

Regulatory Affairs Assistant (m/f)

ThromboGenics NV is seeking a Regulatory Affairs Assistant with experience working with Electronic Document Management Systems

ThromboGenics NV has successfully entered the phase III for our most advanced development candidate and offers now a new position as Regulatory Affairs Assistant. The candidate will have co-operation with external eCTD provider and external consultants. The candidate will also have a co-operation with internal ThromboGenics experts from our non-clinical development group, our Pharmaceutical Manufacturing group, as well as Clinical Operational group. The RA assistant will be part of RA team and daily report to Head of Quality Assurance and Regulatory Affairs Europe in Leuven and overall report to Global Head of Regulatory Affairs in New York.

Challenges:

- Administrative RA support to the practical compilation of Core Common Technical Dossier
- Ad-hoc administrative regulatory support to development of documents like application forms, briefing packages, paediatric investigational plans, various Module 1 documents etc.
- Contact person internally and externally towards provider for newly established internal electronic document management system
- Manage internal queries in newly established internal electronic document management system
- Manage external queries with eCTD provider in the newly established electronic document management system
- Support the organization of meetings, minutes and other RA administrative tasks
- Support the further development of the Global Regulatory Affairs Team

Qualifications:

- A bachelor's degree within chemistry, pharmacy or equivalent by experience
- Minimum 1 year experience with administrative support within regulatory affairs from pharmaceutical/biotech company
- Excellent cooperation skills, sense of details and well structured approach to tasks
- Excellent skills in Office Package (word, excel, powerpoint)
- Experience in (flair for) Electronic Document Management Systems
- High level English writing and oral skills
- The successful applicant should be a good team player, have a positive attitude and feel comfortable with a changing environment and shifting demands.

We offer:

- A highly capable, creative and motivated operational team
- Excellent development opportunities and the possibility to participate in shaping the RA 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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