Biologics Services

Health Inspired, Quality Driven.

SGS

Reduce Costs, Increase Efficiencies and Improve Development Pipelines

A full package of biologics testing services to cGMP standards including Characterization Biosafety, and Quality Control release testing enabling you to outsource your biologics.

Biosafety

- When it comes to Biosafety, our Global Centre of Excellence provides services with ultimate reliability, highest GLP/cGMP quality & scientific expertise. As trailblazers in the development of the biosafety testing industry since the early 1990s, our team in Glasgow has developed and validated novel nucleic acid technologies, such as real-time PCR, RAPD, Sequencing, Non-Radioactive Southern Blot, and DNA Sanger Sequencing. For any of your biologics, we help you comply with the global regulatory guidelines and testing requirements.

Biologic characterization

- When it comes to biologics characterization, you need an organization with established expertise and resources for all aspects of biopharmaceuticals characterization, from

physico-chemical properties, to primary, secondary, and tertiary structures as well as aggregation. Our team pioneered the development of mass spectrometry mapping of biotechnology products together with other mass spectrometry strategies and biophysical methodologies which have become worldwide standards.

Quality control

- The SGS network of inspected QC laboratories enables one-stop full-panel cGMP Biologics release and stability testing in North America, Europe, and Asia-Pacific. From appearance testing to complex cell-based functional assays our QC analytical groups are divided into pillars of excellence to enable reliable, rapid turnaround times, with expert analytical oversight over each analytical category. From raw material, to drug product, our end to end analytical services work to meet all your supply chain needs, quickly and effectively.

The SGS Advantage

Working with SGS can help address capacity limitations, decrease overhead costs, and allow production when in-house capabilities are restricted.

The development of a biologics product is a costly, complex, and exacting endeavor. Safety, Integrity, Strength, Purity, and Quality (SISPQ) 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 testing 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 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 and limit of quantification and detection if appropriated. To ensure success, projects are supported by personnel from our Project Management, Quality Assurance and Clinical Research Regulatory Affairs teams. SGS offers a strong synergies between formulation development, laboratory and clinical expertise for biologics drug development including, cell and gene therapy, vaccines and biosimilars with biosafety/virology lab expertise and viral challenge unit in SGS clinical pharmacology unit.

Biologic Solutions Deliver:

- Fast turnaround times
- 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

Quality & Compliance

Pushing the boundaries of innovation can be challenging; identifying, analyzing and mitigating compliance risks are essential in developing an effective compliance program. SGS has over 40 years of experience, bringing products to the market, delivering quality and operational excellence, in compliance with global regulatory bodies.

Expert Guidance

Reduce costs and improve profits by bringing your products to market quickly and safely. We help our clients navigate the complex analytical paradigm, supporting any biologics product development.

Flexibility & Growth

You can rely on our experts to support your global drug development needs. 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
- Diverse testing capabilities matching Biologics and Small Molecules needs
- International network across America, Europe and Asia-Pacific

Get to Market Quickly, Safely & Efficiently

Disease | Discovery | Preclinical | Clinical | Routine production | Market | Curing

Biosafety Services

Our team at SGS pioneered the development of the biosafety testing industry and continue to offer the highest level of services for the detection adventitious agents and residual impurities in the manufacturing of biologics.

Our panel of services are applied to the manufacturing of therapeutic proteins, antibodies, cell therapies, plasmid and viral vectors, and viral vaccines. We perform the GLP/cGMP full testing package for starting materials, cell banks, plasmids, virus seeds, bulk harvests, process intermediates, and purified drugs.

SGS enables health innovators to deliver life-changing solutions in the quickest, safest, and most efficient way, by providing the highest quality and reliable services through our network of laboratories conveniently located around the globe.

We have the biosafety expertise to support the manufacturing of your biologics from early stage research cell bank/virus seed through to GMP manufacturing in Phase I/II/III and then on to routine QC testing and commercial license.

All our methods are validated to meet ICH Q2 R1 guidelines and are fully adapted to meet the requirements of your biologics.

Our biosafety methods for testing cell banks, viral vaccines, gene and cell therapies meet compliance with USP, ICH, Ph. Eur., FDA and WHO guidelines. All methods are performed in compliance with cGMP regulations.

