



Director, Development Chemistry

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking to hire an experienced Director Development Chemistry to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Director Development Chemistry will be responsible for leading our efforts in process chemistry from development to scale up and manufacturing and plays an important role in the successful transition of early clinical candidates from Research to GMP stage. She/he will provide technical leadership with all chemistry related to the manufacturing of TransCon localized delivery projects and the sourcing of small molecule compounds, such as drug substance or raw materials critical for Ascendis' product candidates including the management of external business partners for manufacturing ("CMOs") and testing. The Director Development Chemistry will also contribute to our efforts of designing a state-of-the-art lab facility for technical product development, located on the Peninsula (San Francisco Bay Area). The position will report in to the Head of Product Development US, Palo Alto.

Key Responsibilities

- Develop and optimize process chemistry related to manufacturing of product opportunities for localized delivery
- Scale up and transfer processes from R&D lab to GMP manufacturing ensuring successful implementation at CMOs
- Provide oversight of raw material and drug substance sourcing, quality control and manufacturing as required
- Manage partnered activities and ensure deliverables are being met in time, quality and budget
- Provide input to cross-functional project teams and build a strong foundation for close collaboration throughout Ascendis' global Research and Product Development groups
- Identify development strategy in accordance with regulatory and quality requirements and support the implementation plan to GMP
- Provide the required input to regulatory filings and write the specific sections
- Contribute to our efforts of designing a state-of-the-art R&D facility for technical product development with process chemistry, analytical, formulation and process development labs
- Provide the required input to regulatory filings and write the specific sections
- Other responsibilities as required according to Corporate strategy or group needs

Knowledge, Skills and Experience

- Master's degree or PhD in organic chemistry, polymer chemistry, physical chemistry, (bio)chemical engineering, or other related fields
- Minimum of 10-15 years of experience in the Biotech or Pharmaceutical Industry, preferably in technical R&D, Drug Delivery or Manufacturing Science and Technology, Technical Regulatory or Quality Control at leading Pharmaceutical or Biotech companies
- Proven experience with small molecule chemistry or product development for projects from early to late development and the stage-specific needs and development strategies
- Ideally, experience with polymer-based systems, drug conjugates (e.g. ADCs), small molecules, peptides and therapeutic proteins
- Experience with setting up phase-appropriate analytical control strategies
- Good knowledge of cGMPs, ICH guidelines, regulatory and quality requirements including specifics of highly potent drugs
- Knowledge of product transfers to CMOs and/or method transfers to CROs ideally across all stages from early to commercial
- Pro-active collaborator and communicator, service and customer oriented with a holistic understanding of drug development
- Experience with leading direct reports and developing talents
- Strong team player with an open mindset, that thrives in global collaborations
- Ability to travel up to 10% of the time domestically and internationally

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Director Development Chemistry job description" in the subject field.