

Head of Quality Management ID FM091219

The Company

Our customer is a modern, medium-sized company, which specialize in laboratory diagnostics for medical research and practice. They develop and manufacture new tests to identify risks of diseases for differential diagnosis and for therapy monitoring. Their products include immunoassays (eg ELISA, LFA), LC-MS / HPLC applications, genetic diagnostic tests (PCR) and photometric method.

Currently, we are looking for a 'Head of Quality Management (m/f/d)' for location Hessen, Germany.



Responsibilities

- Personal responsibility for 4-5 people
- Preparation, implementation and follow-up of internal and external audits (ISO 13485, MDSAP, KGMP), possibly in English
- Preparation of the annual management review
- Production, review and approval of technical documentation, SOPs, and other quality-related documents
- Planning studies for performance evaluation in cooperation with the departments
- Consulting and training departments in all aspects of quality management. Work closely with management, sales and marketing as well as the development and production

Requirements

- Successfully completed, scientific training or degree in biology, biotechnology, chemistry or pharmacy
- At least 5 years of professional experience in QM, ideally in an in-vitro diagnostic companies and at least 2 years' experience in personnel management

- Experience in the approval of products for self-testing and / or Annex II of the IVD Directive 98/79 / EC
- Practical experience with audits in accordance with ISO 13485: 2016 and MDSAP
- Experience in the certification medical shear software is a plus and in the development, production and quality control of in vitro diagnostic products are beneficial
- Sound knowledge in the application / implementation of the standards EN 62366, ISO 14971 and, ideally, to EN 62304 / EN 82304
- Very good, fluent German and English, spoken and written

What we offer

- A very diverse and cosmopolitan work environment, having staff of various nationalities.
- Excellent company culture which stands for an ambitious but caring working environment.
- Excellent opportunities for professional and personal development.

Become part of a successful company and apply now via ChemRecs for this position!

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Your contact: Faisal Memon

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