

LIFE SCIENCES

BIOPHARMACEUTICAL SERVICES

LIFE INSPIRED, QUALITY DRIVEN

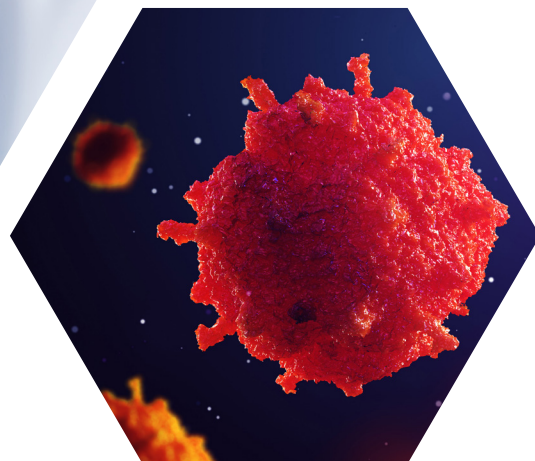


EXPERTISE

EXPERIENCE

TECHNOLOGY

SGS



REDUCE COSTS, INCREASE EFFICIENCIES AND IMPROVE DEVELOPMENT PIPELINES

A full package of biopharmaceutical characterization services to GLP/cGMP standards, enabling you to outsource your protein and peptide analysis.

When it comes to biopharmaceutical characterization, you need a partner with established expertise and resources. As a pioneer of physicochemical characterization, we offer you unrivaled expertise in protein analysis. Our laboratories helped to develop mass spectrometry (MS) mapping of biotechnology products, together with other mass spectrometry strategies related to protein/glycoprotein analysis, which have become standards worldwide.

Our protein analysis package encompasses the requirements of the ICH guidelines (particularly ICH Q6B), the U.S. FDA 'Points to Consider' documents and the concept of a 'well characterized' or 'specified' biological product.

SGS LIFE SCIENCES

SGS Life Sciences enables the medical and health innovators of the world to deliver life-changing solutions in the quickest, safest and most efficient way, helping improve the lives of many, by providing the highest quality services, reliable expertise and guidance through our network of labs conveniently located around the globe.

THE **SGS** ADVANTAGE

Partnering with SGS Life Sciences can help address capacity limitations, decrease overhead costs, and permit production when in-house capabilities are restricted.

The development of a biopharmaceutical product is a costly, complex, and exacting endeavor. Purity, safety, and efficacy must be monitored and confirmed on a continuous basis in order to justify the continuation of the product development process and to meet the requirements of governmental regulatory agencies that must approve and license the product for distribution within its target market.

Our analytical chemistry staff work closely with you to design a customized testing program for your product according to its stage of development. We can develop new methods which are transferred to you, or you can transfer your established testing methods to SGS Life Sciences laboratories. Either way, detailed assay protocols and related information need to be provided, with the recipient laboratory performing validated procedures with respect to precision, accuracy, linearity, specificity, sensitivity and robustness. Method transfers and validations are documented.

To ensure the success of your project, SGS Life Sciences analytical staff are supported by personnel from our program management, quality assurance and Clinical Research regulatory affairs teams. SGS Life Sciences offers a strong synergy between laboratory and clinical expertise for biologics drug development including vaccines and biosimilars with biosafety/virology lab expertise and viral challenge unit in SGS Clinical pharmacology unit.

SGS BIOPHARMACEUTICAL SERVICES DELIVER:

- Production Efficiency
 - Reduced costs
 - Increase capacity & efficiencies
 - Improved development pipelines
 - Development of new assays using new technologies
- Customized Testing Programs
- Validated Procedures
- Method Transfers & Validations
- Regulatory, Technical & Project Management Support
- Integration Of Laboratory and Clinical Expertise
 - Vaccines & Biosimilars
 - Biosafety / Virology
 - Gene Therapy
 - Cell Therapy

QUALITY & COMPLIANCE

Pushing the boundaries of innovation can be challenging; identifying, analyzing and mitigating compliance risks are essential in developing an effective compliance program. With more than 40 years of experience, SGS is a trusted name with a history of excellence in meeting regulatory compliance and bringing products to market. We have a reputation for clinical & laboratory quality & operational excellence (Harmonized QMS and Validation & Transfer methods, LIMS, Lean).

EXPERT GUIDANCE

Reduce costs and improve profits by bringing your products to market quickly and safely; let our experienced consulting and project management teams develop a market access strategy with specific tools and tactics to plan, implement, and monitor your stakeholder engagement activities.

FLEXIBILITY & GROWTH

With a long standing reputation for our integrity, many companies trust SGS as their global drug development partner; our conveniently located network of labs offer an array of integrated services and expertise, providing you with the knowledge, flexibility and ability to scale.

