Director, Clinical Development and Medical Writing

Nabriva Therapeutics is a commercial-stage biopharmaceutical company engaged in the research and development of innovative anti-infective agents to treat serious infections, with locations in the United States (Fort Washington, PA), Austria (Vienna), and Ireland (Dublin). Our dedicated team has extensive scientific and industry experience and a shared passion for addressing the increasingly urgent problem of bacterial resistance worldwide. We are focused on the commercialization and development of existing and new chemical entities (NCEs) for human use to treat indications with high unmet medical need such as serious infections.

For our Fort Washington, PA site, we are currently recruiting for a full-time **Director, Clinical Development and Medical Writing**. The ideal candidate will direct the strategic planning and execution of study-level and program-level clinical regulatory documents to support the advancement of Nabriva development programs. The person in this role will effectively collaborate with internal and external stakeholders to coordinate document content, quickly resolve conflicts, and meet established timelines. The incumbent will provide medical writing leadership and subject matter expertise to cross-functional project teams to facilitate the efficient development of regulatory submission documents across disciplines.

Our Offer

- Responsible and diversified leading position in a well-established international biotechnology company
- Innovative and professional scientific working environment
- Opportunity for personal development and growth
- Dynamic and flexible corporate culture
- Hybrid working model
- Competitive benefits
- Collaborative and entrepreneurial working atmosphere

Your Responsibilities

- Drive the efficient preparation of high-quality, strategically aligned medical writing (MW) deliverables that support the clinical development and regulatory requirements of Nabriva development programs. This includes authoring initial drafts, coordinating contributions & timelines with various authors/ contributors, shepherding through

several levels of reviews, and finalizing clinical documents (IBs, clinical development plans, clinical protocols, CSR's), regulatory documents (clinical summary modules of the Common Technical Document, INDs, NDAs, sNDAs), safety reports (RMPs, periodic safety reports, monitoring reports/DSMB charters), and other documents as needed by various Nabriva teams.

- Manage MW deliverables outsourced to contract research organizations (CROs) and independent contractors. Lead MW vendor selection, define the scope of work to be outsourced, and oversee the performance and budget of MW vendors on outsourced deliverables.
- Lead the development, management, and continuous improvement of MW procedures and standards. Ensure proper and timely training to optimize the introduction and implementation of new procedures and technologies (eg, systems and templates).
- Ensure that MW deliverables are developed, reviewed, and quality checked in accordance with MW procedures, and that document format, structure, and content adheres to regulatory and industry standards.
- Manage consistency of style, format, and content in MW deliverables.
- Contribute to the overall regulatory strategy for Nabriva clinical development programs and align study-level and program-level documents to support key messages and labelling objectives.
- Advise authors from other functions on MW best practices and the use of MW technologies to support the efficient development of regulatory submission documents across disciplines

Your Qualifications / Skills / Competencies

- Bachelor of Arts or Bachelor of Science degree in English or life science.
- Minimum of 10 years of Medical Writing experience in the biopharmaceutical industry or in a Contract Research Organization
    - Experience in the field of antibiotics is preferred

- Thorough understanding of the clinical development process, including the regulatory documents that are required at each stage.
- Excellent understanding of health authority regulations and ICH guidelines pertaining to global dossiers; keen insight on external clinical publication practices and standards (eg, AMA and ICMJE).
- Demonstrated track record of leading complex clinical and regulatory writing projects and in in fostering and managing external writing resources (eg, independent contractors and CROs).
- Mastery of the English language, with a comprehensive understanding of English grammar and punctuation.
- Demonstrated experience in strategic and multi-project planning, including resource allocation, negotiating, budgeting, and contract preparation.

- Ability to analyze critically and synthesize complex scientific information from a range of scientific disciplines and clinical therapeutic areas.
- Excellent written, verbal, and presentation skills, including strong influencing skills in shaping and developing content and wording.
- Expert Microsoft Office skills with a special focus on word processing, tables, spreadsheets, presentations, graphics, and document templates.
- Expert skills with document management systems (eg, Veeva and Documentum).
- Strong experience with submissions in Common Technical Document (CTD) format.