Starting Materials, Cell Banks, Viral Seeds, Vectors, Bulk Harvests, & Control Cells	
SERVICE	DESCRIPTION
Identity	DNA fingerprinting of cell lines, nucleic acid sequencing on ABI 3500xl Systems, Karyology
Sterility/Bioburden Mycoplasma and Spiroplasma Mycobacteria	Direct & membrane filtration. Sterility assays (Phar. Eur 2.6.1, USP<71>, Phar. Eur. 2.6.12) Mycoplasma – Indicator, Broth, Agar qPCR Phar. Eur. 2.6.7, USP<63>, MycoSEQ™ 56 days broth and agar assay; qPCR
Adventitious Agent Viral qPCR	300+ highly conserved Viral Genome targets. QuantStudio Pro, 7500, 7900HT, TaqMan™ Phar. Eur. 2.6.21, USP <1126, 1127>
Adventitious Agent In-vitro assay, including Bovine, Porcine, Equine 9 CFR testing	14 & 28 days assays using MRC-5, Vero & over 20+ different third detector cell lines, HAD, HAG, CPE, IFA end-points, Cytoxicity and interference with or without neutralization antibodies
Next Generation DNA Sequencing (NGS) - Viral Detection	Targeted & Non-targeted NGS, Ion Prime S5™ and Chef Systems
Transmission Electron Microscopy (TEM)	Thin section and negative staining methods for Cell Banks, Viral Seeds and Unprocessed Bulk Harvests
Retroviruses	QPERT, F-PERT, S+L-, XC plaque, Mus Dunni Co-Cultivation, HEK 293 Infectivity, RCR, TEM, NGS, qPCR
Genetic Stability, Genomic Integrity	Gene copy number by qPCR, Gene structural analysis by restriction mapping/Southern Blot, Expression cassette, genomic, plasmid and mRNA nucleic acid sequencing

Purified Bulk/Drug Substance	
SERVICE	DESCRIPTION
Sterility/Bioburden	Direct & membrane filtration, Sterility assays (Phar. Eur 2.6.1, USP<71>, Phar. Eur. 2.6.12)
qPCR Assays (e.g. Residual Host Cell DNA, Residual Plasmid DNA. Genomic DNA Size Determination, Vector Genome Copy Number)	E.coli, Yeast, HEK 293, MDCK, MRC-5, CHO, SP2/0, Sf9, Vero, A549 etc by Real time Q-PCR. Quant Studio Pro, 7500, 7900HT, TaqMan™ Phar. Eur. 2.6.21, USP <1126, 1127>
Residual Host Cell Protein, Benzonase, BSA	BioTek ELISA, Cygnus, Merck Millipore systems
Endotoxin	Kinetic Chromogenic LAL methods. Phar. Eur. 2.6.12, <USP 85>
Vector Identity/Integrity	Nucleic Acid Sequencing
Extractable Volume, Osmolarity, PH, DLS	According to EP or USP
Other residuals eg. Kanamycin, Triton x100, CSCL...	According to EP or USP

Biologics Characterization

SGS pioneered physico-chemical characterization using higher-end mass spectrometry and biophysical techniques to analyse the primary and higher order structure of (glyco)proteins.

Our panel of biopharmaceutical services apply to the analyses of peptides, proteins (natural, PEGylated, Drug Conjugated…) oligonucleotides, oligosaccharides, plasmids, cell & gene therapeutics, viral therapeutics and vaccines.

Our technical specialists have the expertise to take your biologics from research and product development through characterization and quality control tests, and into clinical trials for safety and efficacy testing.

All our methods are specifically developed or adapted to meet the requirements of your large molecules. All qualification, validation and transfer methods are performed in compliance with the cGMP regulations.

Structural Characterization And Confirmation	
SERVICE	DESCRIPTION
Molecular Weight Determination	ES-MS, LC-UV-MS
Amino Acid Sequence Confirmation	Edman Degradation and LC-UV-MS/MS
Amino Acid Analysis	LC-UV-FLD
N- and C- Terminal Sequence Confirmation	Edman Degradation, LC-UV-MS/MS, ES-MS/MS
Peptide Mapping	LC-UV-MS
Sulphydryl Groups and Disulfide Bridges	LC-UV-MS
Carbohydrate Structure Monosaccharide Composition Oligosaccharide Profiling Linkage Analysis Glycosylation Site Determination Sialic Acid Content	HPAEC-PAD, GC-MS, MALDI-MS/MS, LC-UV-MS, LC-FLD-MS
Conjugate Site Identification	LC-UV-MS

Qualitative and Quantitative Impurity Analyses

SERVICE	DESCRIPTION
Proteins Impurity/Variants	LC-UV-MS/MS
Contaminants (e.g. detergents, process additives, growth promoters, antibiotics, redox agents, antifoam, dyes, solubilization agents)	LC-UV-MS, LC-UV-MS/MS, GC-MS
Size Variants	LC-UV-MS, SEC-UV-RI-MALS
Charge Variants	LC-UV-MS, IEX, cIEF, CGE, ICE
Hydrophobicity	LC-UV-MS, RP, HIC
Product-Related Impurity	LC-UV-MS, LC-UV-MS/MS

Physicochemical Properties

SERVICE	DESCRIPTION
Molecular Weight or Size	LC-UV-MS, SEC-UV-RI-MALS, MALDI-MS
Extinction Coefficient Estimation or Determination	Amino acid content and UV Spectrophotometry
Liquid Chromatographic Patterns	SEC, RP, IEX, HIC
Spectroscopic Profiles	CD, FT-IR, Fluorescence (intrinsic and extrinsic) UV-Visible absorbance (2nd derivative)
Aggregation	AUC, SEC-UV-RI-MALS, DLS, Light Obscuration, Microflow Imaging
Thermal Stability	DSC
Electrophoretic Pattern	cIEF, CGE, ICE

Quality Control Services

SGS quality control tests serve to meet global regulatory needs at each stage in the supply chain.

