

TOTAL QUALITY ASSURANCE

# PHARMACEUTICAL SERVICES

Laboratory & Assurance Solutions



# Total Quality Assurance for Pharmaceutical Development and Manufacturing

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Across your product lifecycle, our expertise brings you the insight you need to accelerate pharmaceutical, biopharmaceutical or medical device product development. Our assurance solutions allow you to identify and mitigate risks associated with products, processes, operational and quality management systems, assets and supply chains. Our specialists bring many years of experience across a variety of product areas including:

- Innovative and Generic Pharmaceuticals
- Peptides, Proteins, Biosimilars
- Monoclonal Antibodies
- Antibody-drug Conjugates
- Oligonucleotide and mRNA Products
- Vaccines
- Cell and Gene Therapies
- Orally Inhaled and Nasal Drug Products
- Nutritional Products, Dietary Supplements
- Consumer Healthcare and Cosmetics
- Medical Devices
- Veterinary Medicines
- Over-the-Counter (OTC) Drugs



We have delivered flexible contract services to the global pharmaceutical industry for over 30 years

### Achieving Total Quality Assurance

Our scientists, regulatory experts and auditors work with you at every stage of development and manufacturing, providing responsive, quality compliant solutions.

At Intertek, our wealth of experience and depth of industry knowledge enables our clients to navigate the challenges of new product development, scale up, manufacturing and market release whilst minimising risks and meeting regulatory criteria accurately. We respond precisely to your needs with solutions that go beyond just “testing” to help you achieve total quality assurance.

You can rely on our global network of experts, laboratories and specialists to deliver support including analysis, bioanalysis, formulation development, biologics characterization, specialist inhalation development expertise, regulatory consultancy, risk assessment, auditing and supply chain management solutions.



📍 Laboratory Services    📍 Assurance Solutions



### LABORATORY SERVICES



- GLP and GCP Bioanalytical Services & Biomarkers
- GMP and CMC Laboratory Services
- Pharmaceutical Analysis, Stability and Formulation Development
- Extractables/Leachables Packaging Support
- Process Development Analytical Support

### ASSURANCE SOLUTIONS



- Toxicology and Impurity Risk Assessment Consulting
- Product Development Strategies
- Regulatory Affairs
- CMC Support & Guidance
- Toxicology Consultancy

- Supplier GXP Auditing Solutions, Inspections and Gap Analysis
- Global Supply Chain Management Solutions & Supply Chain Surveillance
- Process Quality Audit, Risk Analysis and Process Improvement
- Environmental Mapping, Inspection and Calibration
- Process, Facility or Equipment Qualification
- Sustainability and Asset Integrity Management

# Bioanalytical Services

We deliver FDA/EMA compliant bioanalytical solutions that optimise value for your development programs

Bioanalysis plays a critical role in the assessment of drug safety and efficacy and we understand that each project will present its own unique challenges. Our teams work closely with you to deploy regulatory bioanalytical studies, ensuring that the best possible solutions are delivered.

To help you to make informed decisions faster, our Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) compliant laboratories provide clinical kit preparation, sample handling and management capabilities, fully integrated with automated data capture and reporting systems using the latest bioanalytical platforms.

Our bioanalytical experts have developed methods for thousands of different compounds, providing phase-appropriate, small molecule and large molecule bioanalytical support, high-throughput sample bioanalysis, pharmacokinetic, toxicokinetic and pharmacodynamic support, immunogenicity and biomarker assays.

## Our centres of excellence

Our 30,000 square foot European Centre of Excellence is located in Manchester, UK. With continued investment in the latest bioanalytical technologies, our services are positioned to expedite delivery of fast and cost-effective bioanalysis results for global clients involved in preclinical and clinical development of small molecule drugs and biologic medicines.

## Diverse bioanalytical technologies

Our innovative use of technologies means that, no matter how complex your samples, we can accommodate the chemistry or biology of your analytes as well as any matrix interferences. Technologies include Multiplex Immunoassays, LC-MS, LC-MS/MS, ELISA, ECL, Ultra-sensitive Biomarker Platforms, Flow Cytometry, qPCR, ddPCR, NGS, NMR, ICP-MS, Cell-based, and more.

