| Job Description | |
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| **Job Title** | **Pharmacovigilance Expert** |
| **Position Type** | **Part time / Full time** |

## Who are we?

We are an ambitious, independent service provider in pharmaceutical development, international regulatory affairs and drug licensing in Badenweiler, located in Southern Germany between Basel and Freiburg. Our clients are pharmaceutical and biopharmaceutical companies of all sizes from Europe and abroad. Our company is highly committed to the success of our clients, and works to highest quality standards. To strengthen our Medical Team further, we are now searching for an experienced medical writer.

We look for a PV professional with relevant experience in pharmacovigilance to support our PV Team with PV services. Ideally, this function can also act as QPPV/Stufenplanbeauftragter and strengthen our expertise and capacity in this field.

The *Qualified Person Responsible for Pharmacovigilance (QP*PV) is an EU mandated business critical regulatory and safety governance role with broad responsibilities as defined by European legislation. The EU-QPPV is involved in routine tasks and leads targeted investigations and initiatives to enhance the PV system.

The *Stufenplanbeauftragter* is the legal function as per German Drug Law to act as contact to the Federal Institute for Drugs and Medical Devices (BfArM) and fulfill all obligations as set in the AMG and AMWHV.

The position is available immediately and due to our structure as PV Team possible as part-time position.

## The main responsibilities of this position:

- Liaising with our clients to provide best possible PV service, either on a local German or on an EU level for a given scenario. This also includes routine PV tasks.
- Establishment and/or maintenance of our clients pharmacovigilance system in terms of having an oversight over the functioning of the system in all relevant aspects, including its quality system
- Acting as a single pharmacovigilance contact point for the competent authorities and the EMA in the function of the EU QPPV/Stufenplanbeauftragter
- Risk assessment expertise
- Providing input into the preparation of regulatory action in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals)

**Qualifications/Experience/Competencies:**

- Biologist, Medical Doctor, Pharmacist or other life scientist
- Experience in Pharmacovigilance on a local German and EU level
- Knowledge of EU Pharmacovigilance legislation and preferably experience with data submission to EudraVigilance
- Willingness to liaise with clients for various levels of PV consultancy
- High ethical standards as well as personal credibility
- Able to work effectively and collaboratively across the PV Team
- Has the expertise, determination and courage to resolve or escalate issues as appropriate
- Good German language skills are necessary, English language skills fluid in speaking and writing

**Are you interested?**

Please send your application to: pers@regenold.com or call us on tel:
+49 7632 82 26-0