



**DRIVEN
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NEEDS?** | **AT BAYER
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EXPECTED
TO BE.**

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At Bayer you have the opportunity to be part of a culture where we value the passion of our employees to innovate and give them the power to change.

Regulatory CMC Manager (m/f)

YOUR TASKS AND RESPONSIBILITIES

- Responsible for the creating and implementation of a regulatory CMC strategy with regard to assigned products in close cooperation with the supervisor and other relevant functions
- Early identification of major regulatory hurdles and issues with regard to CMC related topics, regulatory guidelines and legal requirements, as well as coordination of respective corrective actions
- Active input into the global regulatory teams (GRTs) for the assigned products to ensure the submission and registration in due time
- Responsible for timely availability and final content of CMC sections of IND/IMP, NDA/MAA submissions to health authorities with respect to assigned product portfolio
- Responsible for the CMC change management for assigned development and market products incl. tracking of CMC changes and processing of requests for related documentation
- Coordination of responses to health authority requests and implementation of CMC changes after health authority approvals to ensure regulatory CMC compliance
- Prepare proposals and support implementation of standards concerning CMC documentation

WHO YOU ARE

- University degree in natural or medical science, ideally with a PhD
- Experience within the pharmaceutical industry, preferably within development- or quality assurance functions
- Knowledge of medicinal product registration is an advantage
- Scientific and technical expertise including the ability to develop robust regulatory timelines and action plans
- Ideally knowledge of drug development as well as country specific regulations and guidance documents and license variations
- Good analytical skills and experience in project management
- Ability to build partnerships in a global environment and work collaboratively with others to meet shared objectives
- Being open-minded, goal oriented and challenging the status quo
- Fluency in English, both verbal and written; good knowledge in another language

Country
Germany

Location
Wuppertal Elberfeld

Division
Pharmaceuticals

Contact us
Phone +49 214 30 99779
www.karriere.bayer.de

Reference Code
0000194408

Bayer welcomes applications from all individuals, regardless of race, national origin, gender, age, physical characteristics, social origin, disability, union membership, religion, family status, pregnancy, sexual orientation, gender identity, gender expression or any unlawful criterion under applicable law. We are committed to treating all applicants fairly and avoiding discrimination.



(preferably German)

YOUR APPLICATION

We offer a competitive salary in an international environment as well as excellent opportunities for professional and personal development. If your background and personal experience fit this profile, please send us your complete application at www.career.bayer.de, submitting a cover letter, your CV and references as well as your salary expectations.

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