JOB OPPORTUNITY

innate pharma

Innate Pharma S.A. is a clinical-stage biotechnology company dedicated to improving cancer treatment and clinical outcomes for patients through first-in-class therapeutic antibodies that harness the innate immunity. Innate Pharma specializes in immuno-oncology, a new therapeutic field that is changing cancer treatment by mobilizing the power of the body's immune system to recognize and kill cancer cells.

The Company's broad pipeline includes four first-in-class clinical stage antibodies as well as preclinical candidates and technologies that have the potential to address a broad range of cancer indications with high unmet medical needs.

The expertise of the Company has enabled it to enter into major alliances with leaders in the biopharmaceutical industry including AstraZeneca, Bristol-Myers Squibb, Novo Nordisk A/S and Sanofi.

Based in Marseilles, France, Innate Pharma has more than 170 employees and is listed on Euronext Paris.

As our research and development pipeline is expanding and advancing, Innate Pharma faces new exciting challenges and we therefore now seek a:

CMC PROJECT MANAGER, BIOLOGICAL PRODUCTS

Permanent contract
Réf: CMC/FB/2017/1

Mission

Evolving in a transversal organization you will endorse management responsibilities of one or several CMC projects for therapeutic candidates (monoclonal antibodies) currently in preclinical and clinical development stages.

You will manage all CMC activities from development to cGMP manufacturing to allow delivery of investigational medicinal products (IMP) and quality part of the FDA and EMA investigational dossiers (IND/IMPD) for clinical studies. As part of these, you will define all technical, quality and regulatory requirements needed for manufacturing and quality control (QC) operations that you will coordinate and appreciate until their achievement.

You will manage a multidisciplinary CMC project team and work in collaboration with the program managers. You will be responsible of the planning and budget of your CMC projects and efficiently report them to program managers.

You will manage subcontracted activities with CMO/CRO. You will be involved in their selection; coordinate the execution of contracts and set up an efficient follow up of their activities and deliverables. You will take part of quality audits as a technical expert.

You will ensure the scientific and regulatory compliance of all CMC activities performed in the studies. You will participate to the definition of the CMC regulatory strategy for the submission of clinical trial authorization dossier. You will be involved in the writing of quality and viral safety parts of the IND/IMPD.

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Experience and qualification requirements

- Scientific education minimum bac+5 (pharmacist-option Industry, engineer or PhD) with a specialisation in biochemistry, biotechnology or biologic engineering with around five years of experience in pharmaceutical development of biological products (monoclonal antibodies) ideally acquired in a pharmaceutical company or in a CMO. Experience in cGMP bio production or USP/DSP development would be appreciated.
- Knowledge in analytical methods for quality control and characterization of proteins / monoclonal antibodies would be a plus.
- Familiar with cGMP and FDA, EMA, ICH guidelines referring to quality part of clinical trial authorization dossier (IND / IMPD).
- Practical experience in technical aspects and operational management of complex CMC projects.
- Good communication skills with critical mind and global approach.
- Motivated and committed to project achievements, rigorous and dynamic.
- Good English written and oral communication skills. French language is mandatory for interaction with Innate teams.

Position based in Marseilles (France).

Additional information

Please **send your resume and a cover letter in support of your application** with the reference «CMC/FB/2017/1» par email– Oliver.Hurst@srg.co.uk

innate pharma is an equal opportunity employer. innate pharma will consider all qualified applicants for employment without discrimination on grounds of age, race, religion, sex, national origin, disability.

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