PHARMACEUTICAL LABORATORY SERVICES

SGS LIFE SCIENCE SERVICES

WHEN YOU NEED TO BE SURE

LIFE INSPIRED

CREATIVE SOLUTIONS IN BIO/PHARMACEUTICAL CHARACTERIZATION, ANALYTICAL DEVELOPMENT, BIOSAFETY, UTILITIES QUALIFICATION, AND QUALITY CONTROL TESTING

Just as LIFE derives its source from nature's flora and fauna, the Life Science industry finds its inspiration in nature for past and future discoveries. In our industry's constantly evolving world of science and regulation, finding creative solutions is mandatory for success. We find common ground with our clients being Inspired by Life from drug discovery to market to solve these daily challenges in order to save lives. With a strong focus on biologics, SGS Life Science Services' mission is to safeguard the quality of medicines by providing professional and independent services in clinical research, analytical development, biologics characterization, biosafety and quality control testing of pharmaceuticals, biopharmaceuticals and medical devices – thereby creating value for our clients, employees, shareholders and patients worldwide.

A TRULY GLOBAL NETWORK

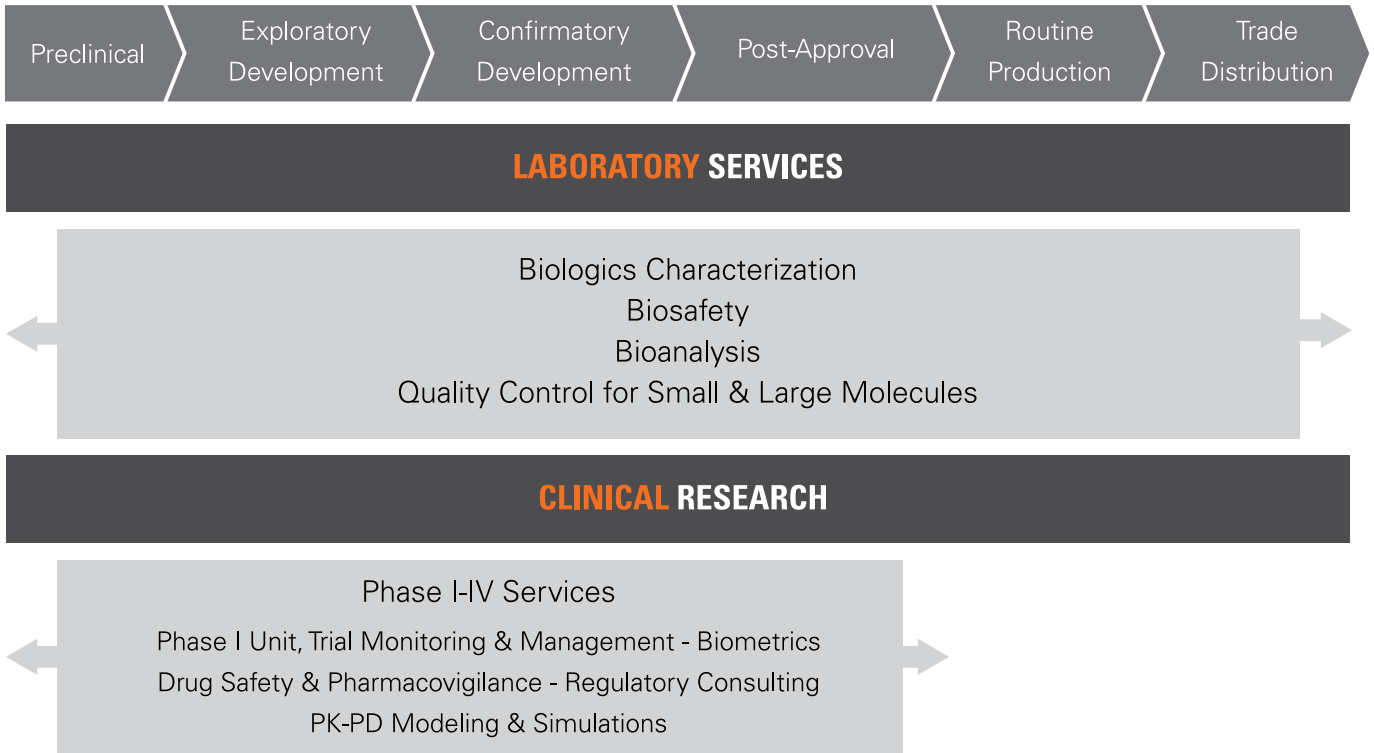
With 1,600 employees, state-of-the-art clinical pharmacology units and the world's largest wholly-owned network of GMP/GLP compliant laboratories, SGS serves the pharmaceutical, biotechnology and medical device industries across Europe, the Americas and Asia with 27 facilities located in 14 countries. SGS's mission is to safeguard the quality of medicines by providing professional and independent services.

