Our pharmacovigilance offers you safety!

The HWI group is a family-owned, independent service provider. For more than 30 years HWI has been recognized as a reliable and innovative partner for the international pharma and biotech industry. We offer a broad range of technological and analytical solutions for the development, manufacturing and testing of medicinal products. When it comes to Pharmacovigilance HWI is one of the first outsourcing partners in Germany, since the introduction of the EU-Pharmacovigilance Systems, supporting and advising its customers with the implementation of these regulations.

That's what makes us special!

1. Customised solutions for your pharmacovigilance requirements
2. Experienced and interdisciplinary team
3. Support for 350 products with 250 active substances
4. We work with AI-supported app's

Our support for pharmacovigilance tasks:

- Literature research
- Evaluation and timely submission of adverse drug reaction reports (incl. follow-up)
- Maintenance of your company-specific safety database
- Periodic reports (PSURs/PBRERs) and addendum to the clinical overview
- Risk-management plans (RMPs), signal management and continuous safety evaluation
- Extended EudraVigilance product report message/ medicinal product dictionary (XEVPRM/XEVMPD)

Our Support for your pharmacovigilance system:

- Consulting and support during set-up, the further development and review of your pharmacovigilance systems
- Creation and maintenance of your pharmacovigilance system master file (PSMF) and of SOPs
- Conducting audits
- Training as well as preparation and follow-up of inspections
- Taking on the functions of the responsible person (EU-QPPV, graduated plan officer, information officer)
- Undertaking pharmacovigilance in clinical trials
- Consulting on EudraVigilance

We look forward to hearing from you!

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