



Regulatory Services

# Regulatory Services

## Development

- Evaluation and consultancy concerning “Regulatory compliance” already in early phases of drug development
- Compilation of Briefing Books, submission and coordination of Scientific Advices
- Compilation of IMPDs/INDs for clinical studies
- Review and assessment of documents and reports concerning their regulatory compliance (e.g. specifications, method validations)
- Processing of requests from authorities



# Regulatory Services

## Marketing Authorisation

- Regulatory and strategic advice
- Compilation of the dossier
- GAP-analysis of module 3 and dossier update
- Processing of requests from authorities
- Submission & procedure management

## Life-cycle Management

- Regulatory consultancy
- Update of the dossier and product information texts
- Preparation and submission of e.g. variations, extensions
- Management of procedures, incl. authority requests

**Thank you for your attention.**

**Lilia Selinger** | Head of Sales

Mobil: +49 172 2113128 | Email: [sales@hwi-group.de](mailto:sales@hwi-group.de)

**Silvia Öttl** | Sales Manager

Phone: +49 7272 7767-2561 | Email: [sales@hwi-group.de](mailto:sales@hwi-group.de)