

4TEEN4 Pharmaceuticals GmbH is a company with a clear mission: Improving the management of critically ill patients (e.g. in sepsis, cardiogenic shock, severe trauma). Based on data that prove the reliability of DPP3 as a cardiac depressant factor associated with short-term patient outcome, 4TEEN4 identified DPP3 as a druggable target. The long-term vision is to provide a therapeutic solution for critically ill patients that neutralizes circulating DPP3 in order to restore proper organ function and improve survival. To achieve this mission, 4TEEN4 develops monoclonal antibody therapies accompanied by targeted diagnostic assays. Our lead product is a first-in-class drug candidate, the humanized monoclonal antibody Procizumab, followed by its companion diagnostic. The 4TEEN4 Pharmaceuticals GmbH was established in 2013 and is located in Hennigsdorf near Berlin, Germany.

Project Manager CMC Development (f/m/d)

Essential Duties and Responsibilities

- Manage the development of drug substance and drug product production process, manufacturing operations, including tech transfer, batch record review, change controls, QA investigations, review of validation protocols and reports, development of specifications
- Generate budgets, technology packages and RFPs
- Serve as an expert in drug substance and drug product for the team
- Develop risk mitigation strategies to support the achievement of project aims
- Negotiate MSAs, WOs and SOWs
- Support R&D, Quality Control, Intellectual Property and Legal as a cross-functional experts

Qualifications

- M.Sc. or Ph.D. in chemistry, biochemistry, chemical engineering or related disciplines
- Minimum 5 years of relevant industry experience as Project or CMC Manager
- Experience in process development, technical transfers, support of cGMP manufacturing and technical trouble shooting for clinical and commercial biopharmaceutical manufacturing
- good knowledge of US and European Good Manufacturing Practices (cGMP)
- Possess a willingness and ability to work hands-on and with a sense of urgency, in a fast-paced, entrepreneurial environment
- Is able to organize and assimilate data and information, to prepare contingency plans and future strategies
- Excellent communication and technical writing skills in English and German
- Background in formulation or fill and finish of biologics are a plus

What we offer

- A challenging, hands-on and cross-functional position with interaction to all stakeholders in a developing pharma company and in an international framework
- The possibility to build in your own experiences and ideas
- A small, motivated team that successfully combines experienced managers with young high achieving employees
- Performance oriented, fair remuneration
- Permanent employment contract
- Training and development opportunities
- Parking place and good connection to the Berlin public transportation

4TEEN4

Pharmaceuticals

Contact

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