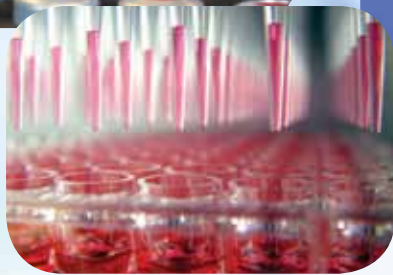


Intertek



**Experience, innovation
proven results**

Pharmaceutical Services

www.intertek.com/pharmaceutical

Service at a higher level

Intertek's global network of pharmaceutical laboratories provides a diverse range of GLP and cGMP services to support customers engaged in the research, development and manufacture of pharmaceuticals, biopharmaceuticals and related healthcare products.

Services range from bioanalysis of both large and small molecule drugs, to analytical research programs designed to support every stage of pharmaceutical development from discovery to manufacture.

- Intertek Alta Bioanalytical LCMS (El Dorado Hills, CA)
- Intertek Alta Immunochemistry (San Diego, CA)
- Intertek ASG (Manchester, UK)
- Intertek BioClin (Athlone, Ireland)
- Intertek QTI (Whitehouse, NJ)

GLP Bioanalytical Services

Intertek provides extensive expertise in method development, method validation and GLP sample analysis for LC-MS/MS, immunochemistry and ICP-MS.

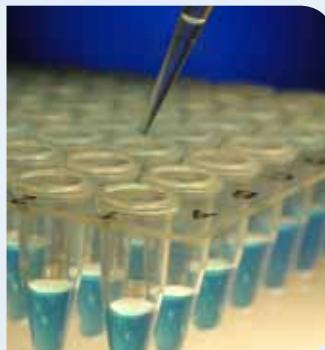
- LC-MS/MS
 - Ocular tissue bioanalysis
 - Rapid discovery phase bioanalysis
 - High throughput sample analysis
- Immunochemistry
 - Quantitative immunoassays & immunogenicity assessments
 - Cell-based neutralization assays
 - Biomarker assays
- Metals and inorganic bioanalysis
- Sample management and handling

cGMP Analytical Services

Intertek is unique in providing clients with a wide range of cGMP services to support the development of both pharmaceutical and biopharmaceutical products.

- Analytical research and development
- Stability and pharmaceutical testing
- Elemental and trace metals analysis
- Advanced compound characterization
 - pharmaceuticals
 - biopharmaceuticals
- Reference standard materials program
- QC testing services
- Extractables and leachables
- Consulting and auditing

Comprehensive GLP bioanalytical LCMS, immunochemistry and cGMP analytical services for pharmaceuticals, biologics and specialized healthcare products



Bioanalytical Services

Intertek offers clients a unique combination of expertise and technology in bioanalysis for both small and large molecule drugs through a global network of state-of-the-art, GLP-compliant laboratories located in California (El Dorado Hills and San Diego), the UK (Manchester) and Ireland (Athlone).

Capabilities include proprietary method development, validation, transfer and high throughput sample analysis. Clinical sample management services are also provided for collection and shipment to Intertek laboratories from clinical sites.

Recognizing the critical role bioanalysis plays in drug development, Intertek's mission is to consistently deliver accurate and reliable data on-time that is subject to rigorous scientific and regulatory review at the highest level. Intertek takes pride in close and active collaboration with clients to ensure the success of both preclinical and clinical programs in addition to lead optimization studies.

LC-MS/MS Services

- Method development and validation
- High throughput sample analysis (GLP)
 - Preclinical
 - Clinical (Phase I-III)
 - Bioequivalence
 - Bioavailability
- Rapid discovery phase bioanalysis (non-GLP)
 - Discovery screens
 - Lead optimization
 - Lead qualification
- Ocular tissue bioanalysis
- Pegylated small molecules and peptides
- Dose formulation analysis
- Sample handling and management

Metals and Inorganic Bioanalysis

- Method development and validation
- ICP-MS (GLP)
- ICP-AES (GLP)



We are pioneers in the application of efficient sample preparation and LC-MS/MS technologies to the analysis of drugs and metabolites in a wide variety of biological matrices, including ocular tissues

Immunochemistry Services

Intertek offers the latest in method development and validation techniques to support biotechnology and pharmaceutical clients working in the area of preclinical and clinical drug development. Technical expertise, creativity and expert customer service enables Intertek scientists to provide clients with critical data on-time, and to support a broad range of requirements.

Intertek's laboratory based in San Diego, Alta Immunochemistry, is dedicated to meeting the requirements of industry and the expectations of regulatory agencies worldwide. Intertek assures reliable assay development and validation, and maintains the highest quality control standards to provide clients with reproducible and robust assays for both preclinical and clinical studies.

