SENIOR SCIENTIST CMC

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

The company is a late-stage biopharmaceutical company that is creating and developing a pipeline of differentiated antibody therapeutics. The unique SIMPLE Antibody™ platform and suite of Fc engineering technologies combined with the complementary expertise of our people enabled us to build a clinical-stage portfolio of novel product candidates – tailored from discovery through development to address patient needs.

To further strengthen the CMC team, we are looking for an experienced and motivated CMC scientist/ senior Scientist. The scientist/ senior scientist CMC will play a lead role supporting cell line development, drug substance (DS) manufacturing process development and analytical method development with external manufacturing partners (CMOs) to enable clinical manufacture of the therapeutic antibodies and Fc engineered molecules.

ROLE AND RESPONSIBILITIES:

- Supports early CMC development activities on drug candidates including:
  - Manufacturability assessment;
  - Formulation development;
  - Productivity assessment;
  - Cell line and manufacturing process (USP and DSP) development;
  - Development/selection of appropriate analytical methods;
- Keeps oversight of cell line and process (USP and DSP) development track at CDMO and provides expert input;
- Technical review of CMC documentation (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;
- Actively (hands-on) supports the internal development of analytical methods (chromatography, bioassays, etc.);
- Proactively identifies and tracks project critical path items, ie identify risks and gaps, formulate, develop and monitor corrective actions and communicate risk to CMC leadership;
- As a member of the CMC (Early Development) team, actively contribute to technical and strategic discussions.
- Update project dashboards/presentations with project status to provide timely communication of status to internal team.
- Facilitate the establishment of integrated CMC operational plans with internal and external service providers by providing expert input, problem resolution definition and priority setting and oversee their execution, scope and budget.

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- Work in close collaboration with quality assurance to ensure activities are performed in line with the required quality standards;
- Provides input to budget forecast cycles.

QUALIFICATIONS:

- Masters / PhD in chemistry, pharmaceutical sciences, bio-engineering, or other discipline within pharmaceutical / biotechnology sciences
- Ability to lead tech transfer activities and previous experience in this area is desired.
- Strong technical expertise in the field of biological development and drug substance manufacturing, product and process characterization
- Strong knowledge of analytical methods (chromatography, bioassays, etc)
- Expected experience: >3y within relevant industry
- Desired hands on experience in chromatography, Viral inactivation, Virus filtration and UF/DF operations.
- Desire to work in a fast-paced environment, and relevant experience in managing outsourced projects with external vendor
- Ability to provide hands-on problem-solving skills and strong critical thinking.
- Excellent organizational and coordination skills;
- Ability to provide attention to detail whilst keeping the view on the overall project goal;
- Strong technical expertise combined with good interpersonal skills and ability to communicate effectively with internal and external stakeholders;
- Flexible attitude, capable to balance multiple priorities;
- Quality conscious attitude;
- Knowledge of the preparation of regulatory submissions;
- Able to operate in a dynamic surrounding of a fast-growing biotech company with challenging timelines;
- Fluent in English, written and spoken
- Good knowledge of ICH and GMP regulations;
- 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;