Senior Scientist CMC Dossier Development

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

To further strengthen the CMC team, we are looking for a Senior Scientist / Principal Scientist CMC Dossier Development. The candidate will be responsible for authoring and reviewing of quality submission packages for the company's large molecule therapeutic drug candidates throughout their clinical development towards marketing approval as well as global life cycle management projects. In this role you will have a front seat in the heart of a development / commercial organization and able to weigh into CMC development strategies.

This is a unique opportunity to contribute to the development of innovative therapeutics to treat patients with severe auto-immune diseases.

Report to: Head of Dossier Development

KEY ACCOUNTABILITIES AND RESPONSIBILITIES

- Contributes to the CMC development of pre-clinical, clinical, and commercial stage programs in close collaboration with the CMC team members by:
- Participate to the 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.
- Participate to the authoring and preparing BLA, J-MAA, MAA and ROW applications (module 2 and 3) and related life cycle documents.
- Ensuring submission packages are complete and compliant with applicable regulatory and country specific requirements.
- Coordinating activities with 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.
- Tracking execution of regulatory commitments.

QUALIFICATIONS

- 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.

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Excellent writing skills coupled with comprehensive knowledge of pharmacopeial requirements, ICH guidelines, FDA and EMA/CHMP regulations and guidelines, and other international regulatory requirements.

- 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.
- Proactive – can do mentality;
- Fluent in English – our working language.

OFFER

- 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