



Bio-Rad Inc. is the number one worldwide Company in the specialist diagnostics. It develops, produces, Sold and supported A large portfolio of products in the field of medical diagnostics and life science.

Bio-Rad is looking for its subsidiary Bio-Rad Medical Diagnostics in Dreieich near Frankfurt

Regulatory Affairs Specialist (m/w) (temporary for 2 years)

Your job

- Creation of documents for the approval / registration of existing and new products in German and English
- Coordination of smaller projects in connection with changes requiring approval
- Verification of the product identification for compliance with regulatory requirements
- Revision of the technical documentation
- Collaboration and consultation with relevant Regulatory Affairs employees and distributors within the Bio-Rad organization
- Assessment of amendments with regard to reporting requirements and authorization procedures for authorities and coordination of the preparation and submission of the necessary documentation
- Maintenance of regulatory requirements in the ERP system due to existing product licenses

Our requirements

- Study of natural sciences (biology, bio-chemistry, pharmacy, etc.)
- Knowledge of US FDA requirements (IVD, BLA)
- Experience in preparing approval dossiers
- Strong team and communication skills
- analytical and systematic work style
- quick grasp
- Use of MS-Office routinely
- Fluent English

If you are interested in this challenge and would like to become part of a dynamic team in a varied and international environment, we are looking forward to your application.

Bio-Rad Medical Diagnostics GmbH

Industriestraße 1
63303 Dreieich

www.bio-rad.com

Please send us your full application documents in English including your salary statements claudia_simon@bio-rad.com.

BMD as a subsidiary of Bio-Rad offers products from the fields of blood group and transplantation diagnostics. Our products are manufactured with state-of-the-art manufacturing technology according to international quality standards and meet the high regulatory requirements of the US market. The areas of production, research and development are located in Germany. Our business is innovative and has a world-wide reputation. High international customer orientation and a bilingual environment (German and English) combined with attractive working conditions characterize corporate culture.