Regulatory Medical Writer – Medical Writer
Position open only to Canadian citizen/resident or with Canadian work permit
Montreal Health Innovations Coordinator Center
Full Time

The Montreal Health Innovations Coordinating Center (MHICC) is a full service contract research organization targeted on multicenter and multinational clinical trials. We provide services to the academic community and to the pharmaceutical, biotechnology and medical device industries. Our main goal is to establish a partnership with our customers to ensure a successful implementation of their project while respecting the scope of work, budget, timelines and highest standards of quality.

RESPONSIBILITIES

- Leads medical writing projects including the design, planning and preparation of regulatory documents in a cross functional manner in accordance with regulatory requirements
- Works collaboratively with the MHICC management team, project managers, and sponsors to ensure timely, high quality and accurate medical writing projects
- Develops regulatory documents using appropriate and approved templates, create new templates adhering to MHICC Standard Operating Procedures (SOPs) and industry guidelines
- Develops, revises, implements, and provides training on the standard operating procedures
- Ensures that all medical writing projects are edited effectively before releasing them for internal or external review
- Monitors all assigned medical writing project’s progress and provides timely and regular updates
- Identifies and escalates to the management team all issues that could affect project quality and timelines and provides realistic and applicable solutions
- Serves as the primary contact between the clinical research team the sponsor, and vendor, as applicable, for all assigned medical writing projects
- Ensures that all assigned medical writing projects are executed according to agreed-upon timelines
- Provides clients specific and concise guidance on all assigned medical writing projects
- Builds strong and effective relationships with sponsor and vendors to enhance the medical writing department’s workflow
- Participates in ongoing process improvement to enhance departmental and organizational effectiveness
- Shares knowledge by facilitating training sessions and mentoring with other team members
- Participates in project-related meeting as required

REQUIREMENTS

- A B.Sc. degree in Life Science/Health Related Science or equivalent. A M.Sc. is an asset
- Bilingual (French/English) (preferred)
- A minimum of 3 years of experience as a medical or scientific writer in the life sciences industry, pharmaceutical or biotechnological industry in a multi-therapeutic field that involves Phase I through IV clinical trials
- A minimum of 3 years of experience working with sponsors, vendors or authors of regulatory or scientific documents and managing review cycles and project timelines
- Experience in preparing regulatory documentation for submission to regulatory authorities like Health Canada, Food and Drug Administration, European Medicines Agency would be an asset
- Excellent written, oral (including presentation), interpersonal and negotiation communication skills.
- Ability to prepare any type of clinical documentation with minimal supervision (e.g., Clinical Protocols, Investigator Brochure, Abstracts, Manuscripts, CSRs, DSURs etc.) according to MHICC’s adhering guidelines
- Ability to research multiple health-related databases for complex scientific information, synthesize the information quickly and able to explain it to both the public and scientific peers
- Ability to be flexible when it comes to last-minute and tight deadline work assignments
- Ability to manage multiple tasks with enthusiasm and prioritize workload with a quality focused approach, i.e., excellent organizational skill
- Must have strong analytical and problem-solving skills.
- Ability to escalate issues to departmental management as required
- Excellent knowledge of clinical research methodology and solid understanding of clinical studies, ICH E3, E6 and E9, GCP, and other applicable regulatory requirements
- Excellent knowledge of Statistical analysis methods and reporting guidelines
- Excellent knowledge of medical terminology and clinical trial design
- Computer literacy and proficient in Microsoft Office including SharePoint and Excel, Adobe Acrobat, and document management systems

WORK CONDITIONS
- 35 hours weekly base
- Pre-approved overtime paid
- Flexible work schedule for work-family balance
- Hybrid model (working from home and office)
- 4 weeks' vacation after one year
- 13 statutory holidays
- Defined retirement benefits
- Group insurance
- 9.6 day off sick days

The Montreal Heart Institute offers a wide range of benefits aimed at employees' health, well-being and quality of life at work, including free access to the EPIC Centre, Recharge cabins and silence rooms, as well as various other benefits.

TO SUBMIT YOUR APPLICATION
- Final date to apply: November 15, 2023
- Send your application to the following address: rh@mhicc.org
- Please indicate the job title for which you are submitting your application


We offer equal employment opportunities to all.

Only candidates that have been selected for an interview will receive a written answer.