



Pharmacovigilance You Can Rely On

HWI is an independent, family-owned service provider for pharmaceutical and biotechnology companies. Our interdisciplinary team of pharmacovigilance experts and QPPVs manages approximately 350 medicinal products containing more than 250 active substances and serves as a reliable partner in all aspects of drug safety.

With many years of experience in pharmacovigilance, we support companies in meeting national and international regulatory requirements reliably and efficiently. Using innovative digital approaches and AI-driven applications strategically, we make processes more efficient, transparent and secure.

As a result, you benefit from our high quality standards, streamlined workflows and dependable support for your teams.

We Provide Practical and Compliant Solutions for Your Pharmacovigilance Needs

- Literature screening and continuous monitoring
- Collection, assessment and timely reporting of adverse events, including follow-ups
- Safety database management and maintenance
- Signal management and continuous benefit-risk assessment
- Preparation of PSURs, PBRERs and Addenda to Clinical Overviews
- Preparation and maintenance of Risk Management Plans (RMPs)
- EudraVigilance services, including XEVPRM/XEVMPD support

We Support the Development, Optimisation and Continuous Improvement of Your PV System

- Preparation and maintenance of Pharmacovigilance System Master Files (PSMF)
- Writing, reviewing and updating Standard Operating Procedures (SOPs)
- Gap analyses and system assessments
- Regulatory inspection readiness and preparation
- Conducting audits and self-inspections
- Staff training and staff development programmes

HWI's Team of Experts Can Assume Key Pharmacovigilance Responsibilities for You

- EU-QPPV
- Graduated Plan Officer (Stufenplanbeauftragter)
- Information Officer



Our HWI-Experts Take Responsibility

Whether you are a start-up, a medium-sized pharmaceutical company or an international Marketing Authorisation Holder (MAH), we support you in establishing an efficient pharmacovigilance system that complies with all relevant regulations and is fit for future. Together, we keep medicines safe.

Working with HWI, You Will Benefit From

- Maximum regulatory compliance
- Reduced workloads for your teams
- A wide range of service packages, from individual projects to full-service solutions
- Innovative digital and AI-powered solutions
- Client dedicated contact persons and quick response times
- Extensive experience with regulatory authorities, inspections and audits



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As an end-to-end service provider, HWI complements its portfolio with drug development, manufacturing of clinical trial materials (CTM) and small commercial batches, laboratory services, QP services as well as regulatory support, all from a single source.

Whether you are looking for short-term expertise or a long-term strategic partner, HWI delivers tailored solutions to meet your specific requirements.

Get in touch with us to find out how we can support your project.

HWI group

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