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Medical Writer, GBS

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Company: Zimmer Biomet

Location: Bogotá

Category: arts-design-entertainment-sports-and-media

At Zimmer Biomet, we believe in pushing the boundaries of innovation and driving our mission forward. As a global medical technology leader for nearly 100 years, a patient's mobility is enhanced by a Zimmer Biomet product or technology every 8 seconds.

As a Zimmer Biomet team member, you will share in our commitment to providing mobility and renewed life to people around the world. To support our talent team, we focus on development opportunities, robust employee resource groups (ERGs), a flexible working environment, location specific competitive total rewards, wellness incentives and a culture of recognition and performance awards. We are committed to creating an environment where every team member feels included, respected, empowered, and recognized.

What You Can Expect

The Medical Writer is primarily responsible for preparing Clinical Evaluation Reports (CERs) for regulatory submissions and Post-market Surveillance Plan literature reviews (PSPs) for analysis of existing product clinical performance. Both involve conducting searches of peer-reviewed publications, national implant registries, risk management files and post market quality tabulations to compile relevant data. Report preparation involves summarizing data found and drafting risk versus benefit analyses for review by Senior Medical Writer or designee. The scope includes products of Reconstruction, Trauma, Biologics or other ZB Divisions as needed.

How You'll Create Impact

Identify pertinent internal and external sources of clinical data and conduct systematic literature searches of peer review publications.

Prepare Clinical Evaluation documents according to the applicable regulations (including MDR (EU) 2017/745) and Zimmer Biomet internal procedures using relevant information compiled from clinical research, peer reviewed publications, risk management files and post market data.

Summarize findings and draft risk versus benefit analyses and conclusions, for review by Medical Writing Manager or designee, based on clinical and post market data.

Distribute reviewed final draft reports to Clinical Affairs, Regulatory Affairs, Post-Market Surveillance and Development Engineering groups to verify and approve content of final draft document.

Prepare reviews of peer-reviewed literature for inclusion in Zimmer Biomet post-market surveillance (PMS) reports.

Support the Manager or Team Leader for Audit activities including the participation in Audits as clinical evidence SME as needed

File work in the Clinical Evaluation archives, provide clinical data searches and documentation as a service to various functions within Zimmer Biomet, and provide verbal and/or written progress reports monthly.

What Makes You Stand Out

Demonstrated technical and medical writing competence

Strong organizational skills, attention to detail and proofreading skills

Understanding of statistical methods

Ability to critically analyze and interpret scientific data

Have an analytic and strategic mindset

Ability to work within tight deadlines, adjust to changes in priorities

Ability to function independently

Ability to identify problems and research possible solutions

Takes actions that are best for the company versus his or her individual unit

Encourages and supports information sharing and collaboration across teams and departments

Demonstrates sound business ethics; shows consistency among principles, values and behaviors.

Strong ability to interpret and disseminate relevant clinical studies / medical product information.

Proficiency in MS Office applications and proficiency in or ability to learn EndNote or Reference Manager or other similar software tools needed for performing the job.

Basic understanding of regulatory compliance for medical devices.

Your Background

English proficiency is required (C1).

Minimum of a Bachelor's degree or equivalent education in health, life sciences, engineering or a similar discipline required. MD, MS and PhD preferred.

Demonstrated authorship of scientific publications in peer review journals will be an asset.

3-5 years of experience in medical writing, clinical affairs, regulatory affairs, or product engineering in the medical device industry required, with a strong preference to those with similar work experience in the orthopedic medical device industry.

In lieu of the medical device industry experience, 3-5 years as a professor or senior investigator in a healthcare related field, with a demonstrated record of research and scientific publications.

Travel Expectations

Up to 5%

EOE/M/F/Vet/Disability

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