

Global Quality Manager

We are a pharmaceutical company, and the next generation partner to pharma, biotech, and healthcare. We bring medicines to patients through clinical trial services, early access programs and commercialization of products. We recognize that investing in talented people creates value for our customers, our employees, our suppliers, and the communities in which we live and work. Our success is based on the motivation, dedication, and performance of our people. We strive to go the extra mile and achieve excellence in all our services.

We are hiring for the position of **Global Quality Manager** to be based in our office in Berlin for an immediate start.

You will become part of our global Quality Assurance (QA) Team and you will be working closely with different internal functions to support Inceptua's manufacturing, storage, and distribution activities for medicinal products mainly in EU but also world-wide.

As an experienced professional, you will independently plan, execute, and document all Quality-related activities with focus on efficiency and the required level of detail to ensure the high-quality standards for the world-wide distribution of clinical trial material, commercial products, and unlicensed medicines in early access programs.

You will be able to contribute with innovative ideas to build and improve internal structures in the changing environment of our growing organization.

Responsibilities include, but are not limited to:

- Support the Inceptua Group for manufacturing, storage, and distribution related GxP activities for medicinal products world-wide
- Perform independently supplier, vendor, and customer qualifications in collaboration with other internal Departments
- Perform internal audits (self-inspections) on strategic Quality-related processes and write resulting audit reports
- Perform external audits of Inceptua's partners on company's behalf and write resulting audit reports
- Coordinate, communicate and follow-up on deviation and complaint reports with root cause analysis including corrective and preventive actions (CAPAs)
- Monitor license status of customers and suppliers and ensure qualification status is maintained by performing regular re-qualification activities
- Act as point of contact for internal and external Quality-related questions
- Issue Statements of Authenticity and other QA confirmation letters of supplied products
- Support the development and update of internal SOPs and other regulated documents supporting Inceptua's global Quality Management System

- Contribute to change control management together with the affected Departments and external partners, if required
- Ensure that externally subcontracted Quality-related activities are in line with Inceptua-internal Quality standards and GDP
- Ensure that Quality-related customer complaints are addressed immediately and root cause analysis with corrective and preventive actions (CAPA) are implemented where required
- Qualification of customers, suppliers, vendors, and clients as required

Your profile:

- You hold a university degree in natural sciences (e.g., Biology, Biochemistry, Pharmacy) or Quality Management
- You have a minimum of 5 years' experience in a GMP / GDP environment
- Have experience with Clinical Trial and Early Access programs (preferred)
- You have extensive knowledge in and understanding of GMP, GDP and associated regulations
- You are business fluent in English
- You have a pragmatic Quality mind-set
- You have an overall company view and mindset
- You are a proactive team player

Our company is home to employees from various backgrounds that speak a range of languages. If you have a forward-thinking attitude and are ready to go the extra mile with us, we look forward to receiving your application.

Please send your application in English, including a covering letter, to

recruitment@inceptua.com

Attachments must be in PDF format.