Director Quality Assurance

Open vacancy: COR2103

Industry sector:	Biotech, Pharmaceutical & Clinical Development
Work location:	Home Office or Braunschweig (Germany)
Function:	Quality Assurance
Reports to:	Chief Executive Officer
Financial responsibility:	Quality Assurance 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 program as well as the development of further product candidates, CORAT is seeking for a new team member.

Primary objectives & goals

The Director Quality Assurance (QA) is responsible for all quality related aspects within the company and its related product pipeline to treat infective diseases including SARS-CoV-2 mediated Covid-19. The Director collaborates with other staff and external service providers to establish and maintain procedures and quality standards and to monitor these against agreed targets and in accordance with EMA, FDA, and general ICH GMP, GCP, and GDP regulations in support of regulatory authority audits and submissions.
The Quality Assurance Manager also works to improve an organization's efficiency and profitability by reducing waste.

Scope & Responsibility

- Build up and maintain a quality system.
- Represent QA for the assigned portfolio at management and external stakeholder levels.
- Oversee all QA programs and projects, guide teams to ensure cross-functional integration, coordination, and alignment.
- Build up and lead a QA team.
- Ensure direct reports are actively and appropriately aligning with other teams to ensure timely and on-target results.
- Provide leadership guidance and direction in ongoing enhancements/development of core and sub-team processes, structures, systems, tools, and other resources.

Overall team's responsibility:

- Cooperation in setting up and maintaining the quality system.
- Creation and revision of standard operating procedures (SOPs).
- Verification of compliance with regulatory requirements in internal documents.
- Implementation of regulations into the internal quality system.
- Autonomous monitoring the quality system.
- Close cooperation with all departments and external service providers to ensure quality policy.
- Guidance and management of the company's documentation system.

- Creation, update, review, and approval of documents according to the defined steering activities.
- Creation of deviation reports, evaluation, and monitoring of the implementation of the preventive measures to be carried out.
- Monitoring of change controls and evaluation.
- Assistance in conducting self-inspections, and government audits.
- Vendor qualification and auditing.
- Approval of qualification and validation plans and batch releases.
- Perception of process ownership for the processes in their own area of responsibility:
  - regular checking / updating / improvement of processes,
  - adequate training of affected employees,
  - continuous training with the aim to know the latest requirements and trends,
  - contact person for the affected processes internally and externally (for example also during audits and inspections.

Desired Professional & Technical Requirements

Education/Qualifications

- Completed studies in pharmacy, natural sciences, biotechnology, engineering, or a comparable degree with corresponding professional experience.

Experience, Skills, Knowledge

- At least 5 years of experience in a GMP-regulated environment, i.e. biopharmaceutical production, quality control, or quality assurance.
- Knowledge of biopharmaceutical development stages including production and analytics, non-clinical and clinical development.
- Comprehensive knowledge of regulatory requirements in Europe and USA.
- Leadership/management experiences.
- Very good knowledge of English written and oral.

What we offer

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

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 COR2103, as one PDF file by email to jobs@corat-therapeutics.com.

We look forward to receiving your application!