Regulatory filing services, medical writing and study monitoring

Client: Large Medical Device Company

Situation:

A large orthopedic medical device company approached Pearl Pathways for medical writing services for the creation of several clinical evaluation reports (CER) for upcoming CE Marking regulatory submissions for implantable orthopedic medical devices. The scope included new and existing medical devices. The company provided all past documents needed to create the CER. The company was working towards manufacturing in Europe and needed a medical writer to create and submit the necessary files to maintain regulatory filing status and clear new orthopedic devices in Europe.

Solution:

Pearl provided a team of medical writers proficient in not only creating CERs but also at interpreting past CE Markings, 510ks, and other documents needed for the project.

Result:

Pearl Pathways worked closely with the client to ensure the format of the CERs met with their corporate standards and expectations. Pearl Pathways' delivered over 15 clinical summaries in less than 9 months, and continues to provide ongoing regulatory medical writing services for their client.

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

29 East McCarty Street
Suite 100
Indianapolis, IN 46225

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com

www.pearlirb.com