## Unique bioanalytical expertise

Our teams are adept in method development, method validation and transfer of efficient and accurate methods which are optimized for your compound. Projects are assigned to and managed by experienced Principal Investigators with support from teams of Project Managers, Project Coordinators, Senior Scientists and Chemists. We provide:

- Bioanalysis for Large and Small Molecules
- Immunogenicity & Neutralizing Antibody Assays
- Antibody Drug Conjugate (ADC) LC-MS and Immunochemistry Services
- Long History of Bioanalytical Support for Biosimilar Drug Development
- Post Marketing Antidrug Antibody (ADA) assays
- Demonstrated Expertise in Ocular Tissue
- Clinical Kit Preparation, Sample Handling & Management

We apply our bioanalytical expertise and industry insight to design strategic and efficient bioanalytical programs



## CASE STUDY

### Novel Approaches for An Enzyme Activity Assay

A client desired an activity assay for a PEGylated enzyme for which a commercial colorimetric assay was available. The colorimetric assay did not meet the performance criteria for regulated work. An immunoassay was then developed but was subject to significant matrix effects.

### Our Solution

Development of a replacement assay was complicated by endogenous substrate and enzymatic product. To overcome this, the specificity of LC-MS/MS was employed and an activity assay developed using a stable labeled substrate which produced a labeled product, which could be differentiated from the endogenous analyte.

### Benefit Delivered to our Client

A enzymatic activity LC-MS/MS assay was developed and successfully validated to regulatory standards. The method was used in multiple pharmacokinetic studies and enabled the client to move forward with their drug development program.

### Large molecule bioanalysis

We have extensive experience in the development, validation, and sample analysis of quantitative and qualitative GLP and non-GLP immunoassays in support of clinical and preclinical studies for the measurement of therapeutic drugs, synthetic peptides, humanized monoclonal antibodies, chimerics, conjugated drugs, growth factors, hormones, cytokines and biomarkers.

- Quantitative Ligand Binding Assay - Pharmacokinetics
- Immunogenicity Studies using a Tiered Approach
- Cell-based Neutralising Antibody Assay
- Biomarker Solutions
- Enzymatic Assays
- Fluorometric Assays
- Biotinylations and Ruthenium Labeling of Molecules
- Mode of Action Studies
- Bioanalytical LC-MS/MS for Proteins and Biologics
- Quantification of PEGylated Drugs in Biological Matrices by Nuclear Magnetic Resonance Spectroscopy (NMR)

### Biomarker assays

Intertek's GLP/GCP/GMP compliant laboratories provides support to clients focused on the development of pharmaceuticals and biological medicines.

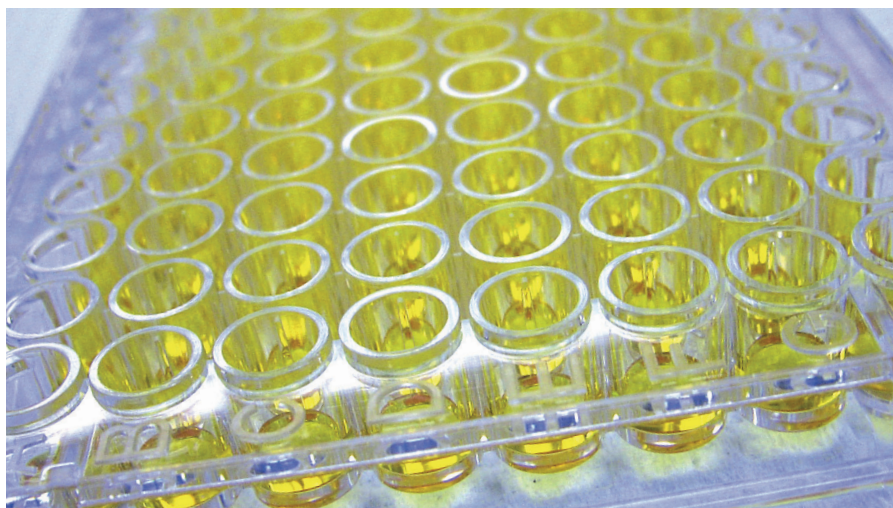
Our biomarker services provide fit-for-purpose validations in support of your context of use. We provide a continuous and iterative process which evolves with your context of use for the biomarker data.

Intertek deploy a diverse array of analytical platforms to support biomarker analysis including ELISA, flow cytometry, cell-based assays, ECL multiplex platforms and high sensitivity measurements by the Quanterix Simoa HD-X Analyzer™.

