SENIOR SCIENTIST CMC

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

A **senior scientist CMC** plays a key role supporting Chemistry, Manufacturing and Controls (CMC) development of Argenx drug products, ensuring that projects move forward in time and within budget. He/she drives internal and external efforts with the aim of developing, producing and characterizing these differentiated antibody therapeutics and is responsible for technical mastery of scientific and technical documents as well as follow-up on CMC project progress. The CMC Senior Scientist utilizes his expertise to resolve obstacles and by bringing creative solutions to the table. This person will report to the Director CMC DP.

ROLE AND RESPONSIBILITIES:

- Drives the execution of CMC activities for early and late phase drug development candidates and changes to validated commercial processes;
- Facilitate the establishment of integrated CMC operational plans with external service providers by providing expert input, problem resolution definition and priority setting and oversee their execution within agreed timelines, scope and budget; external service providers include drug product manufacturing, pack & labelling and analytical testing services;
- Leads drug product site transfer and scale-up activities;
- Critical quality/technical review of CMC documents (e.g. process development protocols/reports, validation protocols/reports, stability protocols/reports, etc.) and batch manufacturing records with minimal guidance and able to draw appropriate conclusions;
- As a member of the CMC team actively contribute to technical and strategic CMC discussions;
- Identify and track project critical path items - identify risks, formulate and monitor corrective actions;
- Support development and execution of supply strategies for clinical studies;
- Prepare CMC sections to support timely submission of clinical trial applications;
- Develop SOPs effectively describing CMC processes;
- Liaise with quality assurance on quality related matters

SKILLS AND COMPETENCIES:

- Thorough knowledge and experience with GMP
- Works independently within the scope of his 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
- Ability to go into detail whilst keeping the view on the overall project goal;

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- 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;
- In depth knowledge of ICH and GMP regulations;
- 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 characterisation and process validation; good understanding of statistics;
- Expected experience: 2-5y within relevant industry
- Fluent in English, written and spoke