

Innovative Services for Pharma & Biotech



Dr. Stefan Wissel



Dr. Philipp Wissel

Our purpose is to discover new ways to improve and extend people's lives.


With novel technologies and innovative services we aim to advance the development of highly effective medicines for everyone.

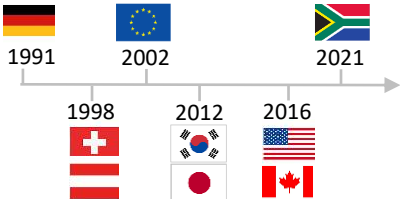
Well-reputed outsourcing partner for 30 years

Milestones


 1991 - 2023

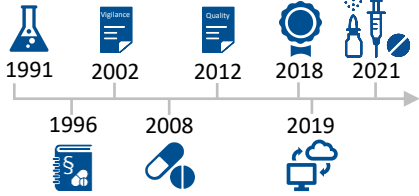


 New Markets



1991: Germany, EU
1998: Switzerland
2002: EU
2012: South Korea, Japan
2016: USA, Canada
2021: South Africa

 HWI Value Chain



1991: Lab equipment
1996: Finance
2002: Vigilance
2008: Pills
2012: Quality
2018: Award
2019: Cloud
2021: Medical devices

 Digital Transformation

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



 AIQNET 2019 – 2023

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



Gefördert durch:
Bundesministerium für Wirtschaft und Energie
aufgrund eines Beschlusses des Deutschen Bundestages

 InnoTop 2020 - 2022

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



Key Facts

- Full service provider for pharma and biotech in development and life-cycle
- 3 sites – more than 2,000 m² lab space and 600 m² clean room space
- EU-GMP, FDA, manufacturing licence
- 150 employees

Frankfurt Site

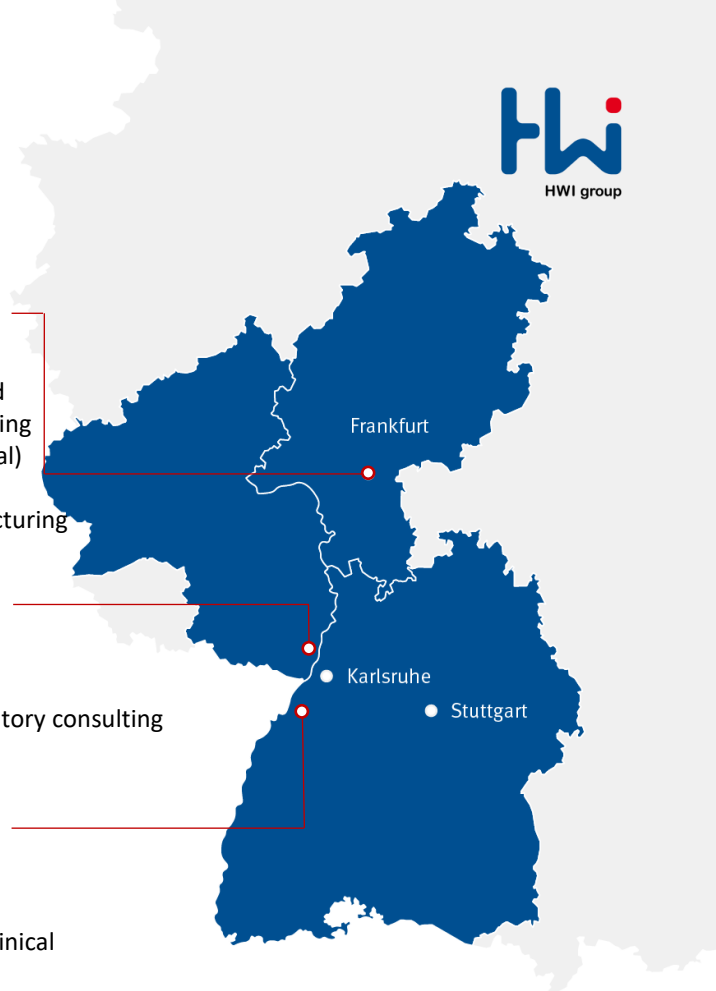
- Drug development
- Semi-solid and liquid formulations (including parenteral, intranasal)
- Small batches and clinical trial manufacturing

Ruelzheim Site

- Laboratory services
- Pharmacovigilance
- QP services & regulatory consulting

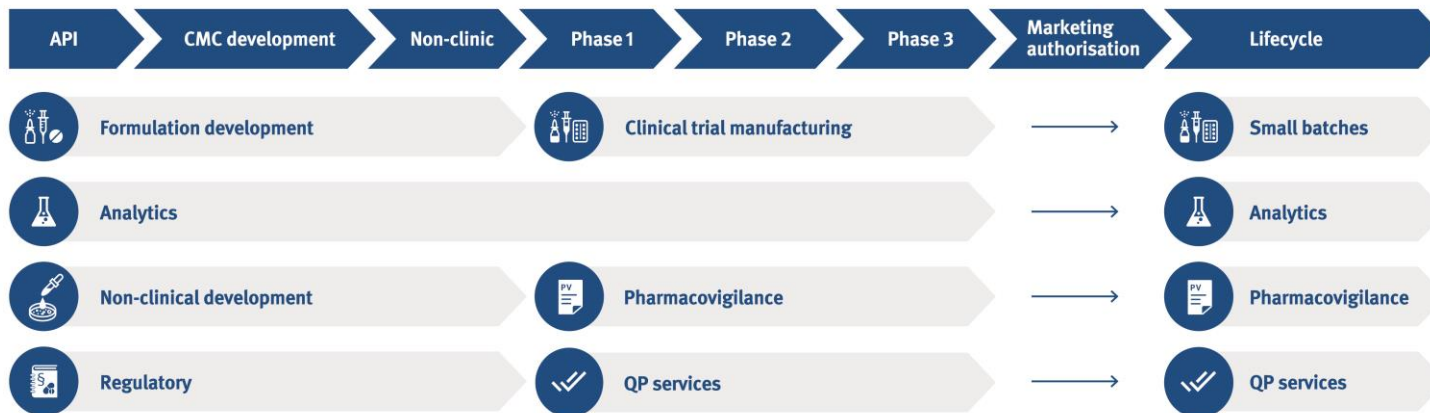
Appenweiler Site

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



End-to-end service concept

Our services cover the entire value chain of medicinal products with small and large molecules



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

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, nasal, 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
- Regulatory services for medicinal products
- QM officer
- Wholesale representative

Our Media Centre



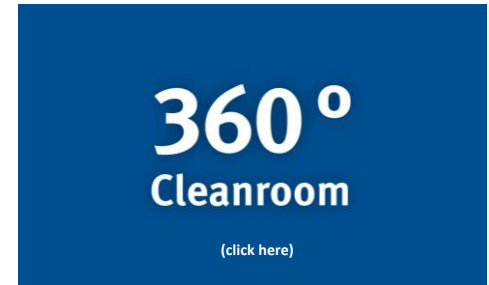
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Manufacturing and lyophilisation of a nanosuspension



(click here)

Tabletting under Containment



(click here)

Virtual Tour Cleanroom

More Videos are available in our media centre on: www.hwi-group.de

Thank you for your attention.

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