InflaRx is a NASDAQ listed biotechnology company with offices in Jena and Munich, Germany. We research and develop new medicines for the treatment of inflammatory diseases within a global development approach. We stand out for an excellent team of highly motivated and skilled individuals who put strong emphasis on a team effort.

In order to support our quality assurance team we are looking for a

Qualified Person (m/f/d)

to join our team at the earliest possible date. The position is located in Jena.

Main responsibilities:

- Ensure that the (investigational) medicinal products have been manufactured and checked in accordance with applicable laws and in accordance with EU-Good Manufacturing Practice (GMP) principles and guidelines
- Evaluation, confirmation and certification of batches on the basis of GMP compliant manufacture and testing according to the EU GMP guidelines, Annex 16
- Act/perform the tasks of a Qualified Person (QP) in accordance with Annex 16 of the EU GMP Guidelines and the Code of Practice for Qualified Persons for products manufactured or packaged by contracted manufacturing organizations
- Review of batch records and disposition of batches as a QP under EU Directive 2001/83/EC and comply with all the applicable GMPs, national legislation and requirements of the relevant Quality Agreement
- Monitoring the compliance with pharmaceutical regulations
- Evaluation of deviations and changes
- Review and approval of Quality Assurance Agreements
- Support, develop and maintain the Quality Management System (QMS), and drive continuous improvement within the QMS
- Perform internal audit/self-inspections
- Perform vendor selection, maintenance & for cause audits (contract manufacturers, testing facilities, raw material suppliers, etc.)
- Primary resource for pharmaceutical product release, ensures batches meet manufacturing authorization requirements and fulfil requirements in Quality and/or Technical agreements as applicable
- Assist in the drafting and approval of master batch manufacturing records
- Review and approve SOPs, validation protocols, change requests, annual Product Quality Reviews and Planned Process Variations in accordance with company procedures and guidelines
- Provide support in the preparation and hosting of regulatory inspections

Education/Experience/Skills:

- Degree in pharmacy with license to practice as a pharmacist or equivalent

- Qualification/legibility to perform the duties as QP in accordance with §15 AMG
- Three or more years' experience performing the duties of a QP with expertise (practical experience) in the release of multiple licensed and unlicensed dosage forms (biologics and sterile product manufacture and supply)
- Thorough understanding of US, EU and local regulatory requirements governing the duties/role of a QP, sterile (biological) product manufacture, testing and release
- Previous experience in implementation of quality management systems and processes supporting the development of large molecule biologics
- Thorough understanding of national and international laws, regulations and guidelines regarding GMP
- Good understanding of the EU Clinical Trial Directive
- Several years of professional experience in a GMP-regulated environment
- Lead Auditor with expertise in IT systems audits, excipient/raw material suppliers, Contract Manufacturing Organizations, Contract Distribution and Manufacturing Organizations and wholesale dealers/equivalent organizations
- Fluent in written and verbal English and German
- Excellent organization and communication skills
- Assertive and team-oriented personality
- Highly motivated, self-driven and dependable
- Champions a top down quality culture within the business

We offer:

- An open-ended employment contract with 30 days leave per year
- Attractive remuneration and above-average employer participation in the company pension scheme
- You work in an ambitious company with a highly motivated team

We offer you a challenging and varied opportunity with an innovative, dynamic and expanding company. InflaRx strives to be a company that is recognized by its employees as best place to work for in the industry. We want to accomplish this by working with passion and professionalism. We pride ourselves in maintaining a friendly, honest and trusting relationship with each other.

If you think you fit the profile, we look forward to receiving your application in English, including CV, motivation letter and salary expectation at the following e-mail address:

InflaRx GmbH

Winzerlaer Str. 2

07745 Jena - Germany

+49 3641 508 180

contact:

Katrin Reiher

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Human Resources Department:

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