

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 designing, managing and coordinating analyses and analytical development required for the completion of biosimilarity studies based on physicochemical and biological methods. The studies will be performed at our external partners with the aim of generating results required successful demonstration of similarity between our candidate product and the reference product. 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 completion of biosimilar studies.

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 qualification / validation of analytical methods
- Compile, evaluate, and present data to internal project teams
- Write study plans and study reports
- 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
- Keep up to date with recent developments within the field of biosimilars with a particular focus on methodologies and analytical technics

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 and to advanced protein characterization
- Experience of working in a GMP regulated environment
- Experience of technology transfer and of qualification / validation of analytical methods
- Experience of working in early and/or late stage projects
- Experience of writing regulatory documents
- 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.