DRUG DEVELOPMENT SOLUTIONS
Part of Alliance Pharma, Inc.

Analytical and Materials Science Solutions

A team of problem solvers ready to partner with you.

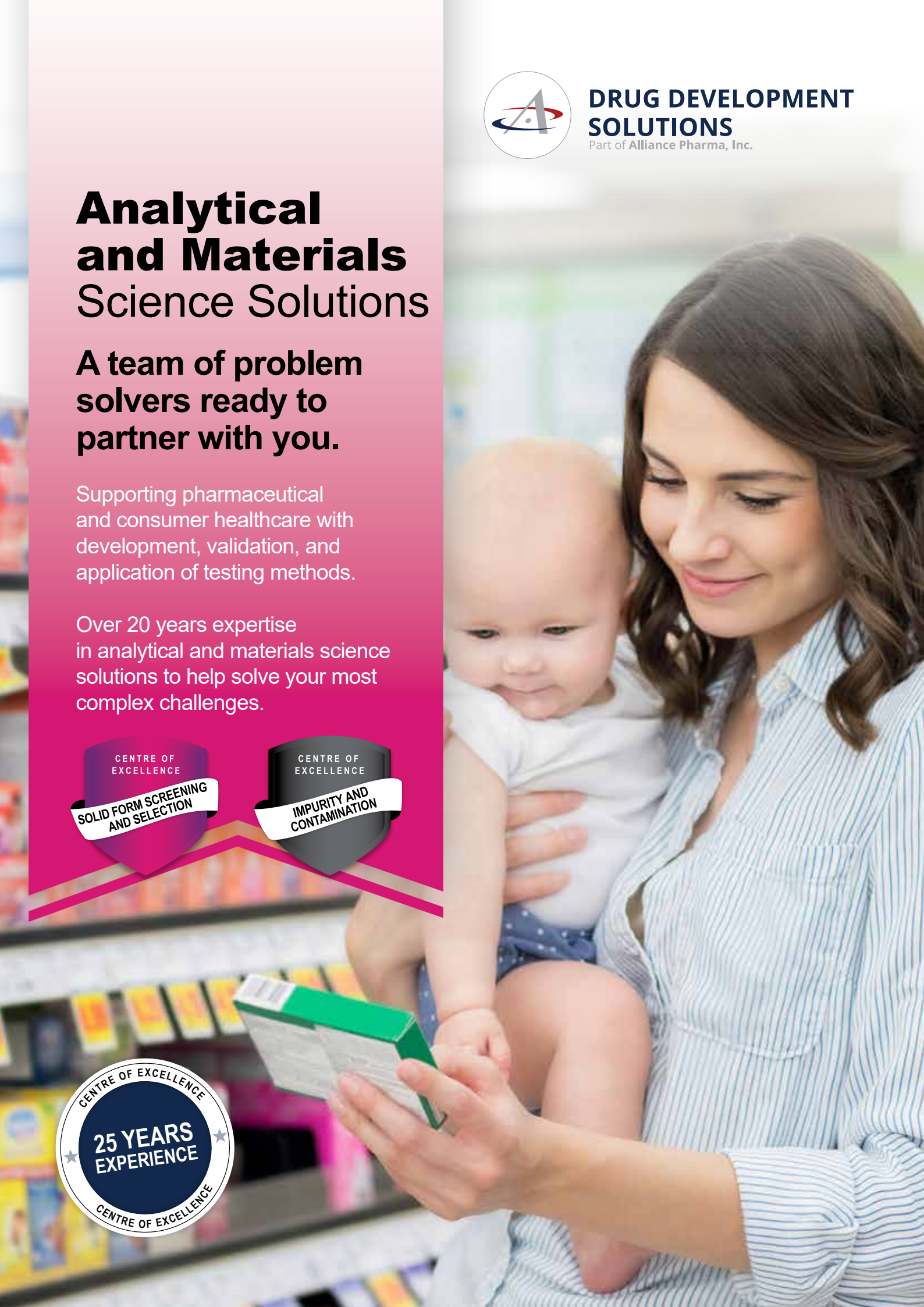
Supporting pharmaceutical and consumer healthcare with development, validation, and application of testing methods.

Over 20 years expertise in analytical and materials science solutions to help solve your most complex challenges.

