

Global Quality Manager

Inceptua is a global pharmaceutical services company with market-leading capabilities across multiple business areas. We have over 25 years of experience serving life science companies of various sizes and global operations with offices across Europe, North America, and Asia.

We provide clinical trial supply, services and logistics, including comparator sourcing of medicines, packaging, labelling, storage, and distribution services. And we offer strategic advice, design, facilitation, and implementation of global early access programs, and distributes unlicensed and other medicines worldwide.

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 Princeton, US 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 GxP activities for medicinal products world-wide.

As an experienced professional, you will independently plan, execute and document all QA-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.

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 the Inceptua SME and SPOC for DSCSA compliance, including communication with customers and external regulatory bodies
- Responsible for management of the multiple US licences required to support the business, including communication with the US FDA
- Support the Inceptua Group for manufacturing, storage and distribution related GxP activities for medicinal products and medical devices world-wide
- Perform independently supplier, vendor, and customer qualifications in collaboration with other internal departments
- Develop and conduct internal trainings on Quality Assurance-related standard processes
- Perform internal audits (self-inspections) on strategic Quality Assurance-related processes and write resulting audit reports
- Perform external audits of Inceptua's partners on company's behalf and write resulting audit reports
- Coordinate Clinical Services projects / GMP activities and oversee packaging and labelling activities from a Quality Assurance-perspective

- Coordinate, communicate and follow-up on deviation and complaint reports with root cause analysis including corrective and preventive actions (CAPAs)
- Process change controls and provide Quality Assurance-guidance and input as required
- Perform qualification of healthcare professionals, pharmacies, and clinical trial sites to receive medicinal products in multiple global geographies
- Act as point of contact for internal and external Quality Assurance-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 proven 5 years' experience in US FDA 21 CFR & EU Good Distribution Practices (GDP) environment, ideally in a multinational environment
- You have a significant experience with the Drug Supply Chain Security Act
- You are able to function independently, showing attention to detail
- You have a **pragmatic** Quality mind-set, and show tenacity in finding compliant solutions from complex data.
- You are able to build constructive and effective relationships with multiple internal stakeholders in an multi-cultural environment

Compensation and benefits:

- Base Salary: \$115,000 – \$125,000 and eligibility to a discretionary bonus
- Comprehensive benefits package including 401(k) with match, dental, health, and vision insurance, and paid time off.

This is a full-time position with a hybrid work schedule, three days per week in the office, and the flexibility to work remotely for two days. Our company values diversity and is proud to be home to a multicultural team, with employees from a wide range of backgrounds and languages.

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

recruitment@inceptua.com

Attachments must be in PDF format.