



Pharma Consulting and QP Services

As experts in pharmaceutical consulting, we develop tailored solutions precisely aligned with your needs. Our interdisciplinary quality team combines years of experience with proven expertise. We deliver solutions that perfectly fit your requirements.

Regulatory Services

- Ensuring compliance with regulatory requirements (AMG, TAMG, AMWHV, AM-HandelsV, CTR), EU-GMP, GDP, and GACP guidelines, as well as authority expectations and inspection standards
- Support with applications for manufacturing/importation, and/or wholesale distribution authorisations
- Continuous improvement of your processes across manufacturing, testing, storage, release and distribution
- Proactive risk minimisation instead of reactive troubleshooting

Audits and Inspections

- Execution, preparation, and follow-up of GMP/GDP audits, including realistic mock audits
- Comprehensive support during regulatory inspections: inspection readiness training and coaching of your team, on-site support, and post-inspection follow-up including CAPA management
- Acting as an interface for communication with authorities

Quality Management

- Development, review (GAP analysis), optimisation, and maintenance of your quality management system (GMP, GDP, ISO 9001:2015)
- Supplier qualification, third-party audit evaluations, and QP declarations
- Self-inspections (planning, execution, support)
- Handling complaints, quality defects, and returns
- Supporting the continuous improvement process

Training and Qualification

- Hands-on training programs in GMP, GDP, and quality management
- Sustainable competence development across all quality-relevant areas

Filling of Key Roles

- Qualified Person
- Responsible Person GDP
- Quality Management Representative
- Information Officer
- QPPV (Pharmacovigilance)



Dr. Stefan Wissel
Managing Director/QP



Dr. Frank Böttcher
Managing Director/QP



Dr. Inge Unsöld
Expert Quality Services/QP



Dr. Lucia Weber
Expert Quality Services/QP

Our 4 QPs Take Over Responsibility

QP Services

- Batch certification (or confirmation of partial manufacturing) according to EU GMP for finished medicinal products (human and veterinary) and investigational medicinal products
- Comprehensive evaluation of quality-relevant data, including deviations, OOS results, change controls, and supplier assessments
- Import certification in accordance with EU GMP Annex 21

Pharma Consulting

- Support in establishing your pharmaceutical company
- Acting as a sparring partner for your responsible persons
- Lifecycle management for your products
- Classification and Regulatory Assessment of Your Products (MPs, FSs and MDs)
- Individualised and solution-oriented consulting on pharmaceutical and regulatory issues



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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, pharmacovigilance 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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