M/F REGULATORY AFFAIRS MANAGER

- **About us**

Advanced Accelerator Applications (AAA) is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine (MNM) products. AAA's lead therapeutic product candidate, Lutathera®, is a novel MNM compound that AAA is currently developing for the treatment of neuroendocrine tumors, a significant unmet medical need. Founded in 2002, AAA has its headquarters in Saint-Genis-Pouilly, France. AAA currently has 21 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 550 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA reported sales of €109.3 million in 2016 (+23% vs. 2015). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information, please visit: www.adacap.com.

Advanced Accelerator Applications is looking for a **Regulatory Affairs Manager** to join the Company's global Regulatory team and support operations in our growing Geneva office.

- **Key tasks:**

- Author and/or review CMC documentation (CTD sections, IMPD or briefing books etc.) for Health Authority submissions for small molecules and biological radiopharmaceutical products.
- Manage global and regional submissions such as clinical trial applications, new marketing authorization applications, lifecycle management activities and responses to Health Authority questions.
- Provide leadership on regulatory interactions on CMC related topics, lead preparation of meetings with regulatory agencies and ensure CMC regulatory issues impacting global regulatory strategy for proposed CMC filings are considered.
- Proactively participate in design of global regulatory strategies for the development of therapeutic and diagnostic products in adherence to regulatory guidelines,
- Actively participate in RA infra-structure (SOPs) and capability building.
- Represent Global Regulatory CMC on interdisciplinary project teams; partner with Regulatory, Quality, Research, Manufacturing, Nonclinical and Clinical teams,
- Assist during regulatory agency inspections.
- Participate in regulatory intelligence activities; monitor regulatory guidelines and trends.

- **Professional skills and experience:**

- Life science degree.
- +5 years regulatory experience in the pharmaceutical/biotechnology/life science industry including both development and commercial pharmaceutical products.

- Extensive writing experience of Biologic CMC regulatory documents, proven participation to EMA CP application or FDA BLA.
- Experience with CMC regulations for biological compounds.
- Proficiency in MS Word; strong formatting skills.
- Professional proficiency in both spoken and written English.
- Ability to work independently (with minimal supervision) as well as work in a team environment with changing timelines and priorities.
- Demonstrated verbal and written communication skills.
- Ability to multi-task, pay close attention to detail, and follow projects through to completion.

- **Submission of your application**

We offer you a challenging position within an innovative, dynamic, international and goal-oriented working environment where your contribution can make a difference.
Compensation is competitive and based on your professional and educational background.

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