Regulatory Strategy Consulting

Client: Mid-tier pharmaceutical company

Situation: A mid-tier pharmaceutical company approached Pearl for help in preparing an IND for a biologic product and providing consultation on phase 4 post approval supplements.

Solution: The company had not prepared an IND for a biologic before, so Pearl's experts reviewed the first draft of the IND for a . The team reviewed the IND and identified gaps in content and format to FDA expectations. Staff rearranged the data so it was included in the appropriate sections for FDA, and reviewed drafts to ensure consistency throughout the document. Further, Pearl reviewed the data to ensure it supported the proposed studies.

For a second project, Pearl reviewed a product involving a complex formulation involving microspheres for extended release. Pearl reviewed the proposed changes and helped the client establish reporting criteria and organize the sequence of changes to minimize the risk. Ultimately, Pearl shared a plan to allow their client to make all post approval changes within one year and also meet FDA reporting criteria.

Result: The client valued the expert and experienced opinion that the Pearl provided for the IND. The first project led to an IND being filed, and it is currently waiting for the FDA review. For the 2nd project, the client used the plan Pearl created and is thrilled with the reduced reporting requirements. They will continue to monitor the drug supply change to ensure their supply is high quality and adequate. The client will remain to utilize Pearl for ongoing regulatory strategy guidance and consulting.

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. We partner with the clinical team, in-house regulatory experts, the quality compliance specialists, the quality auditors, and the senior leadership team to get lifesaving 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

29 E McCarty Street, Suite 100
Indianapolis, IN

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com

www.pearlirb.com