

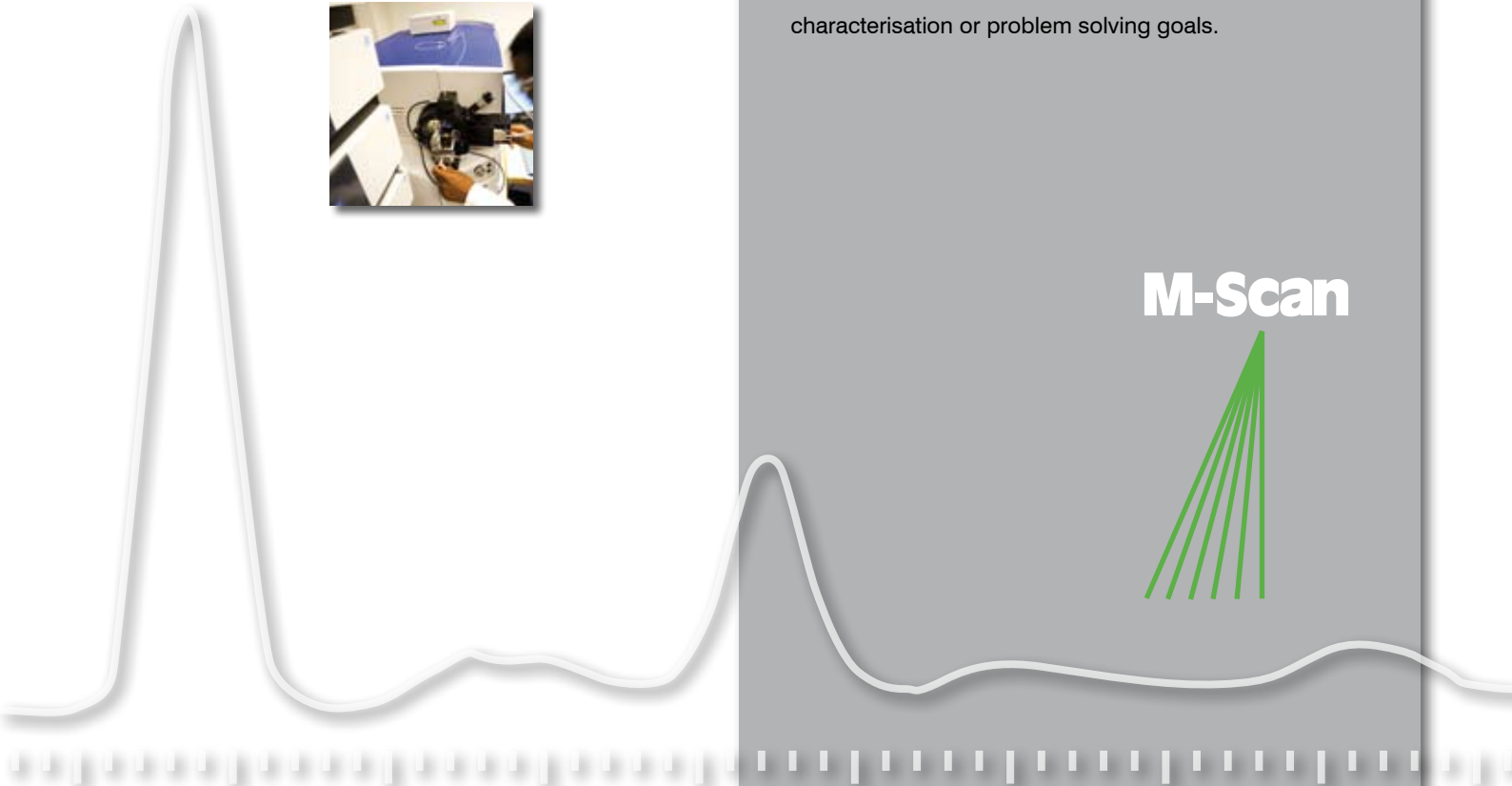
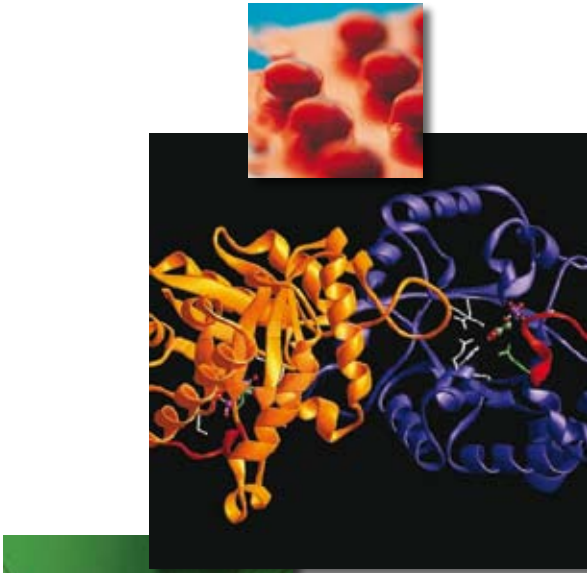
Expert Analytical Services

