POSITION: QUALITY ASSURANCE MANAGER

Date: 17/10/2024

Type of contract: Long-term

Field: Biotech / Health / Antibiotic resistance

Working time: Full-time

Location: Lyon Gerland, France

Workplace type: Hybrid

Ref: ATX24-08

Start date: As soon as possible

Presentation of the company:

AUROBAC THERAPEUTICS is a biopharmaceutical company founded in 2022 by three highly renowned life sciences innovation companies, Boehringer Ingelheim, Evotec and bioMérieux.

Dedicated to addressing high unmet medical needs associated with infections in acute hospital settings, amidst the growing antimicrobial resistance (AMR) epidemic, AUROBAC is advancing a robust pipeline.

With strong growth ahead, within an international environment, the company is now looking for a **Quality Assurance Manager**.

Description:

As **Quality Assurance Manager** at AUROBAC, you will (1) participate proactively in the implementation and maintenance of the Quality Management System (QMS) in line with the company's quality policy, and in maintaining a strong quality culture within the company. (2) You will also contribute to the company's continuous improvement approach, by conducting audits and quality controls of the company's internal processes, and monitoring the implementation of corrective and preventive actions in conjunction with all company employees. (3) You will monitor standards and regulations in order to anticipate any changes in standards applicable to the company's areas of activity and likely to have an impact on its QMS.

The Quality Assurance Manager will report to the Quality and Regulatory Affairs Director and work closely with all teams.

Missions:

- **Development, maintenance and continuous improvement of the company's quality system.**
  - Drafting and/or checking procedures and other QMS documents.
  - Distribution of created/revised QMS documents to relevant employees, and management of associated awareness and training actions.
  - Initial QMS training for new employees.
  - Coordination and follow-up of periodic reviews of QMS documents.
  - Centralizing and processing requests for continuous improvement, non-conformities and complaints.
  - Updating and monitoring the implementation of the corrective and preventive action plan (CAPA) in collaboration with the operational teams and third parties.
  - Updating of the annual QMS action plan and regular reporting on progress.
  - Participation in the preparation of quality management reviews.

- **Quality controls and internal process audits to improve the performance of the company's activities.**
  - Participation in the implementation of the internal audit/quality control plan.
  - Planning, execution and follow-up of internal quality audits/controls for the company's key processes.
  - Support for the implementation of action plans resulting from external audits (audits of the company's subcontractors).

- **Standards and regulations watch**
  - Monitoring of changes in standards applicable to the company.
  - Analyze standards and assess their impact on company's processes/activities.
  - Informing and training teams on changes in standards and regulations.

Technical skills:

- Solid knowledge of quality assurance standards (e.g. ISO 9001) and GxP regulations applicable to drug development in an international environment (e.g. GCP, GMP, GLP, GCLP).
- In-depth knowledge of R&D processes (preclinical and clinical stages prior to drug registration) and the players involved.
- Good document management practices.
- Proficiency in audit techniques.

Personal skills:

- Fluency in English is essential, French would be a major asset.
- Planning, anticipation and organizational skills.
- Observation and listening skills, and excellent communication skills.
- Excellent writing skills.
- Thoroughness and precision.
- Ability to analyze, synthesize and solve problems proactively.
- Ability to be accountable.
- Ability to work both independently and cross-functionally (project mode) in a constantly changing work environment.

Professional experience :

- Training in pharmacy, engineering or higher science (Bac +5), supplemented by training in quality assurance.
- Junior-level position; 1 to 3 years' experience in managing a quality documentation system in the pharmaceutical R&D sector would be a plus.

To apply, please send your **CV and cover letter** application to jobs@aurobac-tx.com mentioning the reference **ATX24-08.**

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