



Scientist, Analytical Development

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 Scientist, Analytical Development to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Scientist will be responsible for analytical development activities to support Ascendis Pharma's growing pipeline of pre-clinical and clinical programs. The Scientist will work as a part of cross-functional teams across discovery and development to quickly advance new drug candidates to the clinic. The Scientist will work closely with global Ascendis Pharma sites and CMOs to implement and improve analytical methods, will collaborate on testing and release activities. The Scientist will also serve as a leader in helping Ascendis Pharma establish internal laboratory capabilities in the Palo Alto area.

Key Responsibilities

- Develop analytical methods to support clinical/commercial manufacturing and product development
- Develop characterization assays for small molecule and polymeric systems, including highly potent molecules
- Manage analytical method transfer and phase-appropriate validation at CMOs
- Review method qualification/validation, in-process, and release testing data packages from CMOs
- Author technical reports as part of method development, transfer, stability studies, etc.
- Coordinate GMP testing, release, and stability activities with external and internal quality groups, as well as establish reference standards
- Contribute to analytical control system design
- Design and implement quality testing procedures to support GLP studies
- Perform early studies to characterize intermediates and complex drug products to support pre-clinical animal studies
- Design and execute internal stability studies for complex drug products containing small molecules or biologics
- Commission new equipment, techniques, and laboratory expansions. Identify need for new personnel and equipment resources as needed
- Contribute to authoring CMC-related IND sections
- Work with global teams
- Creation of standard procedures for equipment and processes
- Other responsibilities as required according to Corporate strategy or group needs
- Ability to travel domestically and internationally up to 10%

Knowledge, Skills and Experience

- PhD in chemistry or a related field with 4+ yrs. experience in industry is preferred. Candidates with master's degrees and commensurate experience will also be considered.
- Experience designing analytical control systems for small molecule pharmaceutical intermediates, drug substances, and drug products. Similar experience with biologics a plus.
- Experience authoring and executing method validation plans
- Experience authoring regulatory submission documents (e.g. relevant CMC sections of INDs, NDAs, BLAs, etc.)
- Hands-on experience using standard small molecule analytical techniques such as HPLC/UPLC, Karl Fischer, UV/Vis, IR, pH, etc.
- Experience interpreting MS, IR, GC, NMR, DSC, light scattering, and microscopy data
- Experience with protein analytical methods a plus, including ELISA, SEC-HPLC, CE-SDS, IEF/iCIEF, and osmolality
- Ability to appropriately summarize complicated data sets and draw appropriate conclusions
- Strong communication skills and comfort working across global boundaries
- Creative problem solver generating solutions from knowledge across disciplines
- Ability to plan and conduct work with limited guidance. Clear communication, especially across global boundaries, is a key required skill
- Is curious, observant, detail oriented, and practices good record keeping

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Scientist, Analytical Development" in the subject field.