Quality Assurance Manager (m/f) for Medical Devices (Pharmaceutical Industry)

We are driven by our mission to make pharmaceutical products of the highest quality affordable for everybody. Among our 400 employees some of the brightest talents in the industry develop, register, produce and market the latest generics.

We are a family-owned business and believe in entrepreneurship and flat hierarchies. That enables us to act quickly on the needs of our global clients as well as to changing market conditions.

With well over 50 years of experience we are a pioneer and leading company in the generics industry. We have a track record of changing industry standards and continuously entering new markets to fuel our growth.

Your expertise and commitment can make a difference to patients all over the world. Join us at our global headquarters in Hamburg (Fulltime 38.5 h/week)

YOUR RESPONSIBILITIES

- Responsibility for the maintenance of the quality management system to be in compliance with all applicable regulations (i.e., ISO 13485, 93/42/EWG, FDA requirements such as QSR 21 CRF820 prospectively)
- Initiative assistance in obtaining a certification according to ISO 13485
- Organizing and accompanying of certification audits
- Assisting in preparation for and conduction of audits
- Communicating with regulatory authorities and appointed office/ notified body
- Implement and follow up on quality system improvement initiatives
- Contribute to our documentation system and to our risk management procedures
- Issue and update reports and evaluations
- Assisting in and maintenance of technical documentations
- Management representative

YOUR SKILLS & QUALIFICATIONS

- Technical engineering or science background (preferably a university degree in medical technology, physics, polymer chemistry, or pharmacy)
- Familiar with ISO 13485 and US FDA Quality System Regulation (21 CFR 820)
- At least 4 years of professional work experience (of which you have spent at least 2 years within the field of quality management for medical products in the pharmaceutical industry)
- Preferably work experience in the area of drug-device combination products
- Thorough knowledge of regulatory requirements for the development and manufacturing of medical products in Europe and the United States
- Demonstrated high technical understanding of the development and production of medical products
- Outstanding work ethic and ability to cope with busy/hectic periods in a calm manner
- Excellent communications skills (in writing and verbally) as well as solution-oriented way of thinking when dealing with business contacts from different cultural backgrounds
- Fluent language skills in English and German

LOOK FORWARD TO

- working for an internationally-established company in the pharmaceutical industry
- the opportunity to implement your own ideas in solving challenging tasks
- our modern offices in the buzzing heart of Hamburg right at the Elbe river
- a competitive salary and benefits package

Send your CV and cover letter, (including your salary expectations and availability) to jobs@aet.eu. We look forward to hearing from you!