Our QC biologics labs serve to provide a one-stop-shop service to meet raw material, in-process, bulk intermediate, drug substance, and drug product testing requirements. Furthermore, our facilities and staff have a wide range of experience testing numerous product categories ranging from cell and gene therapies, to peptides, proteins, and therapeutic antibodies.

SGS offers secure high-redundancy stability storage and testing services, including ICH Q5C shelf-life studies, in use, photostability, and degradation pathway elucidation studies.

With over 30 years biologics testing experience, our team of experts will help design, implement, and execute your analytical test strategy to ensure the safety, integrity strength, purity and quality of your product. All testing and studies are performed in compliance with cGMP regulations.

Structure and Function Testing

SERVICE	DESCRIPTION
Cell Based Functional Assays	Cell Based Potency Testing (e.g. Proliferation, Cytotoxicity, Uptake, Biomarker, Gene Expression, and Other Functional Assays) Analytical Cell Banking (MCB/WCB) and characterization)
Enzyme Activity	Spectrophotometric (eg. substrate turnover) or other endpoint
Binding Affinity	SPR, Bio-layer Interferometry, ELISA
Peptide Mapping	HPLC-UV, UPLC-UV
Charge Distribution And Heterogeneity	cIEF, ICE, Gel IEF, Ion-exchange Chromatography
Carbohydrate Composition Monosaccharide Composition Oligosaccharide Profiling Sialic Acid Content	LC-FLD-MS, HPAEC-PAD, CE-LIF

Microbiology

SERVICE	DESCRIPTION
Bioburden	USP<61> EP 2.6.12 and 2.6.13.
Sterility	Direct & membrane filtration Sterility assays (EP 2.6.1, USP<71>)
Endotoxin	Kinetic Chromogenic, Gel Clot <USP 85>, EP 2.6.14
Monocyte-activation test	PyroDetectTM, PyroMATTM

**Inquire for full Microbiology services*

Physical Compendial Testing

SERVICE	DESCRIPTION
Container Closure Integrity	USP <1207> Dye Ingress High-voltage Leak Decay Laser based gas headspace analysis
Content Determination	Content determination by UV spectrophotometry meeting requirements of USP <1057> method I and USP <857>. Protein quantitation (ELISA, Bio-layer Interferometry, UV, Solo-VPE, HPLC-UV, BCA, Bradford, Lowry)
Weight Variation	Uniformity of dosage units meeting requirements of USP <905> and EP 2.9.40.

Quantitative Purity & Impurity Analyses

SERVICE	DESCRIPTION
Host Cell Protein	ELISA, Bio-layer interferometry, 2D-PAGE coverage analysis, SDS-PAGE, Western-Blot
Host Cell DNA	qPCR with manual and automated preparation Quant-iT™ PicoGreen
Process Impurities	Leachates (eg. ProA, ProL) by ELISA Residual solvents USP<467> Elemental Impurity USP <232> <233> and ICH Q3D
Chromatographic Purity (process/product related)	Bio-separation Sciences (Size Exclusion, Ion-exchange, Hydrophobic Interaction, Reverse-Phase) HPLC/UPLC/IC based Purity Analysis with UV, FLD, ELSD, CAD, ECD, RI, or MS detection
Electrophoretic Purity	CGE, CZE, Nucleotide Fragment Analysis, SDS-PAGE, Native PAGE, Western Blot, 2D-PAGE, Agarose
Charge Distribution and Heterogeneity	cIEF, ICE, Gel IEF, Ion-exchange Chromatography

Physical Compendial Testing	
SERVICE	DESCRIPTION
Appearance	Clarity, colour and visible particles as per EP 2.2.1, EP 2.2.2 and EP 2.9.20. Meets requirements for USP <790>
Water content	Coulometric water determination meeting requirement of USP <921> method 1c
Reconstitution time	Visual determination of reconstitution time
pH	pH of solution meeting requirements of USP <791> and EP 2.2.3.
Extractable volume	Determination of volume of injection in containers meeting requirement of USP <697> and EP 2.9.17.
Osmolality	Osmolality measurement by freezing point depression meeting requirement of USP<785> and EP 2.2.35.
Turbidimetry	Ratio turbidimetry meeting requirements of EP 2.2.1.
Particulate matter	Particulate matter in injections using light obscuration particle count test as per USP <788> or subvisible particulate matter in therapeutic protein injections as per USP <787> HIAC, >2, >5, >10, >25µm Microflow Imaging, Microscopy

SGS's global network of analytical testing, formulation, clinical research, and clinical manufacturing solutions offer a wide range of integrated services and expertise across America, Europe, and Asia-Pacific.

SGS experts are ready to support customers throughout the development and commercial manufacture of their drug products, helping ensure the delivery of safe, effective, and compliant medicines to global markets.

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WHEN YOU NEED TO BE SURE

SGS