CENTRE OF EXCELLENCE
SOLID FORM SCREENING AND SELECTION

CENTRE OF EXCELLENCE
IMPURITY AND CONTAMINATION

CENTRE OF EXCELLENCE
25 YEARS EXPERIENCE
CENTRE OF EXCELLENCE

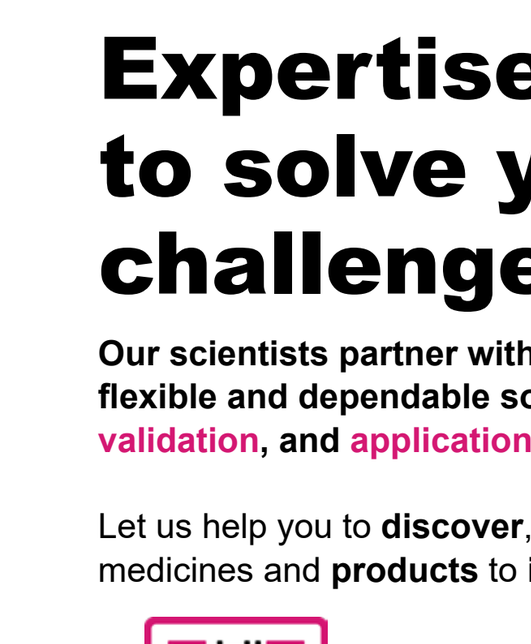


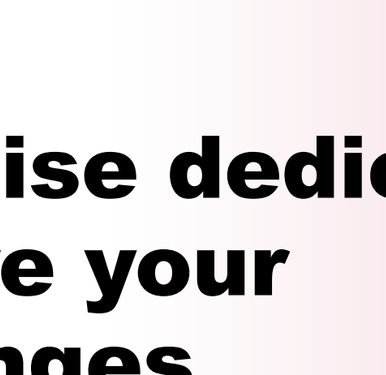
Expertise dedicated to solve your challenges.

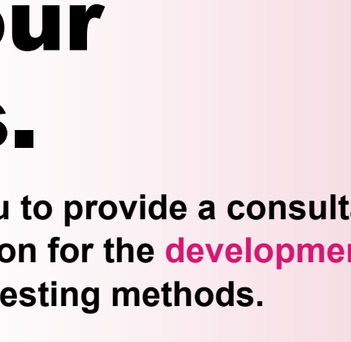
Our scientists partner with you to provide a consultative, flexible and dependable solution for the development, validation, and application of testing methods.

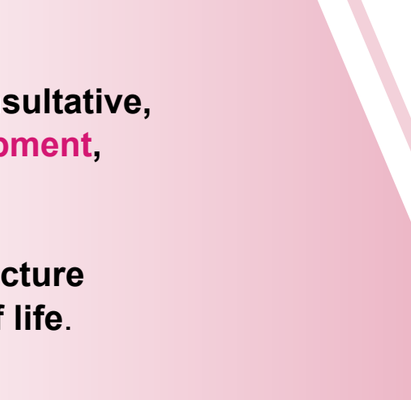
Let us help you to **discover**, **develop**, and **manufacture** medicines and **products** to **improve the quality of life**.

LEARN MORE









	ANALYTICAL SCIENCE	MATERIALS SCIENCE
1 Experience	Raw Materials, Excipients, Active, Formulated Product, Packaging, Devices Small Molecule Pharmaceuticals, Consumer Products & Healthcare	
2 Capability	Analytical Chemistry, Impurity ID, Elemental Impurities, Extractables and Leachables	Materials Characterisation, Foreign Matter Analysis, Solid Form Screening
	Development and Validation of Testing Methods, Sample Analysis	
3 Solutions	Product Discovery, Development, Characterisation, Quality Control, Stability, Troubleshooting	
4 Excellence	CENTRE OF EXCELLENCE – IMPURITY AND CONTAMINATION CENTRE OF EXCELLENCE – SOLID FORM SCREENING AND SELECTION	Specific Centres of Excellence are focused on being at the forefront of scientific and industry developments, requirements, and solutions.

UK GMP labs

Analytical Chemistry

Specialising in bespoke analytical methods for identification, characterisation, and testing of your pharmaceutical or consumer healthcare material to aid the development and ensure continued quality control of your drug product, drug substance or raw materials.

