

Global Quality Manager

Inceptua is a specialty pharmaceutical company and a premium global service partner. Inceptua Pharma commercializes and markets orphan and specialty care products and have the expertise and capabilities to supply unlicensed medicines globally. Inceptua Services supports pharma and biotech companies with global clinical trial comparator sourcing, packaging, and labelling solutions, pre-approval and medicines access programs and consulting.

Inceptua partners with life science companies of all sizes, drawing on over 20 years of industry experience, and has global operations with local offices across Europe, North America, and Asia.

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:

- Act as Deputy Responsible Person (Verantwortliche Person für den Großhandel mit Arzneimitteln) of Inceptua GmbH, Germany according to § 52a German Medicinal Products Act (Arzneimittelgesetz, AMG)
- 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
- Develop and conduct internal trainings on Quality-related standard processes
- 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 notifications from National Competent Authorities regarding recalls, support product recalls
- 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

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.