Based in Wallonia, our client is a publicly-traded clinical-stage biopharmaceutical company dedicated to extending and improving the lives of patients with cancer by designing and developing next generation immunotherapies.

Their values based on Excellence, Team Work, and Boldness form the foundation of who they are as a company and define who they are at our core.

To carry on its growth and reinforce its team, we are looking for a **Preclinical Lab Quality Manager.**

Preclinical Lab Quality Manager

RESPONSIBILITIES

As a Preclinical Lab Quality Manager, you develop, implement and manage nonclinical and non-regulated research quality assurance activities according to the regulatory requirements (**GLP**).

Your main responsibilities are:

- Oversee supporting preclinical analytical **Quality Operations activities**.
- Serve as GLP compliance/nonclinical quality subject matter expert.
- Write/review/approve written standards, including Master Production Records, Standard Operating Procedures, Specifications, Test Methods, and Change Control Documentation.
- Conduct **Quality / Technical review of lab quality-related** issues pertaining to test methods and results, analysis, sterility, method/assay validation activities, etc. Provide oversight of Biomarker/Translational Medicine Program management via oversight of activities conducted by Biomarker, Biobank and Translational Operations departments.
- Manage lab technical investigations (deviations, out of trend, out of specification) associated with clinical study testing.
- Establish strong interfaces with contract testing laboratories to address and resolve complex and routine activities while building client relationship and continuous improvement.
- Provide in-depth technical advice to project teams regarding Phase I-IV sample analysis, analytical and assay development.
- Work closely with Quality Systems group to support inspection readiness both internally and at key contract laboratory organizations.
- Present key issues related to product quality to Quality Management.
- Support submission of INDs and NDAs.

PROFILE

- Bachelor or Master's in science related field or equivalent experience with **10+ years of related Quality Assurance experience**.

- 5+ years of quality oversight experience in a Quality Assurance Manager and leadership related function.
- Knowledge of **GCLP, GLP, Part 11 regulations, FDA Guidances for Industry, EU regulations**, and other standards.
- Knowledge of regulatory requirements for computer system validation.
- The ability to think strategically and maintain an attention to detail.
- Strong problem-solving and analytical skills.
- Ability to understand and verify scientific data.
- Proficiency in Microsoft Office applications (Excel, Word, PowerPoint, Project).
- Ability to work independently and interact with all staff levels under pressure, maintaining professionalism.
- Excellent written and verbal communication, negotiation, and decision-making skills.
- Ability to comprehend and apply regulations, with strong critical thinking.
- Strong organizational skills to handle multiple tasks.

OFFER

- A stimulating position within a high-potential innovative biotech company.
- The opportunity to work in a science-driven, dynamic, respectful and professional environment.
- A challenging scientific and business growth in which you get to bring your knowledge and skills.
- An employment agreement contract with an attractive salary package in line with the position responsibilities and your experience.

INTERESTED ?

Please send your CV together with an adapted cover letter to recruitment@pahrtners.be.

YOUR APPLICATION AND RELATED INFORMATION WILL REMAIN STRICTLY CONFIDENTIAL.