

Innovative technologies & services

HWI group is a family-owned, independent service partner in the pharma and biotech sector.

Our end-to-end service concept covers the entire value chain of medicinal products with small and large molecules.

Our portfolio ranges from drug product development, analytical development and quality control, manufacturing of clinical trial batches and small market batches to non-clinical development, pharmacovigilance and GxP services.

HWI looks back on 35 years of experience and a large number of successfully completed projects and drug approvals on behalf of its clients.

HWI's technology platform for parenteral, nasal and oral applications focuses on the development of innovative and affordable drugs with a special focus on challenging small and large active ingredients. Our purpose is to discover new ways to improve and extend people's lives. With novel technologies and innovative services, HWI aims to advance the development of highly effective medicines for everyone.

Please visit our website www.hwi-group.de for detailed information on our services.

Contact

We are happy to discuss your enquiries in person and look forward to hearing from you! Or you can send an email to sales@hwi-group.de.



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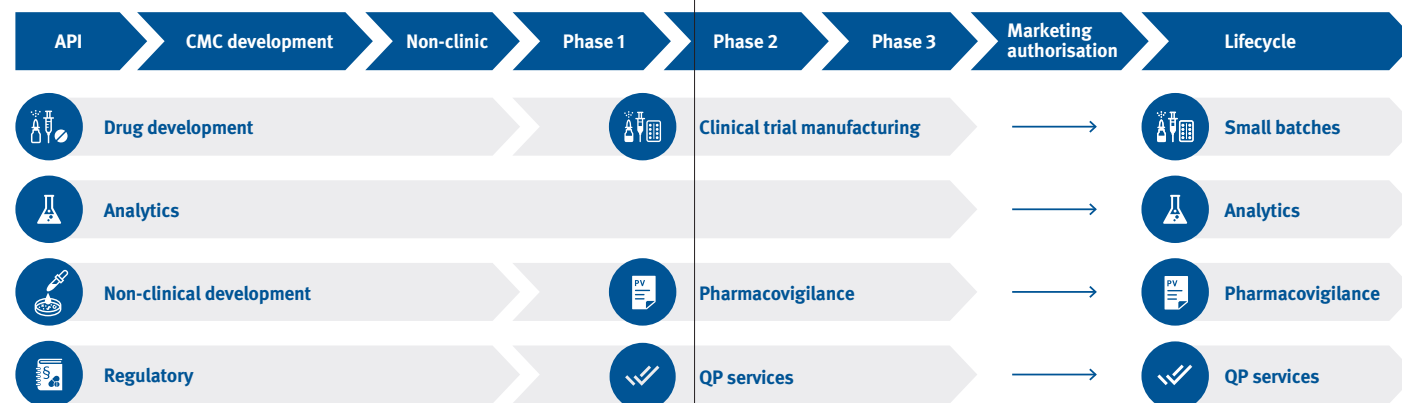
End-to-end service concept

Innovative technologies and services
for pharma & biotech

www.hwi-group.de

End-to-end service concept

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



Drug development & manufacturing

- › Solid, semi-solid and liquid formulations
- › Parenteral, nasal, oral and topical applications
- › Manufacture of CTM and small commercial batches
- › Secondary packaging, labelling, serialization and aggregation
- › Handling of high potent drugs
- › High-throughput screening for poorly soluble APIs
- › Micro- and nanosuspensions
- › Manufacture of commercial sterile products up to 20,000 units – liquid and lyophilized powders (from 2029)

Pharmacovigilance services

- › Pharmacovigilance in clinical trials and life cycle
- › Automated literature search and assessment
- › AI supported vigilance processes
- › Pharmacovigilance system
- › EU-QPPV, graduated plan officer, information officer

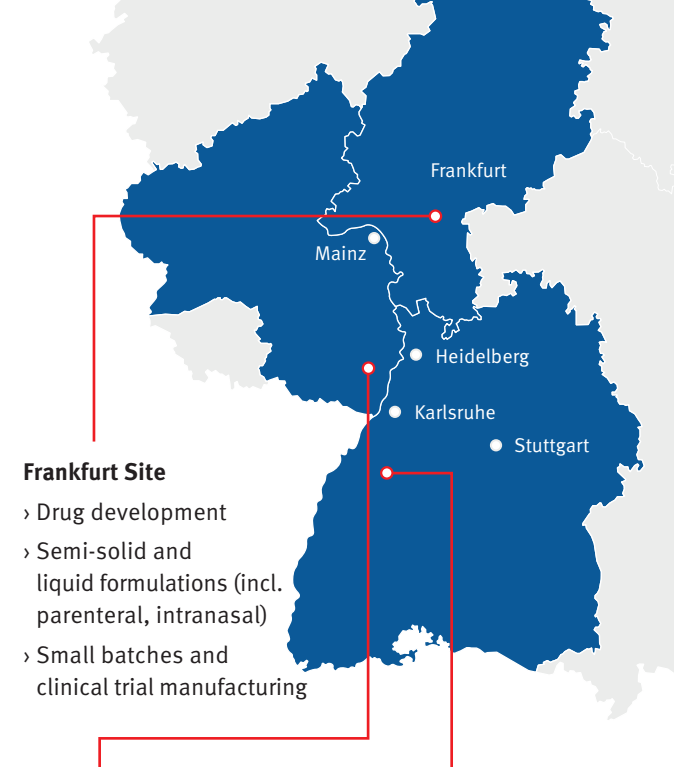
Analytical development & laboratory services

- › Method development and validation
- › Purity testing, trace analysis & structure elucidation
- › Release testing & ICH stability studies
- › Stress testing & forced degradation studies
- › Extractable & leachable studies
- › Root cause analysis of manufacturing & production issues (troubleshooting)
- › Latest test methods in testing drug formulations, APIs, excipients, biologics

QP services & regulatory consulting

- › QP batch release
- › GxP services and audits
- › Application for manufacturing, import and wholesale authorisation
- › Implementation and maintenance of quality assurance systems
- › Regulatory services

HWI sites in Germany



Frankfurt Site

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

Headquarters, Ruelzheim Site

- › Laboratory services
- › Pharmacovigilance services
- › QP services & regulatory consulting

Appenweier Site

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

- › Innovative technologies and services for pharma & biotech for small and large molecules
- › 2,000 m² lab space
- › 600 m² clean rooms
- › EU-GMP, FDA approved, manufacturing authorisations