

# CASE STUDY

## Alexion Pharmaceuticals Translates Groundbreaking Science into Successful Business

*On the eve of its first commercial drug launch, Alexion approaches its transformation to commercialization with the same vigor and discipline that it applies to research and development.*

### Challenge

Alexion Pharmaceuticals, a global biotechnology company on the brink of bringing its first product to market, needed to transition from a research and development (R&D) organization into a viable commercial business. It sought to create the infrastructure, capabilities and processes to support commercial operations while not impeding its ability to gain approval for its first prescription drug and without endangering its pipeline or ongoing clinical trials. Above all, Alexion needed to do these things quickly and cost-effectively.

### Solution

Working with Clarkston Consulting, Alexion realized the long-lasting benefits that could be gained by taking a process-driven approach in designing both its company and its systems. An SAP system was implemented in a manner that supported the launch of Alexion's first product, and provides the flexibility for growth as the company's pipeline matures. Important to the effort's success was the establishment of a Program Management Office (PMO) to manage the interdependent project components and resource demands.

### Benefits

By leveraging Clarkston's industry experience and process-driven approach, Alexion has designed and built an organizational structure that will sustain its growth well into the future. The company now has the key systems and processes in place to support its commercial operations and 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.

*"Clarkston helped us understand that before we could begin implementing SAP—or any technology, for that matter—we needed to better understand what we had, what we would need, when we would need it and how it would all fit together."*

**David Keiser**  
President & Chief  
Operating Officer  
Alexion Pharmaceuticals

### Sailing into unknown waters

Alexion Pharmaceuticals is a global biotechnology company based in Cheshire, Conn. It was founded in 1992 and, over the last 15 years, has focused on studying and developing drugs to address serious and life-threatening medical conditions, such as autoimmune diseases and cancers.

The company has brought two drugs to Phase III clinical trials and, in 2006, submitted a Biologic License Application (BLA) for its first commercial product. On March 16, 2007, it received marketing approval from the U.S. Food and Drug Administration (FDA) for Soliris™, the first drug therapy approved for a rare, life-threatening blood disorder that causes the immune system to destroy the body's red blood cells. The disease is known as paroxysmal nocturnal hemoglobinuria, or PNH, and is estimated to affect 10,000 people worldwide.

Developing an effective drug for a complex disease like PNH is an amazing scientific feat. However, Alexion still faced perhaps its greatest challenge yet—transforming from an R&D organization into a successful commercial business.

### Defining Alexion's future business requirements

With two drug therapies in Phase III clinical trials, Alexion engaged Clarkston for help with an SAP implementation. As the first step, Clarkston's industry experts led a cross section of senior-level Alexion decision-makers through a series of strategic discussions to establish the business requirements around which the SAP system would be configured.

These discussions quickly exposed a number of fundamental business questions that needed to be answered—particularly the future-state capabilities Alexion would need and when it would need them. Clarkston proposed that Alexion take a holistic approach by focusing on business process design in order to ensure alignment of all business functions and to guide the design and implementation of the SAP system.

This strategy resonated with Alexion, which viewed Clarkston—with its extensive industry knowledge, business process design experience and reputation for outstanding customer service—as being singularly well-equipped to help it define its future business requirements and establish those capabilities.

“Clarkston helped us understand that before we could begin implementing SAP—or any technology, for that matter—we needed to better understand what we had, what we would need, when we would need it and how it would all fit together,” explains David Keiser, Alexion's president and chief operating officer.

### Taking a process-driven approach

Using a proprietary assessment protocol, Clarkston evaluated existing processes and identified those that needed to be modified, enhanced or created. The analysis entailed:

- Assessing existing and planned processes, systems and organizational structure;
- Creating a business roadmap to navigate the critical transition from current-state to commercial business;
- Re-engineering existing processes (such as pharmacovigilance) to support commercial activities;
- Developing processes to support new capabilities, including sales, marketing, case management, customer service and distribution; and
- Evaluating and enhancing standard operating procedures (SOPs) in support of GxP audit and pre-approval inspections.

Upon completion, the results of the assessment were organized into a set of work streams. Each work stream focused on a key area of the business and was comprised of sub-projects covering processes, systems and resource requirements. This approach made it possible to see the interactivity between the lower level projects while maintaining information at a level useful to senior management.