The following pages outline the services we perform within our global network and offer to our clients in order to facilitate R&D, analytical development, biosafety, and quality control release of medicines and medicinal products, as well as qualification and testing of utilities used in manufacture.

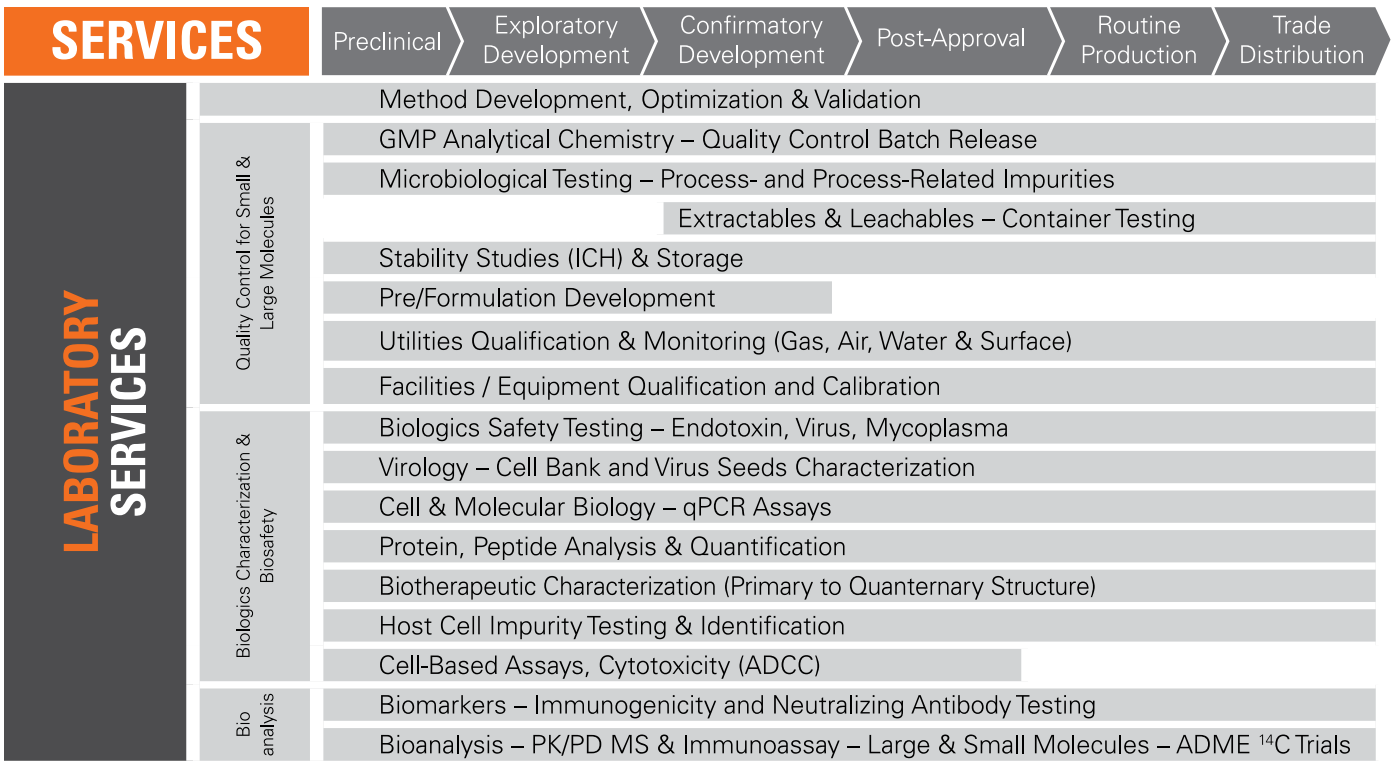
FROM MOLECULE TO MARKET

SGS Life Science Services helps bio/pharmaceutical and medical device companies by providing services along the entire drug development pathway. With over 35 years of experience as a global contract service organization, SGS provides integrated solutions from preclinical activities to Phase I-IV trials, bioanalytical, R&D, characterization, biosafety, and quality control testing of small and large molecules, raw material products and containers.

