

ENABLE REGULATORY COMPLIANCE MAINTENANCE

Accenture Scientific Informatics Services

BUSINESS CHALLENGE

The client, a global biopharmaceutical company, recently experienced a high level of success in getting a number of important therapeutics to market very quickly, and the planned pace of regulatory filings and product launches showed **no sign of slowing over the coming years**. However, the internal mix of laboratory information management systems (LIMS) and paper-based **laboratory processes were straining under the increased volume** of work. The client's growing effort to keep up with the workload, while at the same time demonstrating control and compliance, threatened to slow down the pipeline. Additionally, the client faced significant negative impact to revenue as a result of various compliance-related communications issued by the U.S. Food and Drug Administration. The Head of Product Development & Manufacturing sponsored a project with Accenture Scientific Informatics Services to help them address these issues.

PROJECT APPROACH

The Accenture team led an end-to-end business process and data management program. To guide the selection of an integrated electronic laboratory application portfolio, the Accenture team defined end-to-end processes within laboratory operations, identified gaps and inconsistencies in current practices, and helped the business articulate a future vision for harmonized processes. From this, the team determined requirements for subsequent, parallel system implementations. Five integrated, best-in-class systems, validated for GMP, were selected for implementation. The Accenture team then re-architected, designed, and deployed the compliant laboratory and instrument systems, which included:



Enhancing the selected LIMS to resolve stability sample handling



Integrating instrument use, consumables and reagent management, and data capture with the selected electronic laboratory notebook and laboratory method execution

The Accenture team also performed a **market assessment** and **calculated estimates** for the cost and hours of effort to implement the future platform. Socialization messages and value cases were developed to align leadership. The analysis led to a **follow-on engagement** where Accenture assessed potential platform options.

RESULTS

The Accenture team successfully implemented **systems supporting late-stage development and commercial manufacturing operations** for more than 1,000 scientists across multiple international sites. The systems helped the client to mitigate the FDA's concerns with data integrity and resolve compliance issues in two years with zero impact to client revenue. Thanks to this success, the client engaged the Accenture team to be its systems integration partner.