


## Innovative Services for Pharma, Biotech & Medtech

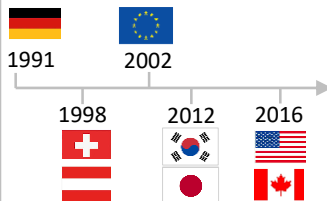
# Well-reputed outsourcing partner for 30 years

## Milestones


 1991 - 2021

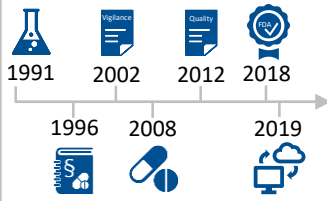


 New Markets



1991: Germany, EU  
1998: Switzerland  
2012: South Korea, Japan  
2016: USA, Canada

 HWI Value Chain



1991: Lab equipment  
1996: Finance  
2002: Vigilance  
2008: Pills  
2012: Quality  
2018: ISO 9001  
2019: Cloud computing

 Digital Transformation


Applying new digital technologies to enable solution and process innovation and prepare next generation business Models.



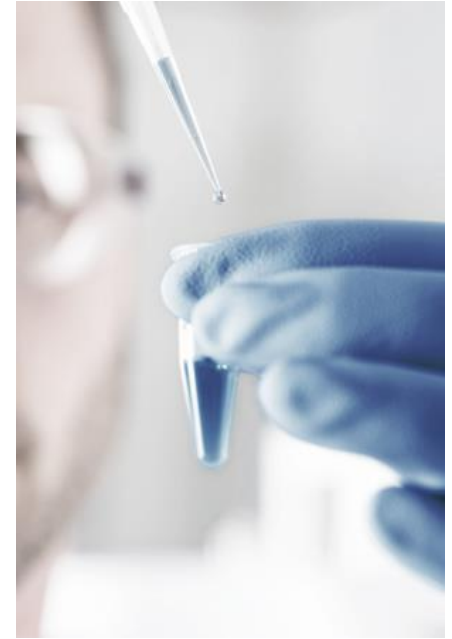
 KIKS 2019 (AIQNET)

Development of AI-supported data management technology using for digital vigilance services.



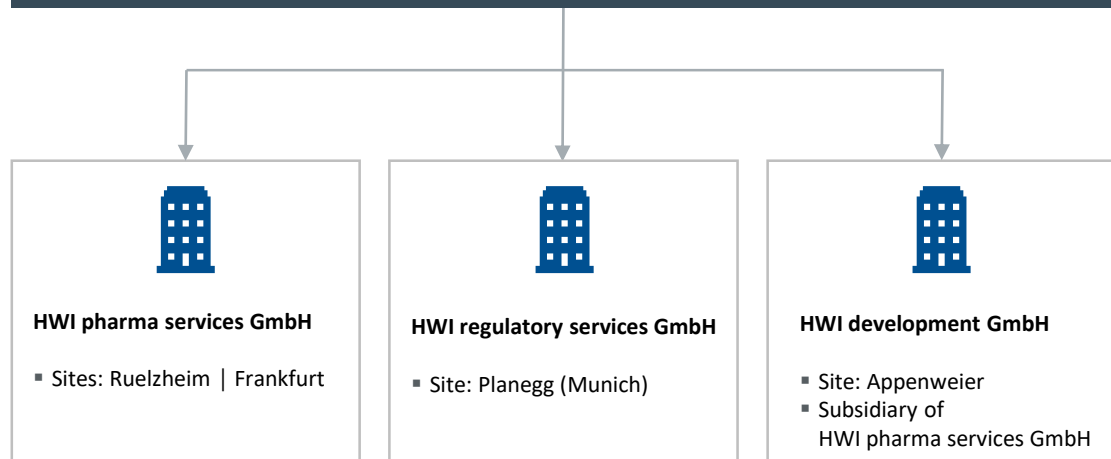
 InnoTop 2020

Establishment of an innovative screening and technology platform for manufacturing of sterile drug formulations.

