

Senior Process Engineer

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 Senior Process Engineer to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

This Senior Process Engineer position will develop, scale up and transfer the manufacturing process and control strategy for our localized delivery technology platform. This role will also be responsible for assistance in the start-up of a new lab building, including input on facility design, ordering, installation and commissioning of key equipment. Initial location is Palo Alto with subsequent move to the new lab facility in the Bay Area (Peninsula). The position will report in to the Director of Process Development in Palo Alto.

Key Responsibilities

- Oversee key process development efforts to deliver a robust and efficient process for the transfer to internal labs and to external CMOs
- Collaborate with the global Ascendis Research team in efforts to acquire product and process knowledge of the platform technology, and transfer this knowledge to new labs
- Plan and manage key elements in the commissioning of the processing labs for localized delivery and oncology
- Order equipment, work with vendors, and oversee installation
- Produce R&D material in the lab for further assay and development use
- Design and execute experiments to optimize and characterize key process operations. Work with CMO's to ensure robust process validation.
- Work with analytical team to assist in the development and optimization of formulation and lyophilization parameters, selection of primary containers, and product assays
- Develop/provide input on in-process controls
- Provide process input in accordance with regulatory and quality requirements for the definition of cGMP processes
- Creation of standard procedures for equipment and process
- Foster collaborations across Ascendis to provide development support to projects in all therapeutic areas
- Other responsibilities as required according to Corporate strategy or group needs

Knowledge, Skills and Experience



- Bachelor's degree (Master's degree preferred) in Chemical Engineering, Chemistry, Biochemistry, or related field
- Minimum of 5 years of experience in the Biotech or Pharmaceutical Industry, preferably in Process Development / Manufacturing Science and Technology / Formulation or Analytical Development at leading pharmaceutical or biotech companies
- Experience with aseptic processing, e.g. drug delivery solutions, ADC's or polymer conjugates, novel technologies
- Strong hands-on expertise in process optimization, characterization and development, including drug product operations from early to commercial stage
- Expertise in cGMP, regulatory and quality requirements of parenteral drug manufacturing
- Experience in equipment design preferred (tanks, fittings, custom assemblies)
- Expertise in complex technology transfers
- Prior experience working with CMOs preferred
- General knowledge of polymer-based drug delivery preferred, including handling of highly potent drugs
- Pro-active, collaborator and communicator, with a solid understanding of drug development and an ability to plan and conduct work with little guidance
- Strong team player with an open mindset, that thrives in global collaborations
- Ability to travel up to 10-15% of the time domestically and internationally

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Senior Process Engineer job description" in the subject field.