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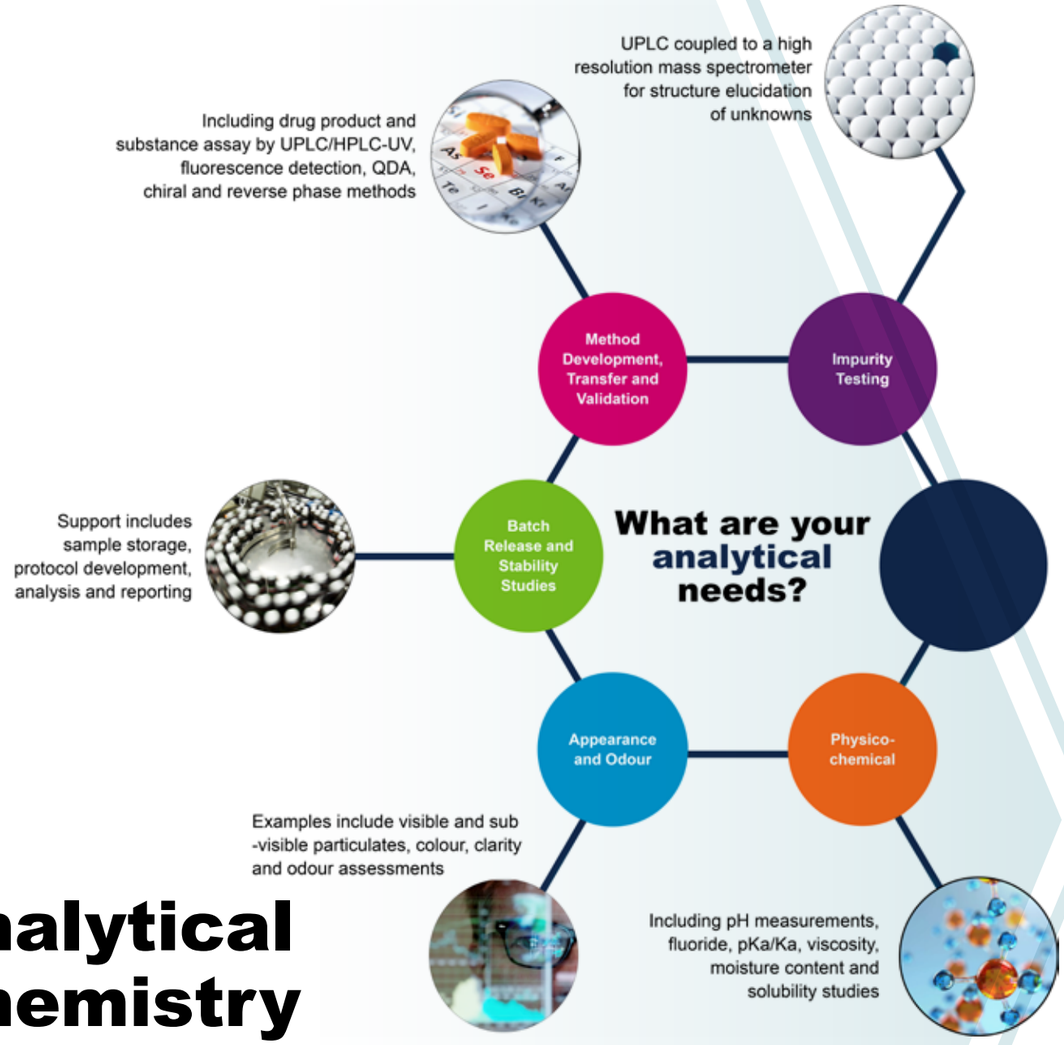

Our team of industry experts can design and optimise novel test methods for your materials. Subsequent, phase-appropriate method validation is tailored to the ICH Q2 (R1) guidelines to provide confidence in the data produced for quality control, batch release and during the life of your stability program for conformance with regulatory guidelines and expectations.

Routine and Pharmacopoeia testing are supported by our experienced scientists who are also available to provide technical support as well as troubleshooting and problem-solving advice for any other analytical issues you may encounter.

Impurity ID

The presence of contaminants or impurities in pharmaceutical and consumer healthcare products may lead to undesirable pharmacological and/or toxicological effects, which in turn may affect the safety, efficacy and quality of the product.

Contamination and impurity identification and profiling is therefore critical to the safety, efficacy and quality of a pharmaceutical or consumer healthcare product and is a regulatory requirement.

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Our Impurity and Contamination Centre of Excellence are experts in the identification and quantification of trace impurities in a wide range of materials used throughout the global pharmaceutical and healthcare sectors.

