



**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 Manager (m/w)

### Your job

- Managing a team of 3-4 RA specialists
- Assessing compliance with the relevant regulation for in vitro diagnostic medical devices at national and international level (CE marking and US FDA)
- Evaluation of regulatory impact for product and process changes, definition of action plans to sustain conformity with applicable regulations and standards.
- Acting as regulatory referent within projects core team to support the introduction of new products on Bio-rad key markets (including US).
- Developing, coordinating and implementing strategy to get market authorization according to project planning.
- Supervising the preparation of documents for Worldwide registration
- Communication and reporting to supervisory authorities (BPDR), and notified bodies
- Evaluation and research of the relational literature and regulations, advice on all regulatory issues, the interpretation of directives and the design and implementation of internal regulations
- Active participation in association committees as well as standardization organizations
- Conduct of audits and trainings

### Our requirements

- Management skills and leadership
- Degree in technical studies
- GMP knowledge
- Experience in licensing projects (FDA BLA's, 510k's)
- Detailed knowledge of the Medical Devices regulatory framework (CE marking, CFR part 820,..)
- Fluent in English
- Organizational capacity

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](http://www.bio-rad.com)

Please send us your full application documents in English including your salary statements [claudia\\_simon@bio-rad.com](mailto: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.