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.

Project Leader Regulatory Affairs (m/f/d)

YOUR TASKS AND RESPONSIBILITIES

- Take responsibility for national registration applications incl. national activities within EU-procedures and act as an interface between Global RA and national health authority BfArM in case of DE being RMS in an MRP or DCP as well as life-cycle activities for defined Consumer Health medicinal product portfolio and similar activities on non-medicinal products
- Generate regulatory strategies to enable optimized product launches in Germany in cooperation with Global RA
- Take responsibility for generation and life-cycle management of national product dossiers, if DE is dossier owner
- Act as a member (m/f/d) within global project teams for new product launches for CH-DE within given product portfolio
- Ensure local regulatory compliance according to given SOPs, roadmaps etc. and take responsibility for regulatory advice to other departments working for CH Business (e.g. marketing, new business dep., legal dep., project management dep.)
- Generate and/or assess scientific texts (e.g. SmPC, PIL, mandatory information for advertising, expert reports) in cooperation with local medical and/or PV department
- Timely update of internal and external databases/document management systems
- Adhere to the global and local Standard Operating Procedures (SOPs)
- Ensure sufficient communication to the EU-country RA Groups
- Act as a reliable contact partner (m/f/d) for local (health) authorities, associations and further external RA contact points within responsible product portfolio

WHO YOU ARE

- PhD or master degree in a natural scientific field (e.g. pharmacy, biology, chemistry)
- Knowledge of national and European regulatory requirements (at least for pharmaceuticals)
- Several years of experience in national and european registration procedures
- Adequate negotiating, interpersonal and influencing skills
- Ability to work in a team
- Fluent in English, both written and spoken

Please apply online at https://career.bayer.com/de/career

Your application

Are you looking for a new challenge where you can show your passion for innovation? Are you interested in working as part of a global team to improve people’s lives? Then send us your online application including cover letter, CV and references.

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.

Country: Germany
Location: Leverkusen
Reference Code: 46451
Functional Area: Regulatory Affairs