M/F REGULATORY AFFAIRS ASSOCIATE- Lifecycle Management

• 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 Affairs Associate – Lifecycle Management** to be based in **Saint Genis Pouilly (01).**

As part of the regulatory affairs team, you will report directly to the Associate Director, Global Regulatory Affairs.

• Key tasks

- Plans and implements regulatory activities in support of lifecycle management including renewals, variations, labelling activities and PSURs,
- Write and/or review high quality CMC variation dossiers (Module 1, 2 and 3) and response documents for submissions via Centralised/Decentralised procedures,
- Prepare submission packages in eCTD format, perform and coordinate submission activities of post-authorization regulatory activities,
- Ensures post-market regulatory compliance: Evaluate/analyse all proposed post-approval product changes through Change Controls, and provide regulatory expertise and/or classification based on current regulations, guidelines and policies.
- Provide a regulatory surveillance in accordance with planned and on-going projects.

• Professional skills and experience

- Life Science degree, with pharmacy qualifications a plus
- 2-3 years regulatory experience and requirements expertise in European regulatory procedures (additional experience with FDA will be an asset)
- Knowledge of pharmaceutical life cycle management
- Knowledge of CTD granularity and eCTD format
- Proficiency in MS Word; strong formatting skills and use of templates is a plus.
- Professional proficiency in both spoken and written English

• 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.