

## 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 25 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 / Responsible Person** to be based in our office in Windsor 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:**

- Perform duties of Responsible Person and Responsible Person (import) for UK
- Management of QA personnel
- Perform duties as responsible for Quality Control (Manufacturers 'Specials' Licence)
- Develop a clear understanding of the legislative and regulatory aspects of importing and exporting medicines
- Support the NOI process for compliant import of unlicensed medicines into the UK
- Contribute to consultancy projects and client meetings when required
- Support the development of the Early Access programs

- Interpret and guide on the logistical aspects of country regulations relating to importing and exporting medicinal products and medical devices
- Support with general day to day quality questions
- Qualification of customers, suppliers, vendors and clients
- Monitor license status of customers and clients and ensure qualification status is maintained by performing regular re-qualification measures
- Review and develop SOPs (existing and new ones where required)
- Support the review of quality agreements as needed
- Assist in preparation and submission of license applications and variations in the UK
- Process change controls and deviations and provide quality guidance and input as required
- Oversee packaging and labelling activities from a quality perspective
- Execute the responsibilities according to lawful and ethical standards
- Suggestions for improvement that benefit the Inceptua Group
- Accomplish individual goals as per requirements determined by the Head of Quality

**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.