### Small molecule LC-MS services

Our scientists deliver robust and reproducible bioanalysis solutions that apply validated methods in a high-throughput environment to accelerate development times for proprietary and generic drugs across many types of biological matrices. We apply regulatory guidelines to a diverse array of platform technologies including ICP, NMR and GC.

- Method Development & Validation
  - High Throughput GLP & GCP Sample Analysis
  - Pre-clinical & Clinical Bioanalysis
  - Bioequivalence & Bioavailability Studies
- Non-GLP Rapid Discovery-Phase Bioanalysis
  - In Vitro Screening Bioanalysis
  - Tissue Bioanalysis
  - Early Pharmacokinetic (PK) Studies
  - Lead Optimization Studies
- Clinical Kit Preparation, Sample Handling & Management
- NMR Approaches for PEGylated APIs
- Bioanalysis for Trace Metals Using ICP-MS
- GC-MS Approaches for Volatiles
- Oligonucleotide LC-MS Immunochemistry and Immunogenicity



# GMP and CMC Laboratory Services

Through specialist laboratory services for complex products, we help you to accelerate your development process and support your post-marketing requirements

Chemistry, manufacturing and controls (CMC) development strategies and Good Manufacturing Practice (GMP) laboratory services play a key role in reaching your next milestone. We provide regulatory-driven, phase-appropriate, CMC laboratory and GMP analytical services that can help you to identify sources of risk early in development and provide sufficient information to help you meet the stringent regulatory requirements of registration and production.

## Integrated formulation & analytical development

Our formulation development scientists are experienced across a range of dosage forms including orally inhaled and nasal drug products (OINDP), oral, solid, liquid and transdermal or topical. Strategic integration of formulation development with analytics ensures a detailed understanding of the pharmaceutical materials, their compatibility, physical properties and stability.



## Stability studies

With a network of ICH stability storage facilities in the UK, USA and Australia, we offer an extensive capacity and a range of conditions including climatic walk-in chambers and cabinets as well as freezer storage. Our stability teams provide professionally managed cGMP stability programs for even the most complex of dosage forms including orally inhaled and nasal drug products (OINDP), biopharmaceuticals, medical devices or vaccines.

## Elemental impurity analysis and risk assessment

Our elemental impurities experts can help you to develop a compliance strategy to achieve successful implementation of guidance such as ICH Q3D / USP General Chapter <232>, 'Elemental Impurities - Limits'. Our teams design tailored analytical programs involving both screening studies and toxicological risk assessment of the data if required. Additionally, we can develop and validate methods tailored to your specific products.

## Clinical trial supplies manufacturing services

Our clinical trial supplies manufacturing services are delivered from our state-of-the-art GMP compliant facility supporting investigational medicinal product (IMP) or investigational new drugs for clinical trials around the world. Integrated with

raw material characterisation and sourcing, formulation development, scale up, pilot batch manufacturing and testing, cleaning development and validation, GMP batch manufacturing and GMP release testing with QP release, we offer a one source solution for supplies for use in Phase I and II clinical trials.

## Extractables and leachables studies

Extractables and leachables studies are conducted in accordance with regional guidance, GMP PQRI recommendations, and United States Pharmacopeia (USP) requirements. Our experience in method development for controlled extractables studies, coupled with our vast knowledge of leachable compounds, means that we can anticipate and identify potential sources of risk. We support a wide range of closure or delivery systems such as pre-filled syringes, parenteral products, OINDP and bioprocessing equipment. We conduct glass delamination and extractables studies for glass packaging. Scientific support is available at every stage of the testing program, including toxicological risk assessment of identified extractables / leachables.

## Service Overview

- GMP Pharmaceutical Analysis
- Method Development & Validation
- Biopharmaceutical CMC Solutions
- GMP Stability Studies
- GMP Batch Release Testing
- Extractables / Leachables
- Glass Delamination Studies
- Elemental Impurities
- Formulation Development
- Preformulation and Physical Characterisation
- GMP Quality Control Testing
- Reference Standard Certification
- Impurities and Particulates Analysis
- Clinical Trial Supplies Manufacturing Services
- Regulatory Affairs
- GMP Auditing and Supply Chain Assurance
- GMP Training Sessions and eLearning For Staff

# Inhalation and Nasal Product Development

Our unique project management approach enables you to interact directly with our scientists at every stage of the process.

