[Ref 2022-01] Medical Writer

EOS imaging is an international group, specializing in innovative imaging and image-based solutions for musculoskeletal pathologies and orthopedic surgical care. EOS imaging dedicates its efforts and skills to the improvement of patient treatments and outcomes through low dose imaging, complete and precise patient data and surgical planning based on 3D patient anatomy.

The company is part of the Alphatec Spine group.

This position is based in Paris.

The Medical Writer will be responsible for developing clinical, scientific and regulatory documentation in support of clinical research studies, scientific literature and regulatory submissions. This role will partner closely with marketing, regulatory and clinical departments to provide the necessary documentation in domestic and international markets.

ROLES AND RESPONSIBILITIES

- Analyses, assesses and assembles the clinical data pertaining to a medical device for submissions to regulatory bodies, including the EU, US and various APAC authorities to establish and maintain global regulatory compliance.
- Works directly to support the clinical, R&D and regulatory teams by authoring documents and managing the document review process.
- Develops procedures and best practices for the process of document review, completion, and approval, ensure adherence to regulatory requirements and industry standards, where applicable.
- Creates / revises relevant document templates and guides as needed.
- Provides effective communication to support clinical research study activities, including management of projects with external contractors and business partners.
- Supports / participates in manuscript writing with/without external/internal collaborators for scientific publication.
- Supports the creation or revision of product labeling and risk management files.
- Supports / conducts literature searches activities and data gathering activities to support various internal/external education clinical strategies as well as regulatory documents such as clinical evaluation reports.
- Can interpret and summarize statistical results of clinical studies and present the data in a clear, concise, and scientifically accurate manner to a wide range of audiences.
- Provides guidance on analysis and presentation of clinical and safety data, including risk/benefit assessments, for post-market surveillance activities.
- Trains and promotes effective writing techniques throughout the company.

REQUIRED KNOWLEDGE, SKILLS & ABILITIES

- Requires BS/MS/PhD/PharmD/MD degree in Medical Science, Life Science, Science, or Engineering, and a minimum of 3+ years of experience in medical device studies and/or clinical study support or with the completion of clinical trial programs, ideally for clinical evaluation.
- Very strong communications skills – both written and verbal. Possesses both technical and organizational skills and the awareness needed for effective and open communication.
- Experience in Clinical Evaluation Reports (CERs).
- High level of English and French in speaking, reading, writing
- Strong emphasis on medical terminology and/or research methodology.
- High level of writing literature reviews, state of the art summary, previous experience strongly appreciated
- Proficient with Microsoft Outlook, Word, Excel
- Knowledge of regulatory and quality guidelines related to clinical research studies.

You want to join a dynamic team and you are passionate about the field of medical healthcare? Do not hesitate any longer and send us your application on careers@eos-imaging.com by precising the reference number: 2022-01