Director Regulatory Affairs

Open vacancy: COR2102

Industry sector:	Biotech, Pharmaceutical & Clinical Development
Work location:	Home Office or Braunschweig (Germany)
Function:	Regulatory Affairs
Reports to:	CEO
Financial responsibility:	Regulatory Affairs budget

CORAT Therapeutics GmbH is a clinical phase biopharmaceutical company founded in May 2020. The company is dedicated to developing therapeutic products to fight SARS-CoV-2 mediated COVID-19 disease and help to cure COVID-19 affected people suffering from this disease. The lead product COR-101 is under investigation in the clinical phase Ib/II, currently.
To support the CORAT team within the ongoing COR-101 clinical development program and future marketing authorization applications, CORAT is seeking for a new team member.

Primary objectives & goals

The Director Regulatory Affairs is supporting the company in all aspects of Regulatory Affairs, including CMC, non-clinical and clinical development as well as marketing authorization related activities of therapeutic antibodies within the company's product pipeline. The Director acts as a link between CORAT and regulatory authorities in combination with the CMO/CEO, ensuring that products are developed, manufactured, and distributed in compliance with appropriate legislative requirements.

Scope & Responsibility

- Development of regulatory strategy including CMC; non-clinical and clinical trial strategies as well as marketing authorization applications.
- Represent Regulatory Affairs for the assigned portfolio at management and external stakeholder levels.
- Oversee all Regulatory Affairs programs and projects, guide teams to ensure cross-functional integration, coordination, and alignment.
- Provide leadership guidance and direction in ongoing enhancements/development of core and sub-team processes, structures, systems, tools, and other resources.
- Plan and oversee department budget.

Overall team's responsibility:

- Ensure compliance with regulations, guidelines, and ICH as required by the Health Care Agencies in Europe (EMA) and the US (FDA), and potentially additional regions.
- Prepare and review clinical trial applications (CTA) to both Ethics Committees and Competent Authorities.
- Gather, evaluate, organize, manage, and collate information in a variety of formats, including trial data.
- Maintain familiarity with company products.
- Plan, undertake and oversee product trials and regulatory inspections.
- Keep up to date with changes in regulatory legislation and guidelines.

- Offer advice about company policies, practices, and systems.
- Outline requirements for labelling, storage, and packaging.
- Liaise and negotiate with regulatory authorities.
- Provide advice about regulations to manufacturers and scientists.
- Prepare regulatory filings for marketing authorizations.
- Write comprehensible, user-friendly, clear product information leaflets and labels.
- Ensure that quality standards are met, and submissions meet strict deadlines.
- Prepare any relevant documentation.
- Develop and author SOPs.

Desired Professional & Technical Requirements

Education/Qualifications

- Completed studies in chemistry, physics, biochemistry, biotechnology, pharmacy, medicinal chemistry, biomedical science, life or applied science.

Experience, Skills, Knowledge

- At least 5 years of experience in Regulatory Affairs in a Biopharmaceutical or Biotechnology Development environment.
- Leadership/management experiences.
- Very good knowledge of English written and oral.

What we offer

- A full-time job (40 hrs./week).
- Flexible working hours.
- The possibility to work independently.
- The opportunity to make a significant contribution to fight COVID-19 pandemic.
- Highly enthusiastic team and collegial atmosphere.

Severely disabled applicants will be given preference in case of equal qualification.

Please send us your complete application (cover letter, curriculum vitae, proof of practical qualifications, employer's reference, etc.), incl. the reference number COR2102, as one PDF file by email to jobs@corat-therapeutics.com.

We look forward to receiving your application!