This position "Preclinical Writer" covers all pre-clinical writing activities across all phases of development for small molecules, biologicals, cell based and modern targeted/personalized therapies. Experience in any of these areas is a prerequisite.

Tasks & Responsibilities:

- Authoring high-quality preclinical regulatory documents
- CTD summary documents (2.6) and overviews (2.4) and IBs (preclin)
- Compilation of any preclinical documentation required for approval and conduct of clinical studies
- Preclinical documentation to support agency meetings (briefing books, presentations)

Requirements:

- Advanced degree in life sciences, medicine or veterinary medicine
- Broad experience in preclinical development and potentially medical writing (>5 years) on wide range of regulatory documents
- Understanding of FDA and ICH regulations and guidelines
- Ability to work independent, analyse and summarise data
- Ability to manage multiple tasks simultaneously under time constraints
- Excellent communication skills in English and a second language, preferably German
- Strong knowledge of Microsoft Office and graphical software

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