

CASE STUDY

Celera Diagnostics

Laying the Groundwork for Burgeoning Growth

Challenge

Celera Diagnostics needed to move from a non-FDA regulated environment to one that would meet FDA requirements and be scalable to support burgeoning sales from a successful alliance partner program.

Solution

Invested in an ERP system to support the business, with special consideration given to 21 CFR Part 11 to ensure that electronic records were in compliance with FDA regulations.

Benefits

During the implementation, Celera Diagnostics received FDA approval to market one of its diagnostic products; within just a few months, sales volume increased 20-fold. The business is no longer constrained by internal systems, and is poised with the infrastructure to experience additional high growth.

“Clarkston Consulting’s approach for managing and delivering is a model for other consulting firms to follow.”

**David Dunn, VP Quality Assurance,
Celera Diagnostics**

Challenge

Celera Diagnostics is a joint venture of Applied Biosystems and Celera Genomics, two Applied Biosystems Corporation businesses. Its mission is to improve human health through the discovery, development and commercialization of diagnostic products.

Prior to this project, Celera Diagnostics conducted business as part of Applied Biosystems, which operated in a non-FDA regulated environment. Celera Diagnostics provided products to research facilities under a “Research Use Only” label; therefore, a regulated environment was not required.

However, the company’s long-term strategy was to separate its operation from Applied Biosystems and convert its systems and infrastructure to comply with FDA regulations in order to open the door to manufacturing and distributing its products as the FDA approved them for marketing.

Celera Diagnostics had also formed several alliances for research, testing, marketing and/or distribution with other biotechnology companies. The company needed the systems and processes to support these relationships.

And finally, Celera Diagnostics needed the systems and infrastructure muscle to help the company grow through continued alliances and burgeoning sales of its products.

Solution

Celera Diagnostics chose Clarkston Consulting to implement an enterprise resource planning system independent from Applied Biosystems, and to design and execute the processes to support the business. A critical aspect of Clarkston’s mission was to validate the new system in accordance with 21 CFR Part 11 to ensure that electronic records were in compliance with FDA regulations.

Specifically, Clarkston:

- Created a process blueprint for the implementation of SAP® 4.6C and the core modules—Finance/Controlling, Materials Management, Production Planning and Sales and Distribution.
- Created an interface with a separate financial reporting system.

- Designed and established a rigorous change procedure to ensure that any systems or process modifications would be FDA-compliant.
- Initiated a 21 CFR Part 11 validation program.
- Developed a curriculum for the initial round of training and for all future hires/users. Clarkston trained 60 users using a holistic, role-based technique.
- Developed an on-going systems support process in which issues and requirements are documented, prioritized, escalated and implemented within validation compliance.

Benefits

Clarkston delivered an SAP environment, independent from Applied Biosystems, that employs industry best practices and is validated to be in compliance with FDA regulations. The consultants accomplished all of this in 14 weeks—20–25 weeks is a typical timeframe for a company of Celera Diagnostics’ size.

When the project began, none of Celera Diagnostics’ products were ready for market—all were at various stages of development or FDA review. However, as the project was wrapping up, the company received FDA approval to market one of its diagnostic products. Within just a few months, company sales increased 20-fold. Because Clarkston was able to implement the project in such a short timeframe, the company had the systems and processes in place to handle this surge in orders.

Also noteworthy:

- Clarkston was instrumental in helping Celera Diagnostics and Abbott Diagnostics settle the details of their sales and distribution agreement. Acting as facilitators, the consultants guided the alliance partners through the issues to be resolved to move forward with the agreement and finalize the processes and procedures needed in the new system.
- Through the coaching they received during the course of the project, the system-related skills of key Celera Diagnostics users were greatly improved, which enhanced their ability to do their jobs more efficiently.

The business is no longer constrained by internal systems, and is poised to experience high growth with an infra-

structure that will scale to support that growth. Clarkston continues to work with Celera Diagnostics on additional training, systems modifications and new functionality that was not part of the original project scope.

Company Profile

Headquartered in Alameda, California, Celera Diagnostics focuses on the development and commercialization of new genetic markers for disease and configuring these into diagnostic tests to predict, characterize, monitor and select therapy for cardiovascular disease, auto-immunity, central nervous system disorders and cancer.

Clarkston Consulting is a leading management and technology consulting firm that provides strategic business solutions for clients within the life sciences and consumer products industries worldwide. These market leaders turn to Clarkston to help them bridge the gap between strategy and execution to sustain a competitive advantage. Clarkston is a sought-after business partner because of its recognized industry thought-leadership and superior client relationships, as measured by The Conference Board's survey on client satisfaction. For more information, visit www.clarkstonconsulting.com.