### Managing many moving parts

A PMO was established to help organize and manage the effort's various moving parts and ensure that all areas of the company were progressing through consistent project planning and reporting. “The Clarkston Project Manager assigned to the PMO kept information organized in a consistent manner while regularly scheduled steering committee meetings provided a forum for decision-making at critical junctures.” David Falconer, executive director, drug development, Alexion Pharmaceuticals.

The Project Manager also was responsible for managing competing demands for resources, ensuring that the right people were available for the right project at the right time. The need for resources to develop SAP requirements and support process improvement activities was carefully balanced with the need for resources to manage priorities in other areas of the business, such as development of the BLA, ongoing clinical trials and preparation for pre-approval inspections by the FDA.

### **Building a foundation for growth**

Working with Clarkston, Alexion also implemented SAP in a manner that supported its business model and the launch of Soliris™ in the United States and Europe. With functionality that includes financial accounting and controlling (FI/CO), material and inventory management (IM/MM), and sales and distribution (SD), to cover the business' global operations, the system provides more than enough horsepower to support Alexion through its continued growth.

### **Achieving business success**

A comprehensive business roadmap provided Alexion with a clear understanding of what it needed to fully develop into a successful commercial business. The process-driven approach led by a centralized PMO ensured that management received complete and accurate project information for decision-making throughout the transition.

Multiple legacy systems were replaced with a common SAP platform that is capable of handling pre-existing processes, as well as the capabilities to support the new commercial operations. The company now has a fully prepared commercial infrastructure and processes aligned with both regulatory requirements and each other.

Clarkston also provided Alexion with educational materials, SOPs, technical documents and process documentation—everything Alexion needs to sustain these efforts going forward.

While these accomplishments are important, the true measure of project success rests with Alexion's business accomplishments. These include an on-time BLA submission, FDA approval and the first successful shipment of Soliris™

- An on-time BLA submission was possible because the key people involved with the development of the application were available. Clarkston not only worked closely with the Pharmacovigilance, Quality Assurance, Clinical Quality Assurance and Clinical Development groups to help them create their processes and systems, it also provided additional support while these departments were focused on the BLA submission.
- FDA approval resulted from a sound application and a sterling data set for the drug in clinical trials. But it also was due in part to well-documented SOPs and an organization that was well-prepared for commercial and clinical inspections.
- The first order of Soliris™ was shipped successfully as the result of commercial readiness. The Alexion mantra, "we will help any patient who can benefit from Soliris™ gain access to it," required robust case management capabilities and a well-defined distribution and reimbursement chain. Clarkston worked extensively with these areas to help define and implement the processes and systems required to support them.

"While we're proud to have helped Alexion, the most important accomplishment is that they gained approval of Soliris™, successfully launching the drug with no delays. That means patients are now receiving this critical therapy, and Alexion has a revenue stream to recoup its investments and eventually bring new life-saving drugs to market." Mike Fein, managing partner, New England, Clarkston Consulting.

## Why it matters

Biotechnology firms spend years—sometimes even decades—without a penny of revenue relentlessly studying complex diseases and the compounds that may treat or even cure them. According to the Biotechnology Industry Organization, there are more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases, ranging from various forms of cancer, to heart disease, to AIDS and arthritis.

When an effective drug therapy is finally created and approved for use, a remarkable transformation must occur within the biotech firm. Once solely an R&D organization, it must morph into a commercial entity with all of the responsibilities, systems and processes required of any for-profit business.

On the verge of this transition, perhaps the most perplexing question facing the company is: How will we proceed down the path to commercialization?

Without understanding exactly what's required, it's difficult—if not impossible—for the company to make informed decisions, such as if it should partner, sell or go it alone.

“Companies on the path to commercialization need a comprehensive understanding of the cost and resources required of them,” says Paul Allen, vice president for life sciences at Clarkston Consulting. “Otherwise, they lack the confidence and ability to adequately evaluate the various opportunities that will no doubt present themselves.”

Benefits of having a comprehensive understanding of the costs and requirements of, as well as a clearly defined path to, commercialization include the ability to:

- Fend off or renegotiate potential acquisitions at discount prices;
- Determine what capabilities to outsource versus maintain internally;
- Recruit specialized talent at the right time and with a clear understanding of what's expected of them;
- Diligently conduct pharmacovigilance; and
- Raise additional investor capital.

## 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.

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