Belgium Jobs Expertini®

Principal Medical Writer

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Company: PRA

Location: Belgium

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

As a Principal Medical Writer you will be joining the world’s largest & most comprehensive clinical research organisation, powered by healthcare intelligence.
As principal medical writer, you will be supporting a Top-5 biotech company. You have the chance to help our customer to deliver best-in-class regulatory and submission documents. While being stably employed with ICON, you will be fully embedded with our client. Your excellence in medical writing will help them reduce time to market of their deep antibody pipeline.
The position is home-office based. Your contribution will be in the challenging field of autoimmune diseases. While working for our client, you will be able to profit from ICON through continued learning opportunities and building a longer-term career.

What you will be doing:

Medical Writing Excellence
You will deliver all types of clinical, regulatory, and submission documents.

You will draft and manage documents that are superbly organized, accurate, consistent, unambiguous and written for the target audience.

Key documents to develop will be clinical protocols, informed consents (ICFs), clinical study reports (CSRs), investigator brochures (IBs), patient narratives, annual reports, eCTD modules and other clinical and regulatory documents.

You will take up a lead role in advising and guiding clinical teams on content and processes.

You will ensure that all applicable company SOPs and regulations are upheld.

Lead in a multi-shareholder environment to ensure seamless delivery of best-in-industry regulatory documents.

Closely interact with clinical program leadership and clinical teams to set up and safeguard challenging project deadlines.

Functional Leadership
You will be a pivotal member of clinical teams in pro-actively guiding them on best-in-class medical writing processes.

You will drive consistency of documentation using document templates and company style guide across programs

Ensure dissemination of industry and health-authority regulatory guidelines.

Represent medical writing function at internal meetings (e.g. project and program management status updates).

You will proactively provide recommendations for potential process improvements to foster best-in-industry delivery of regulatory documents of the highest quality.

May represent Medical Writing department in industry standards working groups.

Represent the medical writing function during an audit of clinical trial documents to guarantee timely response to findings

You are:

Minimum of 6 years of pharmaceutical/biotechnology-related medical writing required

Master degree in a scientific, medical or clinical discipline or related field required, PhD preferred

Can interpret and implement all FDA and ICH guidelines for clinical reporting.

eCTD development and submission experience preferred.

Pivotal understanding of key phases, processes, and techniques of drug development from protocol development through submission.

Excellent communicator and driver of cross-functional collaborations.

Innovative mind-set and proactive contributor of process improvement ideas.

Ability to proofread documents for compliance with internal and external guidance
Can drive consistency of documents across indications.

Experience in electronic publishing preferred.

Benefits

You will be provided with a comprehensive and very competitive total reward package that comprises an excellent level of base pay completed with a wide range of variable pay and recognition programs. We offer you best-in-class employee benefits, supportive policies and wellbeing initiatives tailored to support you and your family at all stages of your career with ICON.

You will profit from being a key medical writer at a Top-5 biotech company, all the while being a full employee of ICON.

ICON is an equal opportunity and inclusive employer.

Why ICON?

Our focus is to provide you with a comprehensive and competitive total reward package that comprises, not only an excellent level of base pay, but also a wide range of variable pay and recognition programs. In addition, our best in class employee benefits, supportive policies and wellbeing initiatives are tailored to support you and your family at all stages of your career - both now, and into the future.

Our success depends on the knowledge, capabilities and quality of our people. That’s why we are committed to developing our employees in a continuous learning culture – one where we challenge you with engaging work and where every experience adds to your professional development.

ICON, including subsidiaries, is an equal opportunity and inclusive employer and is

committed to providing a workplace free of discrimination and harassment. All qualified applicants will receive equal consideration for employment without regard to race, colour, religion, sex, sexual orientation, gender identity, national origin, disability or protected veteran status.

If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or in order to perform the essential functions of a position, please let us know.

Interested in the role, but unsure if you meet all of the requirements? We would encourage you to apply regardless – there's every chance you're exactly what we're looking for here at ICON whether it is for this or other roles.

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