Head of Quality Assurance

Job Summary:

By joining Xbrane Biopharma as Head of Quality Assurance you will have the opportunity to join an innovative and growing team within the development of Biosimilars. You will have the possibility to 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.

You will be responsible for the full scope of Quality Assurance within Xbrane and will be part of the Biosimilars Leadership Team. You will engage in all quality aspects of the company and the project portfolio together with colleagues responsible for R&D, Project Management, Supply Chain, Clinical and Regulatory Affairs. This position will have direct influence on the compliance for our Biosimilar products, process development and manufacturing, both internally and externally. You will also have managerial responsibilities of other QA representatives within the function.

What You'll Be Doing:

Build quality into our company by

- Setting up a QA function
- Implementing and maintaining a Quality System that addresses the critical role quality and regulatory compliance plays in Xbrane Biopharma's business.
- Collaborating with all of Xbrane's departments to identify relevant quality standards and to ensure GxP compliance is met and maintained
- Sharing information, organise training and evolve the quality culture within Xbrane
- Keeping up to date in the field of Quality Assurance and GxP

Build quality externally by

- Establishing strong relationships with internal and external partners
- Establishing and maintaining Quality Agreements with external partners in e.g. Manufacturing, Supply Chain, Clinical Affairs and ensuring the commitments are honoured
- Reviewing documentation by external partners to ensure relevant quality standards and agreements are met
- Creating and maintaining an audit plan and lead internal and external audits
- Supporting inspections (e.g., FDA, EMA) and the closing out of associated findings
- Review and approve quality related documentation such as Change Control, Deviation Reports and CAPAs

Qualification:

- A university degree in life sciences with several years of QA experience within the biopharmaceutical industry, including experience from a R&D environment
- Experience from leading a QA function
- Extensive knowledge of US and EU GxP requirements and industry practices
- Experience working with external partners and contractors
- Experience from coordinating quality management reviews and quality metrics exercises
- Experience of building a QMS and implementing an electronic QMS
- Experience of launching pharmaceuticals in different territories
- Strong interpersonal skills and the ability to deal effectively with a variety of business areas
- Collaborative approach and proactiveness combined with a strong team focus

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 in your areas of expertise in a fast-changing environment
- You will have exciting days at work

Send your application to: siavash.bashiri@xbrane.com no later than **6th of November 2020**.

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