Our inhaled and nasal product development team focus on the critical parameters that can affect the efficacy of drug delivery to the intended target across all respiratory product classes including dry powder inhalers (DPIs), pressurised metered dose inhalers (pMDIs), nebulisers and nasal sprays (solution, suspension or dry powders), as well as a range of novel respiratory delivery systems.

We have been working in the inhaled and nasal fields for over 30 years and have the necessary experience to support the entire product development process, delivering formulation development / optimisation, product performance testing, stability / CMC support and clinical manufacturing services that are designed to provide the right information at the right time.

## Inhalation and nasal product development / testing services

Alongside typical drug product specification testing such as identification, assay, degradation products, moisture and pH, our OINDP services include drug delivery characterisation, aerodynamic particle / droplet size distribution, spray pattern/plume geometry, physical characterisation for particle size, droplet size and powder rheology. With extensive experience in method development and validation, we also perform GMP compliant clinical batch and finished product release testing, and offer flexible resources for raw materials quality control testing.

To address the control of leachables from device components, we apply our unrivalled knowledge of polymer materials and expertise within extractables / leachables studies to drug / packaging interaction areas.

## Formulation development

Intertek's integrated formulation and analytical teams carry out early stage pre-formulation support, solubility screening, drug-excipient compatibility, stability testing and device selection support to aid clients working to develop more efficient devices and formulations with both small molecule and biologic drug substances.



## Expertise:

- Method Development / Validation
- Bioequivalence Studies
- Comparator Studies
- Device / Excipient Compatibility Studies
- Quality by Design (QbD) Studies
- ICH and Accelerated Stability Studies
- Formulation Development
- Clinical Trials Materials Manufacturing
- Product Characterisation Studies (e.g. patient in-use / misuse, spacer and cleaning studies, etc.)
- Device Verification Testing
- Foreign Particulates Analysis and Identification

The development of inhaled biologics brings together two of our core strengths; formulation development for inhalation technologies and biological product characterisation, in particular, applying methodologies to assess potential degradation routes.

## CASE STUDY

### Supporting our client's novel device development

An innovative developer of inhalation medicines wanted to ensure that its new inhaler design was suitable for registration.

#### Our Solution

Intertek characterised the parameters that define performance and function (critical quality attributes). The effects of long term storage (stability study) and simulated patient use / mis-use were studied.

#### Benefit Delivered to our Client

Our experts confirmed that the device displayed consistent performance across 60 days in use and the medicine was stable for three years under recommended storage guidelines. We were able to verify that the design was suitable for our clients to proceed with their market release, which was successful.

# Biopharmaceutical Services

In an era where financial prudence is a necessity, getting your analytical or bioanalytical strategy right the first time is more important than ever

Ensuring the purity, identity, safety and quality of your biopharmaceutical product is critical to success

Our thought-leaders have nearly 30 years of experience in biopharmaceutical development support across a wide range of product types. We provide regulatory-led, phase-appropriate, tailored analytical program design and GLP or GMP compliant laboratory services which help you to navigate the challenges of development, regulatory submission, and manufacturing.

With broad capabilities in India, Europe (UK, France, Switzerland) and the USA, our experts provide strong scientific and technical leadership coupled with project management and regulatory support to drive your development and manufacturing programs forward.

## Analytical programme design across a range of product types

- Recombinant Proteins & Glycoproteins
- Bispecifics
- Monoclonal Antibodies
- Antibody-Drug Conjugates
- Peptides
- Biosimilars & Biobetters
- Growth Factors
- PEGylated Proteins
- Interferons
- Interleukins
- Oligonucleotide Therapeutics
- mRNA Products
- Cell & Gene Therapies
- Vaccines, Viral Vectors, VLPs

## Tailored analytical packages

Protein therapeutics can present significant analytical challenges. Our characterisation packages are tailored to your biomolecule and reflect the requirements of ICH Guidelines to meet the analytical challenges of a 'well characterized' or 'specified' biological product.

Programs encompass many different analytical techniques and provide information ranging from evaluation of physicochemical properties and structural features including primary, secondary and higher order structure and assessment of post-translational modifications. Programs also include determination of biological potency and assessment of purity / impurity profiles.

