Sr Scientist Dossier Development

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

To further strengthen our CMC team, we are looking for a Senior Scientist CMC Dossier Development. The Senior Scientist CMC will be responsible for authoring and reviewing of quality submission packages for our large molecule therapeutic drug candidates throughout their clinical development towards marketing approval. In this role you will be able to weigh into CMC development strategies.

This is a unique opportunity to contribute to the development of novel therapeutics to treat patients with cancer and severe autoimmune diseases

KEY ACCOUNTABILITIES AND RESPONSIBILITIES:

Contributes to the CMC development of pre-clinical and clinical stage development programs in close collaboration with the CMC team members by:

- Authoring and preparing IND, IMPD, scientific briefing documents, Investigator Brochures and regulatory agency response documents for therapeutic compounds in development in close collaboration with external and internal stakeholders;
- Authoring and preparing BLA, MAA quality documentation packages (module 2.3 and 3);
- Ensuring submission packages are complete and compliant with applicable regulatory and country specific requirements;
- Coordinating activities with internal and external partners ensuring that deliverables are executed with the right priorities and to the required standards;
- Authoring technical source protocols and reports related to drug development activities;
- Providing strategic input into CMC development activities from regulatory perspective;
- Tracking execution of regulatory commitments.

QUALIICATIONS:

- Master degree or PhD in biotechnology, pharmaceutical sciences or bio-engineering, with relevant expertise in CMC development and CMC regulatory dossier development (IND/IMPD/BLA/MAA);
- Science oriented, experience with large molecules is a plus;
- Excellent writing skills coupled with comprehensive knowledge of pharmacopoeial requirements, ICH guidelines, FDA and EMA/CHMP regulations and guidelines, and other international regulatory requirements;

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- Excellent interpersonal and communication and project coordination skills, team player; able to build effective relationships with internal and external stakeholders;
- Well organized and able to handle multiple assignments in parallel;
- Proficiency with MS-Word and preferably with document management systems;
- Eye for detail and quality conscious attitude;
- Well organized;
- Fluent in English – our working language;