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Specialist Regulatory CMC at Merck Group, India

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Ensure provision of high-quality CMC dossiers that meet company's and health authorities' requirementsEnable representatives from all major disciplines

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United As One for Patients, our purpose in Healthcare is to help create, improve and prolong lives. We develop medicines, intelligent devices and innovative technologies in therapeutic areas such as Oncology, Neurology and Fertility. Our teams work together across 6 continents with passion and relentless curiosity in order to help patients at every stage of life. Joining our Healthcare team is becoming part of a diverse, inclusive and flexible working culture, presenting great opportunities for personal development and career advancement across the globe.

Job Title :- Specialist Regulatory CMC

Job Location : Electronic city Bangalore

Job contents

- Provide end-to-end support for Annual Reports and Renewals for all products, e.g. planning of required activities, attend kick-off/jour-fixe meetings, contribute to DSP and ensure timely collection of respective requirements and deliverables Update and review CMC specific documentation, incl. coordination with countries to compile local CMC variations (RSTs/JF).
- Ensure provision of high-quality CMC dossiers that meet company's and health authorities' requirementsEnable representatives from all major disciplines involved to reach agreement on the CMC dossier and strategy.
- Position will be working in a matrix organization, with extensive communication and collaboration with stakeholders from various functions within or outside Global Regulatory Affairs.
- The role will support the resolution of complex tasks, under close supervision and guidance provided from the more experienced CMC personnel.

Additional technical experiences :-

Ability to understand and support the life cycle management of regulatory CMC activities.
Experience in management of regulatory CMC documentation, including variations.
Experience with regulatory CMC life-cycle management activities.
Practical experience in one of the following areas for biotech or chemical molecules: manufacturing process development, transfers, validation or analytical development and quality management.

Awareness of global pharmaceutical legislation specifically linked to regulatory CMC aspects in the ICH countries

Education: Degree in a Life Science or a related discipline, preferably MSc with excellent written and verbal English communication

Work Experience: 5-6 years of overall work experience in Pharma environment, Competent authority or Academia/R&D experience related to the role.

Minimum 3 years of Global CMC regulatory experience

What we offer: With us, there are always opportunities to break new ground. We empower you to fulfil your ambitions, and our diverse businesses offer various career moves to seek new horizons. We trust you with responsibility early on and support you to draw your own career map that is responsive to your aspirations and priorities in life. Join us and bring your curiosity to life!

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