## Biopharmaceutical development support

- GLP Clinical & Preclinical Bioanalysis (PK, ADA, Nab)
- Immunogenicity Studies
- Analytical Programme Design
- Structural Characterisation (ICH Q6B)
- Physicochemical Properties (ICH Q6B)
- Biophysical Characterisation
- Comparability Studies
- Biosimilar Programmes
- Process Residuals Determination
- Product Related Impurities Determination
- Purity and Impurity Assessment
- GMP Potency / Cell Based Assays
- Method Development & Validation
- Extractables / Leachables
- GMP Quality Control Testing
- GMP Batch & Final Product Release Testing
- ICH Stability Studies
- Forced Degradation Studies
- Drug Delivery / OINDP Expertise

## Ensuring a safe and efficacious product

Our GLP bioanalysis capabilities include developing and validating assays for pharmacokinetic (PK), toxicokinetic (TK), immunogenicity and biomarker studies to evaluate efficacy and safety from early discovery through to late stage clinical studies. Core services include immunochemistry and LC-MS/MS technology to provide sensitive and versatile support for customers' development programs in full regulatory compliance (FDA, EMA and OECD GLP regulatory standards). We also offer industry-unique instrumentation to support complex products, for example; quantitative NMR which is an ideal tool for bioanalysis of PEGylated biomolecules.

## CASE STUDY

### Antibody Drug Conjugate (ADC) Characterisation

A client developed an ADC drug product with an innovative linker technology. They wished to understand the structure of the drug-linked species and the effect of conjugation on biological activity.

#### Our Solution

We performed characterisation studies to evaluate the antibody structure, drug load distribution, individual drug load variants and the drug-to-antibody ratio (DAR). An assessment of the impact of conjugation chemistry on the biological function included binding and effector function studies.

#### Benefit Delivered to our Client

Our experts delivered the insight the client required to understand the drug load distribution, the impact of conjugation and confirmed other structural parameters, allowing the client to progress towards their next milestone.

## Regulatory Analytical Packages (ICH Q6B)

Structural Characterisation	
Amino Acid Sequencing/ Peptide Mapping:	Sequencing studies and peptide mapping using a broad range of enzymatic or chemical digestion followed by Mass Spectrometry (LC-MS/MS or MALDI-TOF MS).
Amino acid composition:	Pharmacopeia methods.
Terminal amino acid sequence:	Confirmation of N- and C-terminal sequences and evaluation of modifications and / or heterogeneity.
Disulphide bridge mapping:	Assessment of the degree and positions of both expected and mis-matched disulphide bridges by extended LC-MS/MS study and colorimetric test for free sulfhydryl groups.
Carbohydrate structure:	Glycosylation studies typically including levels of monosaccharides and sialic acid, N/O linked glycan profiling (NPLC, HILIC, IEX or CE-LIF), enzymatic digest and MALDI -TOF or LC-MS/MS.
Physico-chemical Properties	
Molecular weight:	Molecular weight of intact proteins by MALDI-MS, ESI-MS and LC-MS supported by orthogonal techniques such as MALLS, and SDS-PAGE.
Isoform pattern:	Isoform and impurity studies using PAGE, SDS-PAGE, IEF, CE, HPLC.
Extinction coefficient:	Determination and Validated Extinction Coefficient studies.
LC patterns:	For ID, homogeneity, purity - HPLC, UPLC, SEC, RP HPLC, IEX, AEX.
Spectroscopic patterns:	CD, FTIR, 1D & 2D NMR, Fluorescence, UV-Visible.
Electrophoretic patterns:	CE(CZE), cIEF, CGE, cSDS, SDS and NATIVE PAGE, Western Blot.
Concentration:	Lowry, BCA, Total AA, Total Nitrogen, Bradford.
Aggregation studies:	SEC (MALLS), DLS, Western Blot, CE, Gel Electrophoresis, SEM/TEM.
Process Impurities:	Residual host cell DNA by qPCR, Residuals (such as antibiotics, antifoaming agents).
Potency Assays	
Cell-based Assays:	To support characterisation, stability, comparability testing and product release, for example, Complement-dependent cytotoxicity (CDC), Antibody-dependent cell cytotoxicity (ADCC) and Neutralisation and Proliferation Assays.



# Scientific and Regulatory Services

We deliver innovative and effective solutions that address complex product development, toxicological, and safety issues to our clients worldwide

## Toxicology consulting

Intertek provides expert toxicology consulting services to pharmaceutical, biotechnology, and medical device companies. Intertek's Board-certified experts and their teams offer clients years of scientific research and hands-on industry experience.

