Job opportunity: QA Manager & Qualified Person Biologics

Eurofins Amatsigroup is one of the leading CDMOs in Europe providing high-quality, customized drug development solutions for specialty and biopharma clients. Our focus is to support clients on the earliest phases of their development pathway (from API to the clinical packaging).

Its Belgian subsidiary, Eurofins Amatsigroup NV, is based in Ghent, offering a c**omplete drug development package for new drug entities (biological and chemical) up to early clinical phases** to third parties to help them in speeding up the development and manufacturing of their drugs:

- Drug substance biological process and analytical method development and production, including GMP manufacturing. The principal technological expertise is production and purification of recombinant proteins derived from microbial and eukaryotic systems, for research purposes and toxicological studies as well as for clinical trials, including formulation development and stress stability studies. The company also has extensive expertise in the manufacturing of viruses and living cells for vaccine purposes and in-depth knowledge of working under pharmaceutical and GMP quality requirements.
- Drug product development of new drug candidates focusing on difficult to formulate drugs that are in preclinical, phase I or phase II clinical development. The company offers a full suite of drug development services encompassing preclinical development, preformulation development, formulation development, analytical development, dosage forms development, scaling-up and GMP manufacturing of chemical and biologicals drug candidates.

Eurofins Amatsigroup NV develops and produces non-sterile and sterile biologicals (drug substance and drug product) and chemicals (drug product) in preclinical and early clinical development phases.

With approximately 300 staff worldwide, we operate out of 6 sites either in France and Belgium. To support our ambitious growth plan, we are today looking for a **QA Manager & Qualified Person Biologics** for our site in Ghent, Belgium.

Position: QA Manager & Qualified Person Biologics

Function description

Eurofins Amatsigroup wishes to enforce its team with a QA Manager & Qualified Person for its Biologics Business Unit, which manufactures and controls biological drug substances and related final products. You will report to the Head of Quality Assurance.

Your main responsibilities are

- You implement, maintain and manage a GMP compliant Quality Management System for manufacturing and quality control of biological drug substances and related final products (buffer preparation, upstream and downstream processes) based on applicable regulations and guidelines.
- You manage the CAPA system: changes, deviation, non-conformities.
- You manage, support and coordinate risk assessments.
- You manage the supplier qualification process (materials and services).

- You support and review the qualification of production equipment, test equipment and cleanroom facility.
- You lead audits and inspections.
- You will review and approve batch records.
- You will release batches of biological intermediate products, drug substances and related final products (Investigational Medicinal Products).
- As a Qualified Persons you certify final products (Investigational Medicinal Products).
- You promote the awareness of quality, regulatory and customer requirements throughout the company.

Competences and education

- Master of Science degree in pharmaceutical sciences, chemistry, biochemistry or related discipline
- You are registered as a Qualified Person
- 10 years of quality assurance experience in the pharma and/or biotech industry.
- Knowledge of GMP quality system and regulatory requirements (Eurdralex, ICH)
- Knowledge of biological process development and manufacturing is a real asset
- Excellent organization, facilitating and coordination skills. Ability to work independently as well as a member of a team in a dynamic environment
- Strong decision making and problem-solving skills
- Leadership skills
- Excellent oral communication, reporting and presentation skills
- Fluent in Dutch and English, written and spoken.

We offer you

- A position with responsibility within a dynamic company.
- Professional and personal development is supported.
- A salary, depending on your experience, based on market practice.

Interested in this challenging job?

Please send your application including CV and motivation letter via e-mail to Alexandrine Abbeloos (alexandrineabbeloos@eurofins.com).