We are highly experienced in contamination investigations and the accurate quantification of trace levels of organic and inorganic impurities (down to sub-ppb levels) in materials including:

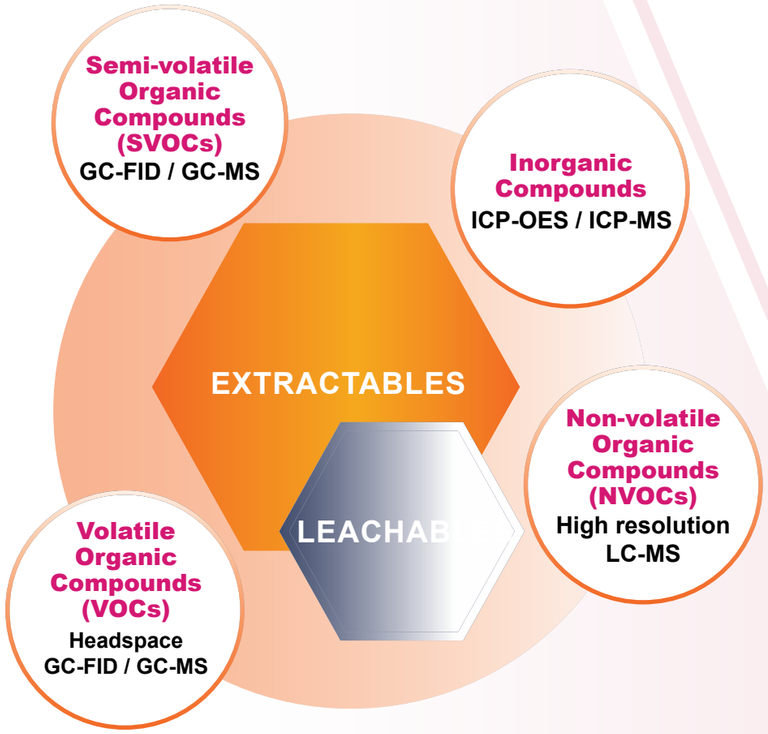
- APIs
- Excipients
- Intermediates
- Metabolites
- Formulated products

Our Experience

We support a wide range of products at the discovery, development and manufacturing stage with the following typical work packages:

- Discovery/Development
- Reaction monitoring, impurity profiling, impurity method development
- Characterisation
- Defining impurities as Critical Quality Attributes, impurity method validation
- Forced degradation/stability
- Product related impurities
- Extractable and leachables
- Foreign particulate matter (counting and characterisation)
- Genotoxic Impurities e.g. N-nitrosodimethylamine (NDMA)
- Process related impurities e.g. surfactants, catalyst residues
- ICH Q3D elemental impurities
- Residual solvents quality
- Troubleshooting - unknown ID and structural elucidation
- Quality control testing and batch release

These services are delivered from our AMS facilities which have been inspected by the UK MHRA for cGMP compliance.



Extractables and Leachables Testing

Extractables and leachables (E&L) testing provides vital information concerning the potential for impurities deriving from container closure systems, drug delivery devices and manufacturing processes. This contamination can present a risk in terms of both patient safety and product efficacy.

E&L studies utilise organic and inorganic screening methods to profile extractables from polymeric componentry, see the table below for examples, and target leachables in final drug product formulations.

Our expert team designs bespoke study protocols in accordance with the latest regulatory guidelines to ensure drug product safety and compatibility with storage and delivery devices.

- Extraction under exaggerated or simulated use conditions
- Accelerated leachable studies
- Screening and compound specific validated assay methods
- Characterisation of unknowns
- Toxicological assessment (using our partner provider

All testing is performed at our cGMP facilities in the UK as part of our Impurity and Contamination Centre of Excellence.

Drug container / delivery devices
pMDI
Vials, ampoules and bottles
Blister packaging
Syringes
Process components and consumables

Elemental Impurities Testing

Our dedicated elemental impurities team offer targeted, bespoke screening and quantitative analysis of elemental impurities in final products, excipients, APIs, raw materials and packaging materials.

We can perform reliable and accurate analysis in accordance with ICH Q3D and USP<232><233> guidelines by using a combination of ICP-MS and ICP-OES as appropriate. This combination enables us to measure down to ppt levels as required for impurity quantification in high dose materials, as well as up to ppm or wt% levels where an assay is required.

