



*I advance*

because, at the company,  
innovation isn't limited to  
research – it's everywhere

Join us to grow, collaborate,  
innovate and improve lives.

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.

## ***CMC RA Manager (ID: 226624)***

### **Tasks & responsibilities**

As CMC RA Manager you represent Global CMC Regulatory Affairs on development projects, approved products and inter-disciplinary strategic projects. You contribute to development, innovation and continuous improvement of processes and standards within Regulatory Affairs.

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

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

## Requirements

- Master 's in Pharmacy, Chemistry, Biology or other relevant life science disciplines
- Global CMC regulatory experience with small molecules, for development projects and/or marketed products
- Preferably global CMC regulatory experience with drug-device products and medical devices
- Experience in, and sound scientific understanding of CMC development and/or production including quality control
- Inter-disciplinary, innovative, result oriented and strategic thinking
- Strong communication skills
- Strong organizational skills as well as the ability to work both independently and within a team structure
- Fluent in English (written and spoken); German language would be a plus

## 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

Not exactly the position you are looking for but have someone else in mind? Share it via the button on the bottom of the page with friends or colleagues who might be interested.