HWI group as your one-stop shop

With 25 years of experience we are your partner in biopharmaceutical development and regulatory affairs.

We provide expert regulatory CMC compliance advice throughout development, compile your dossiers and applications and manage marketing authorisation procedures. Our team of qualified consultants has many years of experience in regulatory affairs and compliance.

We have a strong expertise in drug substance characterisation and drug development and offer a wide range of analytical services, including mass spectrometry (e.g. LC-MS), chromatography-based purification methods (e.g. UPLC and HPLC), and other biophysical methods (e.g. fluorescence spectroscopy, DSC, electrophoresis, ELISA , multi-angle light scattering).

Our labs are GMP and FDA certified and we hold a manufacturing license for the production and release of small clinical and commercial batches.

Whether you are dealing with small or large molecules, we meet your needs with tailored concepts and help you to make your therapeutic visions come true.

Contact

We are pleased to personally discuss your current questions and are looking forward to our collaboration!

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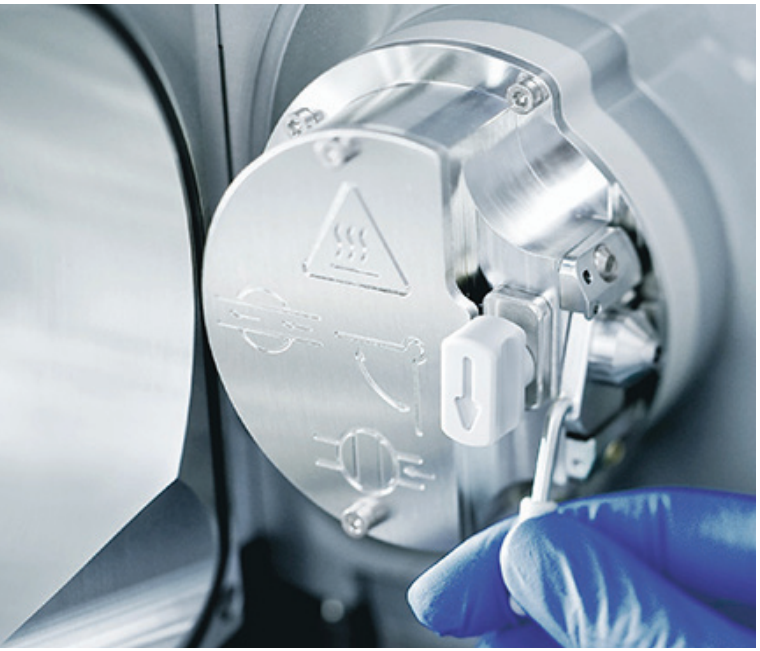
HWI group

Biopharmaceutical Services

your success is our success

HWI group



HWI group - your experts in pharmaceuticals and biopharmaceuticals from concept through development to market approval and life-cycle management.

With our extensive knowledge and experience in regulatory affairs, quality control, drug development and manufacturing, we are your competent and reliable one-stop shop partner.

We close your gaps in resources and experience and guide you through the complex regulatory framework to accelerate drug development, save costs and meet critical timelines. Our dedicated, highly qualified team strives to find the best strategy for your projects in a constantly changing environment.

Due to the different regulatory requirements in biopharmaceutical development, HWI's services, including a broad network of experts and partners, are tailored to the respective stage of development.

Our services for early-stage biopharmaceutical development

- regulatory consultancy and strategic advice
- implementation of QA system and consulting in GxP aspects, including supplier audits
- comprehensive laboratory services – development and validation of analytical methods for structure elucidation and API characterisation, identification as well as purity testing and assay
- qualification of GMP compliant pharmaceutical reference standards
- formulation development and reporting (PDR)
- storage and stability testing according to ICH guidelines
- project management

Our services for mid-stage biopharmaceutical development

- analytical method development and validation according to ICH guidelines
- analytical method and technology transfers
- establishment of impurity profile (e. g. related substances including process-related impurities, residual solvents, elemental impurities and particulate matter)
- extractables & leachables investigations and evaluations
- stability and batch release testing as well as batch release by HWI's Qualified Persons (QPs)
- development of regulatory strategy for candidate drug product
- preparation of briefing books, coordination of scientific advice meetings with authorities
- interaction with regulatory agencies
- management of partners for pre-clinical assessment
- preparation and submission of IMPDs, INDs for clinical investigational purposes
- manufacturing and release of clinical batches

Our services for late-stage or commercial-stage biopharmaceuticals

- analytical method validation and consolidation of CMC package
- stability studies and batch release testing
- batch release by HWI's QPs
- management of partners for the pre-clinical and clinical program
- consultation in marketing authorisation procedures and interaction with regulatory authorities
- filing and submission of dossiers for the investigational drug product (IMPD, IND)
- dossier writing for marketing authorisations in eCTD format
- submission of applications and RFI management
- project management
- GxP audits
- life cycle management (e.g. dossier updates, variations, renewals, line extensions)
- vigilance and quality services to ensure regulatory compliance of marketed products, QP and QPPV provided by HWI group

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