



## M/F HEAD PHARMACEUTICAL DEVELOPMENT

- **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<sup>®</sup>, 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 22 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 500 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA reported sales of €88.6 million in 2015 (+27% vs. 2014) and sales of €81.3 million for the first 9 months of 2016 (+23% vs. 9 months 2015). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information, please visit: [www.adacap.com](http://www.adacap.com).

AAA has a broad pipeline of products in development. In addition to the company lead product, Lutathera<sup>®</sup>, and its Gallium-68 Dotatate and Dotatoc products NetSpot and Somakit approved by the FDA and the EMA, Phase II studies have been initiated with Annexin V-128, a diagnostic 99mTc tracer for apoptosis and necrosis, and the company has other imaging and therapeutic radiopharmaceutical products in development.

AAA is looking for a **Head of Pharmaceutical Development** to be based in Geneva, Switzerland. This position will report to the Global Head of Research and Development.

- **Role**

The selected candidate will be in charge of the overall operational management and oversight of pharmaceutical development. He/She will work closely with all R&D members as well as Regulatory Affairs, Project Management and the Group Responsible Pharmacist, to coordinate and ensure the successful completion of the pharmaceutical development activities within the agreed timelines and budget, and in compliance with the required quality, Good Manufacturing Practice and ICH Guidelines.

- **Key tasks**

- Oversee and coordinate radiopharmaceutical product development (ready-to-use injectable solutions and kits for radiopharmaceutical preparation).
- Lead a team of pharmaceutical development managers and radiochemists with cross functional project management responsibilities.
- Ensure manufacturing processes and control methods are successfully transferred to the manufacturing sites at full manufacturing scale for supporting clinical development and marketing license approval process.
- Lead contract negotiations with CMOs for API supply, drug product process development and cGMP manufacturing, including API sourcing strategy.

- Take part in due diligence activities and represent pharmaceutical development function in licensing-in initiatives and partnership.
- Responsible for the accuracy and reliability of the information generated in the drug development programs, including drug product and API stability testing programs.
- Ensure that the scope of work, planning, training, expectations and timelines are unequivocally understood by all team members and stakeholders.
- Anticipate, recognize and resolve issues proactively with the project team
- Develop / maintain related processes, policies and SOPs.
- Ensure the appropriate communication among all functions within the company and with external vendors.

- **Professional skills & experience**

- PharmD or PhD in Pharmaceutical Sciences, with comprehensive knowledge in injectable products manufacturing.
- Strong awareness of GMP standards and drug development regulatory guidelines.
- Hands-on knowledge of analytical chemistry and injectable formulation development, including analytical method development, manufacturing processes and technology transfer.
- Industry experience in (radio)pharmaceutical products development, including radiopharmaceutical kits.
- Expertise in small molecules, peptides and proteins to the level of API GMP manufacturing and controls.
- Problem solving, creativity and proactivity to implement new approaches and complete product development in full and on time.
- Track record in CMC documentation review and interactions with regulatory authorities for relevant parts of regulatory submission related to pharmaceutical development, including IMPD, IND, CTA, MAA and NDA.
- Highly developed management and communication skills, with experience in working in a matrix organisation.
- Professional proficiency in both spoken and written English.

- **Personal skills & abilities**

- Strong organizational and time management skills.
- Quality oriented with attention to details.
- Highly proactive, self-motivated, professional and dedicated.
- Flexibility and ability to prioritize and manage multiple tasks in a challenging environment.
- Ability to influence and convince key stakeholders in completing pharmaceutical development on time and within budget.
- Excellent English written and oral communication skills; other languages an asset.



- Proficient PC skills: Word, Excel, PowerPoint, email.
- Accept to travel as required.

• **Submission of your application:**

Please send your application in English via email to [recrutement@adacap.com](mailto: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](http://www.adacap.com)