

Senior CMC Specialist (m/f)

COMPANY BACKGROUND

- ThromboGenics, as an early stage development company, is increasingly expanding its activities towards becoming a leading drug development organisation.
- ThromboGenics is a global biopharmaceutical company aiming to register drugs in the US, Europe or other specific regions.
- ThromboGenics is registered on the stock exchange and requires a transparent and professional organisation with the highest quality standards and with a responsibility towards patients, stockholders, regulatory bodies and its employees.

All these short and long-term objectives demand the highest quality standards across all aspects of the business at ThromboGenics. The successful candidate will need to deliver hands-on expertise in a growing organisation.

ThromboGenics has a strong pipeline of biological drug candidates in ongoing clinical trials. Our lead compound is in pivotal phase III trials. For all programmes manufacture of biological drug candidates is outsourced to third party contract manufacturing organizations.

POSITION PURPOSE

The individual is expected to make an active contribution at a strategic level and in the day to day running of outsourced manufacturing activities to support supply of biological drug candidates in early and late stage clinical trials through to commercialisation. Reporting to the Head of Manufacturing the individual will be required to act as technical expert for aspects of biological manufacturing processes which will include expertise in the writing and reviewing of GMP documentation and Regulatory documentation and in addition may act as manager and key contact for third party contractors.

TASKS:

- Provide specialist and expert manufacturing input into quality and manufacturing documentation to ensure that products are manufactured in accordance with quality and regulatory requirements
- Write and review reports GMP SOP's and regulatory documents such as IMPD's and BLA's on all areas of biological manufacturing processes
- Act as technical expert for areas of manufacturing processes and aid troubleshooting
- Manage external manufacturing contractors as required, continually assessing their performance and identify and address issues as they arise.
- Work with the Head of manufacturing as required in sourcing new contractors and managing existing ones.
- Provide expert input into process development activities, process transfer, scale up and process validation as required.
- Write, assemble and review technical documentation required for regulatory submissions such as INDs and IMPDs

PROFILE:

- Bachelor's degree or PhD in Biochemistry or other relevant discipline.
- Minimum of 10 years of experience in the pharmaceutical industry, or similar business with extensive experience of biological manufacturing processes.
- Good knowledge of all aspects of biological manufacturing processes. Must have expert knowledge of either fermentation, purification or analytical areas
- Experience in writing sections of regulatory submission documents including IMPDs amendments and supplements and experience in writing BLA's and MAA's.
- Good understanding of the drug development process. Sound knowledge of GMP. Experienced in writing GMP's SOP's
- Excellent knowledge and experience of EU and US quality standards and regulations.
- Strong problem solving skills, able to resolve complex problems and identify creative solutions.
- Highly organized with strong project management skills. Excellent communication skills.
- Excellent oral and written skills in English with a focus on accuracy, clarity and attention to detail.

We offer:

- Open and dynamic work environment with the opportunity to further develop your skills
- Competitive salary

Submit resume to:

Laurence Raemdonck

HR Manager

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