Non-clinical Senior Scientist

Job description

Now you have the opportunity to join Xbrane Biopharma, where 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. Xbrane's Non-clinical Senior Scientist will, as a core team member, represent the Non-clinical branch on new biosimilar development programs and report directly to the Head of Non-clinical.

The successful candidate will be responsible for developing non-clinical assays intended to characterize Xbrane's biosimilars with respect to binding and potency. Moreover, the applicant will oversee the development of methods to support clinical bioanalysis (PK, ADA, and Nab). The development and analysis will be performed at our external partners to successfully demonstrate similarity in terms of safety, immunogenicity, activity, and binding between our candidate biosimilar and the reference product. To be successful in this role, you must be highly motivated, flexible, creative, and organized. You must also be able to plan and work independently and collaboratively while providing vital support to the team within your area of expertise.

What You will be doing:

- Managing projects and technical-scientific collaborations with Contract Research Organizations (CRO) to develop, validate, and maintain biological assays and bioanalytical methods.
- Directly report on project progress to the Head of Non-clinical and Management, including preparing oral presentations and written reports.
- Contribute actively to collaborations on inter-departmental and inter-company project teams.
- Participate and drive interdisciplinary technical-scientific collaborations within ad hoc teams that aim to solve issues emerging in the biosimilar development programs by contributing expert knowledge of target biology and associated indication(s).
- Contribute to technical-scientific collaborations to support regulatory activities, e.g., drafting briefing books for scientific advice, IMPDs, and marketing authorization dossiers.
- Actively review developmental, analytical, and manufacturing documents and ongoing projects' non-clinical and clinical study documentation.
- Keep up to date with recent developments within the biosimilar field, focusing on methodologies and analytical technics for bioanalysis and biological assays.

Your Qualifications:

- B.Sc., M.Sc., or Ph.D. degree in Pharmacology, or related field within Life Sciences preferentially specializing in monoclonal antibodies, cancer immunotherapy, and immune-oncology.
- Demonstrable strong expertise in developing and troubleshooting biological assays and bioanalytical methods. Preferentially, expertise with in vitro assays of, e.g., PD-1 inhibiting antibodies.
- Experience from working with CROs.
- Expertise with the qualification/validation of bioanalytical assays (PK and immunogenicity).
- Previous experience in developing a biotechnology-derived medicinal product, ideally direct experience with biosimilar development.
- Experience of working in a GxP regulated environment.
- Experience in writing regulatory documents.

About you:

- You ***get it done***! You have the ability to drive activities independently and proactively while being part of a team where we encourage each other in a dynamic, fast-paced environment. Transparency and honesty are important to you.
- Every now and then you ***beat yesterday***! You use a flexible, creative, pragmatic and collaborative approach ready to jump in where and when needed. You use your creativity in problem-solving, you are open-minded and there is no such thing as a bad idea.
- You truly believe that ***impossible is nothing***! You have the ability to look at a problem from alternative angles, are open to out-of-the-box solutions and have a "can do" spirit. You are brave, persistent and like turning challenges into opportunities – for each problem, there is at least one solution.
- You contribute to creating an environment where ***we win as one***! Solidarity and togetherness are key to our performance and well-being. You enjoy being part of a team sharing the same values and purpose, working together, giving trust, recognition & support as we grow as one Xbrane family – at Xbrane you will never walk alone.

What's in it for you:

- You will be working with the development and commercialisation of products in the fast-emerging field of biosimilars
- You will be able to contribute with your experience and expertise in a changing environment and will have the opportunity to learn and develop in your role as Xbrane grows
- You will be part of a strong, dynamic team and will have exciting days at work

For more information, or to apply, please contact Nina.Ivers@xbrane.com. Please apply by February 15th, 2021.

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.