

The "Consultant CMC" is the quality expert in the Granzer team, providing knowledge on broad range of drug substances (from small molecules to synthetic oligonucleotides to biologicals) and drug products (from solid orals to sterile solutions to nanoparticulate formulations). This function will cover all quality related topics from pre-clinical development to approved commercial products.

Tasks & Responsibilities:

- Provide advice to clients on quality aspects of drug development and regulatory requirements, in close collaboration with cross-functional experts from the team
- Ensure that the content of CMC work-packages and documentation are phase appropriate, meet regulatory expectations and enable approval of regulatory submissions
- Preparation of quality sections for MAA and BLA/NDA as well as for IMPD and IND
- Perform gap analyses of client-provided packages. Identify critical CMC development issues and develop strategies for their resolution
- Support due diligence processes
- Prepare briefing packages for agency meetings (e.g. scientific advice, oral explanation, EoP2) and conduct such meetings together with the client
- Management of operational and strategical aspects with CDMOs
- Coordination of filing activities within the cross-functional Granzer team and with contributing parties
- Continued observance of regulatory guidance and regulations

Requirements:

- Ph.D. or master's degree in Pharmacy, Chemistry, Biopharmaceuticals, Biochemistry, Biology or comparable
- At least five years in a scientific/technical CMC development or regulatory affairs function
- Experience with regulatory filings (IND/IMPD, BLA/NDA/MAA)
- Excellent communication and negotiation skills in English. German language skills are a plus
- Experience with CMC and regulatory requirements for all development stages, from pre-clinical to Phase III or commercial
- Highly motivated team player with strong interpersonal abilities
- Sound knowledge of Microsoft Office applications
- Willingness to travel moderately (Meetings with clients, agencies or CMOs)

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 .

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