- Wide-range of laboratories and clinical research infrastructure
- Size appropriate and diverse testing capabilities matching Biopharmaceutical and Small molecules needs
- International network across America, Europe and Asia

GET TO MARKET QUICKLY, SAFELY & EFFICIENTLY





INDUSTRY GROUP LEADER IN DOW JONES SUSTAINABILITY INDEX

- RobecoSAM Gold Class sustainability award winner 4 years in a row
- Ecovadis Gold Rating Sustainability Performance 3 years in a row
- RobecoSAM Industry Mover
- CDP Climate A List
- 356+ community projects

OUR GUIDING PRINCIPLES

At SGS Life Sciences, we are guided in all that we do by the values of trust, quality, expertise, reliability, global partnership and integrity; these are the bedrock upon which our organization is built. We also believe that while we are in the business of life sciences, our commitment lies equally in life-saving. This means taking responsibility for our own operations and practices to ensure we are protecting and preserving all life, in its many forms:

PEOPLE



No testing of weapons or anything that could be used to threaten life.

ANIMALS



As a cruelty-free organization, we do not conduct any tests on animals.

PLANET



Award-winning leader in sustainability and recognized carbon neutral organization.

SERVICES

BIOLOGICS CHARACTERIZATION

SGS pioneered physicochemical characterization using high-end mass spectrometry and ancillary techniques to analyze the primary and higher-order structure of (glyco)proteins. These services include protein and peptide, glycosylation, and oligonucleotide analyses, as well as protein aggregation services. Our technical specialists have the expertise to take biopharmaceuticals, such as recombinant proteins and peptides, monoclonal antibodies, and nucleic acid-based drugs, from research and product development through characterization and quality control tests, and into clinical trials for safety and efficacy testing.

- Protein Characterization
- Protein Sequencing
- Proteomics Services
- Post-translational Modifications
- Higher Order Structures
- Antibody Product Analysis

BIO SAFETY TESTING SERVICES

We provide a comprehensive range of biosafety services for biologics, including: virology, cell and molecular biology, ICH Q5A, as well as microbiology and electron microscopy. Health Authorities, including the US FDA and the EMA, require biologic products to undergo safety testing to demonstrate that all cell banks, viral banks, raw materials of animal origin, bulk harvests, and batches of clinical drug are free of bacteria, fungi, mycoplasma, viruses and other potential contaminants such as endotoxins.

- Molecular Biology Services
- Virology Services
- Electron Microscopy Services
- Microbiology Services
- DNA Sequencing
- Genetic Stability

BIOANALYSIS

As a leading bioanalytical service provider, with GLP/GMP compliant laboratories, SGS serves pharmaceutical and biopharmaceutical companies of all sizes with PK/PD testing, immunoassays, and cell-based assays at the preclinical and clinical stage of drug development. At SGS, bioanalysis testing is underpinned by a large list of validated methods and biomarkers – over 700 assays to date. SGS actively pursues assay development and validation of the most innovative biomarkers.

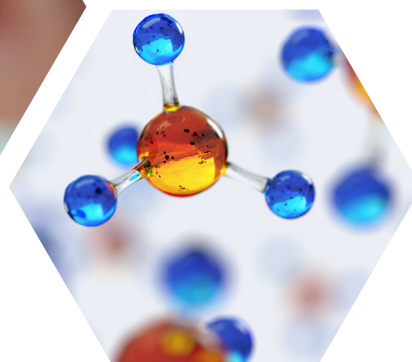
- Biomarker Services
- Cell-based Assays
- Serology, Immunogenicity & Neutralizing Antibodies
- Pharmacokinetic Testing
- Metabolic Profiling

BIO PHARMACEUTICAL ANALYSIS LABORATORY SERVICES

PRECLINICAL	EXPLORATORY DEVELOPMENT	CONFIRMATORY DEVELOPMENT	POST-APPROVAL	ROUTINE PRODUCTION	TRADE DISTRIBUTION
BIOLOGICS CHARACTERIZATION & BIOSAFETY					
Aggregation Analysis (AUC, SEC-MALS, DLS)					
Amino Acid Sequencing & Analysis (Edman, MS/MS) - Extinction Coefficient					
Biosafety Testing					
Cell Bank & Virus Seeds Characterization - Electron Microscopy Studies					
Characterization & Quantification of Process and Product-Related Impurities					
Comparability Studies					
Final Product Testing for Residual DNA & Host Cell Protein (by Immunoassay & Mass Spectrometry)					
FTIR & Fluorescence to Spectrometric Profile (CD, DSC, NMR)					
Glycosylation - Monosaccharides, Sialic Acid, Linkage, Glycan Profile, and Site Analysis					
High Order Structures Analysis					
Isoform & Electrophoretic Patterns					
LC Patterns (SEC, RP, IEX)					
Method Development, Optimization & Validation					
Peptide Mapping by MS - Disulphide Bridge Analysis					
Raw Material & Bulk Harvest Testing (Sterility, Mycoplasma, Viruses)					
Stability					

REGULATORY GUIDELINES

- Compendial Assays
- European Pharmacopoeia (EP), US Pharmacopoeia (USP) and Japanese Pharmacopoeia (JP)
- ICH guidelines Q5A, Q5B and Q5D
- EMEA/CHMP/410869/2006 Guideline for Human Cell Based Medicinal Products
- CBER/FDA/1998 Guidance for Human & Somatic Cell & Gene Therapy
- FDA/CBER/2008 Chemistry, Manufacture and Control of Human Gene Therapy Vectors INDs
- EMEA/CHMP/BWP/Sept 2009, Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Product
- CBER/FDA/1993, Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals
- CBER/FDA/1997, Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use
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WHEN YOU NEED TO BE SURE

