Analytical Services for Development, Release and Lifecycle

HWI group is an independent, family-owned service provider to the pharmaceutical and biotech industries. With more than 35 years of experience in pharmaceutical analytics and quality control, we support customers throughout the entire product lifecycle, from early development to commercial release.

Combining scientific excellence with regulatory compliance, we provide tailored solutions for small molecules, biologics and complex pharmaceutical products. Our services range from routine quality control and stability testing to advanced analytical investigations.

Quality Control Across Modalities

- Small molecules and intermediates
- Peptides, proteins and oligonucleotides
- Polymers and biopolymers
- Herbal products and complex natural extracts
- Highly potent APIs (up to OEB 5)
- Excipients and finished drug products
- Medical devices and combination products
- Reference standards qualification and management

Biologics and Advanced Modalities

Supporting analytical development and characterisation of

- Proteins & Peptides
- Oligonucleotides, Polymers & Biopolymers
- Complex therapeutic modalities

Capabilities include

- LC-MS for peptide mapping, sequence confirmation and impurity identification
- CAD, RI and MALS detection for multi-dimensional characterisation
- Advanced protein concentration assessment using VPE technology
- Purity and heterogeneity assessments for proteins, peptides and oligonucleotides

Method Development and Validation

- Development, optimisation and lifecycle management of analytical methods
- Ph. Eur. and USP analytical procedures
- Assay, purity and dissolution methods
- Chromatographic techniques (e.g., HPLC, UHPLC, GC, IC)
- Titrimetric and wet-chemical testing
- Validation, verification and method transfer
- Stability-indicating method development
- Forced degradation studies

Advanced Analytical Characterisation

- Structural elucidation using LC-(HR)MS and NMR spectroscopy
- Advanced characterisation of peptides and oligonucleotides
- Peptide mapping and sequence confirmation
- Impurity profiling and trace analytics
- Method troubleshooting and analytical root cause investigations
- Advanced material characterisation by Raman, SEM-EDX and X-ray Microtomography

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Analytical Excellence Throughout the Product Lifecycle

Purity Testing – Trace Analysis

- Identification and quantification of process-, degradation- and formulation-related impurities
- Extractables & leachables studies for packaging and manufacturing systems
- Analysis of genotoxic impurities, residual solvents and elemental impurities (via ICP-MS)
- Root cause analysis of unexpected impurities and quality deviations

Routine Testing

- Batch release testing and GMP-compliant quality control
- ICH-compliant stability studies in qualified storage facilities
- Photostability studies according to ICH Q1B requirements

Lilia Selinger | Head of Sales
Mobile: +49 172 2113128
Email: sales@hwi-group.de

As an end-to-end service provider, HWI complements its portfolio with drug development, manufacturing of clinical trial materials (CTM) and small commercial batches, pharmacovigilance and QP services as well as regulatory support, all from a single source.

Whether you are looking for short-term expertise or a long-term strategic partner, HWI delivers tailored solutions to meet your specific requirements.

Get in touch with us to find out how we can support your project.

HWI group
HWI pharma services GmbH | Rheinzaberner Strasse 8 | 76761 Ruelzheim / Germany
Phone: +49 7272 7767-0 | Fax: +49 7272 7767-11 | sales@hwi-group.de

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www.hwi-group.de

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