MEDICAL WRITER

- **About us**

Advanced Accelerator Applications (AAA) is an innovative International pharmaceutical company and a leader in molecular nuclear medicine. We have an established pipeline of unique products, continuous double-digit annual revenue growth for the past 10 years and a unique entrepreneurial culture with approachable, hands-on management that partners with employees and empowers them to contribute to the success of the business.

Our team of over 500 people is based across 13 office locations in Europe and the U.S.

As a valued team player, you will enjoy a competitive compensation package, excellent healthcare benefits, 401K match, flexible working hours and very generous PTO.

Due to continued growth, we are looking for an experienced **Medical Writer** to join our organization. This is an exciting newly created role with global responsibility working on some high-profile projects.

The selected candidate will be in charge of clinical/regulatory document preparation through all phases of the drug development process, interacting with various functions, and leading cross-functional processes. He/She will work closely with all R&D members as well as Regulatory Affairs, Medical Affairs and Pharmacovigilance teams to coordinate and ensure the successful completion of the clinical activities within the agreed timelines and budget, and in compliance with the required quality, Good Clinical Practice and ICH Guidelines.

Key Tasks And Responsibilities

- Provides medical writing expertise for multiple compounds and/or projects. Interfaces with external and internal teams (e.g. clinical investigators, external advisors, pharmaceutical development, preclinical, clinical, data management, regulatory) to ensure accurate and timely completion and review of clinical regulatory submissions.
- Converts data and information into a format that meets clinical regulatory document requirements.
- Ensures successful preparation of high quality submission-ready documents and effective implementation of the clinical writing process.
- Implements all activities related to the preparation and compilation of data and information into a single comprehensive package for new and updated clinical regulatory documents (EU and US).
- Coordinates the review, approval, and other appropriate functions involved in the production of clinical documents e.g. investigator brochures, study protocols and amendments, patient information and informed consent forms, study manuals, clinical trials reports, elements of CTD Modules 2, 4 and 5.
- Understands, assimilates, and interprets sources of information with appropriate guidance/direction from product teams and/or authors ensuring required documentation is obtained.

- Performs literature searches as needed for drafting document content. Interprets literature information and makes recommendations for application to clinical regulatory documents.
- Interacts with key internal and external stakeholders, authors and investigators in the preparation of publications.

Professional Skills & Experience

- Minimum 3 years of relevant industry experience in medical writing in a clinical research environment.
- Advanced scientific degree (MSc, PhD, PharmD).
- Proficiency in medical / technical writing and editing, document building and rendering, editorial skills.
- Ability to independently analyse and synthesize data from a broad range of disciplines, including oncology and medical diagnostic products.
- Thorough knowledge of international regulations, requirements and guidance associated with clinical regulatory document preparation and submissions.
- Practical knowledge and experience with Common Technical Document content templates.
- Good understating of data management and biostatistics.
- Able to identify and propose solutions to resolve issues and questions arising during the writing process, including resolution or elevation as appropriate.
- Proficient in literature searches, their analyses and evaluation.
- Professional proficiency in written English.
- Personal skills & abilities
- Dynamic self-starter with strong influencing skills; adaptable and flexible to change.
- Excellent written and oral communication skills (mainly in English).
- Exceptional organizational and planning skills with particular attention to details.
- Ability to prioritize and manage multiple tasks in a challenging environment.
- Strong interpersonal skills and the ability to relate and work in a cross-functional environment with a wide range of people to achieve results.
- Highly proactive, self-motivated, professional and dedicated.
- Proficient computer skills: Word, Excel, PowerPoint, Internet. Experience of scientific databases.

This position is located in Millburn, NJ.

Submission of your application:

Please send your application in via email to recruitment-US@adacap.com. Your application shall include all the information you consider relevant, and at a minimum, a motivation letter, your personal data, education, employment history and details on your current position and salary as well as your salary expectations for this position.

Please note that we will only reply to candidates that we wish to bring to interview stage.