Regulatory Affairs

HWI group

www.hwi-group.de

Our Services for Pharma, Biotech and Medtech

HWI group

Laboratory Services

Vigilance & Quality

Drug Development

Regulatory Affairs

- Broad service portfolio of the HWI group
- Regulatory services for APIs, drug products, medical devices and combination products
- Support in product and process development
- Support in marketing authorisation / certification procedures
- Life cycle management

Experts and Expertise

- Regulatory services since 2006
- Our people for your success
  - 18 experts pharmaceuticals and medical devices
  - Physicians, pharmacists, biologists, biochemists, food chemists, biotechnologists
- Quality management system
  - DIN ISO 9001

Regulatory Affairs Services

HWI group

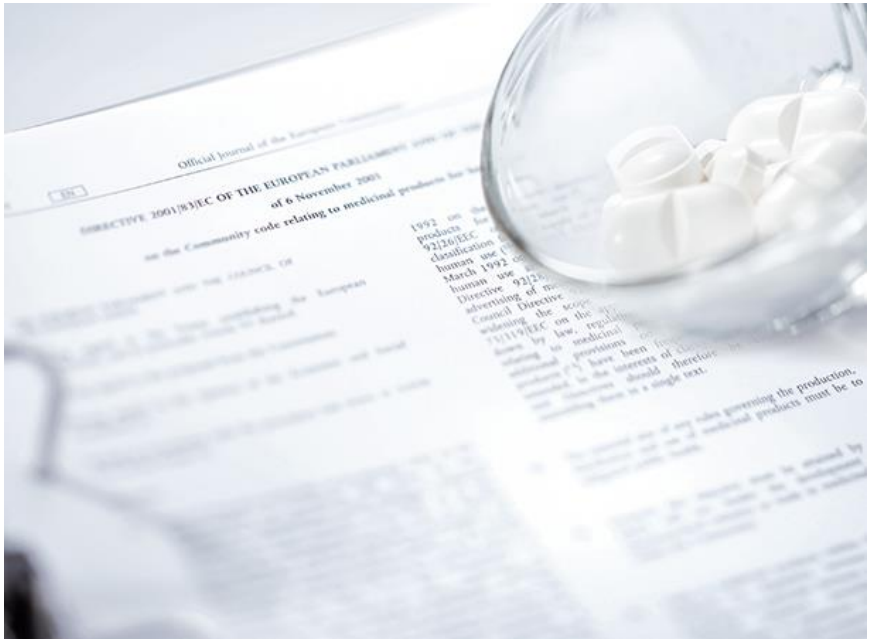
Pharmaceuticals (Medicinal Products)

Combination Products & Substance-based medical devices

Medical Devices

Pharmaceuticals

- Chemical, biotechnological/biological and herbal active substances and drug products
- Scientific advice and meetings with competent authorities
- Review and assessment of dossiers, documents and reports (GAP analysis)
- Dossier filing
- Project management and consulting
- Marketing authorisation application
- Life cycle management



Medical Devices

- Clinical Evaluation
- Concepts on the generation of clinical data and of clinical evaluation reports
- Reports on biological safety
- Compilation of technical documentations for substance-based medical devices
- Risk analyses (clinical/biological part)
- Support of manufacturers with certification and conformity assessment procedures / strategic consultancy, scientific advice
- Expert reports on demarcation and classification
- PMS, PMCF, PSUR

Drug-Device Combinations

Medicinal product & medical device / medical device & medicinal product

- Strategic consultancy, preparation and professional support of scientific advice meetings
- Compilation of the documentation for the competent authority and the notified body
- Procedure management and consultancy within the scope of consultation procedures
- Scientific support during the conformity assessment process

Development

Pharmaceuticals

- Compilation, review and assessment of IMPDs and IBs for clinical studies
- Interaction with authorities
- Expert statements and reports
- Consulting in GMP aspects

Medical Devices

- Clinical evaluation plan
- Clinical development plan
- Risk analyses (clinical/biological part)
- Clinical investigational plans
- Preclinical testing strategy

- “Regulatory compliance" already in early phases of the development
- Strategic consultancy, preparation and professional support of scientific advice meetings
- Review and assessment of documents and reports (GAP analysis)
- Project management for development projects, procedure management
- Regulatory strategy

Marketing Authorisation / Certification

HWI group

Pharmaceuticals

- Dossier compilation and marketing authorisation applications
- Dossiers and certificates for active substances and excipients (DMF, ASMF, CEP)
- Drug product support (CMC, clinical, non-clinical)
- Submission & procedure management (national, EU, US)

Medical Devices

- Clinical Evaluation
- Expert reports on demarcation and classification
- Reports on biological safety
- Compilation of technical documentations for substance-based medical devices
- Support of manufacturers with certification and conformity assessment procedures / strategic consultancy, scientific advice

