

“ARAC“ AT REGULATORY AFFAIRS CONSULTING GMBH is a leading consulting company in Austria for Regulatory Affairs, Pharmacovigilance and Pricing & Reimbursement (Market Access).

To support our team in the increasing demand in pharmacovigilance we seek support in this area and we offer the following position:

Pharmacovigilance Manager

Goals

- Support of pharmaceutical companies in all matters regarding pharmacovigilance.

Key Tasks

- Contact maintenance with authorities
- Interface/Contact partner between client (pharmaceutical company) and authorities

Pharmacovigilance

All aspects of pre- and post-marketing pharmacovigilance including

- MedDRA-Coding
- Data Entry/QC/Medical Review (AB Cube PV Database)
- Conducting of pharmacovigilance audits
- Eudravigilance Database Registration
- Conducting PV Trainings

GVP

- Local Safety Officer for Clients or deputy Local Safety Officer
- PSMF (authoring/maintenance)
- PSUR (authoring/reviewing)
- RMP (authoring/reviewing)
- ICSR Processing/Case Management/Reporting
- Signal and Risk Management
- (eventually EU-QPPV or dEU-QPPV for clients)

GCP

- RPEV or dRPEV for clients
- SMP (authoring/maintenance)
- DSUR (authoring/reviewing)
- SAE/AE Processing/Case Management
- SUSAR Reporting
- (Medical Assessment of Cases)

Additional

- Basic understanding of regulatory affairs (interface management)

Measurement criteria

- Timeliness (towards authorities, clients, etc.)
- High quality of regulatory and pharmacovigilance activities
- Legal compliance of regulatory and pharmacovigilance activities
- Professional archiving (in paper and electronically) and management of documentation

Your qualification

- Experience in pharmacovigilance
- independent and structured way of working
- High flexibility
- High level of accuracy
- Application-related IT-Knowledge (MS Office, Adobe Acrobat, electronic archiving)
- Team oriented and social skills

If you feel that this challenging and responsible job would be of interest for you and if you bring the required qualification and would like to cooperate with a committed and familiar team, then we appreciate your application.

Please contact:

Dr. Ingrid Huber-Strubl, General Manager

huber@aracgmbh.com

Tel. 01 524 05 89

Mobile: 0676 844771100