

## CASE STUDY

### Alexion Pharmaceuticals Builds Foundation for Future Growth

#### Challenge

On the brink of bringing its first product to market, Alexion Pharmaceuticals was undergoing a fundamental transformation from a research and development (R&D) organization into a viable commercial business. The company recognized that it needed to create the infrastructure, capabilities and processes necessary to support commercial operations while not impeding U.S. Food and Drug Administration (FDA) approval of its first prescription drug or endangering its pipeline and ongoing clinical trials. Above all, Alexion needed to do these things quickly and cost-effectively.

#### Solution

Alexion turned this challenge into an opportunity to build an enterprise strategy. The company selected Clarkston Consulting to implement an integrated enterprise resource planning (ERP) system that aligned with its business goals. In addition to providing complete project management for the engagement, Clarkston helped Alexion design processes from the ground up that would support operations following the launch of the company's first FDA-approved product.

#### Benefits

Alexion has a single, unified system that will sustain its growth well into the future. The company has gained crystal-clear visibility into its commercial operations, as well as the ability to manage its business in a fully integrated and compliant manner. It was able to accomplish these efforts in a condensed timeline that minimized costs and created capabilities precisely when they were needed.

*"I've never worked with a company that said, 'we have no desire to grow and we'll never have a need to change.' That's why every company needs to design its systems for the change and growth that will inevitably occur. Thinking things through now will have immeasurable benefits going forward and avoid the need to retrofit systems and processes later."*

**Mike Fein**  
Partner  
Clarkston Consulting

## A New Set of Challenges

For a biotechnology company, the pressure to innovate is unrelenting. With more than 1,400 competitors and over 400 products currently in clinical trials in the United States, the race is on to bring new treatments to market as quickly as possible while maintaining compliance with governmental regulations and industry standards.

But victory—that is, successfully developing, testing and delivering a new drug to the market—brings forth a whole new set of challenges associated with transforming from an R&D organization into a profitable commercial business.

This is the challenge that Alexion Pharmaceuticals faced. Founded in Cheshire, Conn., in 1992, the company has focused on developing drugs to address serious and life-threatening medical conditions such as autoimmune diseases and cancers.

In March 2007, the company received marketing approval from the FDA for its first commercial product. Called Soliris™, the drug is the first therapy approved to treat a rare, life-threatening blood disorder that causes the immune system to destroy the body's red blood cells. Known as PNH, or paroxysmal nocturnal hemoglobinuria, the disease is estimated to affect only 10,000 people worldwide.

In this case study, we share how Alexion, an organization that operates on the cutting-edge of science, leveraged its transformation from an R&D organization into a commercial business as an opportunity to create a foundation for future growth.

## Forming a Best-in-Class Team

With two drug therapies in Phase III clinical trials, Alexion knew it needed to develop infrastructure to support its rapidly changing business and maintain compliance with increasingly complex regulations. It also wanted to gain visibility across its entire operations. But instead of addressing these tasks incrementally, Alexion wisely decided to implement an integrated ERP system that would provide needed functionality now, as well as in the future.

“We made a commitment to be an enterprise organization from day one of our commercial operations,” says Jim Bilotta, director of information and technology at Alexion. “This gave us the opportunity from the very beginning to build an enterprise system and map behaviors around it, as opposed to interrupting commercial operations later on in order to retrofit disparate systems and processes.”

To accomplish the project on time, on budget and with minimal disruption to its business, the company assembled a best-in-class team. Alexion selected SAP software, including mySAP™ Business Suite applications, for its capacity to support a unified multinational, multifunctional implementation. With a full suite of applications designed specifically for life sciences companies, SAP also provided embedded industry-specific best practices and an understanding of the unique biotechnology environment.

After another consulting company failed to meet Alexion's expectations, it turned to Clarkston Consulting to help get the project back on track with its original goals. Having worked with more than half of the world's leading life sciences companies, Clarkston brought extensive industry knowledge, proven SAP experience and unmatched process design expertise to the team.

“From the start, Clarkston walked in with strict methodology and tremendous functional depth,” says Bilotta. “Because an ERP implementation is so broad and involves so many people, you need structure and you need experience, and Clarkston had both. The team's professionalism was unparalleled.”

## Staying on Course

Alexion's leadership team started with a clear vision for the project. With a strong focus on creating business value, they identified the key milestones the company had to reach and when. Next, they defined exactly what was and was not needed in order to achieve each milestone and used those factors as guideposts for designing and building the ERP system. As a result, the initial implementation was limited to capabilities that were deemed essential, with additional bells and whistles to be added later.

