ORGENTEC Diagnostika GmbH is a leading player in the market of in-vitro diagnostics specialties. Our strength is autoimmune and infectious disease diagnostics with our own automation and a growing family of instruments. Starting out in 1988, ORGENTEC has built a reputation and tradition of bringing new products to the market. The company is successfully growing with a global network of distribution partners, supporting medical laboratories in more than 100 countries all over the world.

In keeping with our reputation, we accelerate the growth of our portfolio of assays and broaden our own family of instruments. Strong regulatory knowledge supports the dynamics of this development. For further support and to allow for continued and quick conformance with international regulations, we expand our Regulatory Team significantly. Depending on personal qualification there are opportunities in various Regulatory Affairs roles.

Our team of 130 colleagues in Mainz needs you to work with us to grow our global business in the position of:

Regulatory Affairs Specialist (f/m/d)

to start immediately.

This makes your day in the Regulatory Affairs Specialist / Administrator role:

- ✓ Maintaining and updating the product information database
- ✓ Assisting in creation and maintenance of product dossiers including labelling
- ✓ Ensuring timely availability of the requested materials
- ✓ Monitoring validity dates of registrations, initiate renewal in time and ensure timely follow up
- ✓ Submitting product dossiers for product registration and re-registration to international distributors
- ✓ Communicating with international distributors when necessary (usually by email in English)
- ✓ Maintaining a clear and standardized filing system for documents and correspondence
- ✓ Assisting in the development and improvement of Regulatory Affairs processes and procedures
- ✓ Supporting project-related tasks

This is what you bring to the table:

- ✓ Scientific education, Bachelor's degree or biology/chemistry technical assistant with min 2 years of relevant professional experience
- ✓ Professional experience in a regulated, quality-orientated environment; preferably experience in medical device or in-vitro diagnostic industry or the regulatory field
- ✓ Service-minded team player
- ✓ Accurate, focused on detail, yet efficient work approach
- ✓ Good English language skills, especially in writing as a must; fluent German
- ✓ Computer skills (MS Office products) and interest in working with databases
- ✓ Experience in project management would be a plus
- ✓ Of course and very much so: Being a team player, self-motivated, with a strong will to make a difference and contribute to our joint effort to make ORGENTEC the best specialty diagnostics company in the market.

What ORGENTEC brings to the table:

- ✓ An excellent reputation in the global market as an innovative diagnostics manufacturer with products of prime quality.
- ✓ A young and team-oriented environment to welcome, support, and challenge you.
- ✓ Company in-house trainings and sports program.
- ✓ An exciting product portfolio in reagents and instrumentation growing strongly.
- ✓ State-of-the-Art facilities in Mainz – a university-city on the Rhine River with high quality of life.
- ✓ Location in convenient proximity to essential shopping like groceries, bakery, home-improvement.
- ✓ Competitive compensation.

Are you interested? Then send us your application in German or English today, stating your salary expectations and the possible starting date to bewerbung@orgentec.com