Principle Scientist CMC

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Erkenningsnummer
VG. 1690/BO B-AB10.018.

Principle Scientist CMC occupies a key role supporting Chemistry, Manufacturing and Controls (CMC) development for therapeutic antibodies, ensuring that projects successfully move forward within and across functions. He/she drives internal and external efforts with the aim of developing, producing and characterizing these therapeutics antibodies for early and late stage clinical programs up to commercialization. He/she is responsible for technical mastery of scientific and technical documents as well as follow-up on CMC project progress. The CMC principal scientist utilizes his/her expertise to resolve obstacles and bringing creative solutions to the table.

KEY ACCOUNTABILITIES AND RESPONSIBILITIES:

- Support of the set up of integrated CMC operational analytical development plans with external service providers (DS and DP manufactures and QC testing labs) by strategic thinking, providing expert input, and priority setting. Oversee the execution within agreed timelines, scope and budget.;
- Establish robust drug substance and drug product ICH stability and reference standard programs throughout the development of a product;
- Establish and maintain a complete data repository in support of specification setting, expiry dating and shelf-life determination;
- Provide expert input into analytical method validation strategies, protocols and reports;
- As a member of the CMC development team actively contribute to technical and strategic CMC discussions;
- Identify and track project critical path items - identify risks, formulate and monitor corrective actions;
- Prepare and review CMC module 3 sections in support of clinical trial applications and BLA/MAA applications, support preparations of responses to RfI;
- Develop SOPs effectively describing CMC processes; Liaise with quality assurance on quality related matters

QUALIFICATIONS

- PhD in chemistry, pharmaceutical sciences, bio-engineering, or other discipline within pharmaceutical/biotechnology sciences;
- Strong technical expertise in the field of biological drug substance and drug product manufacturing, process and product characterization, analytical method; development and validation; process validation and good understanding of statistics;
- Fluent in English, written and spoken;
- Thorough knowledge and experience with GMP and in depth knowledge of ICH and GMP regulations;
- Works independently within the scope of his/her assigned field and supports others;

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- Keep abreast with relevant scientific and/or technical developments. Searches literature and other sources independently and applies knowledge;
- Excellent organizational and coordination skills;
- Ability to go into detail whilst keeping the view on the overall project goal;
- Strong technical expertise combined with good project management skills and ability to communicate effectively with internal and external stakeholders;
- Flexible attitude, capable of picking up the tasks that require attention;
- Quality conscious attitude;
- Experience and knowledge in the preparation of regulatory submissions for early to late stage programs, including market authorization applications;
- Able to operate in a dynamic surrounding of a fast growing biotech company with challenging timelines;

WHAT THE COMPANY OFFERS

- A competitive salary package with extensive benefits
- Front seat in the development of therapeutic antibodies
- A work environment in a human-sized, dynamic and rapidly growing biotech company