

For its site in Cressier (Fribourg), Bio-Rad is looking for a:

## Regulatory Affairs Manager (100%)

### Your tasks

- Oversees 2-5 direct reports, including senior RA Specialists
- Assess compliance with the relevant regulation for in vitro diagnostic medical devices at national and international level (CE IVDR, TGA, ANVISA, Health Canada, and US FDA). May lead investigations and resolve potential product compliance issues.
- Develops, coordinates and implements strategy to ensure IVD medical devices registration in Europe and targeted markets (incl. AU, BR, CA, JP, US). Supervise the preparation of documents for Worldwide registration.
- Represents regulatory on project teams developing claims for labeling, promotion and the commercialization of new products.
- Reviews change requests to determine regulatory impact and notification requirements.
- Evaluates the standards, guidelines and regulations, provides advices to Company stakeholders on all regulatory issues
- Recommends regulatory departmental improvements and provides corrective action plans.

### Your profile

- Leadership in cross-functional team
- Communication, public-speaking, decision-making, word processor, spreadsheet, and negotiation skills.
- Strong customer orientation and focus.
- Detailed knowledge of the Medical Devices regulatory framework (CE IVD regulation, IUS 21 CFR part 820, ISO standards..)
- Knowledge on Quality Management System certification (13485, MDSAP)
- Minimum Master degree in Science (preferred Biologics) or equivalent in a related field. PhD preferred.
- 2+ years' relevant regulatory experience (CE Marking, US 510k's, BLA's, High risk class devices registration WW) with supervisory experience, or equivalent combination of education and experience.

Our company is involved in the supply of high-quality products and services intended for diagnostic laboratories. Independence, innovation and commitment are the fundamental values that permeate our company culture, as well as a strong orientation towards our customers and a multicultural environment.

If you feel attracted to this unique opportunity and you would like to take on new challenges, we would like to get to know you. Please forward your complete application (application letter, CV, copies of work certificates and diplomas/degrees, etc.) to the address given in the advertisement.

Bio-Rad is an innovative company and thanks to its laboratory diagnostic systems, world leader in the field of blood group serology.

#### Bio-Rad Laboratories

DiaMed GmbH

Human Resources

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