Biotechnology and Pharmaceutical Analysis

M-Scan is an independent group of companies dedicated to providing high quality mass spectrometry and related analytical services in the Life Sciences arena.

Since 1979, M-Scan has been offering expert contract services and innovation in Bio/Pharmaceutical product analysis. With more than 25 configurations of GC-MS, MALDI-TOF, LC-MS and MS/MS instruments, M-Scan is uniquely positioned to assist you with your characterisation or problem solving goals.

M-Scan



Expert Analysis

A Depth of Knowledge

M-Scan's success is due to the unique combination of its range of instruments and the expertise and calibre of its scientists, many of whom are acknowledged worldwide as authorities in their field. M-Scan is the expert, so our clients need not be.

Independent Analysts

There is a clear advantage to having an independent, experienced partner who can concentrate on obtaining the best quality results.

Regulatory Considerations - Quality Assured

Quality is guaranteed at M-Scan. All studies are internally peer reviewed giving you complete confidence in the results, their interpretation and the conclusions drawn. M-Scan Ltd is certified to perform GLP analysis by the U.K. Department of Health. The FDA has inspected both M-Scan SA and M-Scan Inc. M-Scan SA is certified by Swissmedic to perform both GLP and GMP analyses.

Clients are welcome to visit to conduct their own audit by prior arrangement.

Customer Focus

Combined with technical and scientific experience, M-Scan takes pride in the level of service it provides particularly a dedication to delivering projects on-time. Many studies require methods to be developed from scratch. M-Scan has the equipment, expertise and time to tailor the study to optimise the results - something not possible for routine laboratories performing only standard methods. All services are provided on a fully confidential basis together with technical discussion and guidance from our experts.

Advice on suitable analytical protocols can be provided - gained from experience since 1979 of performing studies for regulatory purposes.



Pharmaceutical Analysis

- Identification of New Drug Substances (ICH Topic Q6A)
- Identification of Product & Process Related Organic Impurities & Degradants (ICH Topics Q3A(R)/Q3B)
- Solvent Residue Analysis (ICH Topic Q3C)
- Extractables from Container/Closure Systems (ICH Topic Q6A)
- Process & Production Troubleshooting
- Analysis after Stability Testing
- Cleaning Validation (CFR 21 Part 211.67)
- Ultra pure Water for Injection



A complete range of LC techniques coupled with UV Diode Array, Pulsed Amperometric, Refractive Index and MS detection along with GC coupled with Flame Ionisation and MS detection is available for **identification testing**.

Chromatography-MS techniques are also used for the identification of production and process **impurities**, together with an assessment of changes in the formulation of raw materials or intermediates or interaction between the formulated drug product and flavourings etc.

M-Scan offers analytical expertise in the determination of **residual solvents**. The Thermal Desorption GC-MS method used offers improved specificity over GC-FID and provides identification and quantification of individual solvents by reference to an appropriate external standard.

Development and stability data should demonstrate that **extractables** from the container/closure system are consistently below levels that are acceptable and safe. M-Scan has developed in-house validated methods for the analysis of plasticizers and leachables from rubber seals etc. using GC-MS and pyrolysis mass spectrometry.

TOC analysis provides a screening for carbon-based **cleaning validation** studies.

Licensed by the US DEA and UK Home Office for controlled substances.



