

Project Coordinator/Manager

Inceptua is a specialty pharmaceutical company and a premium global service partner. Inceptua Pharma commercializes and markets orphan and specialty care products and has 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 a **Project Coordinator/Manager** to be based in our **Berlin (Germany)** offices for immediate start. You will be reporting to the Senior Project Manager and will become part of our growing Global Operations Team. You will work closely with internal and external stakeholders of different business units and departments.

Responsibilities include, but are not limited to:

- Comply with Global Standard Operating Procedures related to order execution
- Initiate, plan, manage and close out all aspects of Clinical Trial Services projects
- Responsible for the close communication and continuous proactive updating of project progress within the team as well as with sponsors, external vendors and clients
- Responsible for creating costs estimates according to the project specific supply strategy in consideration of legal requirements and cost efficiency and the subsequent purchasing of services, medicinal products and materials related to manufacturing and distribution activities for clinical trials
- Responsible for the consolidation, handling and tracking of the project budget, cost control of all related activities as well as controlling of incoming invoices and issuing of invoices to clients
- Responsible for the creation of manufacturing documents and label texts as well as other project specific documents and the respective order filing
- Responsible for maintaining company Standard Operating Procedures (SOP's) relevant for the QMS and GxP regulatory requirements
- Understanding of client needs with regards to all aspects of the distribution and manufacturing activities of nIMP/IMP/medical devices

- Serve as a source of expertise both internally and externally with regards all aspects of the regulations and requirements surrounding the handling of nIMP/IMP/medical devices
- Commitment to Quality

Your profile:

- Able to work in an international setting
- University graduate with minimum 2 years work experience in labeling and secondary packaging
- Experienced in working closely with QA to identify, address and resolve any quality issues, assisting in the conducting of any investigations / implementing of CAPAs where necessary
- Experienced in SOP creation/updating and working with outsourced processes run by vendors
- Extensive knowledge of pricing structures relating to clinical services activities, including but not limited to:
 - audit costs
 - handling / project set-up fees
 - import and QP release of IMP/nIMP/medicinal products
 - receipt and quality control
 - clinical manufacturing runs (re-packing, labelling, blinding etc.)
 - shipping
 - storage of IMP/nIMP/retention samples
 - destruction of IMP/nIMP/retention samples
 - costs associated with adherence to FMD
- Profound knowledge of regulations relating to GMP/GDP as well as the AMG
- Good relationship with peers, ability to manage time and stress, excellent self and interpersonal motivational skills, project management ability, proven problem solving and decision-making abilities
- Able to communicate effectively, and with sensitivity to a wide range of people including externally to both vendors and clients
- Able to maintain a positive, results orientated work environment, building and improving upon existing partnerships and demonstrate great teamwork, communicating to the team in an open, balanced and objective manner
- Meticulous attention to detail and computer literacy (MS Word, Excel, Power Point and Outlook).
- Able to influence and negotiate with vendors
- Able to work under pressure
- Fluent in English, both written and oral (fluency in German is an advantage)



This position is full-time, and we offer a competitive salary. We also offer a generous employee benefit package including attractive, central office locations, training courses, and a range of employee well-being perks.

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, including a covering letter, to

recruitment@inceptua.com

(Attachments must be in PDF format)