

InflaRx is a biotechnology company with Clinical Research offices in Jena and Planegg, 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 expanding CRD team we are looking for two

### **Senior Clinical Trial Manager (m/f)**

We are seeking a highly motivated individual to join the Clinical Operations group. The Senior Clinical Trial Manager leads the cross-functional study execution team, is accountable for managing the full scope of clinical trial(s), coordinates vendor efforts and ensures the clinical trials are initiated efficiently and completed on time, within budget and in compliance with SOPs, regulations, and ICH/GCP guidelines in accordance with the Clinical Development Plan (CDP).

She/he reports to the Head Clinical Operations. The position is located in Jena or Munich.

#### **Primary Responsibilities:**

- Lead cross-functional teams and supervise vendors to ensure clinical trials are executed on time
- Provide operational expertise to meet scientific objectives of the clinical studies
- Partner closely with clinical development functions to design and write clinical trial protocols
- Independently draft, review and implement study management plans and vendor oversight plans; ensure CROs and other vendors adhere to study plans
- Provide direction and oversight of CROs and vendors to ensure delivery against scope of work; manage vendors by key performance indicators
- Lead the identification and selection of study CROs and vendors, including negotiation of scope of work and budgets
- Conduct study feasibility assessments; partnering with team and program lead on final country and site selection
- Plan and execute investigator meetings and train vendors/ internal staff on study protocol and processes
- Work with external partners to ensure that clinical data from a variety of sources is appropriately captured and of high quality
- Participate in the ongoing and final review of study data and assessment of the impact of the data to the clinical development program
- Proactively identify and mitigate study-specific risks; effectively communicate study status, risks, and changes that may impact quality, timelines, and cost to internal and external stakeholders
- Manage study budget; identify and communicate variances
- Participate in and lead department process improvement initiatives and system implementation
- Review and provide input on cross functional SOPs, working practices and assist in the creation and improvement of department infrastructure as directed
- Support preparation for Regulatory inspections

#### **Education/Experience/Skills:**

- Advanced scientific degree (MS/MSc/PhD) in life sciences or related discipline
- 5+ years of experience in clinical development in the biotech, pharma or CRO industry
- Experience in immunology or related therapeutic area
- Proven ability to successfully plan, implement, and manage global clinical trials
- Ability to manage cross functional clinical study teams to high performance
- Proven ability to effectively manage and negotiate with CROs and clinical study vendors
- Strategic thinking and project management skills
- Agility and flexibility
- Strong working knowledge of FDA, EMA & ICH/GCP regulations and guidelines
- Highly effective verbal and written communication and presentation skills in English
- Ability to travel (up to 20%)

**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 thru medical innovation. We pride ourselves in maintaining a friendly, honest and trusting relationship with each other. We look forward to receiving your application by e-mail.

InflaRx GmbH  
Winzerlaer Str. 2  
07745 Jena  
+49 3641 508180

**contact:**

**Human Resources Department:**

Heidrun Schwalbe  
[personal@inflarx.de](mailto:personal@inflarx.de)