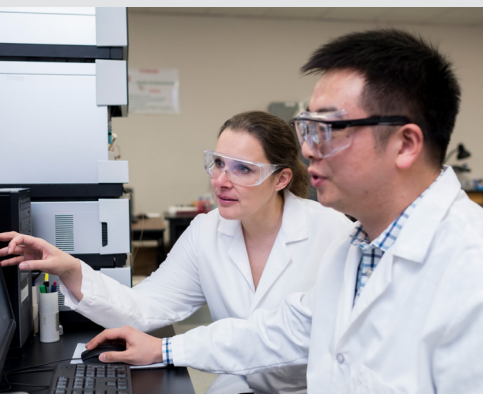


# SGS—Experts in compliant biologic drug characterization services

## A case study in protein characterization for cGMP environments

SGS is a world leading inspection, verification, testing and certification company. SGS has been a world leader in pharmaceutical outsourcing for decades, partnering with companies of all sizes, including the top 20 pharmaceutical companies in the world.

SGS offers a full suite of protein characterization services to GLP/cGMP regulations and is a global partner for clients looking to outsource their pharmaceutical and biologic product characterization services; having a network of laboratories with over 40 years of experience providing protein, peptide, biologic and biosimilar product analysis, their expertise is underpinned by cutting-edge techniques and technology, including a range of high performance mass spectrometers.



“Our experience and continued success within the pharmaceutical and biopharmaceutical industry is the fact that we are not just a testing company, we bring a lot of consultancy with our services and have been providing these services for over 40 years.”

—Dr. Bérangère Tissot,  
General Manager, West Chester, SGS

Ensuring services are fully flexible for their clients' needs, SGS offer a range of stand-alone tests or comprehensive packages that could include:

- Complete (glyco)protein characterization services
- Higher order structure elucidation, including HDX-MS
- Post translational modifications (PTMs)
- Aggregation and charge variance analysis
- Amino acid sequencing and analysis
- Peptide mapping and disulfide bridge analysis
- Glycosylation—monosaccharides, sialic acids, glycan profile and site analysis
- N-terminal and C-terminal sequencing services
- *De novo* sequencing
- Process and product related impurities

As the world's leading inspection, verification, testing and Certification Company, SGS is recognized as the global benchmark for quality and integrity, and are a trusted partner for many companies across the globe requiring glycoprotein and peptide characterization services.

This trust comes from the breadth of knowledge that SGS can provide their clients; over the past four decades many thousands of different products have been analyzed and SGS's results (or data) submitted to a range of regulatory authorities for filing.

Constantly evolving to match the increasing complexity of protein-based therapeutics, SGS are uniquely positioned to deliver high quality services to the industry with confidence due to their ability to meet the latest regulatory guidelines for data integrity and compliance, whilst still utilizing the latest high performance technologies to provide answers to the questions that their clients pose. This ability allows the experienced team at West Chester to bring traditionally complex characterization methodologies into the QC environment as a service.

### **Compliant biological characterization using high resolution accurate mass, mass spectrometry**

High Resolution Accurate Mass (HRAM) Mass Spectrometry (MS) is a technique well suited for protein characterization, but has traditionally been reserved for those with high experience or expertise in its application; recently however it has become the go-to tool for the in-depth characterization of complex products based on the depth of the structural insights that can be achieved.

With the challenges faced when analyzing biologics, from their complexity through to the number of different analyses that may be required, SGS chose the Thermo Scientific™ Q Exactive™ Plus Hybrid Quadrupole-Orbitrap™ MS due to its versatility; SGS routinely perform quantitative, qualitative and semi-quantitative protein analysis from intact mass analysis, through to peptide mapping and higher order structural analysis using Hydrogen-Deuterium Exchange (HDX), with the resolution and sensitivity synonymous with Orbitrap™ technology.

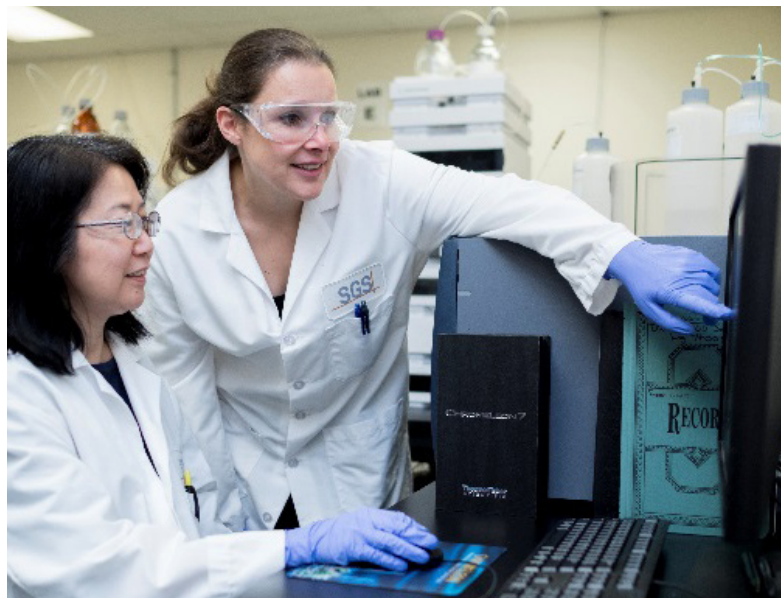


## Flexible laboratory software for all instrumentation

From their high resolution Orbitrap MS systems, Thermo Scientific™ ISQ™ LT GC-MS, Thermo Scientific™ Dionex™ Ion Chromatography systems and other vendors' HPLCs, SGS use Thermo Scientific™ Chromeleon™ 7.2 Chromatography Data System (CDS) software to seamlessly acquire and process all of the resulting data under compliant conditions.