Biopharmaceutical Analysis

- Molecular Weight determination
- Amino Acid Analysis (Molar Ratio, Extinction Coefficient, Protein Concentration)
- 1D + 2D Gel Electrophoresis (IEF, cIEF, SDS-PAGE)
- RP, IEX and SEC
- Peptide MAPPING by Mass Spectrometry
- Protein Sequence determination, including N-/C-terminal blocking groups
- Disulphide Bridge Assignment
- Carbohydrate Composition & Linkage
- Oligosaccharide Mapping
- Glycoprotein Structure and Glycosylation Site Determination
- Oligonucleotide Sequencing
- Identification of Post-Translational Modifications
- Spectroscopic profiles: CD, NMR
- Analytical Ultracentrifugation, SEC/MALLS

Mass spectrometry can be used, in conjunction with protein and carbohydrate chemistry procedures, to solve a variety of structural problems ranging from de-novo sequence determination to the characterisation of recombinant and natural proteins including **antibody** and **vaccine** products. Particular emphasis is placed on the identification of **Post-Translational Modifications**. Many of the techniques used were developed and first applied to the study of recombinant proteins by M-Scan in the early 1980's.

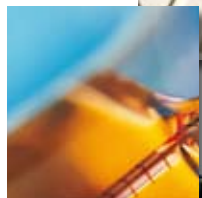
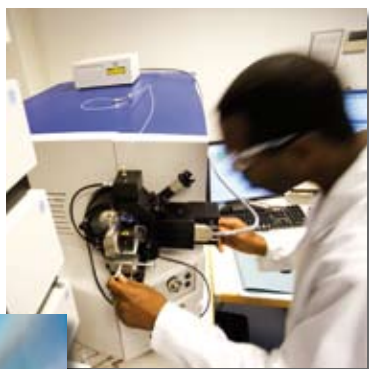
M-Scan has extensive experience in providing structural analysis services to provide data required by the FDA definition of a "well-characterized or specified" molecule and to ICH guidelines, particularly Q6B. A full analytical package can be performed, or individual analyses selected depending on client needs – we are happy to guide and advise.



Proteomics and Glycomics Research

A dedicated Proteomics laboratory for in-gel digest and de-novo sequencing strategies features:

- 2-D Gel Electrophoresis Systems ranging from mini-gels to large format (22 x 22 x 0.1 cm)
- Non-Linear Dynamics Phoretix™ and TotalLab™ software for analysis and recording of 2D and 1D gels
- Four Micromass Q-ToF Mass Spectrometers, with Dionex Ultimate 3000 MDLC, one PE Sciex Q-Star/Pulsar ESI-MS/MS for ultra-high sensitivity sequencing and a PerSeptive Biosystems Voyager-STR MALDI-TOF for digest mapping
- Mascot Server for protein identification



Carbohydrate Research

Glycan analyses are conducted using a combination of mass spectrometry (GC-MS, MALDI-TOF, ES-MS, LC-MS) and chromatography (HPAEC-PAD using Dionex instrumentation).

- Location of glycosylation site(s) including glycoconjugate analysis for both common glycoforms and novel oligosaccharides at each site
- Characterisation of branching, non-reducing ends and polylectosaminoglycan repeats
- Structural information concerning polysaccharides and oligosaccharides
- Point of attachment of non-glycosyl substituents
- Analysis of sulphated and naturally acetylated or methylated carbohydrates
- Molecular weight and sequence determination
- Composition, linkage, branch points and stereochemistry of oligosaccharides
- Sialic acid identification and quantitation



Bioanalysis

- Hepatocytes (fresh human) / Microsome Stability
- PK Analysis
- Metabolite Identification from In Vitro / In Vivo Samples
- LC-MS/MS Analysis (approx. 12 NCE/ Day for Microsome Stability) for early ADME PK or PK/PD
- Method Validation to ICH / FDA / EU Requirements

Mass spectrometry coupled with chromatography is the ultimate choice for the quantification of drug compounds or biomolecules in biological fluids due to its inherent sensitivity and specificity of detection.

Our scientists have extensive experience in the development and validation of methods and utilise an array of cutting edge instrumentation to provide the highest quality bioanalytical service operating to GLP.

