


## Innovative Services for Pharma & Biotech

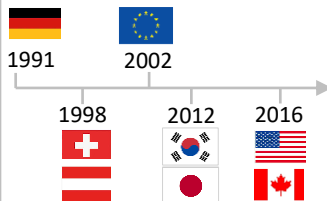
# Well-reputed outsourcing partner for 30 years

## Milestones


 1991 - 2021

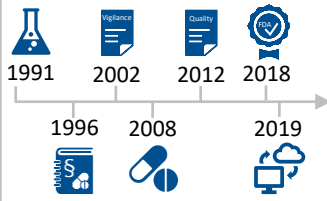


 New Markets



1991: Germany, EU  
1998: Switzerland  
2002: EU  
2012: South Korea, Japan  
2016: USA, Canada

 HWI Value Chain



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

 Digital Transformation

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



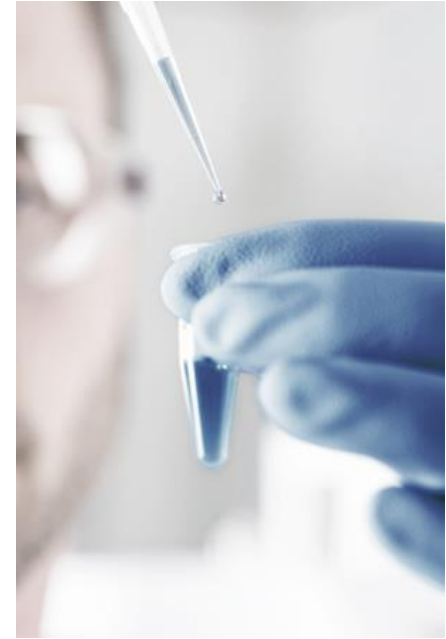
 KIKS 2019 (AIQNET)

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



 InnoTop 2020

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



# End-to-end service concept

Our services cover 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 and biotech in development and life-cycle
- 3 sites – more than 2,000 m<sup>2</sup> lab space and 600 m<sup>2</sup> clean room space
- EU-GMP, FDA, manufacturing licence
- 150 employees
- Audit „berufundfamilie“ certification since 2009

## HWI pharma services GmbH

Frankfurt

- Drug development
- Semi-solid and liquid formulations (including parenteral, intranasal)
- Small batches and clinical trial manufacturing

## HWI pharma services GmbH

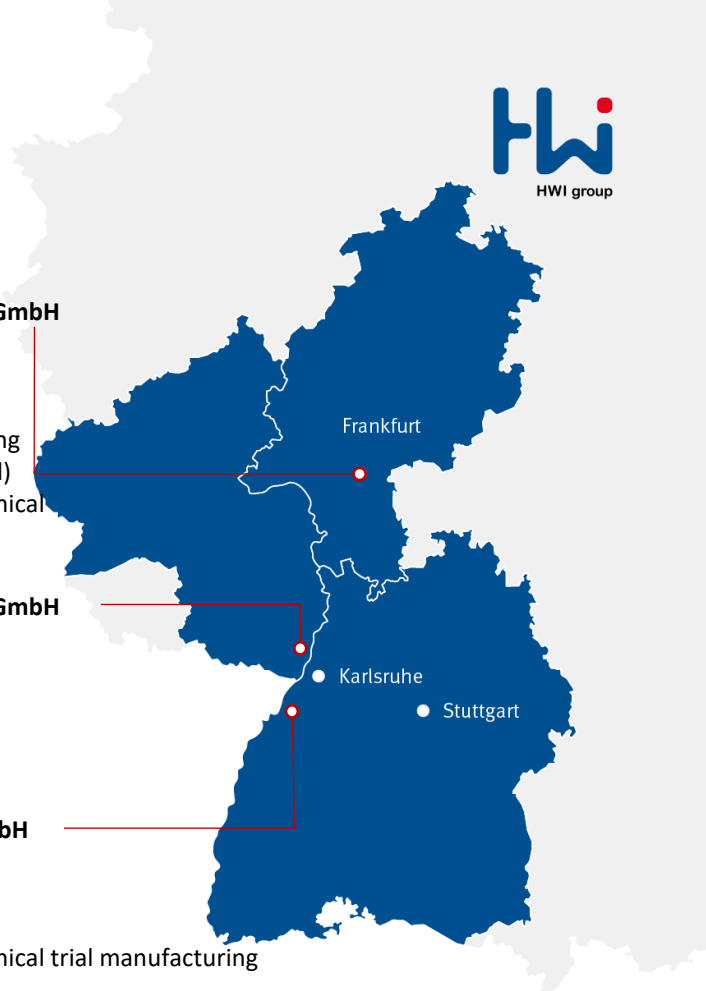
Ruelzheim

- Laboratory services
- Pharmacovigilance
- Quality & QP services

## HWI development GmbH

Appenweier

- Drug development
- Solid formulations
- Small batches and clinical trial manufacturing



# Our Services for Pharma and Biotech



Laboratory Services



Pharmacovigilance



Drug Development



QP services

- 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 and Biotech



Laboratory Services



Pharmacovigilance



Drug Development



QP services

- 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 and Biotech



Laboratory Services



Pharmacovigilance



Drug Development



QP services

- Pharmacovigilance services
- Automated literature search and assessment
- AI supported vigilance processes
- Pharmacovigilance system
- EU-QPPV, graduated plan officer, information officer

# Our GxP Services for Pharma and Biotech



Laboratory Services



Pharmacovigilance



Drug Development



QP services

- Assistance with the application for a manufacturing, import and wholesale licence
- Implementation and maintenance of quality assurance systems
- Conducting supplier audits and self-inspections
- QP-Service; batch release
- QM officer
- Wholesale representative



# 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.**

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