

SGS provides extensive support in the development of all biotherapeutics, from peptides to complex Cell & Gene Therapies (C>). With over 40 years of laboratory experience, SGS has assessed over 300 biotherapeutics, including 100+ monoclonal antibodies (mAbs).

SGS combines deep expertise, broad capacity, and high-quality standards (GMP/GLP/GCP, FDA inspected) to meet regulatory and client expectations.

Peptide/Protein Characterization and Quality Control (QC) Services

- Primary Structure Characterization: Composition, sequencing, and post-translational modifications (PTMs) using technologies such as Edman, LC-MS/MS, NMR, UPLC, and electrophoresis.
- Higher-Order Structure Characterization: Secondary and tertiary structures, and aggregate analysis using techniques such as FT-IR, SEC-MALS, CD, DLS, DSC, and AUC.

- Functional Characterization: Ligand binding, cellbased technology, and surface plasmon resonance (SPR) for in-depth molecular interaction studies.
- QC & Stability: Comprehensive testing for confirmation and monitoring of quality attributes, including - identity, potency, purity, quality, and safety. SGS offers a broad platform of supporting technologies, including - compendial testing for pH, osmolality, bioburden, endotoxin, ICP-MS, slab & capillary electrophoresis, liquid chromatography, and LC-MS/MS.

Bioanalysis

Our preclinical and clinical services encompass comprehensive pharmacokinetic (PK) and pharmacodynamic (PD) analyses, immunogenicity testing (ADA and NAB), advanced LC-MS/MS, and ligand-binding assays (LBA). We support biomarker discovery and validation, cell-based assays, flow cytometry, and molecular biology techniques such as qPCR.

TECHNICAL FACT SHEET

Examples of SGS peptide & protein experience

	Antibodies and Related Molecules	Cytokines and Hormones	Insulins	Peptide Study Examples	Blood Factors
Products	>80 unique Antibody products	IFNs a and b, EPO, FSH, TSH, GH, LH, G-CSF, GM- CSF, interleukins	Bovine, Human, Porcine	Calcitonin Degarelix Eptifibatide Exenatide Glatiramer Glucagon Leuprolide Liraglutide Octreotide Oxytocin Semaglutide Teriparatide Icabitant	Factors VII, VIII,
Number of unique projects	>150	>250	>100	>300	>50
Biosimilar experience/Peptide sameness (comprising full Q6B structural characterization)	>20 comparability projects	>20 comparability projects	>10 comparability projects	>10 peptide sameness projects	>10 comparability projects
Full sequencing (using MSe and MS/MS and Edman based sequencing of isobarics (IIe/Leu))	Yes	Yes	Yes	Yes	Yes
Range of molecules	IgG1, 2 and 4. Fab, ScFv, ADC's, Bispecific Antibodies and Fc-Fusion molecules	Pegylated, native, hyperglycosy -lated	Monomer and hexamer formulations, analogues	Recombinant or chemically synthetized	Recombinant purified



Our global biopharma network supports the development of high-quality biotherapeutics that improve lives. We offer testing solutions for ingredients and finished products:

Ingredients/process testing:

• Raw materials, gases, microbial and chemical excipient testing, and environmental monitoring.

Finished product testing:

• Stability programs, genotoxins (nitrosamines), compendial chemistry and microbial testing, extractables & leachables, and container closure integrity.

SGS stands as your trusted partner in advancing the development, characterization, and safety of biopharmaceuticals, ensuring global regulatory compliance, and supporting your molecule's success across every phase of the product lifecycle.

Contact us







