Sr/Principle Scientist CMC Analytical Development

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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 are successfully transferred to commercial phase. He/she excels in stakeholder management, drives internal and external efforts towards lifecycle management of the commercial product QC related activities.

KEY ACCOUNTABILITIES AND RESPONSIBILITIES:

- Responsible to sets up of integrated CMC operational analytical plans with external service providers (DS and DP manufactures and QC testing labs) and internal stakeholders; oversee the execution of agreed commercial supply plan for outsourced QC testing;
- Close follow up of deviations, change controls, OOS investigations related to QC activities at external vendors, in close collaboration with the DS and DP manufacturing and QA team; investigate OOE/OOT release results including root cause investigations and impact assessments on the process performance capabilities; initiates change controls
- Close follow up and distribution of critical reagents and reference standard inventories; initiate replenishment in due time and in accordance to the regulatory submissions. Follow up of the reference standard trending and stability programs;
- Establish and maintain a complete data repository of product quality via control charts of the analytical critical quality attributes, as part of process performance evaluation
- Set up the annual stability plan, and follow up on stability data trending within the approved shelf-life;
- Follow up on the analytical method life cycle, transfer strategies, protocols and reports; and analytical method performance trending across the multiple QC testing sites
- 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 variations of global submissions for commercial products, support preparations of responses to RfI;

SKILLS & COMPETENCIES:

- 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;
- Keep abreast with relevant scientific and/or technical developments. Searches literature and other sources independently and applies knowledge;
- Excellent organizational and coordination skills;

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- 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 and variations for commercial programs;
- Able to operate in a dynamic surrounding of a fast growing biotech company with challenging timelines;

EDUCATION, EXPERIENCE AND 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;