CMC Manager

Barcelona, Spain | Full-time | on-site

Who we are

Orikine Bio is taking a new approach to treating immune-mediated diseases: instead of simply suppressing the immune system, we reprogram the immune cells that keep inflammation going. Our lead candidate, ORK1, is designed to turn myeloid cells into regulatory macrophages that help restore balance and resolve inflammation.

We are starting with inflammatory bowel disease and aiming to enter Phase 1 clinical development in 2028. We are a lean team of around 20 internal and external professionals that are backed by leading European healthcare investors, so every person here has real influence on how we get from the lab to patients.

About the Role

To achieve this goal, we are seeking a highly motivated **CMC Manager** to drive the execution of CMC activities for ORK1 and other pipeline candidates.

Functionally reporting to the external **Head of CMC** and in line reporting to the Head of Program Management, you will provide operational and technical support across Drug Substance (DS) and Drug Product (DP) manufacturing, and CMC quality activities. The role combines review of technical documentation, CDMO management, establishing GMP manufacturing readiness, and quality oversight within an outsourced development environment.

This is a great step for someone with a few years of biologics experience who wants to broaden their view across the full CMC picture, from manufacturing to quality to clinical supply, and take on more ownership as the company grows.

Key Responsibilities

- Own the CMC action tracker and ensure that timelines and deliverables are not moving
- Act as the day-to-day contact for our CDMO and external partners on DS and DP development
- Review technical protocols, reports, specifications, and manufacturing documentation.
- Ensure CMC records are maintained, organized, and traceable.
- Support CDMO qualification, audits, and quality oversight activities.
- Track deviations, CAPAs, change controls, and quality actions.
- Support Quality Technical Agreements and interactions with QA consultants.
- Support Drug Product manufacturing, packaging, labelling, and release activities.
- Assist with clinical supply and shipment readiness activities.

Qualifications

Must have

- MSc or equivalent degree in Biotechnology, Biochemistry, Pharmaceutical Sciences, Chemical Engineering, Life Sciences, or a related discipline.
- 3-5 years of experience in CMC biologics development, manufacturing sciences, technical operations or related functions.
- Familiarity with GMP-regulated environments.
- Experience reviewing technical and GMP documentation.
- Strong organizational, analytical, and communication skills.
- Ability to manage multiple activities simultaneously in a fast-paced environment.
- Fluent in English.

Nice to have

- Experience managing CDMOs.
- Experience supporting Drug Substance and/or Drug Product development programs.
- Experience supporting GMP manufacturing campaigns and technology transfer activities.
- Familiarity with quality systems, deviations, CAPAs, change controls, audits, and Quality Agreements.
- Exposure to CMC sections of regulatory submissions (IND, CTA, IMPD, or equivalent).
- Experience working in a biotech company or outsourced development model.

What success looks like

Within your first six months, you will get to know our CDMO partner and programs inside out, together with other team members drive ORK1 through CMC process development and coordinated successful generation of a pilot batch at our CDMO, and be the person the team and our partners turn to for CMC status.

Why Orikine

- Work on a first-in-class approach with real potential for patients with chronic inflammatory disease
- Join a small, collaborative, international team where your voice counts and your scope can grow quickly
- Learn from experienced leaders and consultants across CMC, quality, and development and be part of a cross functional team
- Join an organization, which values diversity, constructive feedback and excels from translation of excellent science into high impact therapies

Learn more at: www.orikine.bio

How to apply

Send your CV and a short note about what draws you to this role to contact@orikine.bio. We welcome applicants from all backgrounds and will treat your application with care.