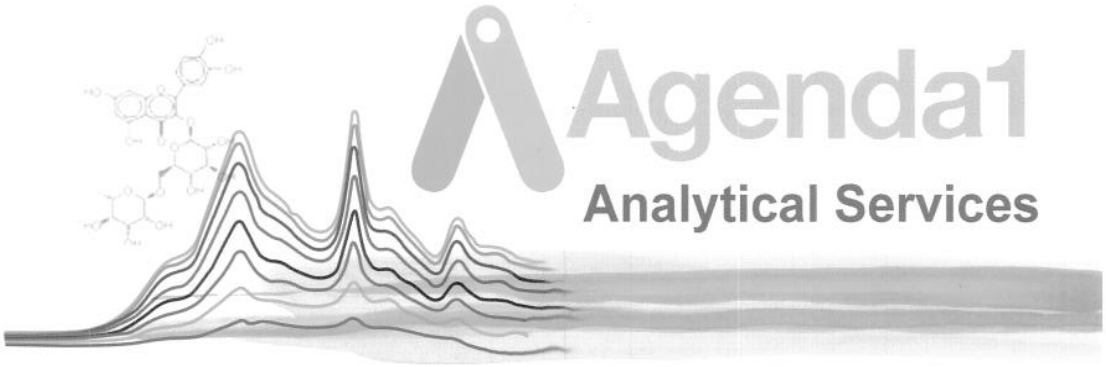


Agenda1

Analytical Services

Drug development experience, with cGMP capability

Agenda 1 spun out from the analytical laboratories of Nektar Therapeutics (UK) Ltd in 2006. At the time Nektar were involved in numerous drug development projects both internally funded and for large Pharma companies.

Based on the Listerhills Science Park and often working closely with the nearby Institute of Pharmaceutical Innovation, the Agenda 1 team comprise a group of scientists with real experience of developing new drug products.

This practical experience of drug development projects is unusual in a CRO, but it is the coupling of that experience with a wide range of cGMP qualified equipment and the associated quality control infrastructure which makes Agenda1 unique.

Qualified equipment and unique services

Agenda 1 provide a wide range of analytical services (see list on reverse) covering:

Early stage characterisation
XRD-TGA-DSC-Particle Size-Porosity and surface area

Assay
HPLC-TLC-HSGC-FTIR, X-Ray Fluorescence and ICP MS/OES

And commercialisation
Dissolution, microbiology, stability, method development and validation

In addition we offer a number of unique services, such as our API solubilising service, SOLENT™, and our toxicology screening service (see details inside). We also offer a unique range of ways to access our services, from one off analysis rates, to fixed price programs and a flexible "lab time share" approach which allows you to buy a set amount of scientist time across any instrument or technique.

Why our clients come to us - and come back to us

Since 2006 we have worked for more than 50 different companies, with many clients returning to us time and again.

Our clients encompass the full range of business models. These include start up and virtual businesses, through to development companies and onto large £multi-million concerns. The common requirement they have is the timely delivery of robust data, be it to support research and development decision making, or regulatory requirements.

As an ISO 9001 company we are regularly check the views of our clients - here are just a few comments we've received:

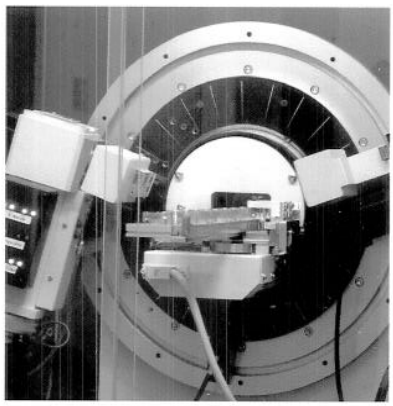
"Many thanks for sending us the results so quickly."

"Thanks for the data – which looks good, and for the speedy service"

"The measurement is exactly what I was looking for"

"Finding a suitable formulation (using Solent™) allowed us to progress a program delayed for almost 6 months"

"I had to email you to say thank you very much for your flexibility … we are extremely grateful for your help on this matter"



Case Studies

A client developing a spray dried product for pulmonary delivery required a team able to carry out particle size analysis with particular emphasis on method development to ensure that agglomerated particles were separated to their primary particle size. We were asked to be involved after the failure of a previous laboratory and are now starting a 9 month program supporting a manufacturing scale up project.