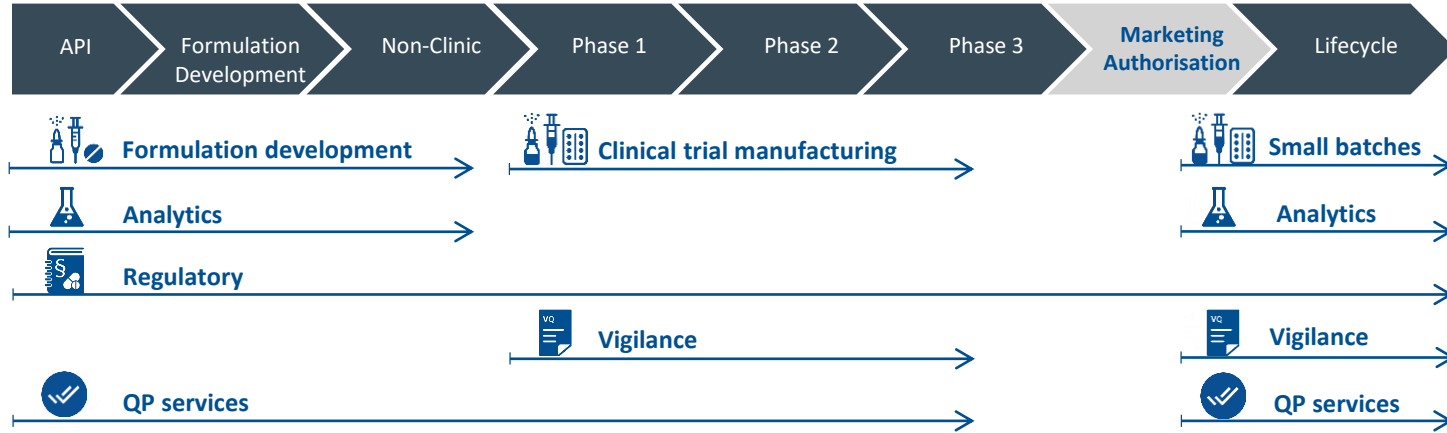


# Corporate Structure

**Wissel Holding GmbH**  
100 % family owned



# HWI covers all phases of a pharmaceutical value chain



**Technologies** Micro- and Nanotechnology | HSA-Carrier system | Highly flexible isolators & filling lines

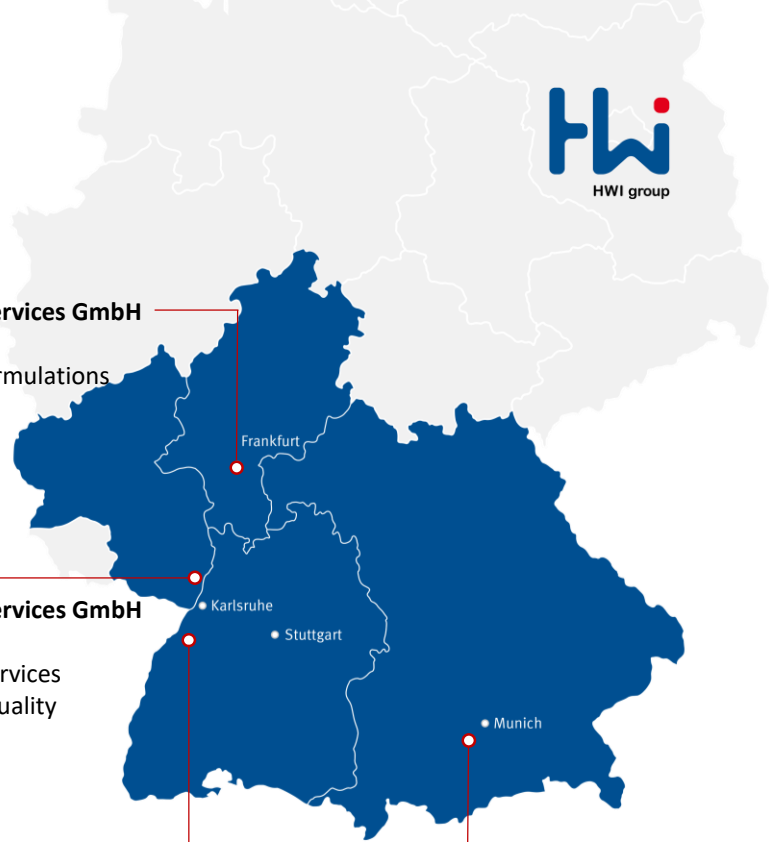
**Integrated Services** Development | Analytics | Regulatory strategy | Quality | Production & Packaging | Batch release

