Quality Assurance Specialist

About the position:

By joining Xbrane Biopharma as Quality Assurance Specialist you will have the opportunity to join an innovative and growing team within the development of Biosimilars. You will be part of a team that will ensure the access of biologics to an underserved patient population and enabling the global health equality. By joining Xbrane you will be part of a journey to create a Swedish success story in biopharmaceutical drug development.

As our new colleague in the RA/QA function, you will be the next important piece of the puzzle making Xbrane Biopharma ready for the future. In the Quality Assurance Specialist role, you will be involved in a broad range of tasks within the Quality Assurance field, both in development as well as clinical and commercial manufacturing of Biosimilars.

What you'll be doing:

- **Build quality into our company by**
    - Collaborating with all of Xbrane's functions to ensure that quality standards and GxP compliance are met and maintained. Supporting organization in creating and implementing SOPs and in handling of deviations and change controls etc.
    - Managing Documentation and archive systems.
    - Be the quality representative within our development projects
- **Build quality externally by**
    - Working closely with internal and external partners maintaining a strong relationship
    - Supporting inspections from authorities and other external parties
    - Review and approve quality related documentation such as Change Controls, Deviation Reports and CAPAs
- **Build quality long-term by**
    - Keeping up to date in the field of Quality Assurance and GxP
    - Share information and evolve the quality culture within Xbrane Biopharma

What you are brining:

- A strong team focus combined with proactiveness, creating an efficient and fun environment
- A university degree in life sciences
- Experience from working with Quality Assurance within the biopharmaceutical industry
- Experience from Quality Assurance in a R&D environment
- Knowledge of US and EU GxP requirements and industry practices
- Strong interpersonal skills and the ability to deal effectively with a variety of business areas including quality, compliance, regulatory affairs, technical development, manufacturing, and external partners/collaborators.
- Good verbal and written communication in English

Quality Assurance Specialist

About you:

- You ***make it happen***! 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 create 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 development in the fast-emerging field of biosimilars
- You will be part of a strong, dynamic team
- You will have the opportunity to learn and develop in your role as Xbrane grows
- You will be able to contribute within your area's of expertise in a fast changing environment
- You will have exciting days at work!

About Xbrane

Xbrane Biopharma AB is a biotechnology company which develops and manufactures biosimilars. Xbrane has a patented protein production platform and world-leading expertise within biosimilar development and in September 2021, the first marketing authorisation application for Xbrane's biosimilar to Lucentis® was submitted to the European Medicinal Agency. This product is being developed together with STADA Arzneimittel, Germany and Bausch Health, US. Xbrane's headquarter research and research and development facilities are located in Solna, just on the border to Stockholm, Sweden. Xbrane is listed on Nasdaq Nordic. For more information see www.xbrane.com.

Interested?

To learn more about this opportunity, please contact Maria Edebrink, Head of RA & QA maria.edebrink@xbrane.com or Björn Lager, Quality Assurance Specialist bjorn.lager@xbrane.com.