

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 Windsor, UK 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 mainly in EU but also 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:

- Have a clear understanding of the legislative, regulatory, and logistical aspects of importing licensed and unlicensed medicines into the EU and the UK
- Contribute to consultancy projects and client meetings when required and support the development of the Early Access programs
- Conduct general day-to-day QA tasks and process QA activities such as training programs, deviations and complaints handling, and change controls
- Prepare and conduct internal audits (self-inspections) to monitor and ensure compliance with GxP and internal QA standards
- Qualify vendors and customers according to GxP requirements and ensure qualification status is maintained by performing regular re-qualification measures
- Assist in preparation of license variations in the UK and MHRA inspections
- Oversee packaging and labelling activities from a QA perspective
- Review and develop SOPs (existing and new ones where required) and assist in maintaining and improving the global Quality Management System

- Support the review of Quality Technical Agreements as needed

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 GxP environment, and preferably an experience with Early Access programs
- You have extensive knowledge in and understanding of GxP and associated regulations, especially importation within the European and UK area
- You are business fluent in English
- You have a **pragmatic** Quality mind-set and are a proactive team player with a solution-oriented mindset
- You are able to work in an international and multi-cultural setting with tight deadlines
- You are able to communicate effectively, and with sensitivity to a wide range of people including externally to both vendors and clients

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.