POSITION: Associate Director Clinical Operations

Date: 15/03/2024

Field: Biotech / Health / Critical Care

Location: Lyon Gerland, France

Ref: ATX24-01

Type of contract: Permanent

Working time: CDI Full-time

Start date: As soon as possible

Presentation of the company:

AUROBAC THERAPEUTICS is a biopharmaceutical company created in 2022 by 3 renowned life sciences innovation companies, *Boehringer Ingelheim, Evotec* and *bioMérieux,* to become a global leader in the fight against bacterial infections, Antimicrobial Resistance (AMR) and their consequences in acute hospital settings such as Sepsis. We focus our efforts to develop the next generation of antimicrobial and acute care products, following a targeted precision medicine approach, i.e. associated with rapid diagnostics to support product use.

With strong growth ahead, within an international environment, the company is now looking for a **Associate Director Clinical Operations,** reporting to the company's **Chief Medical Officer.**

Description:

We are seeking a highly skilled and motivated Associate Director Clinical Operations to join our dynamic team. As a Associate Director Clinical Operations, you will play a crucial role in the planning, execution, and management of clinical trials to ensure successful and timely completion. The ideal candidate should have a strong background in strategic planning and operational execution of clinical research, exceptional project management skills, and the ability to collaborate effectively with cross-functional teams.

Missions:

You will report to the CMO and work closely with the executive team to conduct your mission.

- **Clinical Trial Operational Coordination:**
  - ✓ Co-ordinate and manage all activities inherent in the conduct of a clinical trial (phases I to III)
  - ✓ Co-ordinate the generation and contribute to the development of trial-related documents, including informed consent forms, case report forms, and study manuals, in compliance with applicable regulatory requirements, guidelines, and standards in close collaboration with the Regulatory Affairs manager and the CMO
  - ✓ Develop and maintain detailed project management tools, timelines, ensuring alignment with overall project goals.
  - ✓ Proactively identify and address potential delays, implementing corrective actions as necessary.
  - ✓ Manage functionally all study stakeholders, both internal (Clinical Operations team, Data-Manager, etc.) and external (CRO, etc.)
- **Budget Oversight:**
  - ✓ Work closely with finance and project teams to develop and manage clinical trial budgets.

- ✓ Monitor and control expenses to ensure budget compliance.

- **Site Selection and Management:**
  - ✓ Oversee the selection and initiation of clinical trial sites.
  - ✓ Establish and maintain strong relationships with investigative sites, ensuring adherence to study protocols and timelines.
  - ✓ Prepare documents and organize investigator meetings
- **Vendor Management:**
  - ✓ Select and manage external vendors, including Contract Research Organizations (CROs), central labs, and other service providers.
  - ✓ Ensure vendor performance by very close monitoring and adherence to quality standards.
- **Data Management and Committees coordination**
  - ✓ Collaborate with data management teams to ensure accurate and timely data collection and reporting.
  - ✓ Supervise development of data collection tools and database design, in liaison with the Data Manager and in line with the protocol
  - ✓ Oversee data cleaning and validation activities.
  - ✓ Supervise statistical analysis and interpretation of results, in liaison with the statistician
  - ✓ Supervise/coordinate committees involved in studies (e.g., DSMB, adjudication committees), in close collaboration with the CMO
- **Risk Management:**
  - ✓ Identify potential risks and develop risk mitigation strategies.
  - ✓ Proactively address issues to minimize impact on the trial.
- **Communication and Reporting:**
  - ✓ Facilitate regular project team meetings to ensure effective communication and collaboration.
  - ✓ Prepare and present project updates to internal and external stakeholders.
- **Clinical Operations-related Quality Assurance and Compliance:**
  - ✓ Implement and maintain quality assurance processes to ensure compliance with Good Clinical Practice (GCP) guidelines and the company's Quality Management System
  - ✓ Implement and maintain processes to ensure compliance with data protection regulations (e.g., GDPR, HIPAA) in the regions of trial execution as well as future submission of the data.
  - ✓ Supervise the filing and archiving of all study documents for audit or inspection purposes
  - ✓ Conduct internal audits and oversee external audits, as required.
  - ✓ Participate in audits and/or inspections, as well as in preventive/corrective actions in the event of quality problems within the framework of the clinical study.

Personal skills:

- Fluency in English is a must-have, French language skills would be a major plus.
- Proven expertise in international clinical trial management
- Strong knowledge of GCP, ICH guidelines, and regulatory requirements.
- Detail-oriented with strong organizational and project management skills.
- Analytical and synthetic skills.
- Excellent communication, negotiation, and interpersonal skills.
- Proven ability to work collaboratively in a fast-paced, cross-functional environment.
- A forward-thinking individual who thrives in a dynamic and entrepreneurial environment.

Professional experience:

- **Educational Background:** A double cursus with an Advanced degree (PharmD, Ms, Engineering or PhD) in biotechnology or pharmaceutical sciences.
- **Experience:** 7 to 10 years of experience in a similar role within the biotech or pharmaceutical industry, in clinical trial management, including Phase II-III trials.
- Used to working in an international environment.

To apply, please send your **CV and cover letter** application to jobs@aurobac-tx.com mentioning the reference **ATX24-01**

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