HWI group

Innovative Services for Pharma & Biotech

Dr. Stefan Wissel

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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.

Company History

1991

Foundation of analytical lab Rheinzabern, Germany

2000

Expansion of the GMP-Laboratories

2002

Foundation of regulatory unit

2008

Founding of development unit and purchase of LAZ GmbH

2020

Rent of the **Frankfurt site** focusing on sterile manufacturing

Initiation of nasal spray **F004** development

2022-2023

Start of **Co-development** projects

1995

First **reference standards** services

2001

Introduction of **pharmacovigilance**

2005

Relocation of company headquarters to **Ruelzheim**

2019

HWI wins **funded competition** with AI platform AIQNET

2021

EUROPÄISCHE UNION
EUROPÄISCHER FONDS FÜR REGIONALE ENTWICKLUNG

InnoTop funding for sterile **nanotechnology**

Expansion in large **molecules**

2024

UNIVERSITÄT BONN

Endowed professor-ship with focus on biologics and preclinical research

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/Headquarters

- Laboratory services
- Pharmacovigilance
- QP services & regulatory consulting

Appenweier Site

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

Business Units

- Method development and validation
- Purity testing, trace analysis including structure elucidation
- Batch release and stability testing
- Troubleshooting (root cause analysis)
- Reference standards for quality control
- Latest analytical technologies

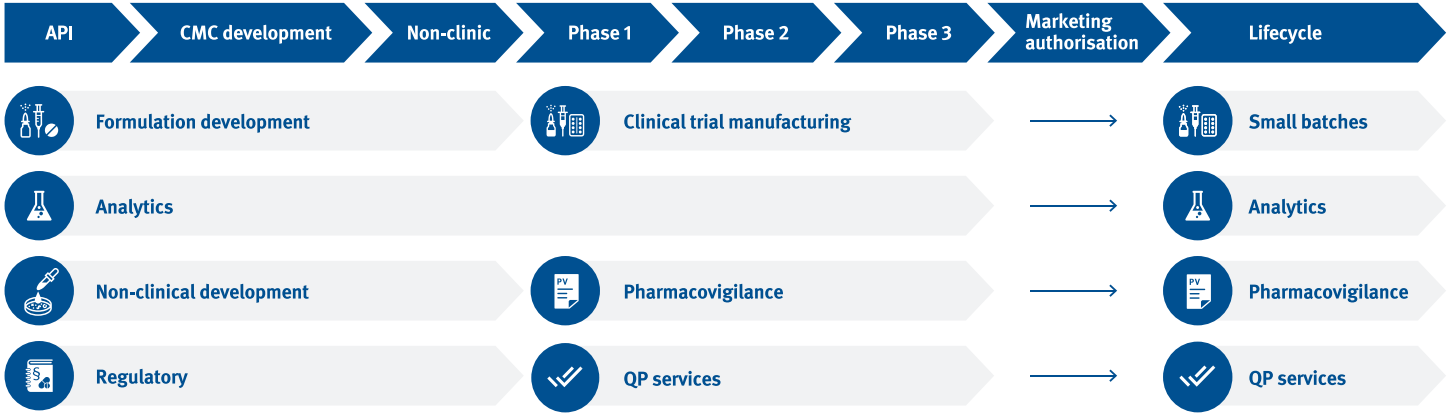
- Development of solid, semi-solid and liquid dosage forms for oral, nasal, topical and parenteral application
- Handling of high potent small and large molecules up to OEB 5
- API characterisation and quality screening
- Innovative and enabling technologies for poorly soluble and complex APIs
- Manufacturing of small and clinical trial batches
- Primary and secondary packaging including labelling and serialisation

- QP Service (4 QPs) including batch release
- Assistance for application of a manufacturing, import and wholesale license
- Implementation and maintenance of quality assurance systems
- Conducting supplier audits and self-inspections

- Pharmacovigilance services
- Automated literature search and assessment
- AI supported vigilance processes and own pharmacovigilance system
- EU-QPPV, Graduated Plan Officer, Information Officer

End-to-end Service Concept

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



Technologies	Micro- and Nanotechnology I HSA-Carrier system I Highly flexible isolators & filling lines
Integrated Services	Development I Analytics I Regulatory strategy I Quality I Production & Packaging I Batch release
Digital Capabilities	Active ingredient data bases I Artificial intelligence I Specific algorithms for text recognition and literature research

Benefits – Why Choosing Us

New Technologies and Digital Services

We create value using innovative and digital technologies and services.

Agile Organisation

Divided responsibilities enable fast and flexible reactions to market changes and client's individual requirements

Risk Management

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

End-to-End Service One-Stop Solutions

Development, analytics, regulatory and manufacture

Lean Management

Cost-effective project execution and reliable time schedules to maximize efficiency and quality

HWI Ecosystem

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

Owner-managed Company

Independent, family owned, short decision-making processes, the next generation already established

35 Years of Forward Thinking

35 years of knowledge and experience: We think ahead for our clients

What’s New in Our Service Portfolio?

A quick look at what’s evolving across our departments.

Analytical services:

Expansion on our analytical capabilities in the GMP area, not only for small molecules but also for **peptides, proteins, and nucleotides such as mRNA**. Our strengths here also include trace analysis, such as extractables and leachables, genotoxic impurities, structural elucidation of unknown impurities, and root cause analysis of quality problems.

Development and small scale manufacture of parenteral products:

Expansion the development of sterile and nasal applications at our site in Frankfurt including lyophilization and now also have an extended manufacturing **license for the production of small batches of sterile products**, e.g., for Phase 1 and Phase 2 studies.

Parenteral fill & finish starting in 2029:

Planning a new **manufacturing area for sterile products**, including lyophilization for medium-sized batches of approximately 20,000 units (vials, prefilled syringes). We want to start production in 2029.

Pharmacovigilance goes digital:

We are working with AI-supported apps and offer our customers comprehensively digitized PV services. We manage around 500 drugs for our customers with more than 250 APIs, primarily in German-speaking countries.

Our Media Centre

Manufacturing and lyophilisation of a nanosuspension

Tabletting under Containment

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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