

Improving Efficiency, Reducing Costs, and Achieving Faster Medical Product Launches

BUSINESS GOALS

The client is a global medical devices company and a leader in cardiology and endovascular devices. They needed help understanding gaps between current and new FDA guidelines for Class III medical devices, in hopes of improving product quality and reducing the review time. They also wanted to map their existing test methods to the gaps and develop new test methods to close any remaining gaps.



BUSINESS BENEFITS

100% acceptance of the client's submissions by regulatory authorities

New products launched faster due to more efficient, better quality submissions

Work efficiency increased by 23% due to standardized processes

Significant cost savings were generated by an efficient onsite-offshore model

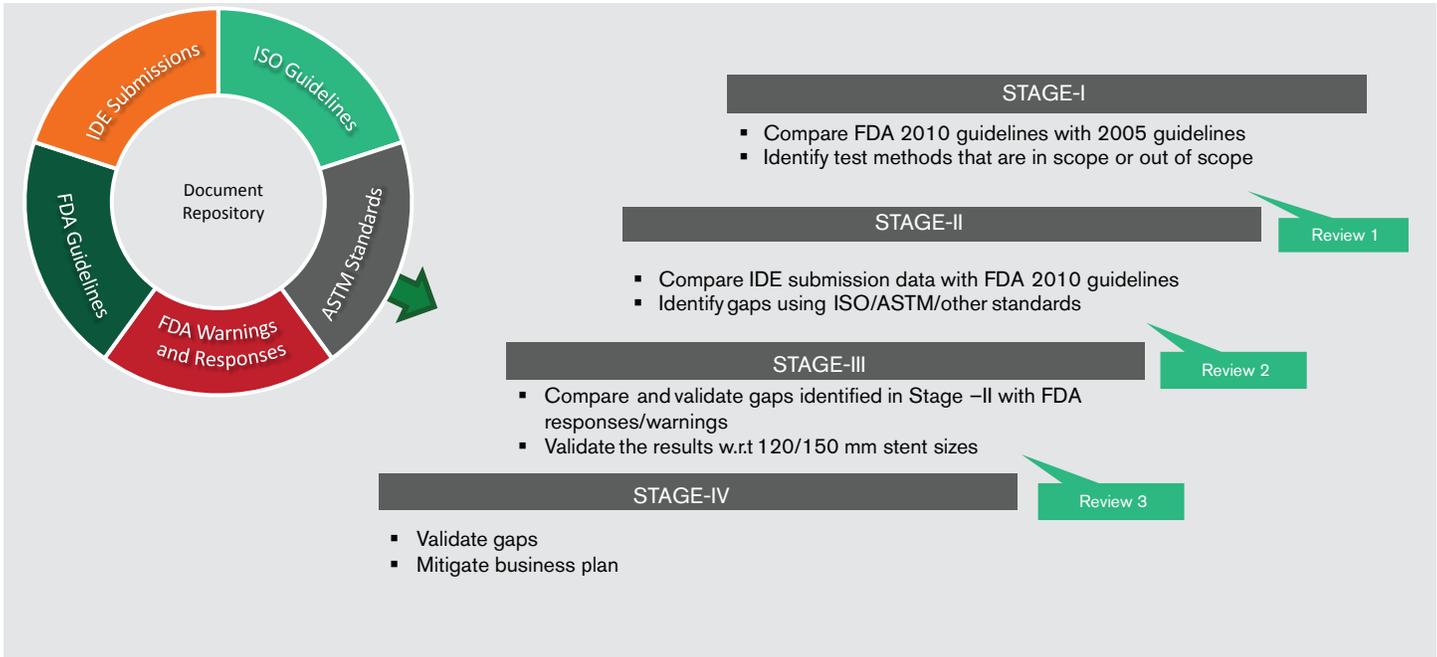
Ramp-up was achieved smoothly by leveraging Syntel's flexible resource pool

CHALLENGES

- Previous regulatory vendor maintained disorganized documentation on past submissions and standards, leading to document duplication
- Stringent timeline to validate data according to new FDA regulatory guidelines
- Insufficient quality checks created a lack of clarity and completeness of information
- Test methods needed to be identified and categorized according to complexity

SYNTEL'S SOLUTION

Syntel performed a thorough due diligence exercise to identify test methods that would generate a detailed gap analysis of the client's past submissions. Through a collaborative document review process, Syntel and the client were able to avoid document duplication and create a highly organized process for document submission. Syntel also advised the client on how to create a standardized process for comparing the differences between past and future regulatory guidelines, and choosing the proper test methods for validation. More details of the complete process can be found below.



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.

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