DRUG DEVELOPMENT SOLUTIONS

Part of Alliance Pharma plc

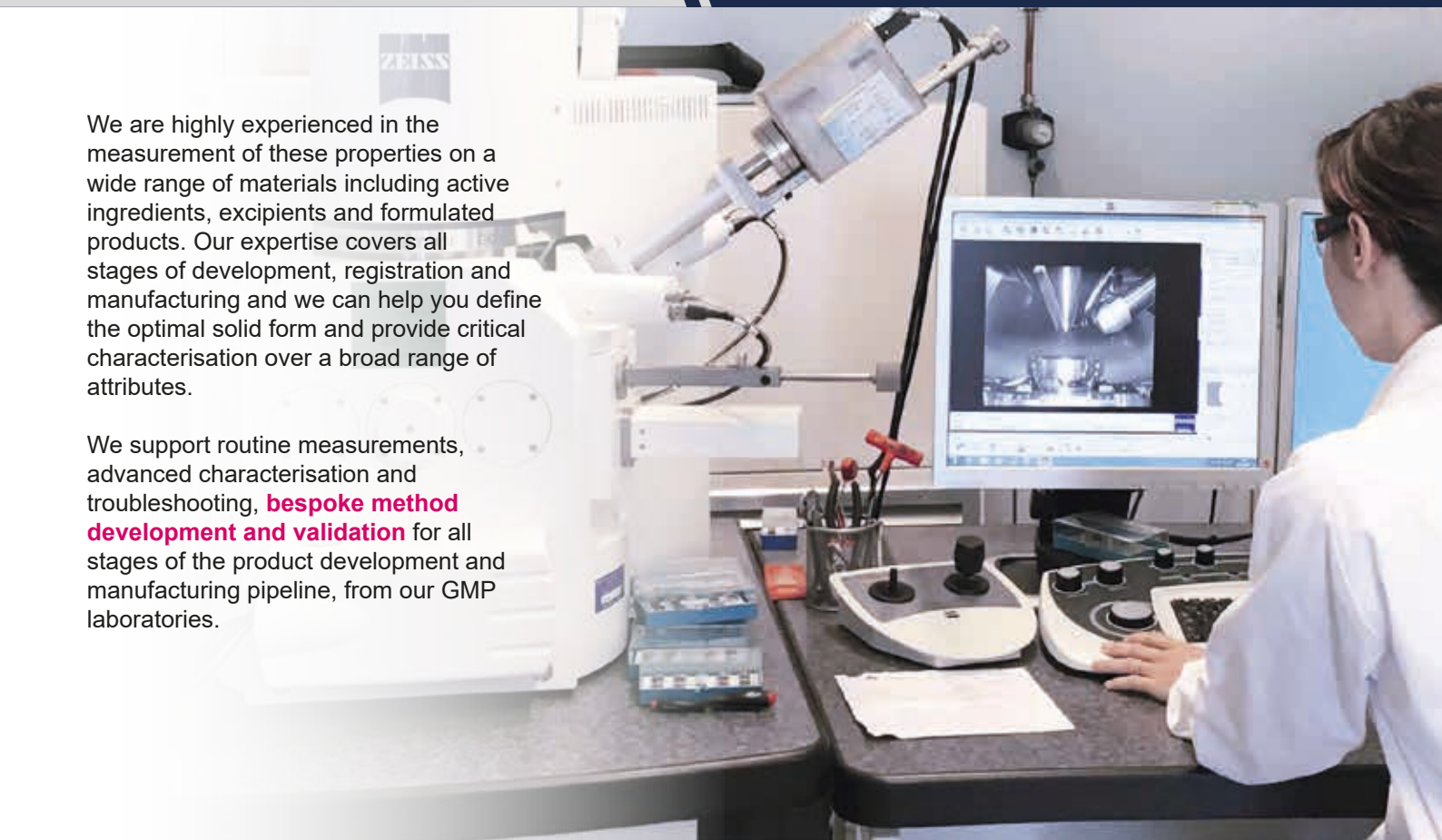
Materials Characterisation

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.

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.



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.

Our key materials science services include:

Physical Properties Testing

» Particle Size Distribution
» Particle Shape Analysis
» Specific Surface Area
» Scanning Electron Microscopy with elemental analysis using EDX
» Inverse Gas Chromatography – Surface Energy Analysis
» Dynamic Vapour Sorption (DVS)
» Density
» Porosity
» Optical microscopy
» Thermal microscopy

Solid Form Characterisation

» Powder X-ray diffraction
» Thermal analysis (DSC and TGA)
» FT-IR (spectroscopy and microscopy)
» Assessment of amorphous / crystalline form
» Determination of hydrates, solvates and co-crystals
» Crystal structure solution and solid form risk assessment

Typical Applications:

» Bulk powder handling and processing
» Solid form issues such as polymorphism, solvates, salts and co-crystals
» Chemical and physical stability
» Dissolution, crystallisation and segregation
» Compatibility between ingredients and packaging
» Polymer deformulation and glass delamination
» Pilot plant and commercial scale manufacturing
» Supplier change and raw materials evaluationstudies
» Foreign particulates and contaminant identification
» Root cause analysis of product failures
» IP, patent litigation and counterfeits testing
» Due diligence activities for in-licensed compounds
» Raw materials testing
» Analytical method transfer exercises.

Our team of industry experts operate to the highest quality standards of Good Manufacturing Practice (GMP), Our laboratories are certified for both chemical and physical testing by the Medicines and Healthcare Products Regulatory Agency (MHRA) and have also been successfully audited by the US FDA.

Let's discuss your project:
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