A customer with tablet formulation challenges asked us to investigate possible causes, we identified by surface area analysis that variations in the specification of Magnesium Stearate was a likely cause.

A dose formulation development company with a very sophisticated dose form needed to ensure that the physical structure of the API had not altered during their processing. It was necessary for us to develop a bespoke method of presenting the samples to the XRD in order to obtain representative data.

A client developing a large molecule product with a wide range of molecular weight targets asked us to develop from a standing start an HPLC separation method. We were able to develop a working method within 10 days of initial discussions with the client.

SOLENT™

The challenge of solubilisation
Often, early stage approaches to solubilising a drug product are not appropriate for a dose formulation for pre-clinical and clinical studies. Finding a suitable formulation to maximise drug loading is crucial.

The SOLENT™ approach
SOLubility ENhancement Technology from Agenda 1 and Synectix utilises a range of proprietary preformulation options, comprising a wide variety of liquid-based GRAS formulation excipients approved for preclinical and clinical use. Utilising a carefully structured and controlled approach the target molecule is tested in up to 96 different formulations to identify the most effective solubilising agent.

The outcomes from SOLENT™
Recommendations for formulations designed for maximum drug loading and exposure.
Identification of formulations tailored specifically for, oral, parenteral or transdermal administration, and aqueous or organic solvent freeze drying preparation.
Rapid delivery of successful formulations for *in vivo* investigations with supporting stability testing to match planned study timelines.

"The Solent Screen was extensive, fast, good value, effective and conclusive. The screen is flexible, client-oriented and would be used again. We really appreciated the way the project was discussed, set up, reported in a timely manner and with high scientific background." **UCB Pharma**

Multicell Biomodules

Biomodules – fast, low cost optimisation prior to your *in vivo* study

The Agenda 1 access to the Kirkstall biomodules system provides a cell culture technology that supports pre-clinical ADME and toxicity screening. Comprising a series of interlinked biomodules containing living human cells, the system allows the introduction of a target compound in a circulating nutrient media, in conditions mimicking the *in vivo* environment. The effect on living cells is monitored by a variety of optical and chemical methods including fluorescence microscopy, liquid chromatography, mass spectroscopy and ELISA. The results show how the compounds might behave in the body and are more accurate and sensitive tests than conventional HTS approaches.

Improving on static cell systems

The laminar flow of the media is a significant improvement on static cell systems. There is literature data that static systems result in an underestimation of the true toxicological impact of a drug product by creating an overly benign environment.

Research applications

By providing this unique approach the Kirkstall biomodules system offers opportunities for a wide range of testing and study prior to going into the clinic with a formulation including:

Toxicity, drug response curves, cell to cell signaling
Tissue culturing.

You need to know...	We can measure...	By employing
FUNDAMENTAL CHARACTERISTICS		
The physical characteristics of your bulk material	Size and particle size distribution Surface area and porosity Bulk and tapped density	Sympatec Laser Diffraction (Wet and dry sample preparation) SEM, TGA, Micromeritics Tristar Tapped volumeter
The solid state characteristics	Quantifying crystalline or amorphous state The morphology of crystals Which polymorph has been made Drug/formulation excipients interaction	SEM, XRPD "Snap" identification software, FTIR, DSC, XRF, ICP-MS/OES
If the material contents are correct	Developing assay methods Impurity analysis Raw material and finished product assay Microbiological bio-burden determination	HPLC. Detection systems include: refractive index, conductivity, fluorescence, and photodiode array
AFFECT OF YOUR TECHNOLOGY		
How changes in process might affect bioavailability	Development and delivery of *in vitro* dissolution systems	Dissolution equipment (on-line UV or off-line HPLC)
How process changes affect material characteristics	State of the art software to interrogate multi-experimental data and experimental design	DOE software
Aerosol performance	Measuring emitted dose characteristics	Inhaler adapter for Sympatec laser sizer
STABILITY FACTORS		
Factors determining the physical and chemical stability of your material	Measuring residual solvent Moisture Organic solvent	TGA, KF, HS-GC
How to store your material	Controlled environment storage	Stability cabinets 25°C/60% RH and 40°C/75%RH
Ongoing chemical and physical stability	Designing and delivering stability studies and supporting methods	Multi-compound experience of stability study development
VALIDATED DATA		
Data that can be submitted to regulatory authorities	We can work to cGMP standards	Appropriate validation documentation, training records and SOPs in place, underpinned by an ISO9001 QMS.

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