

QA Specialist (m/f)

ThromboGenics NV is seeking a Quality Assurance Specialist

ThromboGenics NV has successfully entered the phase III for our most advanced development candidate and offers now a new position as QA Specialist. The person will have co-operation with international Clinical Research Organisation's for GCP and international Contract Manufacturing Organisation's for GMP. The person will also have a co-operation with internal ThromboGenics experts from our Research and Development group, our Pharmaceutical Manufacturing group, as well as Clinical Operational group. The QA Specialist will be part of Global QA team and report to Head of Quality Assurance and Regulatory Affairs Europe in Leuven, Belgium.

Challenges:

- Organise and maintain existing technical agreements for GMP supply of Investigational Medicinal Products and future Commercial Products
- Maintain and develop overview of all existing audits and agreements with external GMP vendors
- Maintain and develop overview of all existing audits in support of external GCP activities at international CRO's and clinical sites
- Participate in internal/external GMP/GCP audits as co-auditor (as necessary)
- QA review of batch documentation, master batch documentation, technical agreements, clinical trial supply plans etc. from GMP vendors
- Support the further development and maintenance of the Global Quality Assurance System

Qualifications:

- A relevant bachelor's degree within life-science
- 3 years experience within quality assurance and cGCP and/or cGMP from pharmaceutical/biotech company.
- Excellent planning, cooperation, and communication skills
- Orientation towards details
- Accountability
- Flair for IT and document management systems
- The successful applicant should be a good team player, have a positive attitude and feel comfortable with a highly innovative environment.

We offer:

- A highly capable, creative and motivated operational team
- Excellent development opportunities and the possibility to participate in shaping the Global QA team
- Competitive salary

Contact information:

Please submit your resume at hr@thrombogenics.com or contact Laurence Raemdonck, HR Manager for further information.

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