CASE STUDY

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™

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.

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