The Consultant "CMC Technical Writer" supports the quality experts in the Granzer team by writing core quality sections for chemical, biological, cell-based and gene therapy products that are presented in various dosage forms.

Tasks & Responsibilities:

- Review of GMP source documents such as batch records or validation reports
- Authoring and review and of high-quality reports, such as comparability reports
- Authoring and review of documents for CTD Modules 1, 2.3 and 3 for IMPDs/INDs and MAAs/BLAs/NDAs
- Authoring of documentation to support regulatory agency meetings in the US and EU (briefing books, presentations)

Requirements

- Ph.D. or master's degree in Pharmacy, Chemistry, Biochemistry, Biology, Biotechnology or comparable
- At least 3 years' experience in technical CMC writing, thereof at least 2 years' authoring experience for INDs, IMPDs, BLAs, NDAs or MAAs
- Knowledge of technical/regulatory requirements for at least one of the product classes listed above
- Excellent writing and communication skills in English. German language skills are a plus
- Sound knowledge of Microsoft Office applications

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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