

This function “Preclinical Consultant - Senior” covers all non-clinical topics from early development, i.e. concerning transition from research to development including nonclinical requirements for FIM studies, selection of and collaboration with CROs for conduct of non-clinical studies, and non-clinical requirements including dossier preparation for MAA or BLA/NDA filing.

Tasks & Responsibilities:

- Provide advice to clients on non-clinical aspects of drug development and regulatory requirements in collaboration with CMC and clinical experts in the Granzer team
- Ensure that the content of non-clinical documents is appropriate, meets regulatory expectations and enables approval of regulatory submissions
- Prepare non-clinical development plan
- Perform gap analyses of development packages provided by clients
- Support due diligence processes
- Support clients in meetings with regulatory agencies and moderate such meetings
- Prepare IBs for CTA
- Prepare responses to deficiency letters in collaboration with CMC and clinical experts in the Granzer team
- Prepare briefing packages for meetings with regulatory agencies (national regulatory agencies, EMA and FDA)
- Continuously check scientific and regulatory guidance

Requirements:

- Degree in medicine/veterinary medicine, pharmacy or biology/biochemistry/chemistry
- More than ten years of experience in the pharmaceutical industry in a position in research, non-clinical development or regulatory affairs
- Knowledge of in non-clinical and regulatory requirements for all stages of drug development
- Experience in the preparation of regulatory documentation related to CTA, MAA, IND, BLA/NDA
- Excellent communication and negotiation skills in English
- Highly motivated team player with strong interpersonal abilities
- Sound knowledge of Microsoft Office applications
- Willingness to travel moderately (meetings with clients, regulatory agencies or CROs)

We offer:

A professional and friendly working environment located in Munich. Working together with a dedicated small and effective team, we provide an outstanding and more than competitive salary, with a very attractive bonus system tailored to your expertise and our business success.

Contact:

If you are interested in working in an innovative and team-oriented environment, please send your application documents to Dr. Stefan Blesse, blesse@granzer.biz .

Granzer Regulatory Consulting & Services
Kistlerhofstrasse 172 C
81379 München
Germany
www.granzer.biz