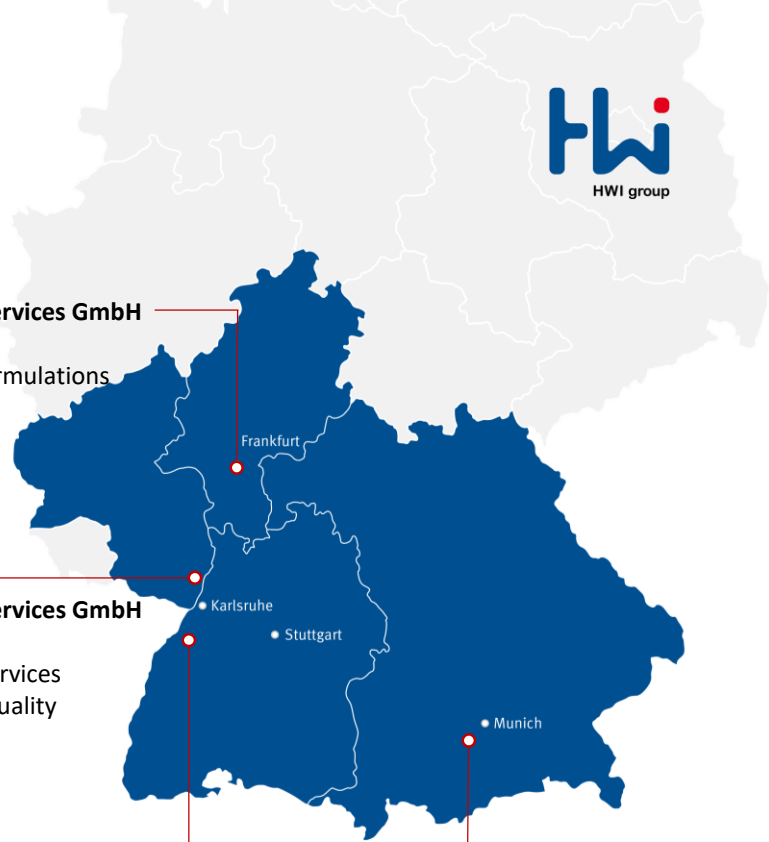
**Digital Capabilities** Active ingredient data bases | Artificial intelligence | Specific algorithms for text recognition and literature research

