CASE STUDY

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™

Pearl Pathways is a comprehensive life science product development services company. Every day we strive to provide our customers top quality service, unyielding ethics, and efficient services through our team of experts. Pearl Pathways supports biopharmaceutical, medical device, and diagnostic companies as well as life science service providers with clinical, regulatory, and quality compliance needs. Our full-service central IRB supports all aspects of human research.

Clinical: Pearl Pathways' expertise in medical practice, science, ethics, and clinical research supports all phases of clinical development. Our expert consultants help implement customized solutions that drive efficient clinical research programs.

Regulatory (drug): Our consultants draw on over 20 years of scientific, industry, and FDA experience to translate your data into strategic drug development pathways, providing guidance from molecule to market while navigating a complex regulatory environment.

Regulatory (device): Delivering superior end-to-end product development and commercialization strategies, our consultants provide regulatory guidance that adds decades of industry and FDA regulatory expertise to your team, helping you balance risk, cost, and time to market.

Quality: From risk-based quality system development to gap analysis and remediation, our partnership helps reduce operational burdens, manufacturing impacts, regulatory agency warnings, and costly recalls—allowing you to focus on ongoing product quality assurance.

IRB: Our accredited independent review board ensures quality research, unyielding ethics, and human subject protection with individualized Expedited and Full Board reviews.

29 E McCarty Street, Suite 100
Indianapolis, IN

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com
www.pearlirb.com