Our services in summary:

- Analytical method development and validation
- Quality control services for drug substances, drug products and medical devices
- Structure elucidation
- Trace analysis: extractables & leachables studies, genotoxic impurities, cleaning validation studies, elemental impurities
- Consulting on CMC-related topics
- Root cause analysis of contaminations in production issues

Laboratory Services

We are your partner for pharmaceutical analysis and quality control.

With 25 years' experience and continuously striving for improvement, we deliver our analytical services for drug substances, drug products, medical devices and drug-device combination products at a high quality level.

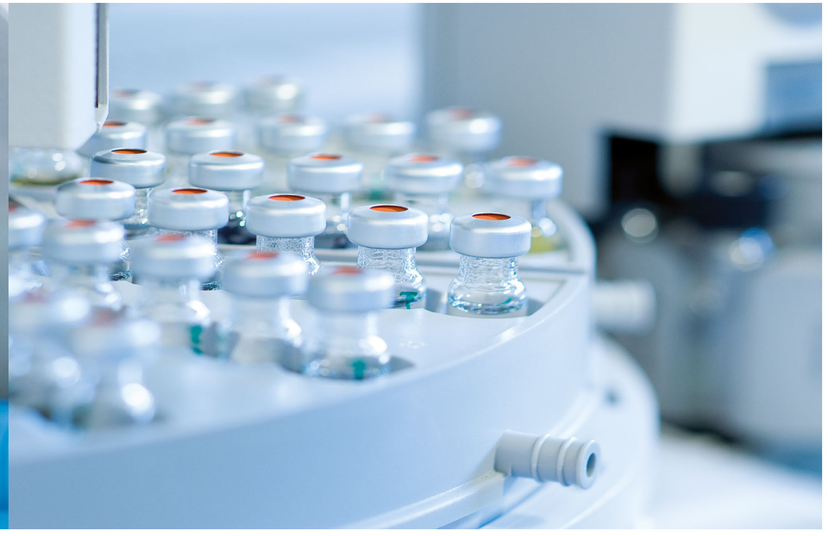
Alongside the development and validation of analytical methods, batch release testing, stability testing and structure elucidation, the risk-based and solution-oriented consultation of our clients according to current regulatory requirements is one of our core competencies.

With our long-term experience in trace analysis we offer the complete management and laboratory services for extractables & leachables studies, cleaning validation studies and the investigation of genotoxic as well as elemental impurities.

We support you with troubleshooting in production issues and offer you express services in root cause analysis using modern screening methods for objectionable organic and inorganic impurities as well as particles.

More than 40 employees in our analytical laboratories implement our clients' requirements, target-oriented and efficiently, supported by lean management tools. With interdisciplinary teams and professional project management, we ensure your complex projects are successful.

Our laboratories are GMP-certified and we have a manufacturing license for the release of clinical batches and market batches.



Contact

For consultation or further information please contact Dr. Melanie Kerst who can provide expertise on all analytical questions. She will also gladly help you with all business-related topics.

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Laboratory Services & Quality Control

HWI group

Quality Control of Drug Substances and Drug Products

Method development and validation

We develop and validate analytical methods for identity testing, assay, related substances and in vitro dissolution testing for drug substances, excipients, intermediates and finished drug products, according to international guidelines and GMP requirements. For that purpose, we implement state-of-the-art analytical methods and chromatographic separation techniques (HPLC, GC) using various detectors such as UV/DAD detection, fluorescence detection, refractive index detection, evaporative light scattering detection, conductivity detection, flame ionisation detection and mass selective detection.

Validation protocols and reports can be issued in German, English or French and can be directly incorporated into marketing authorisation dossiers.

Batch release

We have a manufacturing authorisation according to the German Drug Law (AMG) § 13 (1), for the batch release of drug substances and drug products as well as clinical batches. We conduct analytical testing for the EU release of drug products.

Stability studies

- ICH and ongoing stability studies
- In-use stability studies
- Photostability studies
- Matrixing & bracketing designs
- Stability studies of controlled substances (narcotics)
- Comprehensive capacities for GMP-compliant stability storage
- Consulting on stability concepts and shelf life specifications

Impurities from API synthesis and degradation products

- Development and validation of chromatographic testing procedures for purity testing of drug substances and drug products as well as medical devices and drug-device combination products
- Development of stability indicating methods including stress testing according to ICH Q3A & Q3B
- Identification of impurities and related substances using mass spectrometry (GC-MS/LC-HRMS) and NMR
- Isolation of impurities using (semi-)preparative LC
- Qualification and distribution of purity reference standards
- Consulting for setting up specifications & toxicological evaluation of impurities

Trace Analysis

Extractables & leachables: investigation of packaging materials

- Individual set-up of extractable studies based on packaging material and product composition
- Identification of extractables using in-house LC-HRMS and GC-MS methods
- Toxicological evaluation of extractables and potential leachables
- Development and validation of leachables method based on results of extractable studies
- Migration studies within stability testing for investigation of leachables

Potentially genotoxic impurities

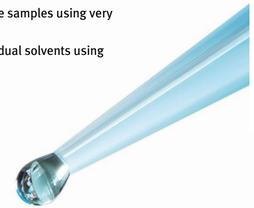
- Development of control strategies according to ICH M7
- Review of synthesis pathways
- Trace analysis and ultra-trace analysis including analytical method development and validation for potentially genotoxic impurities (PGIs)
- Setting up specifications according to TTC approach

Troubleshooting in production issues

- Express services for investigation of production issues including root cause analysis
- Structure elucidation of organic impurities using in-house screening methods with LC-HRMS, GC-MS and LC-SPE/NMR
- Investigation of inorganic impurities using SEM-EDX and ICP-OES/MS techniques
- Determination of particles using X-ray micro/nanotomography, SEM-EDX and RAMAN microscopy/chemical imaging
- Particle size distribution using Malvern Mastersizer® & Helos®

Residual solvents

- Product-specific validation for residual solvents according to Ph. Eur. 2.4.24 and ICH Q3C
- In-house method for high-price samples using very low sample amounts
- Identification of unknown residual solvents using GC-MS and NIST database



Quality Control of Medical Devices

We are specialised in the analytical testing and quality control of borderline medical devices as well as medical devices with ancillary drug substances.

We develop and validate analytical methods for identity testing, assay and purity testing, as well as dissolution testing of pharmaceutical drug substances in combination products, according to national and international guidelines and standards. We conduct analytical testing for batch release and stability according to predefined specifications.

We offer you all required services for a consultation procedure according to MDD and MEDDEV guidelines and for scientific advice meetings with the notified bodies and/or the responsible regulatory authorities.

Consulting on CMC-related Topics

The HWI team has expert knowledge of all currently valid regulatory requirements for human medicinal products, veterinary medicinal products, as well as borderline medical devices and medical devices with ancillary drug substances.

We support you in all analytical questions and relating regulatory questions:

- Setting and reviewing of specifications, analytical procedures and validation reports based on current scientific state-of-the-art and regulatory requirements
- Planning and conducting of method transfers
- Gap analyses of CTD modules 2.3/3, together with our experts from regulatory affairs, product development and production

HWI group

HWI group provides a wide range of individual and specialised services for the pharmaceutical, medtech and biotech industries, in particular for drug substances, drug products and medical devices. Over the last 25 years, our company group has gained a wealth of regulatory as well as scientific knowledge and long-term experience to support our clients. Our services are divided into five business units – Laboratory Services & Quality Control, Reference Standard Services, Vigilance & Quality Services, API Characterisation & Drug Development and Regulatory Affairs Services & Life Cycle Management.

your success is our success