finance went live on time, the Sr. Director of IT and ERP Project Lead commented, "Being on many previous ERP implementations, this team had a unique challenge of starting up an ERP system from a greenfield; there were no documented processes to bring forward. It presented unique challenges for a small team to build the process and data structure for long-term growth of a new business. The challenge to configure, test, and populate data, validate and deliver training and meet scheduled go-live targets was a great result for the team and the business."

Among the factors assuring success was the team effort and a clear understanding of weekly deliverables to stay on course. Communication between the team and Ultra Consultants was open and flexible.

At the end of the engagement, the team agreed that it had been an effective partnership with Ultra Consultants as the company matured its IT and related business functions with an ERP solution that meets its unique needs.



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About Ultra Consultants

Ultra Consultants is an independent research and enterprise solutions consulting firm serving the manufacturing and distribution industries throughout North America, as well as companies with global operations. Since 1994, Ultra has delivered enterprise technology expertise and process management to drive business performance improvement for our clients. More information on the company's services, leadership, industry verticals served, and software vendor relationships can be found at www.ultraconsultants.com.