GLP Services

- Quantitative ligand binding assays
 - ELISA and ECL platforms
 - pharmacokinetic studies
 - biomarker analyses
- Immunogenicity assessments
 - ELISA, ECL and RIP platforms
 - cell-based neutralization assays
- Assay development and validation
- High throughput sample analysis
- Validated data analysis, management and report writing software

Typical macromolecules

- Recombinant proteins
- Synthetic peptides
- Humanized monoclonals
- Chimerics
- Growth factors and hormones
- Cytokines
- Biomarkers

We provide extensive expertise in dealing with various types of therapeutic macromolecules, and with studies associated with PK, TK, immunogenicity and biomarkers.



Pharmaceutical Analysis

Pharmaceutical analysis is focused on the development, validation and execution of many different types of cGMP analytical methods that range from routine tests to highly complex programs. cGMP services are offered through Intertek's global network of pharmaceutical laboratories located in Ireland (Athlone), UK (Manchester) and New Jersey (Whitehouse).

Intertek's pharmaceutical experts provide analytical R&D, characterization and specialized technologies to support every stage of pharmaceutical development for drug substance and drug product. Intertek strives to ensure that all clients' technical and regulatory objectives are met within the required timelines, and that the highest levels of quality assurance and compliance are maintained at every stage of the process.

cGMP Services

- Analytical research and development
- Chemical imaging
- Cleaning validations
- Comparator studies
- Dissolution
- Elemental analysis and trace metals
- Extractables and leachables
- Medical devices support
- NMR analysis
- Counterfeit drug analysis
- Physical characterization techniques
- QC testing services
- Reference standard materials program
- Stability and storage
- Supply chain management



We specialize in supporting the pre-approval stage of the drug development life cycle, and provide expertise for a wide array of drug products, formulations, devices and delivery systems.

Biopharmaceutical Analysis

Biopharmaceuticals often present genuine and unique challenges during development and manufacture. To address these challenges Intertek provides services for large molecules that span advanced analytical R&D and complex characterization studies, method development and validation employing a diverse range of specialized analytical techniques, QC services for biopharmaceutical production and storage and stability studies.

Intertek's biopharmaceutical laboratory in Manchester (UK), Intertek ASG, is focused on helping clients ensure that their biopharmaceutical products such as recombinant proteins, monoclonal antibodies, vaccines, synthetic peptides and oligonucleotides all meet the highest possible standards of safety and quality.

cGMP and GLP Services

- Analysis of process and product related impurities
- Antibody therapeutics - specialized services
- Comparability studies for biopharmaceuticals
- Development and validation of specialized methods
- Elemental analysis and trace metals
- Higher order structural characterization
- Isolation and characterization of product-related impurities
- Method development, validation and remediation
- NMR analysis
- Stability studies for biopharmaceuticals
- Structural characterization and confirmation

We provide comprehensive analysis and highly specialized characterization services for a wide variety of biologics and macromolecules.



Integrated Clinical Bioequivalence and PK Program

Intertek BioClin based in Ireland collaborates with select Phase 1 clinics in the EU to provide generic and drug delivery clients with an integrated bioanalytical and clinical testing program for both pilot pharmacokinetic and pivotal bioequivalence studies.

This program combines Intertek's analytical expertise with European Phase 1 clinics to provide a rapid and cost-effective clinical pharmacology service. Intertek partners and operates as a single vendor to provide speed and flexibility, including interim data reporting and real-time, secure web-based data access during the clinical trial.

Services

- Assay validation
- Bioanalysis (GLP)
- Clinical batch stability
- CTA submission
- ICH integrated reports
- IMP import and QP release
- Pharmaceutical analysis (cGMP)
- Phase 1 clinical conduct
- PK, statistics, protocol design

Pharmaceutical Auditing and Consulting

Global expertise in regulatory requirements combined with a reputation for technical knowledge accrued over many years, enables Intertek to provide a range of consulting services for analytical research, medical devices, QA and IT in the pharmaceutical industry.

Typically, consulting programs are designed to meet specific client requirements and can range from small to large in scope. In addition, services can be provided in-house, on-site at multiple client locations or at third party facilities.

Services

- cGMP Analytical research & development
 - Complete program design
 - Laboratory design and instrumentation
 - Validation planning and design
- IT and computer compliance
- Medical devices
- Quality Assurance
 - DEA sample handling/systems
 - On-site GMP/GLP training
 - Quality management systems
 - Supply chain management, vendor qualification and GMP auditing
 - Validation support (development, planning, equipment)



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