Senior Scientist / Scientist (Analytical team)

Job description

By joining Xbrane Biopharma AB in Solna, you will have the opportunity to join an innovative and growing team developing Biosimilars products. Xbrane is a growing company present on Nasdaq's main list. By joining Xbrane, you will be part of a journey to create a Swedish success story in biopharmaceutical drug development and ensure the access of biologics to an underserved patient population, enabling global health equality. The position as Senior Scientist / Scientist is in the analytical team which is responsible for developing analytical methods required for process development, product characterization, release and stability testing.
If you are the successful candidate, you will be responsible for coordinating analyses and analytical development at our external partners with the aim of generating results required for the characterization and control of biosimilar Drug Substance and Drug Product development. You must be highly motivated, flexible, creative and organized. You must be able to plan and work independently, but also, collaboratively, providing strong support to the team with your expertise within analytical and protein chemistry and the regulatory requirements for successful control of Drug Substance and Drug Product.

Responsibilities:

- Be involved in subcontracting of analytical services to external partners
- Be involved in the development of analytical methods at our contracted service providers
- Responsible for coordinating analytical work at contracted laboratories. This may include the planning and monitoring of shipments, analytical activities and follow-up on relevant parts of the project budget
- Be involved in technology transfers and validation of analytical methods
- Participate in deviation investigations and change requests
- Compile, evaluate, and present data to internal project teams
- Be involved in the planning of analytical activities required for the control of Drug Substance and Drug Product by e.g. by drafting plans for stability and comparability studies
- Support Regulatory Affairs team as needed with input to regulatory filings such as INDs, IMPDs and market applications.
- Keep up to date with relevant guidelines, regulatory requirements, and pharmacopoeia

Qualification:

- BSc, MSc or PhD degree in Life Sciences or related field, depending on experience.
- Experience of the development and analysis of biopharmaceuticals, in particular monoclonal antibodies and related molecules
- Experience of a wide range of analytical techniques applicable to the development of biologics
- Experience of working in a GMP regulated environment
- Experience of technology transfer and of validation of analytical methods
- Experience of working in late stage projects
- Experience of writing regulatory documents
- Experience of analytical requirements relevant for Drug Substance and Drug Product, in particular of parenteral products
- Experience of project coordination

For more information, or to apply, please contact per.edebrink@xbrane.com. Please apply by 31st October 2020.

About Xbrane Biopharma

Xbrane Biopharma is a biotechnology company which develops and manufactures biosimilars. Xbrane has a patented protein production platform and world-leading expertise within biosimilar development. Xbrane's headquarter is located in Solna, just outside of Stockholm, and the company has research and development facilities in Sweden and in Italy. For more information see www.xbrane.com.