CLARKSTON CONSULTING

Auxilium Pharmaceuticals

SAP Delivers Business Value for Commercial Product Launch

SUMMARY

Pennsylvania-based Auxilium Pharmaceuticals, founded in 1999, is a fast-growing biotech company that is focused on R&D, manufacturing of active drug substances and marketing its products globally. Based on the Food and Drug Administration's (FDA) approval of the commercial launch of a new product, Auxilium began a strategic initiative to implement a scalable SAP Enterprise Resource Planning (ERP) solution—adopting a best practice-based, phased approach to support the global launch of their new product.

" We were impressed by the adoptability of SAP to an emerging life sciences company's needs and ability to support global growth. Clarkston's life sciences expertise combined with their project management and methodology enabled us to easily transition our processes into the SAP system."

Kathy Junod, Sr. Director & Head of IT, Auxilium

CHALLENGES & SOLUTIONS

Challenge 1: *Auxilium had to gear up to ensure that it could produce their new product and manage the business processes in compliance with the FDA and other agencies.*

Solution: An integrated, fully validated and compliant ERP system was critical to support business growth as well. The scope of SAP ERP Central Component (ECC) 6.0, which was implemented to support MRP planning in 2009, had to be expanded and validated.

To minimize the overall risk and justify the ROI, Clarkston and Auxilium carried out an ERP and Validation assessment. Clarkston's Life Sciences assessment methodology was adopted to analyze the impact on business processes, SAP technology and landscape, Standard Operating Procedures and training. This provided key information for defining an overall validation master plan; assessing the impact on key validation deliverables as defined in the master validation plan; and conducting an overall GXP risk assessment. The development of a detailed business case to justify ROI and an implementation roadmap was also important.

Validation was not included in the 2009 SAP implementation, and Auxilium's Good Manufacturing Process (GMP) system of record continued to be paper-based—a costly, inefficient way of operating that needed to change.

Challenge 2: *Auxilium had to translate its game plan for change into an efficient and successful business process implementation.*

Solution: The big-picture approach for the implementation was to build new functionality on the existing SAP platform. The scope included the following areas—Supply Chain Planning and Operations, Materials Management, Inventory and Warehouse Management, Manufacturing and Quality.

Other features of the implementation included adopting proven SAP Pharma industry best practices and adhering to out-of-the box functionality, with no modifications made to standard SAP programs.

During the initial assessment phase, Auxilium made decisions about how its SAP functionality would be expanded, including introducing:

- Web-based radio frequency and bar-coding for warehouse and inventory processes.
- Additional quality management functionality in SAP.
- Technical installation of the SAP Enhancement Pack for ERP 6.0.

Challenge 3: *In addition to implementing improved business processes, Auxilium needed to put in place a technology landscape that supports long-term growth and reduces Total Cost of Ownership (TCO).*

Solution: Installing SAP enhancement packs was important because it eliminated the need for future technical upgrades of ERP 6.0. Business functions available within enhancement packs can be selectively activated by a switch framework, based on business requirements. This is critical for Auxilium to support its growth and innovation.

The installation of the enhancement pack was combined with migration of the SAP landscape to the VMware private cloud environment. Some of the key benefits realized included:

- A positive impact on cost and resource requirements.
- Reduction in the overall project risk.
- Eliminating the need for re-testing the transactions
- Minimizing potential business interruptions.

RESULTS

At the highest level, the project was a resounding success based on its solid ROI justification. This was backed up by hard numbers and realized quickly—between the first and second year of implementation. There was a 50-percent payoff even before the six-month project was complete.

Before the implementation, Auxilium's warehouse operation was manual, using papers and spreadsheets; now there is no paper involved, and the difference is dramatic.

There is complete visibility into the inventory at different stages, and its lifecycle can be tracked electronically. Some of the significant benefits achieved included :

- Elimination of manual procedures by automating warehouse management and production logistics processes, enabled by SAP ITS-based RF and 2-D bar codes.

- Laying a strong foundation to support future serialization and country requirements.
- Providing capabilities to track detailed multi-level batch genealogy and product flow.
- Fully validated and compliant system meeting regulatory requirements.
- Improved business process integration across the supply chain, manufacturing, warehouse and quality management.

Auxilium moved from having SAP installed on separate servers to a VMware private "cloud" environment. This reduces the overall investment in hardware platforms and provides flexibility and ease of growth. Key warehouse and manufacturing functions can now be supported on a mobile platform.

In the process of helping Auxilium expand its SAP investment, Clarkston created a new SAP solution: SAP Extended Inventory Management (ExtIM), which extends the capabilities of the standard inventory management functionality provided by SAP. ExtIM integrates with a company's core business scenarios across supply chain, warehouse and production execution.

The ExtIM solution is an ideal fit for small and medium-sized organizations; clients who feel SAP Warehouse Management (WM) is too complex but IM alone will not meet their needs; and the business units of a global company that don't need SAP WM.

PARTNERING for SUCCESS

Auxilium teamed with Clarkston for this initiative because of Clarkston's extensive knowledge of the biotech industry and its compliance and regulations challenges, as well as Clarkston's SAP business solution and technology expertise. Clarkston was also a good fit because of its experience in helping emerging companies that are in varying stages of development. Clarkston's pioneering of the ExtIM solution during the project gave Auxilium just what it needed at this stage of its growth and resulted in immediate cost reductions for the company.

CLARKSTON CONSULTING

Headquarters
Research Triangle Park
1007 Slater Road, Suite 400
Durham, NC 27703
Phone: 800-652-4274
Fax: 919-484-4450

www.clarkstonconsulting.com

ABOUT CLARKSTON CONSULTING

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 10-year average client satisfaction rating of 96%.

For more information, contact Rob Klein: 877.362.3649 / rklein@clarkstonconsulting.com