

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 manufacturing activities we are looking for a motivated and enthusiastic

Chemistry, Manufacturing and Control (CMC) - Manager (m/f/d)

to join our team at the earliest possible date. As CMC Manager you will report to the Head of R&D. The position is located in Jena.

The position is limited on the basis of Section 21 of the Federal Parental Benefit and Parental Leave Act (maternity and parental leave).

Main responsibilities

- Manage Contract Manufacturing Organizations (CMOs) for process optimization, cGMP manufacture, analytical testing and supply of drug substance (API) and drug product (DP) in support of ongoing and future clinical programs
- Develop and implement strategies for optimizing and controlling quality of bulk API and DP in collaboration with Contract Research Organizations (CROs) and CMOs
- Ensure robust, scalable and cost-effective manufacturing routes and DP formulations that meet and exceed the target product profile
- In coordination with Quality Assurance, implement stage-appropriate analytical methods and protocols and ensure that all CROs and CMOs are using systems and processes in compliance with all relevant regulatory standards
- Execute plans for the validation and registration of API and DP as required by cGMP, ICH (International Conference of Harmonization) and FDA/EMA regulations
- Write, review and approve documents for INDs/IMPDs/regulatory section submissions; represent the company as the CMC expert before regulatory authorities
- Prepare, review or edit cGMP batch records, CMC regulatory and Quality documents
- Prepare technical reports, publications and oral presentations

Requirements

- Minimum of 3 years of experience in pharmaceutical industry with emphasis on manufacturing operations, process design and process validation
- Deep understanding of biological manufacturing processes and all CMC requirements of biologics including analytical methods is essential
- Demonstrated experience with cGMP manufacturing and IND, CTA and NDA filings; thorough knowledge of relevant FDA and EMA regulations
- Experience in project management preferred
- Excellent ability to communicate
- Open and friendly manner and a good team-player
- Very good German and English knowledge, both written and spoken
- Ability to work in a multicultural environment
- International travel

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. 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:

Dr. Maria Habel
Head of Research & Development
personal@inflarx.de

Human Resources Department:

Heidrun Schwalbe
personal@inflarx.de