- Strategic consultancy, preparation and professional support of scientific advice meetings
- Compilation of the documentation for the competent authority and the notified body

Life Cycle Management / Vigilance

HWI group

Pharmaceuticals

- Preparation and submission of variations, renewals, extensions, repeat use procedure
- Maintenance of package leaflets, SmPCs and product labelling
- Assumption of the responsibility as Information Officer and QPPV (together with HWI V&Q)

Medical Devices

- PMS plans and PMS reports
- PMCF plans and PMCF reports
- Compilation of PSURs
- Update of clinical clinical evaluations

- Dossier update and maintenance in the life cycle of medicinal products, medical devices and combination products
- Support of change control procedures from the regulatory perspective: assessment, definition of regulatory actions, initiation of necessary variations

Our Services

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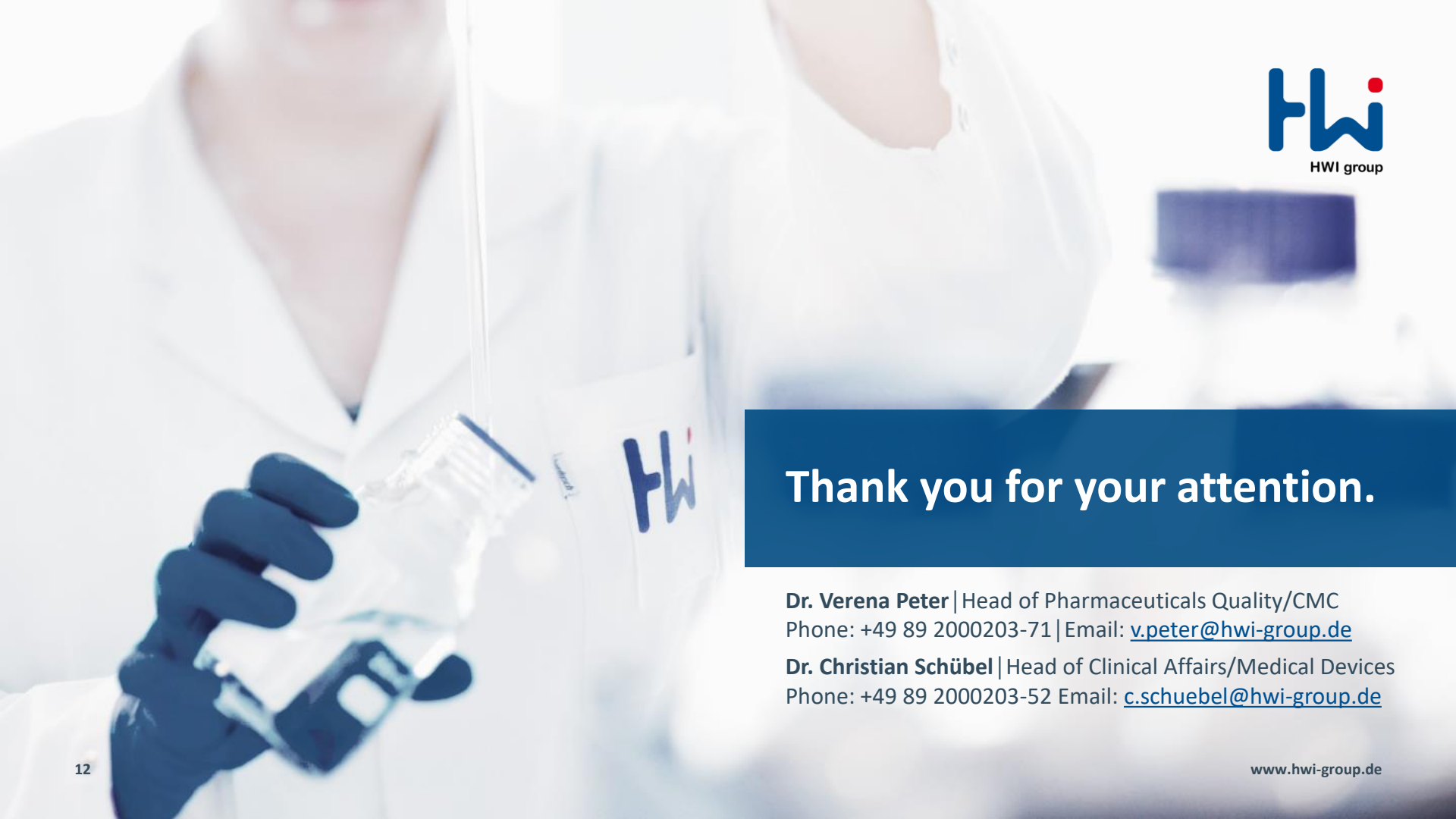

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Thank you for your attention.

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