

Job Summary:

Now you have the opportunity to join an innovative and growing team within the development of Biosimilars. We are recruiting a Senior Manufacturing Manager for the team that wants to ensure the access of biologics to underserved patient populations globally. By joining Xbrane you will be part of a journey to create a Swedish success story in biopharmaceutical development.

You will be part of the Manufacturing and Supply Chain team responsible for contract manufacturing organisation (CMO) interactions. In this role you will focus on Drug Product in late stages of the biosimilar product development and commercialization. This includes CMO management and oversight, coordination of internal and external activities during transfer of manufacturing processes from development to commercial scale, process validations and preparations for product launches world-wide.

Expect intense and interesting day-to-day interactions with CMOs to support the progress of the projects and when needed, you will act as a person-in-plant during manufacturing campaigns. In a team environment with the R&D, QA and Regulatory Affairs team you will be sharing manufacturing expertise securing sustainable and compliant future commercial manufacturing processes. Collaboration with Xbrane's commercial partners is also important to ensure efficient and successful product launches. You will report to Xbrane's Head of Manufacturing and Supply Chain.

What You'll Be Doing:

- Participate in defining Drug Product requirements and processes
- Define requirements in relation to combination products and associated medical device tests to meet Medical Device Regulations
- Participate in sourcing projects for Drug Products and Delivery Systems
- Lead and coordinate project activities at Xbrane and the CMOs with focus on Drug Product and act as key contact person responsible for CMO relationships
- Select and secure supply of primary packaging components and coordinate related studies
- Secure readiness for future commercial manufacturing
- Provide technical support including document review, trending of process data, review of technical investigations and validations
- Provide expertise, educate colleagues and keep up to date in the field of drug product manufacturing

Qualification:

- University degree in Life Sciences with several years of experience within pharma industry
- Extensive project management experience, including coordinating external activities and managing relationships with contractors
- Experience and knowledge in drug product manufacturing and primary packaging components
- Experience and knowledge several of following areas: biopharmaceuticals, biologics manufacturing requirements, process tech transfer, process validation, combination product requirements, medical devices, supply and quality agreements, project budgets, planning of commercial launches and commercial manufacturing
- Additional experience with drug substance manufacturing and packaging and labelling processes is meriting
- Experience from working under GMP requirements
- Proficient in English

Senior Manufacturing Manager



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 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 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

About Xbrane:

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. The headquarters and R&D facilities are located in Solna, just outside of Stockholm. Xbrane is listed on Nasdaq Stockholm. For more information see www.xbrane.com.

Send your application to: anders.wallstrom@xbrane.com no later than **13th of November 2020**.