



Vigilance & Quality

Our Services for Pharma, Biotech and Medtech



Laboratory Services



Vigilance & Quality



Drug Development

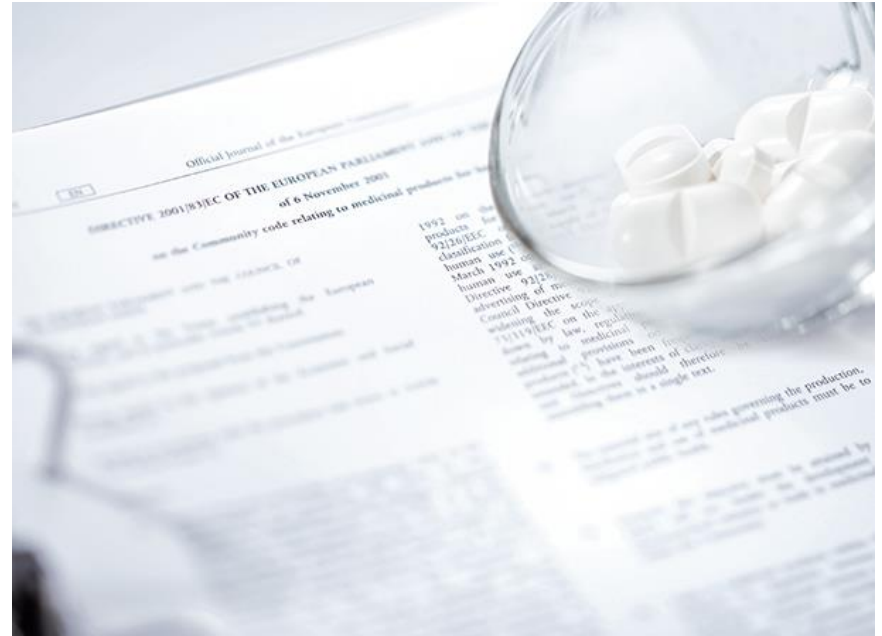


Regulatory Affairs

- 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



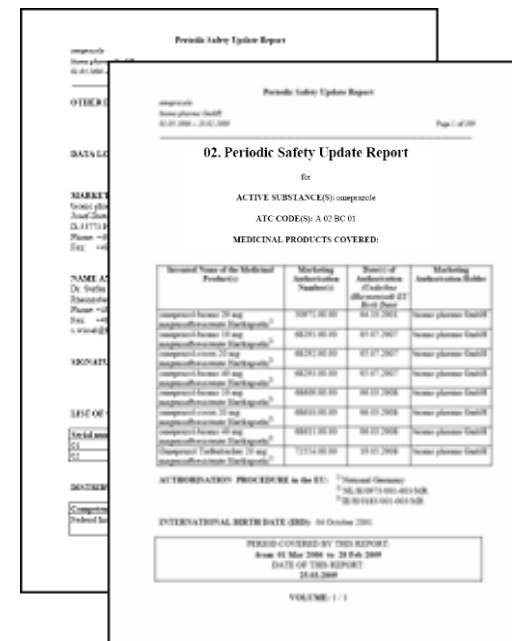
Pharmacovigilance

- 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).



Periodic Safety Update Report

02. Periodic Safety Update Report
for
ACTIVE SUBSTANCE(S): osimipresole
ATC CODE(S): A 02 BC 01
MEDICINAL PRODUCTS COVERED:

General Name of the Medicinal Product(s)	Marketing Authorisation Number(s)	Batch(s) of Authorisation (Citation of International II or III)	Marketing Authorisation Holder
component osimipresole 20 mg [osimipresole] [EurActiv]	10077.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 10 mg [osimipresole] [EurActiv]	48261.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 2 mg [osimipresole] [EurActiv]	48262.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 40 mg [osimipresole] [EurActiv]	48263.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 10 mg [osimipresole] [EurActiv]	48264.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 2 mg [osimipresole] [EurActiv]	48265.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 40 mg [osimipresole] [EurActiv]	48266.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 10 mg [osimipresole] [EurActiv]	48267.00.00	01.07.2007	Novartis pharma GmbH
component osimipresole 2 mg [osimipresole] [EurActiv]	11114.00.00	01.07.2007	Novartis pharma GmbH

INTERNATIONAL BERTH DATE: 06 October 2006

PERIOD COVERED BY THIS REPORT
from 01 Mar 2006 to 28 Feb 2009
DATE OF THIS REPORT
28.02.2009

VOLUME: 1 - 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

Our Services



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Drug Development



Regulatory Affairs



Thank you for your attention.

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