

Head of Analytics



Job Summary:

You will be responsible for Xbrane Biopharma's analytical and biochemical characterization activities for biosimilar product development. This includes: assay development, characterization, biosimilarity/comparability strategies and assessments and evaluation of process influence on product quality.

This position will participate in ensuring successful biosimilar/comparability assessment, process development and compilation of the data package for regulatory filing.

The candidate will work in a team environment, collaborating with small-scale development experts, CDMOs and Regulatory Affairs.

What You'll Be Doing:

- Overall responsibility for analytical method package in the development of biosimilars.
- Lead the development and implementation of analytical methods for biosimilarity/comparability assessment, product lot release testing, stability testing, characterization of product degradation and establishment of reference standard
- Set and justify specifications
- Participate in regulatory authority communication
- Keep up to date in the field of analytical development
- Author analytical reports and provide data/statistical analysis to support data package for regulatory submission(s)

Who We Are Looking For:

- PhD or equivalent in Biology/Microbiology/Biochemistry/Biochemical Engineering/Analytical chemistry with several years of experience within the pharmaceutical industry
- Expertise within common techniques for analyzing proteins, specifically primary structure characterisation, higher order structure determination, purity/impurity analysis and potency is required
- Experience to set up, develop and validate analytical methods
- Experience from comparability assessments and regulatory file submissions
- Knowledge of upstream and downstream process development for biotherapeutic proteins
- Proven working knowledge of GLP & cGMP compliance
- Project management experience

About Xbrane

Xbrane is a commercial phase Swedish biopharmaceutical company specialized in biosimilars and long acting injectables. Xbrane has world leading expertise in developing generics for long acting injectable drugs and proprietary high-yield protein expression technology for the development of biosimilars. Xbranes's headquarter is located in Stockholm and the company's in-house research and development facilities are in Sweden and Italy. For more information see www.xbrane.com.

How To Apply:

Send you application, labelled "Xbrane HoA" to carrer@xbrane.com at latest 30th of August.