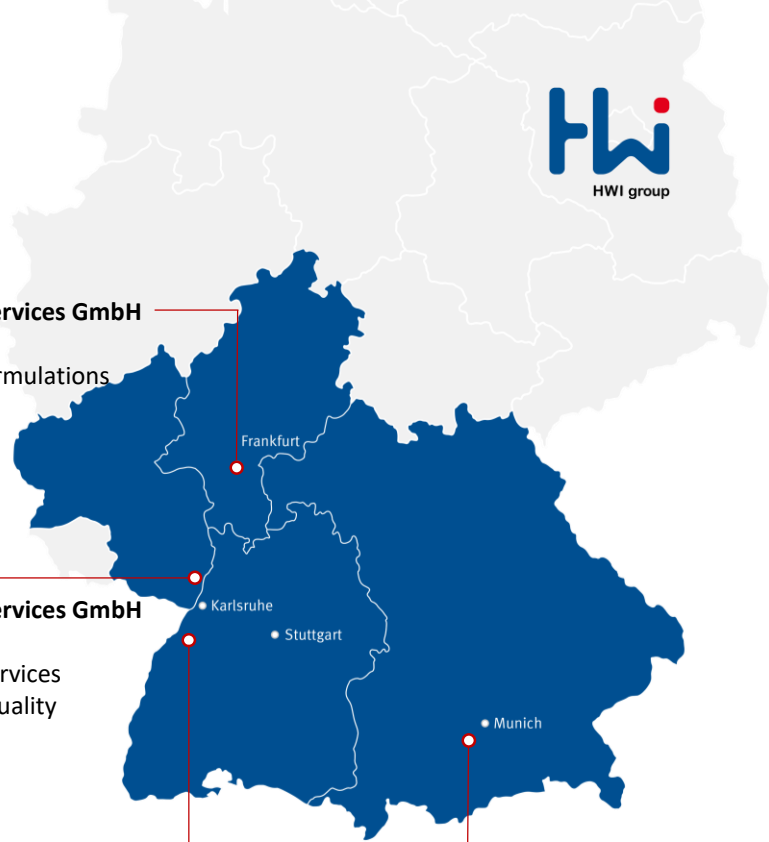
# Key Facts

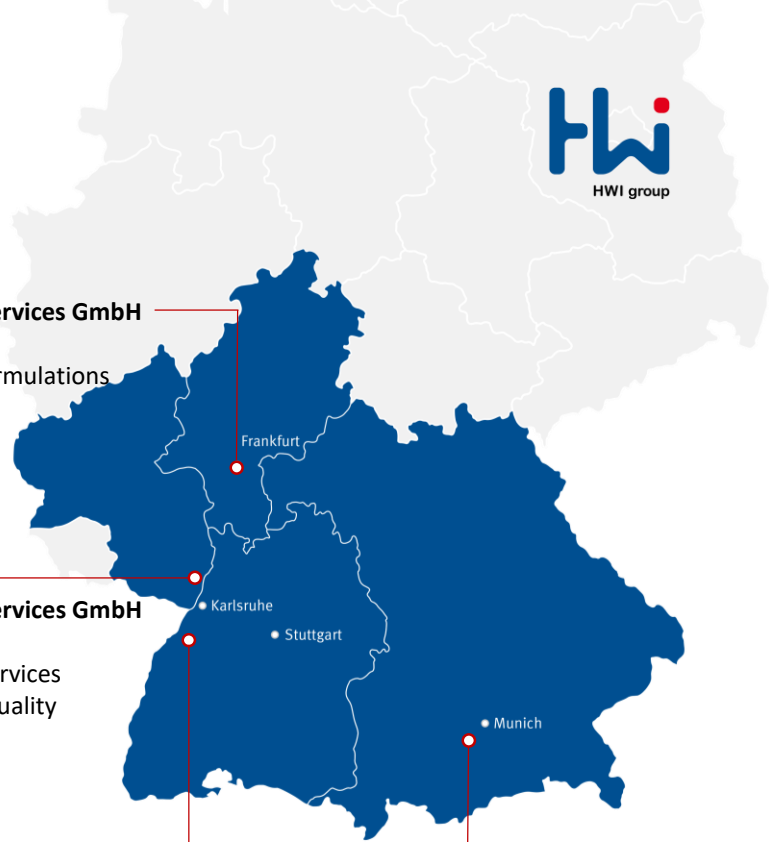
- Full service provider for pharma, biotech and medtech in development and life-cycle
- 4 sites – more than 2,000 m<sup>2</sup> lab space and 800 m<sup>2</sup> clean room space
- EU-GMP, FDA, ISO, manufacturing licence
- 200 employees
- Audit „berufundfamilie“ certification since 2009



- 
- HWI pharma services GmbH**  
Frankfurt
- Innovative formulations

- 
- HWI pharma services GmbH**  
Ruelzheim
- Laboratory services
  - Vigilance & Quality

- 
- HWI development GmbH**  
Appenweier
- Drug development

- 
- HWI regulatory services GmbH**  
Planegg/Martinsried
- Regulatory Affairs

# Our Services



Laboratory Services



Vigilance & Quality



Drug Development



Regulatory Affairs



# Our Services for Pharma, Biotech and Medtech



Laboratory Services



Vigilance & Quality



Drug Development



Regulatory Affairs

- Method development and validation
- Purity testing of particular impurities – trace analysis including structure elucidation
- Troubleshooting (root cause analysis)
- Extractables & Leachables testing
- Batch release and stability testing
- Reference standards for quality control

# Our Services for Pharma, Biotech and Medtech



Laboratory Services



Vigilance & Quality



Drug Development



Regulatory Affairs

- Development of solid, semi-solid and liquid dosage forms for oral, topical and parenteral application
- Handling of potent and high potent APIs
- API characterisation and quality screening
- Manufacturing of small and clinical trial batches
- Primary and secondary packaging including labelling and serialisation



# Our Services for Pharma, Biotech and Medtech



Laboratory Services



Vigilance & Quality



Drug Development



Regulatory Affairs

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

# Our Services for Pharma, Biotech and Medtech



Laboratory Services



Vigilance & Quality



Drug Development



Regulatory Affairs

- Regulatory services for drug products (quality, CMC) and medical devices (clinical, quality)
- Technical documentations for medical devices and drug-device combination products
- Life-cycle management (dossier updates and variations)

# Added Value



## New Technologies and Digital Services

We create value using modern analogue and digital technologies and services.



## Agile Organisation

Divided responsibilities enable fast and flexible reactions to market changes.



## Risk Management

Established to identify, reduce and control risks in development and life-cycle.



## Lean Management

Cost-effective project execution to maximize efficiency and quality.



## HWI Ecosystem

Trusting cooperations and long-lasting partnerships with employees, customers and network partners.



## Owner-managed Company

We are independent and 100 % family owned.



# Our Media Centre



(click here)

**Manufacturing and lyophilisation of a nanosuspension**



(click here)

**Tabletting under Containment**



(click here)

**Virtual Tour Cleanroom**

More Videos are available in our media centre on: [www.hwi-group.de](http://www.hwi-group.de)

**Thank you for your attention.**

**Dr. Frank Böttcher** | Managing Director  
Phone: +49 7272 7767-2309 | Email: [f.boettcher@hwi-group.de](mailto:f.boettcher@hwi-group.de)

**Dr. Stefan Wissel** | Managing Director  
Phone: +49 7272 7767-24 | Email: [s.wissel@hwi-group.de](mailto:s.wissel@hwi-group.de)