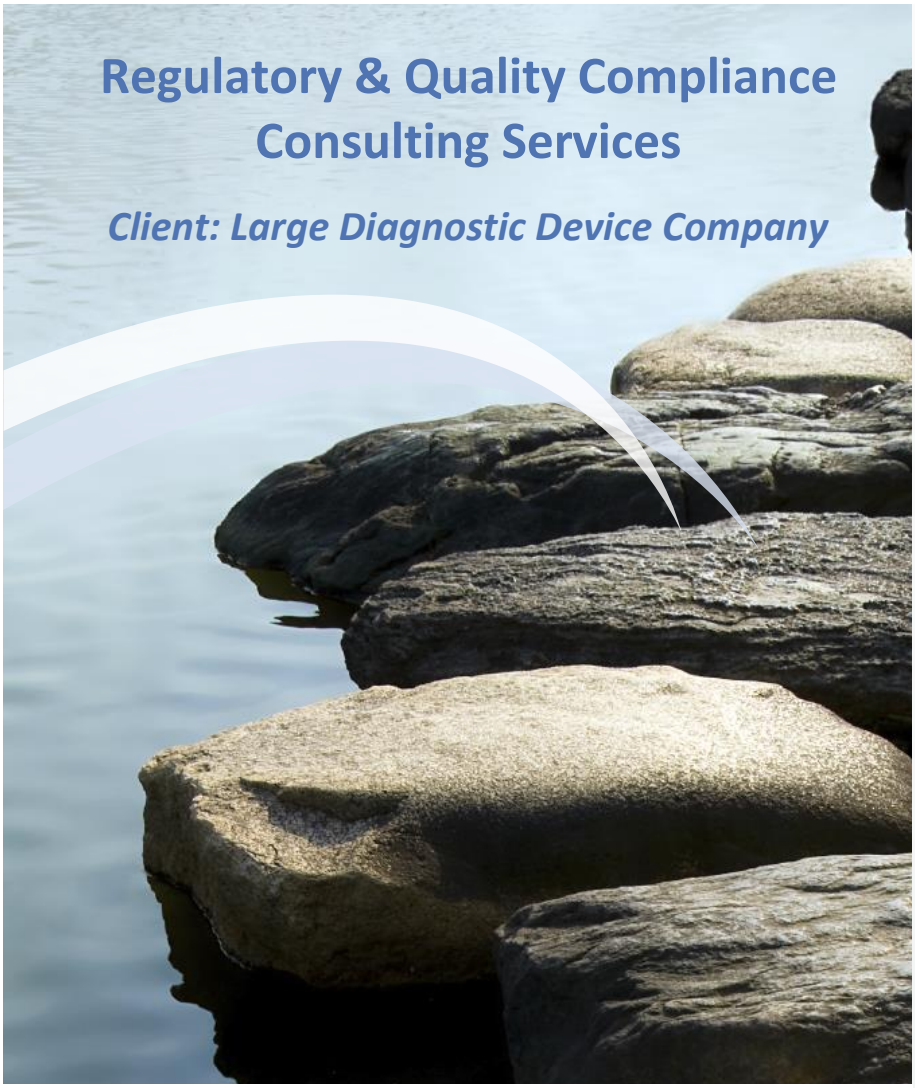
Regulatory & Quality Compliance Consulting Services

Client: Large Diagnostic Device Company



Situation:

A large genetic testing company approached Pearl Pathways with several regulatory and quality compliance needs. The client was expanding their products to include CDRH regulated diagnostic devices. Additionally, this expansion necessitated an overhaul of their quality system. Fifteen OEMs were used in this product's manufacturing process so supply chain management was a key element of their QSR.

Solution:

Pearl drew from our existing staff and assembled a team consisting of regulatory, quality compliance, and clinical trial experts; adept at 820 and ISO 13485, who understood diagnostic device development. The team helped develop the strategy for the regulatory submission and clinical trial strategy, conducted quality compliance gap analyses, assisted with design control processes, authored quality SOPs, provided input for the clinical protocol, and project managed the pieces needed for the De Novo 510k submission. Pearl worked broadly across the company from senior VP leadership levels to the engineering staff, medical team, and OEM suppliers.

Result:

Pearl Pathways' teammates have added value across the client's regulatory, clinical, and quality organizations. Deliverables have included 510k regulatory filing project management and filing documents, global regulatory strategy input, quality system SOPs, vendor management support, and clinical trial design, and review services. Several members of Pearl's staff are closely integrated into product development activities, and are key contributors to hitting the critical path submission of the 510k in Q4 2012. Pearl Pathways was also able to serve the client beyond the original scope of the project by providing IRB review services for several clinical research studies. Pearl's breadth of services and expertise made it easy to broadly address several client problems, all within one company.

Pearl Pathways™

Company Overview

Pearl Pathways is obsessed with accelerating life science product development for our clients. We are an extension of our clients' teams; partnering with the clinical team, in-house regulatory experts, the quality compliance specialists, the quality auditors, and the senior leadership team to get life-saving diagnostics and therapeutics on the market sooner. Our talented staff is focused on getting critical research done, ensuring high quality and efficient manufacturing of products, accelerating global product registrations, and keeping our clients up to date on current regulatory and quality compliance best practices for life science product development.

Pearl IRB: Protecting human subjects and driving improved value and efficiency in protocol reviews and study implementation

Pearl ReGXP: Providing regulatory & quality consulting, and auditing services

Pearl IDEAS: Offering strategic product development assistance through our life science consulting practice

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