Our team includes Eurotox and Board-certified toxicologists and RAC-certified regulatory affairs specialists who possess broad experience in product development, data review, and toxicology issue resolution.

## Regulatory support

Intertek regulatory professionals possess extensive knowledge of the applicable legislations and regulations which govern pharmaceutical and medical products (and other regulated or notifiable materials) in North America, Europe, and many other jurisdictions around the world. We continually survey regulatory policies and practices to provide clients with timely information that reflects developments and changes. Our understanding of the intricacies and processes of regulatory agencies is unsurpassed. The combination helps our clients to develop cost effective and successful regulatory strategies which are 'right the first time'.

## Scope of services

- Product Development Strategies
- Product Classification in Various Markets
- Regulatory Affairs Consulting
- INDs, CTAs, IDE, IMPD, BLA, NDAs, NDSs, MAAs, 510(k)s, PMAs, Briefing Documents, Investigator's Brochures, Annual Reports, Integrated Summaries
- Device Establishment Registration
- Post-Marketing Activities (e.g. Label Review)
- Regulatory Strategies and Guidance
- Management of Interactions and Negotiations with Regulatory Agencies
- Chemistry, Manufacturing and Controls (CMC) Regulatory Support and Guidance
- Toxicology Consulting
- Non-clinical Study Design
- Scientific Program Management
- Data and Report Review and Interpretation
- Expert Reports and Literature Reviews
- GLP Monitoring (Facility and In-Life Audits)
- Risk Analysis and Safety Assessments (Impurities, Extractables & Leachables, Excipients)
- Medical and Scientific Writing
- Assistance with Due Diligence



# Supply Chain Assurance Solutions

Delivering supply chain assurance, which allows you to power ahead safely and with total confidence

## Helping you to drive improvement, manage risk and optimize productivity

In today's global marketplace, pharmaceutical supply chains can be complex, involving a multitude of suppliers, facilities and production processes.

Your primary business focus will be on leveraging competitive advantage through robust, efficient, sustainable pharmaceutical supply chains and manufacturing that demonstrates excellence in quality and compliance. Our supply chain solutions help you to ensure supply chain quality, and security whilst assessing and mitigating risks to achieve total product quality assurance. We can help you to optimise productivity and drive improvements to achieve manufacturing that demonstrates excellence in efficiency, quality and compliance.

### SUPPORTING COMPLEX SUPPLY CHAINS

#### Supplier audit and assessment

Through cost-effective GMP shared supplier audit and inspection services, we help you to ensure that all regulatory requirements (FDA, MHRA) are met. Our online platforms offer supplier assessment that drives improvement and informed decision-making.

#### Global supply chain compliance platforms

We supply Global Supply Chain Compliance Platforms which reduce demands on staff time through effective scheduling, tracking, automated reporting, data mining and analytics.

#### Sustainability assurance for the supply chain

Our sustainability assurance experts help you meet global green regulatory goals and achieve green supply chain management.

#### Pharmaceutical supply chain surveillance for counterfeit or falsified medicines

Tailored pharmaceutical supply chain surveillance programs built upon our many years of experience in anti-counterfeit investigation from World Health Organisation (WHO) prequalified and GMP laboratories.

### OPTIMISING PRODUCTIVITY

#### Processes, facilities and equipment

With an expert team of engineers and inspectors we provide calibration, inspection, and qualification for facilities, processes and your equipment. Through comprehensive risk analysis and planning we help you to implement process improvement.

#### GMP training sessions and e-learning for staff

Training from our GMP experts or cost-effective eLearning modules, drive a positive impact on your compliance and manufacturing goals.

#### Asset integrity management (AIM)

Our specialist AIM programs incorporate design, maintenance, inspection, process safety, mechanical integrity, corrosion, metallurgy, operations and process support and risk analysis to help protect integrity of infrastructure and equipment. Through our AIM expertise - coupled with our corrosion testing - we can help extend production asset lifetimes and reduce downtime.

#### Production contamination resolution

Helping to avoid costly long-term plant shut-down or delayed release of materials, our specialists examine products, plant processes and your supply chain to identify and resolve contamination.

#### Environmental mapping, inspection and certification


Our inspections team conduct facilities and equipment calibration, as well as validation, ongoing monitoring and mapping for facilities and cleanrooms, helping to optimise operations.





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