This position "Project Manager" covers project management of regulatory activities from early development, i.e. pre-clinical scientific advice to Project Management of dossier preparation for MAA or BLA/NDA filing.

Tasks & Responsibilities:

- Manage EU and FDA Marketing Authorisation Application procedures including:
  - preparation of Module 1 documents
  - assignment and management of team resources
  - co-ordination of Mod 2 & 3
  - tracking Modules 4 & 5
  - preparation and track project plans
  - interaction with Regulatory Agencies on behalf of clients before, during and after approval
  - management the MAA procedure on behalf of clients
- Provide regulatory advice to clients
- Prepare and manage project plans
- Request Scientific Advice meetings on behalf of clients including preparation of supportive documentation

Requirements:

- Master of PhD. in life sciences, medicine or veterinary medicine
- At least 5 years Project Management and Regulatory Affairs experience, understanding of FDA and ICH regulations and guidelines
- Competent with Project Management tools and software
- Excellent communication skills, strategic thinker, solution orientated
- Ability to work independently and manage multiple tasks simultaneously under time constraints. Flexible with excellent prioritisation skills

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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