At Boehringer Ingelheim we develop breakthrough therapies and innovative healthcare solutions in areas of unmet medical need for both humans and animals. As a family owned company, we focus on long-term performance. We believe that, if we have talented and ambitious people who are passionate about innovation, there is no limit to what we can achieve; after all, we started with just 28 people. Now, we are powered by 50,000 employees globally who nurture a diverse, collaborative and inclusive culture.

(Senior) CMC RA Manager (ID: 226623)

As (Senior) CMC RA Manager you will represent Global CMC Regulatory Affairs on development projects, approved products and interdisciplinary strategic projects. The focus is on biologicals. You will also contribute to development, innovation and continuous improvement of processes and standards within Regulatory Affairs.

Tasks & responsibilities

Global management of CMC regulatory tasks and responsibilities in development as well as during product life cycle:

- In this role, you will represent the department in international project teams and provide regulatory advice regarding global CMC regulatory requirements, CMC submission strategies and opportunities for seeking scientific advice from health authorities.
- It will be your responsibility to guide project teams to prepare high quality global registrations documents and responses to health authority requests. You will ensure that timelines are met.
- You will plan, define, review and compile global Module 3 documentation for Clinical Trial Applications and Marketing Authorization Applications as well as for post approval CMC activities (e.g., CMC changes and renewals).
- Moreover, you will maintain up-to-date knowledge and expertise within the global CMC regulatory environment (ICH, FDA, EMA, PMDA, China and Emerging Markets).
- In addition, you will represent CMC Regulatory Affairs on interdisciplinary strategic projects.

<u>Additional responsibilities of the Senior CMC RA Manager:</u>

- As (Senior) CMC RA Manager, you will also have responsibility for CMC-regulatory aspects of development projects, strategic and established products worldwide which require your in-depth regulatory expertise.

- You will review CMC documentation for in-licensing products.
- With your insights based on your analysis of product-specific experiences, trends, and feedback you will share best practices and grow your colleagues via knowledge management training and advice.

Requirements

- Master's degree or equivalent in biotechnology, biochemistry, pharmacology, chemistry, biology, or a comparable field within life sciences
- In-depth knowledge in Regulatory Affairs, Pharmaceutical Development, Pharmaceutical Production, Quality Assurance, leadership in an international environment
- Preferably global CMC regulatory experience with small molecules, for development projects and/or marketed products
- Experience in CMC development and/ or production/control of biologicals and /or ATMPs with sound scientific understanding of products and processes
- Ability to lead and motivate people in cross-functional teams, set directions and manage changes
- Interdisciplinary, innovative and strategic thinking
- Strong organizational and communication skills, excellent prioritization and time management skills
- Fluent in English (written and spoken); German language would be a plus

Additional requirements for the Senior role:
- Profound experience in global CMC regulatory for biologicals and/or ATMPs as well as for drug-device combination products
- Substantial knowledge of international CMC regulatory requirements (ICH, FDA, PMDA, EU and emerging markets)
- Track record of leading strategic initiatives

WHY BOEHRINGER INGELHEIM?
This is where you can grow, collaborate, innovate and improve lives.

We offer challenging work in a respectful and friendly global working environment surrounded by a world of innovation driven mindsets and practices. In addition, learning and development for all employees is key, because your growth is our growth. We also offer a competitive salary, generous amount of vacation time, and numerous benefits towards your wellness & financial health and work-life balance. Plus, an onsite gym (Ingelheim), in-house doctor and best-in-class cafeterias and coffee bars to keep you energized and healthy. To learn more about what benefits could be waiting for you, please visit our Career area.

Want to learn more about us? Visit https://www.boehringer-ingelheim.com/

Boehringer Ingelheim is an equal opportunity global employer who takes pride in maintaining a diverse and inclusive culture. We embrace diversity of perspectives and strive for an inclusive environment, which benefits our employees, patients and communities. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity or national origin.

READY TO CONTACT US?

Please contact our Recruiting EMEA Team, Tel: +49 (0) 6132 77-173173