



If you feel like you're part of something bigger, it's because you are. At AMGEN our shared mission - to serve patients - drives all that we do. AMGEN discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, AMGEN was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. AMGEN therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. With a deep and broad pipeline of potential new medicines, AMGEN remains committed to advancing science to dramatically improve people's lives.

This position is located at the Amgen Research (Munich) GmbH, one of Amgen's state-of-the-art Research and Development facilities. Its product development pipeline includes novel antibodies generated with its proprietary BiTE® technology. Our Process Sciences Team is seeking a full-time

Drug Product Technologies Lead (Principal Scientist) m/f/d

who is driven to understand the challenges of a biopharmaceutical company with focus on Research and Development. In your role as Early Operations Lead and Drug Product Team Lead in global early phase CMC-Project Teams, a cross-functional interaction with US sites (west and east coast) is required on a regular basis to align on and to coordinate projects and cross-functional imperatives.

Your responsibilities include

- Scientific and disciplinary leadership of the local Drug Product Technology team
- Responsibility for the technical assessment of early development candidate molecules (Molecule Assessment)
- Planning and coordination of studies to optimize formulations for BiTE® antibody constructs and other large molecule pipeline candidates applying experimental design (DoE) strategies and to assess the fit to internal drug product platforms
- Transfer of Drug Product manufacturing processes to internal and external GMP facilities
- Implementation and advancement of analytical methods to support formulation and process development activities for new drug candidates
- Planning and coordination of stability and compatibility studies
- Contribution to the Module 3 of CTA (Clinical Trial Applications) and regulatory interactions
- Supporting the preparation of the Investigational Product Instruction Manuals (IPIM)
- Supporting clinical programs during the interaction with regulatory agencies and addressing questions related to clinical administration
- Leading and coordinating of global CMC development projects while ensuring timely supply of clinical test materials compliant with the Quality Target Product Profile
- Contributing to the optimization of internal processes as well as cross-functional and regional interfaces
- Initiation and support of overarching innovation projects in the process development area

What we expect of you

- PhD degree (or equivalent) in Pharmacy/Chemistry/Biotechnology or related disciplines
- 10+ years of relevant experience in Pharmaceutical Industry, ideally including people manager experience
- Significant experience in protein formulation and analytics as well as Drug Product manufacturing
- Comprehensive understanding of the CMC regulatory landscape, experience in leading CMC-projects is beneficial
- Excellent English and German communication and presentation skills (both written and spoken)
- Problem solving skills and ability to balance opportunities and risks
- Demonstrated planning, prioritizing and resource management capabilities
- Capability to adapt strategies based on current insights and management guidance
- Ability to proactively build productive cross-functional collaborations
- High level of flexibility and agility, pronounced team spirit

Our Offer

At Amgen we provide a collaborative and creative culture with a strong track record of innovation. Our culture supports open dialogue and diverse views to land on the best solutions, and we help ensure our staff are equipped to excel today and tomorrow and have opportunities for professional and personal growth. We ensure a diverse and inclusive work environment to successfully sustain and grow as a global enterprise and deliver for patients.

We look forward to receiving your online application - please use the following link:

<https://careers.amgen.com/job/11761458/drug-product-technologies-lead-principal-scientist-m-f-d-munich-de/>