M/F Regulatory 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 22 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and over 500 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 is looking for a **Regulatory Medical writer** to be based in **Geneva (Switzerland)**.

As part of the regulatory affairs team and in support of the Clinical development team you will report directly to the European Regulatory Affairs Manager.

- **Key tasks**

- Write and/or review high quality preclinical and clinical sections of dossiers and responses documents for submissions with new Marketing Authorizations, variations and renewals via Centralised/Decentralised procedures,
- Write and/or review Scientific Advice briefing documents and scientific documentation supporting clinical trial applications, such as IMPD's
- Write and/or review other regulatory documents, such as ODDs, PIPs or similar,
- Prepare relevant submission documents, perform and coordinate submission activities of all types of regulatory applications,
- Provide scientific advice and early stage development strategy and project management of all regulatory requirements and show a detailed knowledge of current legislation associated with the regulatory requirements,
- Write internal procedures in relation with Regulatory Affairs
- Provide a regulatory surveillance in accordance with planned and on-going projects

- **Professional skills and experience**

- Life Science degree
- Strong pre-clinical and clinical dossier writing experience

- 3-5 years regulatory or clinical experience and expertise in European regulatory requirements (additional experience with FDA will be an asset)
- Professional proficiency in both spoken and written English

- **Personal skills & abilities**

- Working environment is in English and French. Perfect English is required
- Excellent verbal and written communication skills
- Strong interpersonal and negotiation skills
- Strictness
- Sense of analysis
- Sense of organisation
- Good relationship
- Collective intelligence behaviour

- **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.

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