

Regulatory Affairs Specialist (100%)

Your tasks

- You ensure the compliance of our IVD medical device portfolio with the requirements of the European Directives and regulations 98/79 / EC and 2017/746 (CE marking) throughout the product life cycle (development, manufacture, placing on the market).
- You build up the technical documentation of our IVD reagents and systems and update it in light of changing regulatory requirements.
- You are responsible for coordinating and developing registration dossiers for the worldwide registration of our products in a timely manner.
- You work closely with representatives of our subsidiaries (Asia Pacific, Latin American, Eastern Europe, Middle East, and Russia) to define the regulatory strategy and meet local requirements.

Your profile

- You benefit from a scientific university degree in biology or pharmacy (Bachelor or equivalent level) with ideal knowledge of immunohematology.
- You stand out by your writing skills and can clearly present complex situations (both written and oral).
- You have good skills to analyze and synthesize technical data.
- You have 2 to 4 years of experience in regulatory affairs (diagnostic industry pharmaceutical or) and have a good knowledge of regulations and standards for medical devices.
- US/FDA regulatory knowledge is an asset (BLA, 510k).
- You have a very good command of spoken and written English. Good command of German and/or French would be a strong asset.

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.