

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

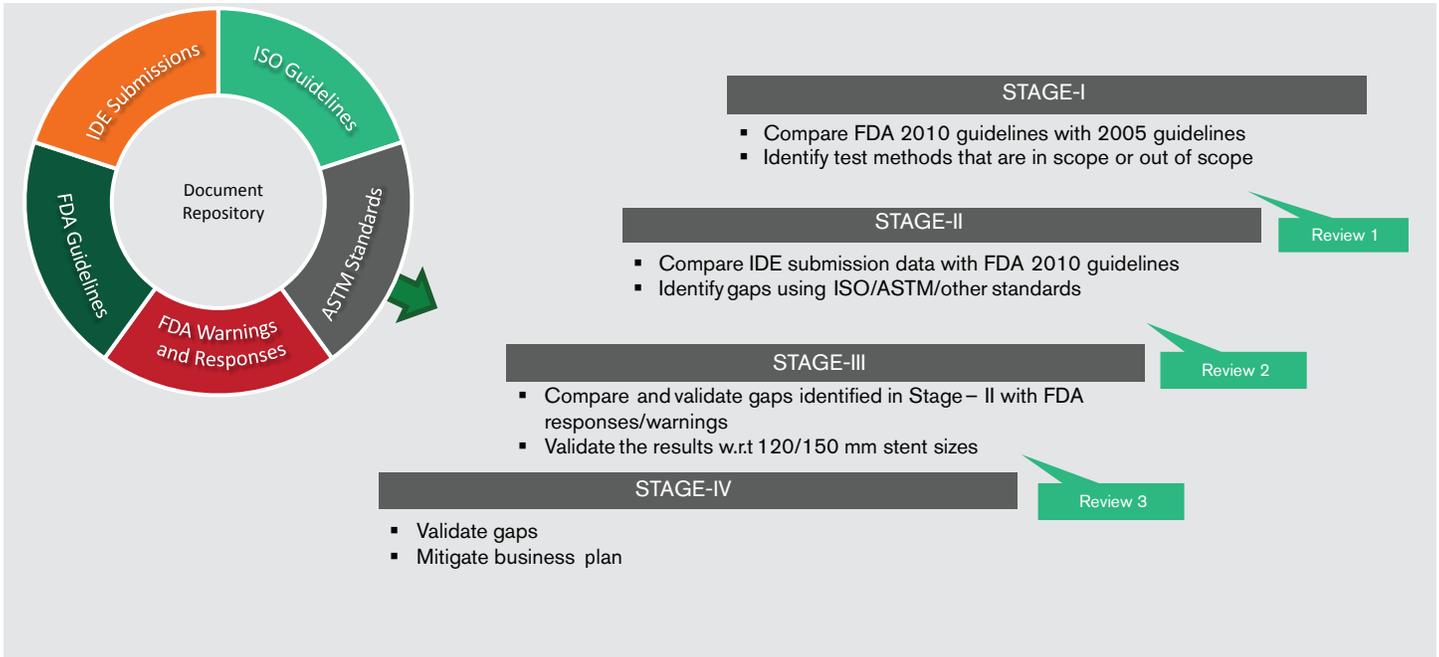
CHALLENGES

- 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 a leading global provider of integrated information technology and knowledge process services. Syntel helps global enterprises evolve the core by leveraging automation, scaled agile and cloud platforms to build efficient application development and management, testing and infrastructure solutions. Syntel's digital services enable companies to engage customers, discover new insights through analytics, and create a more connected enterprise through the internet of things. Syntel's "Customer for Life" philosophy builds collaborative partnerships and creates long-term client value by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

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