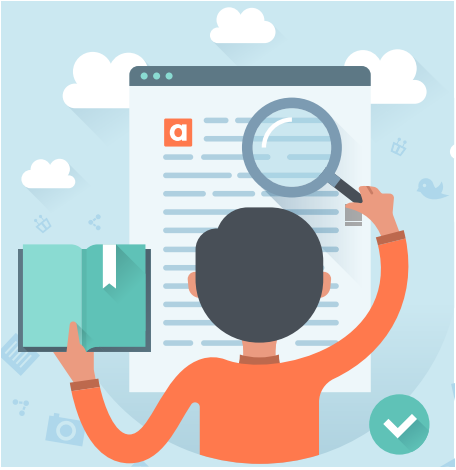
Helping a Client Meet 21CFR11 Regulations and Guidelines

BUSINESS GOALS

The client is a global medical device, pharmaceutical and biotech company. They were facing increased litigation due to regulatory submissions that did not adhere with FDA 21CFR11 regulations and guidelines. They clearly needed help ensuring that their applications were compliant in GxP regulated areas, so they turned to Syntel based on our life sciences expertise as well as our robust, risk-based computer system validation (CSV) methodology.



BUSINESS BENEFITS

- Solution was mapped to 100% of user requirements
- Eliminated the need to print, sign, scan and re-import forms for key submissions
- Enabled the rapid approval of final documents, and improved cross-functional document approval
- Resulting validation was compliant to FDA 21 CFR Part 11 requirements

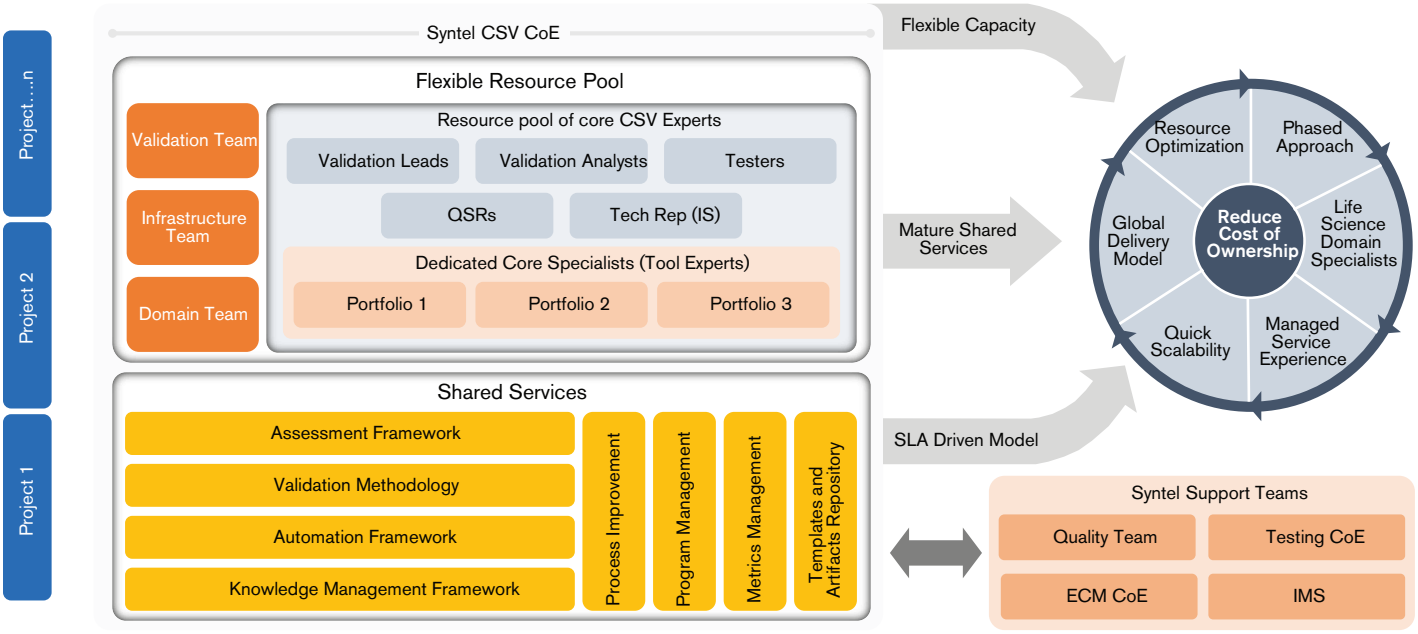
CHALLENGES

- Stringent regulatory timelines
- Corrective & preventive actions (CAPA) were risky and time sensitive, because of the mission-critical systems involved
- Lack of documentation on tools, licenses, and system manuals
- Gaps and inconsistencies in document management conventions
- Lack of standardized (CSV) documentation development methodology
- Differing validation strategies for different GAMP categories

SYNTEL'S SOLUTION

As part of this validation project, Syntel provided a comprehensive, fully-documented computer system validation that is auditable for all internal and 21 CFR Part 11 requirements. Syntel's solution helped the client expedite the validation of business critical applications and ensure adherence to FDA regulations. Syntel's role in executing the project was as follows:

- Developing a project strategy using a risk-based approach
- Performing high-level and detailed risk assessments and assigning applications to high, medium, and low risk categories
- Building protocols for qualifying the system to IQ/OQ/PQ
- Performing quality and regulatory assessment and 21 CFR Part 11 coverage assessment
- Creating a validation plan, user requirement and functional specifications, risk assessment, qualification protocol and qualification test cases
- Working with the client's corporate quality group to develop and implement standard operating procedures (SOP) and update policies, procedures and SOP templates
- Identifying, analyzing and tracking project risks to make test execution more effective
- Ensuring all test cases were accurate and correct, capturing evidence on test case execution
- Implementing virtual machines, making it easier to access and work on the tools remotely
- Documenting the test results concurrently with qualification test execution
- Creating dashboards for senior management



About Syntel

Syntel (Nasdaq:SYNT) is the global leader in digital modernization services, with a core suite of automation-driven IT and knowledge process services. Syntel helps global enterprises thrive in the Two-Speed World™ by building agile, efficient technology infrastructures that blend legacy business models with disruptive digital innovations. Syntel's recursive automation platform, SyntBots®, enables clients to manage, migrate, and modernize their business and technology ecosystems. Syntel believes in a "Customer for Life" philosophy to build collaborative partnerships and creates long-term business value for its clients by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

To learn more, visit us at: www.syntelinc.com

© 2017, SYNTEL INC. 012017