Job Title	Senior Medical Expert (m/f/d)
Position Type	Full time (preferable)

Job Description

Who are we?

Dr. Regenold GmbH specialises in clinical & pharmaceutical development, regulatory affairs and market access. Since being founded by Jürgen Regenold in 1994, we have provided scientific and regulatory advice to a large number of clients, helping them to progress their product developments through to regulatory approval and marketing authorisation both nationally and internationally. In 2001 we founded regulanet®, a network of independent regulatory companies and consultancies with representation in over 90 countries worldwide.

In order to service the increasing importance of medical devices, Dr. Regenold GmbH has an associate company, CE plus GmbH, which specialises in international regulatory affairs for medical devices and in vitro diagnostics including combination products, companion diagnostics and medical apps.

Dr. Regenold GmbH is based in south west Germany near Basel, Switzerland. We have a personalised approach to business and our clients, preferring to conduct our business through recommendation, referrals and repeat business. Our team members hail from several different countries, which makes our company a lively and diverse place to work.

What we offer:

As a Senior Medical Expert (m/f/d) within our Medical & Preclinical Team, you will have the opportunity to work on a wide variety of different projects. Typical tasks will include:

- Regulatory evaluations and clinical gap analyses for novel medicinal products
- Medical input into regulatory strategy and feasibility assessments
- Clinical development planning including design and planning of studies
- Preparation for and implementation of scientific advice procedures at EU and non-EU regulatory authorities
- Clinical trial oversight
- Medical monitor for drug safety in clinical trials
- Evaluation and interpretation of clinical study results
- Clinical input to and/or authoring and compilation of clinical documentation, including
  - Common Technical Dossier (CTD) for medicinal products
  - Risk Management Plans, Risk Assessments
  - OTC Switch Reports
  - Orphan drug applications
  - Paediatric investigational plans
- Structured literature searches for expert reports or clinical documentation
- Response to clinical deficiency letters as part of the drug approvals process
- Due diligence for in-licensing

Skills/Qualifications:

- Medical doctor, preferably with higher qualification (e.g. PhD)
- Several years of experience in clinical development and/or clinical trials
- Used to working in a regulated environment, especially knowledge of GCP and other relevant regulations/guidelines
- Excellent written and oral communication skills in English, proficiency in German is advantageous

Are you interested?

If you possess above mentioned skills please send your application including cover letter, curriculum vitae and references to our human resources team at **perspectives@regenold.com**