M/F MEDICAL WRITER

- **About us**

Advanced Accelerator Applications (AAA) is a radiopharmaceutical company founded in 2002 to develop innovative diagnostic and therapeutic products. AAA main focus is in the field of molecular imaging and targeted, individualized therapy for the management of patients with serious conditions ("Personalized Medicine"). The company has a strong pipeline and has maintained continuous double-digit growth in sales for the last 10 years of commercial operations. AAA is headquartered in St Genis Pouilly, France, and currently has 18 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and over 440 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP".

AAA has also a broad pipeline of products in development. The company's lead product, Lutathera®, is an advanced Phase III theragnostic oncology product developed to treat gastroenteropancreatic neuroendocrine tumors. Another AAA product in development is the radiopharmaceutical Gallium-68 Dotatate which received orphan drug status designation by both FDA and EMA, in early 2014, as a diagnostic agent for the management of GEP-NETs. Also, Phase I/II studies have been initiated with Annexin V-128, a diagnostic 99mTc tracer for apoptosis and necrosis.

AAA is looking for a **Medical Writer** to be based in Saint Genis Pouilly, France. This position will report to the Head of Clinical Development.

- **Role**

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**

  - Provide 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.
  - Ensure 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.
- Interact with key internal and external stakeholders, authors and investigators in the preparation of publications.

• **Professional skills & experience**

- Minimum 3 years 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.

- **Submission of your application**

Please send your application in English via email to recrutement@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.

For further information on the company, please visit our web site www.adacap.com