Applications

- ICH Q3D and USP<232><233> elemental impurity screening
- Method development and validation
- Targeted metals analysis
- Extractables and leachables testing
- Pharmacopeia testing
- Active/Drug substance testing
- Finished product testing
- Raw materials testing
- QC, stability and batch release testing
- Metal speciation
- Contamination identification

Sample Preparation

- Microwave digestion or extraction
- Wet chemical digestion
- Reflux extraction
- Fusion
- Solvent extraction

Techniques

- Inductively Coupled Plasma with Mass Spectrometry (ICP-MS) - Agilent 7700x and Agilent 7900
- Inductively Coupled Plasma with Optical Emission Spectrometry (ICP-OES) - Thermo iCAP7600 Duo

Solid Form Screening and Selection

Understanding the solid forms available to your drug development candidate is a vital step in early development.

Our comprehensive Materials Science Analysis capability allows us to offer a Solid Form Screening and Selection service for salts, cocrystals and polymorphs.

Our experienced team can design and complete efficient screens, interpreting results in the context of candidate development phase and recommending optimal forms for progression.

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Our Solid Form Screening and Selection Centre of Excellence builds on our expertise in Materials Science analysis to offer discovery of high quality crystalline forms of small molecule development candidates.

The centre is supported by expert and experienced materials science analysis using a wide range of analytical techniques operating to the highest quality standards.

Our team has extensive experience in synthetic and medicinal chemistry and will use a chemistry-led approach to design the screening protocols to maximise hit rate while minimising compound requirement. Selected forms will be resynthesized and fully characterised to ensure the smoothest path into the next stage of development.

We can support you with solid form science throughout the drug development process from candidate selection and efficient large scale synthesis through ‘fit for purpose’ formulation and toxicity studies to API and formulated drug substance manufacture.

Solid Form Screening

- Efficient, chemistry-led salt screening by experienced specialists
- Polymorph screening
- Cocrystal design and synthesis
- Scale up and comprehensive analysis of selected forms
- Interpretation and recommendation

Solid Form Characterisation

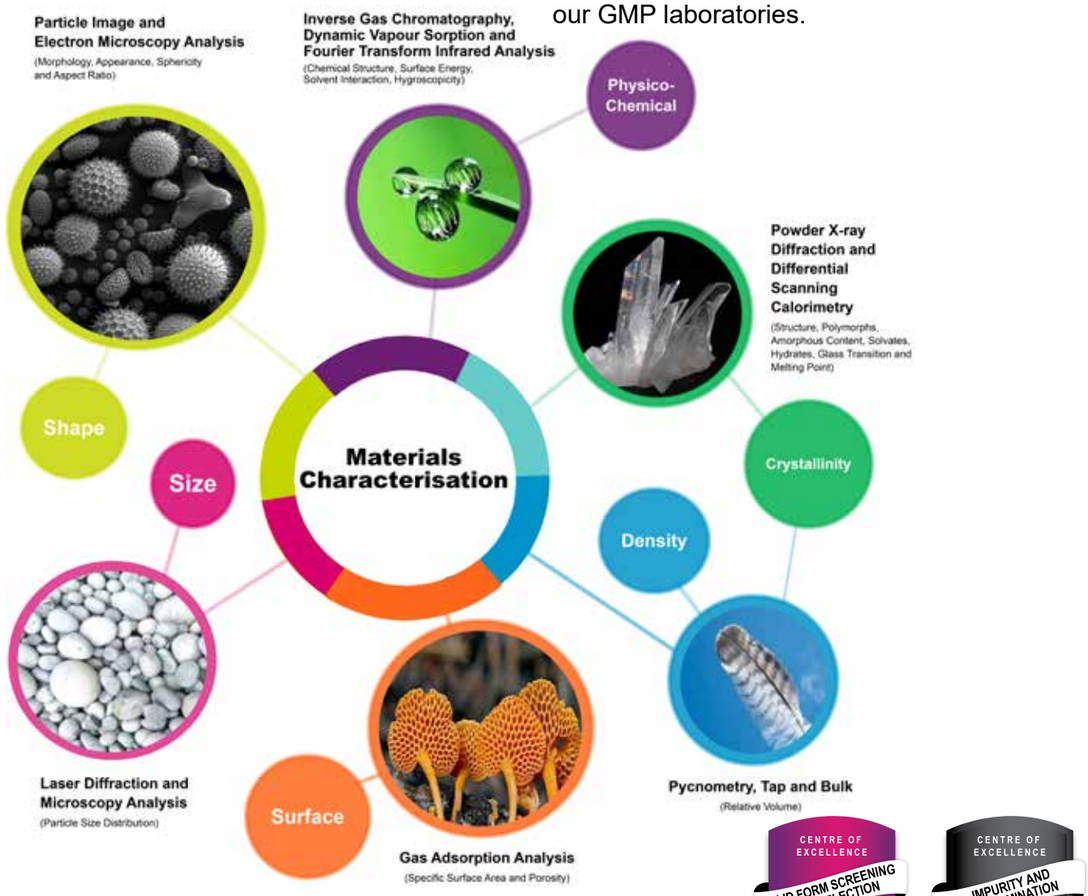
- Powder X-ray diffraction
- Differential scanning calorimetry
- Optical and thermal microscopy
- Dynamic vapour sorption
- Thermogravimetric analysis
- FT-IR
- NMR

