Immunic AG is a Nasdaq-listed, value-driven and dynamic biotechnology company with a pipeline of selective oral immunology therapies located in Gräfelfing (near Munich). We are developing new therapies with best-in-class potential for the treatment of chronic inflammatory and autoimmune diseases.

Currently, we have three small molecule products in different stages of clinical development- For further information, please visit www.imux.com.

Immunic is an exciting place for innovative ideas – apply now and become part of our team!

We are looking for a

CMC Project Manager (m/f/x)

for an unlimited full-time position in Gräfelfing/Munich

In particular, you would

- Be responsible for the seamless execution of CMC project/program deliverables ranging from preclinical development through to clinical Phase III studies
- Have regular engagement with key stakeholders to proactively drive ongoing project success
- Identify, analyse, and manage project risks, opportunities, issues and dependencies of a project
- Provide drug development expertise as part of cross-functional project teams
- Deliver robust, scalable and cost-effective drug substance and drug product manufacturing processes
- Design and develop formulations that meet or exceed the target clinical profile
- Implement stage appropriate analytical methods and planning stability studies
- Plan and execute manufacturing process validation activities to meet regulatory guidelines
- Review and edit quality documents related to the GMP production of drug substance and drug product. As such you would act as a QA representative for specific production campaigns (e.g., review of the master and executed batch records, specifications, Certificates of Analysis and Conformance)
- Review CMC documentation and sections that form part of regulatory submission packages including IBs, IMPDs and INDs.
- Support the Head of CMC in the identification, selection and management of Contract Development and Manufacturing Organizations (C(D)MOs) for process development, optimization, manufacture and supply of drug substance and/or drug product in support of ongoing clinical programs
- Ensure that all partner C(D)MO systems and processes are in compliance with relevant regulatory and GMP standards
- Engage in C(D)MO audits.
- Have involvement in budgetry dicsussions at CMC project level
- Cooperate with our partner lines to plan future drug supply needs for preclinical and clinical programs in compliance with the associated budgets and timelines

Here is how to convince us:

- You have a PhD or MS with 5+ years of experience; alternatively, an advanced degree in Pharmaceutical Chemistry, Organic Chemistry, Pharmaceutics, Pharmaceutical Science, or related scientific discipline
- You have experience in the pharmaceutical development work related to drug substance and/or drug product, in particular oral solid dosage forms
- You have good hands-on of Quality by Design and Risk Management concepts applied to the development of NCEs
- Experience with projects in clinical development e.g. Phase 1 through Phase 3
- Excellent written and verbal communication skills in English, exceptional interpersonal and management skills to collaborate with external and internal partners on assigned projects
- You enjoy working as part of a small team in a dynamic work environment
- You are open-minded and strive to find the best solutions in a team environment
- You are able to self-structure your work and drive processes, have good project management skills, and are willing to take responsibility and make decisions
- You able to work on your own initiative but have a strong team spirit and the ability to network
- You are happy to work in a flat hierarchy environment and have a hands-on mentality

What you can expect:

- High level of decision-making scope and a flexible working environment
- A full-time position in an international, highly motivated team dedicated to our company values.
- A fair salary according to your experience and expertise
- Participation in the success of our company and involvement in project decision making
- A highly motivated team where you can rely on your colleagues
- An innovative company that is constantly growing and moving
- Cross-functional work experience as well as flat hierarchies
- An attractive office with parking space and public transport connections to Munich city center
- State-of-the-art IT support, incl. own MacBook and iPhone

For more information about Immunic please have a look at our website www.imux.com.

Do you feel addressed? Then please send your meaningful application specifying your salary expectations as well as the earliest possible starting date by email to jobs@imux.com.