Chromeleon is the only CDS providing full control of chromatography instrumentation from Thermo Fisher Scientific and many other vendors, including support for quantitative mass spectrometry workflows for all separation techniques and MS variants including HRAM MS, whilst using the same intuitive user interface and offering the highest levels of regulatory compliance.

- **Full Control of LC, IC and GC instruments** – Comprehensive, reliable control for over 450 different instrument modules from over 20 manufacturers: control your whole lab from a single software.
- **Integrated control of mass spectrometry instruments** – Streamline chromatographic and MS quantitation workflows. Full integration of Thermo Scientific mass spectrometry instruments, including the Thermo Scientific Q Exactive series of HRAM Orbitrap-based mass spectrometers.
- **Advanced data integrity and compliance features** – From comprehensive instrument and equipment management services, through to user access controls, training records, electronic signatures and version controlled data capture, you can ensure absolute regulatory compliance and data integrity adherence.
- **Flexible reporting** – Fully customizable spreadsheet-based Report Designer provides a familiar interface simplifying the creation of user-defined report templates and eliminating data export to external spreadsheets, reducing errors.
- **New methods at your fingertips with one-click** – The AppsLab Library of Analytical Applications is a fully searchable online, analytical method repository where you can find applications with detailed method information, chromatograms and related compound information. Download one-click eWorkflows, created and tested by Thermo Fisher Scientific application scientists, which can be directly executed in your chromatography data system.

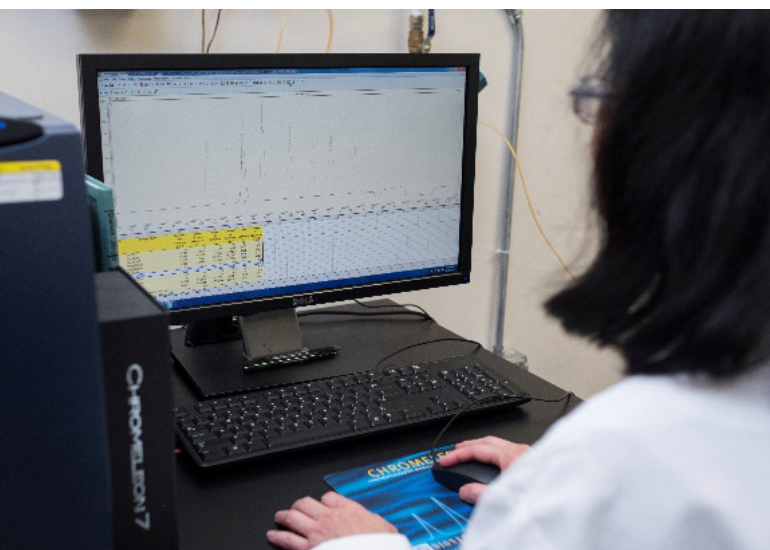
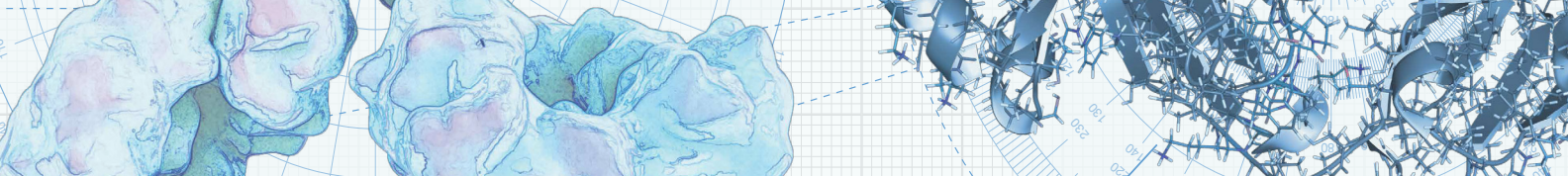


“Everyone wants to have the intact molecular weight of their biologic and peptide mapping run using HRAM-MS; this is the standard everyone should be striving for. We offer intact mass analysis, peptide mapping analysis, quantitative protein analysis, all under compliant conditions, which is where the industry is going; it is the natural evolution of the technique.”

—Dr. Bérangère Tissot



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to download your  
methods today.



## A partnership built on more than just a business to business model

SGS are passionate about the high quality of services that they can provide to their clients, and embrace the role played by technology providers such as Thermo Fisher Scientific in helping them to deliver the quality that is expected. By working closely together, both SGS and Thermo Fisher Scientific look to lower costs, improve performance, increase functionality, all ultimately enabling drug manufacturers to bring life changing therapies to market more readily. These efforts allow us to play our part in making the world a healthier, cleaner and safer place to live.

“Chromeleon can do many things – it has ‘tailorability’. We have hundreds of clients, all with different reporting requirements. Chromeleon allows the flexibility to easily interrogate and integrate the data whilst maintaining full security and regulatory compliance.”

—Dr. Bérangeère Tissot



For more information on analytical technologies for protein characterization, please visit

[thermofisher.com/biopharma](https://www.thermofisher.com/biopharma)

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