Vigilance & Quality

www.hwi-group.de

Our Services for Pharma, Biotech and Medtech

HWI group

Laboratory Services

Vigilance & Quality

Drug Development

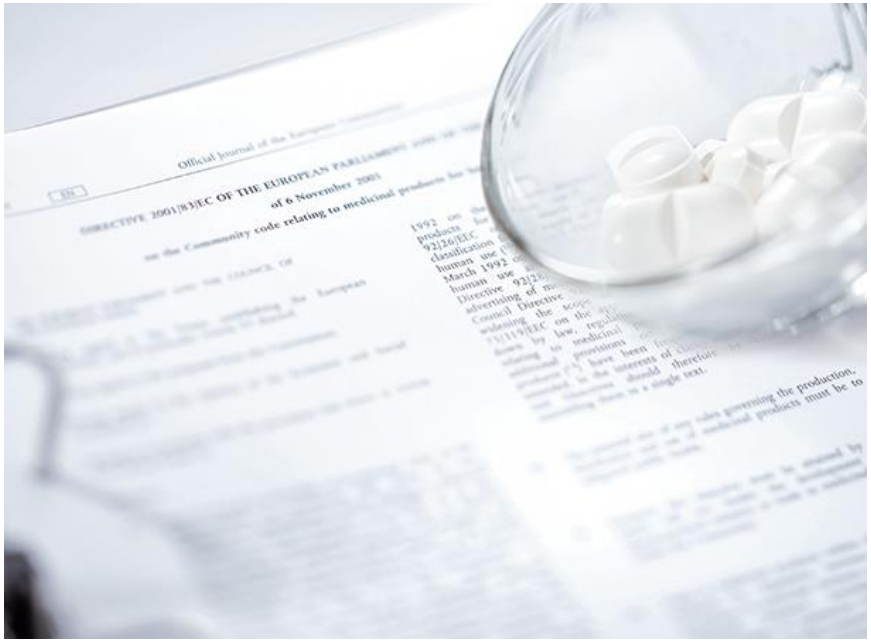
Regulatory Affairs

- Pharmacovigilance and vigilance of medical devices
- EU-QPPV, graduated plan officer, information officer
- GMP, GDP, GVP services
- QP Batch release, GMP/GDP audits
- Application for manufacturing, import and wholesale authorisations
- Implementation and maintenance of quality assurance system

Experts and Expertise

- Certification
  - Manufacturing authorisation for batch release according to section 13 (1) of the German Drug Law (AMG)

- Our people for your success
  - 4 QPs
  - 4 QPPVs
  - 16 experts
  - Administrative staff

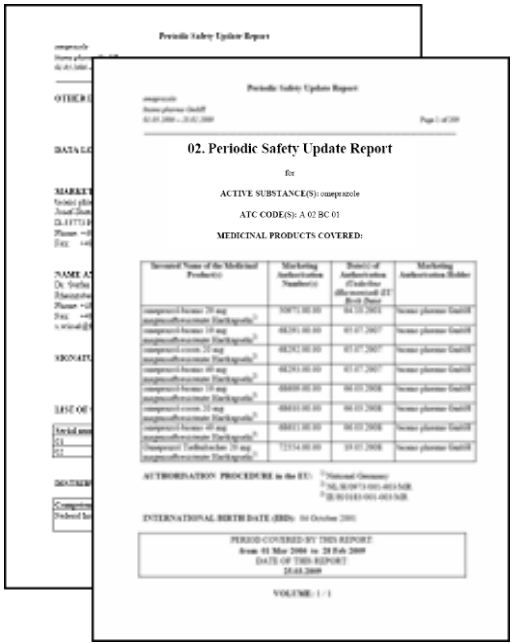


Pharmacovigilance

- Adoption of responsibility as EU-QPPV and graduated plan officer (“Stufenplanbeauftragter”) by our own staff
- Case processing
- Periodic reports
- Risk management plans
- Continuous monitoring of the risk-benefit balance
- Signal management

Pharmacovigilance

- Review and gap-analysis of your pharmacovigilance system
- Compilation and maintenance of the pharmacovigilance system master file (PSMF)
- Planning and performance of GVP-audits and self-inspections
- Performance of PV-trainings
- Submission of data to the Medicinal Product Dictionary (XEVPRM/XEVMPD)
- We have our own comprehensive GVP-compliant pharmacovigilance system (incl. CTD Module 1.8.1).



Quality Management

- Consulting and support in quality management according to
  - the German Drug Law (AMG),
  - Ordinance on the Manufacture of Medicinal Products and Active Substances (AMWHV) and
  - EU-GMP guidelines.
- Implementation, maintenance, documentation and training of QM systems

Batch Release for Drug Products

- Batch release by a Qualified Person from HWI
- Adoption of responsibility as external Qualified Person
- Planning and performance of GMP-/GDP-audits and self-inspections
- Interface for the cooperation and communication with authorities

Manufacturing, Import and Wholesale Authorisations

- Newco applying for wholesale license
  - Import performed by HWI
  - Batch release performed by HWI's QP
  - Newco is Marketing authorisation holder / HWI is manufacturer / importer

- Newco applying for Import / Manufacturing license
  - Import and batch release performed by Newco
  - HWI may adopt responsibility as external QP of Newco
  - Newco is Marketing Authorisation Holder and manufacturer / importer

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Thank you for your attention.

Dr. Yvonne Haagen | Head of Vigilance & Quality Services
Phone: +49 7272 7767-2531 | Email: y.haagen@hwi-group.de