POSITION: Project Manager, Chemistry, Manufacturing & Controls (CMC)

Date: 15/09/2025

Type of contract: Permanent

Field: Biotech / Health / Antibiotic resistance

Working time: CDI Full-time

Location: Lyon Gerland, France

Workplace type: Hybrid

Ref: ATX25-05

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.

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 **Project Manager CMC.**

Description:

- ✓ As a Project Manager CMC at AUROBAC, you will oversee and coordinate some CMC activities on defined projects: manage CDMOs for all aspects of CMC development including formulation, process and analytical development, manufacturing, technology transfer, and stability testing, while ensuring communication across project and executive teams
- ✓ Collaborate cross-functionally and develop expertise: collaborate with internal teams and external experts, contribute to transversal CMC functions and conduct research on scientific, technological, and regulatory topics relevant to the projects.

You will report to Head of CMC and work closely with Project Management, Clinical Operations, Quality Operations & Regulatory Affairs teams.

Missions:

1. CDMO MANAGEMENT FOR CMC DEVELOPMENT & CLINICAL TRIAL SUPPLY ACTIVITIES ON DEFINED PROJECTS

- ✓ Contribute to CDMO or academic partner identification, selection and collaboration set-up process (CDA preparation, Request for Proposal drafting, quote analysis, MSA-QTA set-up in partnership with legal and QA managers, ATX-Partner collaboration management tools…)
- ✓ Monitor development plan execution, timelines & deliverables, identify and escalate risks
- ✓ Lead regular project meetings with CDMOs, produce/review agendas & minutes, monitor and complete CDMO action tracker
- ✓ Ensure compliance of activities with applicable guidelines, quality references & budget
- ✓ Review and manage technical documentation (recording in intranet & sharepoints, version follow-up, communication tracking), analyze and interpret results
- ✓ Suggest additional activities to the development plan based on project progress and challenges to identify solutions, challenge CDMO proposals on the plan

2. COLLABORATION WITH PROJECT TEAM MEMBERS & EXTERNAL EXPERTS

- ✓ Work closely with Scientific and Development team to collaborate on new formulations which would be valuable to develop in early-stage R&D projects
- ✓ Work closely with Quality Operations team to manage quality events (deviations, OOS/OOT, change controls) and ensure Good Manufacturing Practices (GMP) compliance
- ✓ Work closely with the Regulatory team to complete and update CMC regulatory documentation (Module 3 of IMPD &IND, briefing package…)
- ✓ Work closely with Clinical Operations team to coordinate clinical trial supplies, conduct IMP management and gather IMP documentation for Trial Master File
- ✓ As needed, request & prepare meetings with external experts, draft and distribute agendas & minutes

3. REPORTING, ACTION FOLLOW-UP AND COMMUNICATION WITH PROJECT AND EXECUTIVE TEAMS

- ✓ Complete internal trackers for project action follow-up
- ✓ Share progress of development activities during Monthly Project Meetings
- ✓ Produce material to support decision making

4. CONTRIBUTION TO CMC DEPARTMENT TRANSVERSAL ACTIVITIES

- ✓ Supply & consolidate CMC database
- ✓ Manage stock, supply & dispatch activities
- ✓ Write and update CMC Standard Operating Procedures
- ✓ Contribute to continuous improvement initiatives to enhance product quality, efficiency, and cost-effectiveness, in close collaboration with external partners / CDMOs

5. LITERATURE RESEARCH & TECHNOLOGICAL/REGULATORY INTELLIGENCE IN ACCORDANCE WITH PROJECT NEEDS (EXCIPIENTS, FORMULATION TECHNIQUES, GUIDELINES…)

- ✓ Summarize and communicate on information of interest
- ✓ As needed, suggest product or process development strategies adapted to ATX Programs
- ✓ Work closely with legal and IP teams to ensure the protection of intellectual property through patents when relevant

Skills:

- Proven experience in CMC project management, ideally within biotech or pharmaceutical development
- Strong understanding of drug development processes and regulatory frameworks
- Experience working with CDMOs and managing external collaborations
- Excellent organizational and communication skills
- Ability to thrive in an international, dynamic and cross-functional environment
- Scientific background (Pharma, Biotech, Chemistry, or related field) required
- Experience in parenteral forms pharmaceutical development is a plus
- Fluency in English is a must-have, French language skills would be a major plus

Training and experience:

- PharmD, MSc/PhD in biotechnology or chemistry or chemical engineering
- 2-5 years experience as scientist in the pharmaceutical/biotech industry

To apply, please send your **CV and cover letter** application to jobs@aurobac-tx.com mentioning the reference **ATX25-05.**

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