

Would you like to contribute your skills to a future-oriented company that is growing rapidly and support us in making the world healthier and saving lives? Then we, Hain Lifescience GmbH, as the manufacturer and distributor of In-vitro-diagnostics, are the right company for you. Due to our outstanding technical expertise, great reputation in the market and a convincing product portfolio, we are among the most important in the industry. Support us and become part of our family.

Our customers include medical laboratories worldwide. Our main competencies are molecular genetic test systems and devices for the detection of dangerous pathogens or hereditary diseases. Hain Lifescience has been part of the globally successful technology group Bruker based in the USA since October 2018.

In order to strengthen our team, we are currently looking for an

## Engineer (m/f/d) Quality Management / Regulatory Affairs – In Vitro Diagnostics (limited to 3 years)

### Tasks / Responsibilities:

- Further development and maintenance of our QM system according to EN ISO 13485
- Implementing and managing a post-market surveillance process according to the new IVDR EU 2017/746
- Implementation and further development of risk management according to EN ISO 14971
- Communication with sales partners, authorities and notified bodies about regulatory topics
- Regular trend analysis reporting on product quality and internal key performance indicators to support senior management in taking effective decision for quality improvements
- Assistance in the worldwide approval and registration of in vitro diagnostics (EU and non-EU)
- Participation in the organization and implementation of internal and external audits

### Qualifications:

- University degree with a focus on Life Science or an equivalent combination of education and experience
- Professional experience in regulatory affairs and quality management
- Familiar with international regulations and standards pertaining to medical devices; familiarity with EN ISO 13485, EN ISO 14971 and ability to interpret and work with regulations and standards
- Expertise in risk management processes
- Knowledge of data analysis and statistical techniques
- Very good command of German and English, both verbal and written
- Self-starter attitude, strong organizational skills, flexibility, commitment and ability to meet deadlines
- Goal oriented team player with excellent communication and conflict resolution skills

### We offer:

We are a company that is one of the most important in the industry based on excellent technical expertise, a great reputation in the market and a convincing product portfolio. We have a pleasant working atmosphere and extensive training. You get the chance to take on an interesting task in a friendly team in a growing market. Have we piqued your interest?

### Are you interested?

Please use our **online-application form** (Reference number 2020-9190)!

We are looking forward to you!

**Hain Lifescience GmbH**

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