Head of Non Clinical

Job description

Now you have the opportunity to join Xbrane, 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. The Head of Nonclinical is responsible for ensuring that assays are in place for biological product characterization (binding and potency assays) and for bioanalysis (PK, ADA and Nab).

If you are the successful candidate, you will be responsible for designing, managing and coordinating analyses and analytical development required for the completion of nonclinical studies (Potency, binding, PK, ADA and Nab). The development and studies will be performed at our external partners with the aim of generating results required for successful demonstration of similarity in terms of safety, immunogenicity, activity and binding between our candidate biosimilar 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 biological assays and bioanalysis for the successful completion of biosimilar nonclinical studies.

What You'll be doing:

- Project management and technical-scientific collaboration with CROs for the development, validation and maintenance of biological assays and assays for bioanalysis.
- Reporting of project progress (preparation of presentations, development and project reports) to the management.
- Technical-scientific collaboration in development teams for various issues in the respective biosimilar development projects, contribution of expert knowledge on biological assays and bioanalysis.
- Technical-scientific collaboration in regulatory activities, e.g. collaboration in drafting of briefing books for scientific advices, IMPDs and marketing authorization dossiers.
- Collaboration in inter-departmental and inter-company project teams.
- Evaluation of developmental, analytical and manufacturing documents, non-clinical and clinical study documentation of the ongoing projects.
- Keep up to date with relevant guidelines and regulatory requirements.
- Keep up to date with recent developments within the field of biosimilars with a particular focus on methodologies and analytical technics for bioanalysis and biological assays.

Qualification:

- B.Sc., M.Sc. or Ph.D. degree in Life Sciences or related field, with strong background in development and troubleshooting of biological assays and bioanalysis.
- Expert knowledge in biological assays for bioanalysis and potency (PK, immunogenicity, potency, comparability).
- Previous experience in the development of a biotechnology-derived medicinal product, ideally a biosimilar.
- Experience of working in a GxP regulated environment.
- Experience 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.

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 siavash.bashiri@xbrane.com. Please apply by 04 Dec 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.