Materials Characterisation

The physical properties of a material will determine how it behaves in terms of processability, flowability, compaction, strength, dissolution, solubility and compatibility. These will effect its safety, efficiency and stability.

We are highly experienced in the measurement of these properties on a wide range of materials including active ingredients, excipients and formulated products. Our expertise covers all stages of development, registration and manufacturing and we can help you define the optimal solid form and provide critical characterisation over a broad range of attributes.

We support routine measurements, advanced characterisation and troubleshooting, **bespoke method development** and **validation** for all stages of the product development and manufacturing pipeline, from our GMP laboratories.



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Foreign Matter Analysis

Foreign Particulate Matter (FPM) contamination is an issue even in highly regulated and controlled environments such as the pharmaceutical and biopharmaceutical industries.

Presence of FPM can affect product quality, safety and efficacy, leading to loss of batches, product recalls and regulatory action.

FPM can come from a variety of sources, its occurrence is unpredictable and controlling it can be difficult. Identification of FPM is the first step in determining its origin, which is essential for effective root cause investigations.

We have a dedicated team of scientists experienced in the forensic analysis of FPM.

With our in-depth knowledge and expertise in foreign particulate types and their origins, we can help with the characterisation of your contamination, identify any systemic issues and trends, and get you one step closer to achieving the ultimate goal of cleaner processes.

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Technology and Validated Instrumentation

Our cutting-edge laboratories are well equipped with the latest technology to meet your analytical science and materials science needs.
Detailed below are the analytical platforms available at Drug Development Solutions used in our analytical and materials science teams.

Waters Synapt™

- High-resolution mass spectrometers (HRMS) with Ion mobility

Zeiss Sigma FE-SEM

- Field Emission Scanning Electron Microscope
- High Quality Imaging and Advanced Analytical Microscopy

Malvern Mastersizer 3000

- Versatile, compact laser difraction particle size analyzer

Analytical Science

- Waters Acquity UPLC
- Agilent 1100 HPLC
- Agilent 1100 with Micromass ZQ2000
- Waters Acquity UPLC with Waters G2-XS Q-TOF-MS
- Agilent ICP-MS 7700
- Agilent ICP-MS 7900
- Thermo iCAP 7600 ICP-OES
- Agilent 6890 GC-FID/ECD
- Agilent 6890 GC-dual FID
- Agilent 7890B GC with Agilent 5977 MSD
- Agilent 1100 HPLC
- Agilent 1260 HPLC
- Waters Acquity with Sciex API4000 Triple Quadrupole MS
- Agilent 1100 HPLC with Waters Quattro Triple Quadrupole MS
- Waters Acquity UPLC with Waters G2-XS TOF-MS
- Copley Scientific Next Generation Impactor
- Sciex PA800 Capillary Electrophoresis

Materials Science

- Bruker D2 PXRD
- Micrometrics TriStar 3000
- Micrometrics TriStar 3020
- SMS iGC-SEA
- Carl Zeiss FE-SEM
- Nikon microscopes with NIS-Elements software
- EDAX Octane Elect EDX
- Beckman Coulter 9703+ HIAC
- Malvern Mastersizer 3000
- Sympatec HELOS KF
- Sympatec HELOS KR
- Perkin Elmer Spectrum Two UATR
- Perkin Elmer Spotlight 200i FTIR microscope
- PerkinElmer DSC8000 Differential Scanning Calorimeter
- SMS DVS Advantage One
- Sympatec QICPIC
- TGA (TA Instruments TGA550)
- Karl Fisher Titrino 870KF (volumetric) Methrom
- Varian tapped density analyser
- Helium Pycnometer (Accupyc II 1340)
- Brookfield DV2T-RV Viscometer

Let us help you to discover, develop, manufacture medicines and products to improve the quality of life.

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Your Trusted Partner