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.

To support our Quality Assurance Team we are looking for a

Quality Assurance Manager GCP (m/f/d)

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

Main tasks and responsibilities:

- Plan, prepare and conduct (external) audits (investigator sites, vendors, processes, systems, documents etc.);
- Plan, prepare and conduct internal (GCP) audits;
- Write audit reports and communicate findings and recommendations and evaluate the adequacy and completeness of corrective and preventive action plans;
- Ensure the timely and effective follow up of all identified or assigned quality issues;
- Conduct QA review of study protocols, ICFs, CSRs and other clinical trial specific documents as requested;
- Provide help, advice and guidance to operational departments on matters of quality/GCP;
- Coordinate, conduct and track GCP training of new and existing staff;
- Create, maintain and revise departmental Quality Documents (SOPs, WIs, Forms etc.);
- Management of Quality Documents according to the respective written procedures;
- Provide support/participate in authority inspections;
- Maintain required knowledge of applicable regulations, guidelines and company standards and procedures;

Education/Experience/Skills:

- Academic degree in a scientific, medical or related field;
- Minimum of 3+ years' current work experience in biotech/pharmaceutical industry Quality Assurance;
- Demonstrated Quality Management System experience (GCP specific QMS experience preferred);
- Profound knowledge of current GCP regulations and best practices, as well as experience in FDA and EMA inspections;
- Experience with global late-stage clinical trials leading to market authorization;
- Demonstrated Issue Management and CAPA experience in a clinical environment;
- Experience with FDA or other Regulatory Inspections of Investigator sites, Sponsors or CROs;
- Excellent written/oral communication skills in English and German and interpersonal skills;
- Attention to detail with an ability to detect and correct errors/inconsistencies in various types of documents;
- Self-starter and team-player;
- Knowledge in Microsoft Office applications, Adobe;
- Experienced in working with EDC, IRT, eTMF, EMR systems;
- Willingness to travel (national and international).

We offer:

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 on through medical innovation. 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: personal@inflarx.de.

Contact:

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Human Resources
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