Instruments such as the **ABI 4000Q-Trap** and **Sciex API3000** are ideal for high sensitivity routine applications. **Quattro Premier/Acquity Ultraperformance LC (UPLC™)-MS/MS** instruments combine an ultra-high resolution LC system with fast and sensitive quantitative analysis on a triple quadrupole mass spectrometer (run time about 1 min). Special sample organiser units (up to 22 microtitre plates or 388 2ml vials) allow high throughput analysis for pre-clinical, Phase 1 and 2 pharmacokinetic studies.



Instruments

M-Scan prides itself in utilising the most up-to-date instrumentation available and has been directly involved with some of the significant instrument developments for biopolymer analysis.

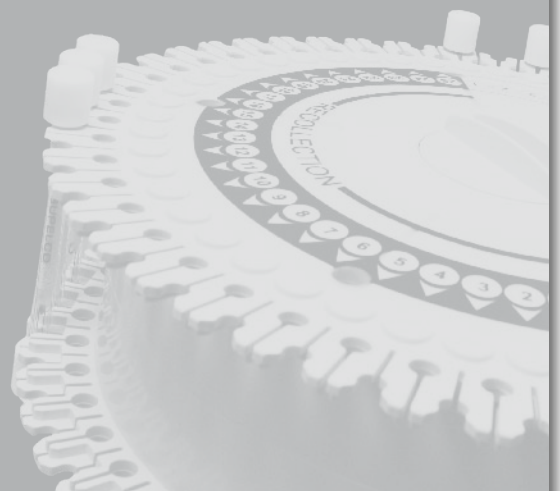


Our current range of over 25 mass spectrometers includes:

- Four Micromass Q-Tofs with Dionex Ultimate 3000MDLC, Waters Alliance HT 2795, GE Healthcare Ettan and MDLC systems
- PE Sciex Q-Star/Pulsar ESI-MS/MS
- Two Micromass/Waters Quattro Premier XE/Acquity UPLC MS/MS systems
- PerSeptive Biosystems Voyager-STR and DE-PRO MALDI-TOFs
- PE Sciex API3000 triple-quadrupole for LC-MS/MS
- Two ABI 4000Q-Traps
- Two Waters LCT Premiers coupled with Waters 1525 HPLC together with a variety of other single and triple-quadrupole LC-MS instruments and various GC-MS with pyrolysis and thermal desorption capabilities

Additional capabilities include:

- Three ABI Procise automatic protein sequencers
- Four Dionex BioLC systems for HPAEC-PAD applications
- Shimadzu TOC-V wp Total Organic Carbon analyser
- Jasco J815 Spectropolarimeter for Circular Dichroism
- Beckman Analytical Ultracentrifuge
- Various other HPLC, GC and UV/VIS spectrophotometers and electrophoresis equipment



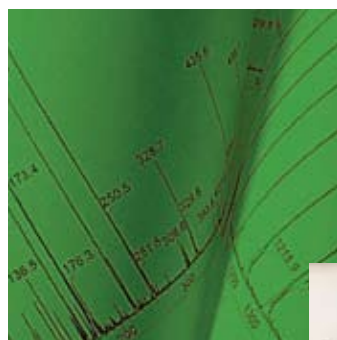
Training Courses

In addition to analytical services, M-Scan also provides Training Courses which cater for the growth of interest in the application of mass spectrometry to a wide range of studies.

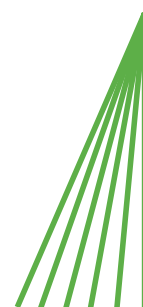
- Tuition is from senior, expert and internationally renowned staff
- Courses at different international venues
- Courses at Client's own sites and tailored to their needs
- Theory, case studies and problem solving tuition
- Participant numbers limited to ensure effective training

Courses include:

- An Introduction to Mass Spectrometry (MS 01)
- Mass Spectrometry in Proteomics and Post-Translational Analysis (MS 02)
- Advanced Biopolymer Mass Spectrometry (MS 03)
- Product Characterisation of Biopharmaceuticals: Bringing a Protein to Market (MS 06)



M-Scan



Europe

United Kingdom
Germany
Switzerland

America

United States

Asia

India
South Korea
Singapore

Please see the web-site for your local marketing office

www.m-scan.com