Careers at Valerius Biopharma, committed to providing specialty biosimilar drugs globally

Are you looking to making a difference?

Valerius Biopharma AG is a biopharmaceutical company in Switzerland, established to provide affordable treatment options for high-priced biologics through development of specialty biosimilars. Our interdisciplinary team of professionals represents decades of experience gained in the biotechnology and biosimilar industry. Expertise in process science, a deep understanding of proteins and their underlying complexity, as well as skilled clinical and regulatory expertise, are key factors to our success. We are committed to making treatment of severe and life-threatening diseases more accessible to all patients worldwide.

For our emerging development hub in the south-east of Belgium (Eupen/Liège) we are seeking highly skilled and motivated associates to join us in building a world leading center for specialty biosimilar drug development.

Activities and responsibilities

Primary objectives & goals

The Head Quality Assurance (QA) is leading the QA team and collaborates with other staff and external service providers to establish and maintain procedures and quality standards and to monitor these against agreed targets and in accordance with EMA, FDA, and general ICH GMP regulations in support of regulatory authority audits and submissions.
The Quality Assurance Manager also works to improve an organization's efficiency and profitability by reducing waste.

Scope & Responsibility

- Lead and manage the QA team.
- Represent QA for the assigned portfolio at management and external stakeholder levels.
- Oversees all QA programs and projects, guides teams to ensure cross-functional integration, coordination and alignment.
- Ensures direct reports are actively and appropriately aligning with other teams to ensure timely and on-target results.
- Provides leadership guidance and direction in ongoing enhancements/development of core and sub-team processes, structures, systems, tools and other resources.

Overall team’s responsibility:

- Cooperation in setting up and maintaining the quality assurance system.
- Verification of compliance with regulatory requirements in internal documents.
- Implementation of regulations into the internal quality assurance system.
- Autonomous monitoring the quality assurance system.
- Close cooperation with all departments and external service providers to ensure quality policy.
- Guidance and management of the company's documentation system.
- Creation, update, review and approval of documents according to the defined steering activities.
- Creation of deviation reports, evaluation and monitoring of the implementation of the preventive measures to be carried out.

- Monitoring of change controls and evaluation.
- Assistance in conducting self-inspections, customer and government audits, auditing contractors.
- Approval of qualification and validation plans and batch releases.
- Perception of process ownership for the processes in their own area of responsibility:
  - regular checking / updating / improvement of processes,
  - adequate training of affected employees,
  - continuous training with the aim to know the latest requirements and trends,
  - contact person for the affected processes internally and externally (for example also during audits and inspections).

Qualification profile

Desired Professional and Technical Requirements

Education/Qualifications

- Completed studies in pharmacy, natural sciences, biotechnology, engineering or a comparable degree with corresponding professional experience.

Experience, Skills, Knowledge

- At least 3 years experience in a GMP-regulated environment, i.e. biopharmaceutical production, quality control, or quality assurance.
- Knowledge of biopharmaceutical active substance production and analytics.
- Leadership/management experiences.
- Very good knowledge of English written and oral.

Contact

Please send your application to:

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