"The trick is to focus on what you truly need and then get it right," says Bilotta. "We stuck with our business goals. We stuck with our budget. We stuck with exactly what we wanted to accomplish. As a result, we've been very successful."

Working hand-in-hand with Alexion, Clarkston provided complete project management support and guided the design and implementation of the SAP system. Clarkston helped design business processes that align with industry best practices, and the system was validated to ensure that Alexion met current Good Manufacturing Practices (cGMP). In addition, Clarkston worked with them to extend the sales and distribution functions to the company's European subsidiaries—a critical success factor in its expanding global operations.

Specifically, Clarkston's team of dedicated professionals provided:

- Full project management of the engagement
- Best practice identification and implementation
- Process design for the company's commercial operations, including sales and distribution, inventory management, materials management and purchasing
- Process documentation
- Installation of all hardware and software
- End-to-end integration of the system
- Comprehensive data conversion support
- Performance and system testing
- System administration support
- Staff resources to minimize disruption to the business
- Extensive hands-on training for initial users, as well as a curriculum for future hires
- Supporting educational materials and technical documentation

The implementation was divided into three phases and included the following SAP modules: Human Resources (HR), Financial Accounting (FI), Controlling (CO), Materials Management (MM), Inventory Management (IM), Sales and Distribution (SD), Production Planning (PP), Quality Management (QM) and Plant Maintenance (PM). In line with the company's initial goals, less than 5% of the system was customized, and the project was completed in a very short amount of time with little disruption to ongoing business operations.

### Key Success Factors

- *Active participation by all parties involved - Alexion, Clarkston Consulting and SAP*
- *Strong commitment from Alexion leadership to create enterprise culture*
- *System and processes aligned with company's business goals*
- *Project scope actively controlled and managed*
- *Minimal customization - virtually all operational processes follow standard SAP best practices*
- *Open lines of communication to ensure user acceptance*

*"Today we have a system that exactly matches our culture because we built the culture right along with the system."*

**Jim Bilotta**  
Director of Information  
& Technology  
Alexion Pharmaceuticals

## Project Success Equals Business Success

Alexion has successfully replaced multiple legacy systems with a single, unified SAP solution flexible enough to support its future growth. Launched in time to support the sale of the company's first commercial product, the system provides crystal-clear visibility across the organization, from inventory, to purchasing, to manufacturing, to sales and distribution. Alexion's leaders have timely, accurate and consistent information in order to make strategic business decisions and respond quickly to changing conditions.

Among the additional business benefits, Alexion has achieved:

- **Better control of cash flow.** The ERP system provides greater visibility into its manufacturing schedule, allowing the company to time the purchase of key materials and ingredients to when they are needed.
- **Streamlined operations.** Alexion is able to better coordinate resources across functional areas. For example, technicians responsible for receiving incoming critical ingredients and conducting quality control assessments have clear visibility into delivery dates, ensuring they are available at the scheduled time and that the manufacturing process continues uninterrupted.
- **Improved cost management.** Alexion has gained greater visibility into costs associated with producing its new drug, particularly during initial manufacturing phases when most pharmaceutical companies' expenses are ill-defined.

While these benefits are important, the true measure of the project's success is illustrated by Alexion's business success. In just the first few months, product sales in the United States and Europe totaled \$9.8 million and are growing. Patients are receiving a life-saving therapy and Alexion has a revenue stream with which it can reinvest in its business.

## Why Clarkston Consulting? Knowledge. Dedication. Results.

Clarkston understands the unique challenges biotechnology firms face on the path to commercialization. With so much at stake, you need a partner that understands the intricacies of your business. Simply put, we do. In fact, in a client survey "knowledgeable" was the adjective used most often to describe us. We've worked with more than half of the world's top life sciences companies, meaning we're familiar with the unique challenges you face. By leveraging this experience we can anticipate and avoid the pitfalls that others have fallen into. Our deep industry focus provides an excellent source for and detailed knowledge of leading practices. Our many success stories, consistently high rate of repeat business, and superb customer satisfaction rate all mean one thing: our knowledge, coupled with dedication, is a winning formula for results.

To learn how Clarkston Consulting can help you align your business strategy with your ERP implementation, please contact us or visit us at [www.clarkstonconsulting.com](http://www.clarkstonconsulting.com).



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