

Senior CMC Manager f/m/d

Adrenomed is a highly innovative biopharmaceutical company based in the Berlin area. It is specialized in preserving vascular integrity in life-threatening conditions and is committed to precision medicine. The main focus is on sepsis and septic shock.

Currently, we have completed a Phase 2 trial in septic shock and are planning to start a pivotal trial with a subsequent market authorization.

We would never have come this far without our enthusiastic, creative, and highly motivated colleagues who are willing to grow and work in a dynamic environment. Exactly these colleagues are ready to welcome you to the team and support you from day one. We offer flat hierarchies and the possibility to directly contribute to the development of the company while also providing competitive salaries.

To expand our team we look for a **Senior CMC Manager f/m/d**

Your Responsibilities

- Coordinate monoclonal antibody manufacturing activities (upstream and downstream workflows) for clinical trials and the upcoming market launch, i.a.:
 - Process coordination with contract manufacturers
 - Scientific evaluation of results from product characterization, validation and stability studies
 - Review and release of manufacturing documentation, logs and reports
 - Responsible for GMP-compliant storage and shipping of cell banks, drug substance and drug product
 - Support in the creation of regulatory documents
 - Perform risk assessments for process related changes
- Preparation for market production of a monoclonal antibody; i.a.:
 - Identification of contract service providers
 - Support contract drafting
 - Coordinate manufacturing requirements (e.g. production slots, logistics) with project timelines
- Project management, i.a.:
 - Create and track project budget and timelines
 - Coordination of manufacturing and documentation activities with external and internal stakeholders
 - Reporting to management
 - CMC Subject matter expert and point of contact for colleagues

Your Profile

- M.Sc. in life sciences, ideally Biotechnology or related fields; PhD is considered an advantage
- Experience in biological drug manufacturing preferably in pharmaceutical or biotechnological companies
- Extensive and successful experience in upstream and downstream manufacturing of biologics; experiences in antibody manufacturing preferred
- Advanced knowledge of GMP requirements for biological drug manufacturing, including GMP regulations (cGMP, FDA)
- Project management skills
- Ability to work collaborative across functional areas and interacting with internal and external stakeholders
- Ability to work independently within the area of assigned responsibility with an analytical and proactive mindset
- At ease with Microsoft Office and usual software tools
- Strong communication skills
- Business fluent in German and English

Our commitments to you

- Opportunity to take part in a project that could change modern treatment options
- Innovative and international environment
- Flat hierarchies & fast decision times
- Implementation of your ideas
- Fair and competitive salary
- Good connection to Berlin's public transport
- Up to 3 days of remote work per week

If you like this role and think that you would be a suitable candidate, don't hesitate!
Send us an application and CV to career@adrenomed.com.