LIFE SCIENCE SERVICES



LABORATORY SERVICES



SERVICES WITHIN OUR NETWORK

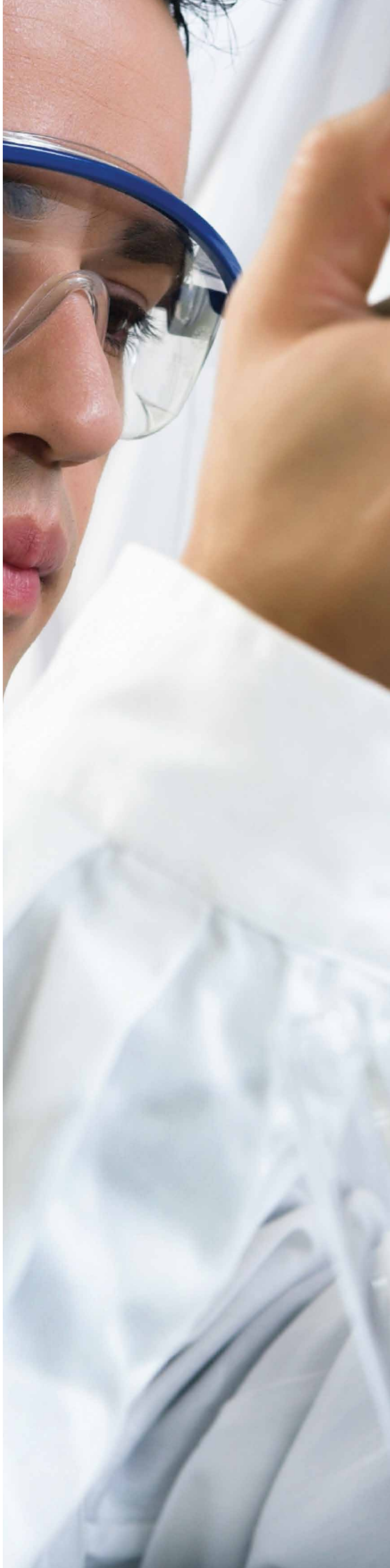
LABORATORY CAPABILITIES

LABORATORIES	COUNTRY	ANALYTICAL CHEMISTRY	MICRO-BIOLOGY	STABILITY STUDIES	METHOD DEV. & VALIDATION	CONTAINER TESTING	BIOPHARMA TESTING	BIO-SAFETY	BIO-ANALYSIS	PLANT/EQUIP'T QUALIFICATION
Toronto (Mississauga)	Canada	•	•	•	•	•	•	•	–	–
Chicago (Lincolnshire)	USA	•	•	•	•	•	–	–	–	–
New Jersey (Fairfield)	USA	•	•	•	•	•	•	•	–	–
Philadelphia (West Chester)	USA	•	–	–	•	•	•	–	–	–
Los Angeles (Carson)	USA	–	•	–	•	–	–	–	•	–
Brussels (Wavre)	Belgium	•	•	•	•	•	•	–	•	–
Paris (Villeneuve La Garenne)	France	•	•	•	•	•	–	–	–	–
Poitiers	France	–	–	–	•	–	•	–	•	–
Berlin	Germany	•	–	•	•	•	–	–	–	–
Frankfurt (Taunusstein)	Germany	•	•	–	•	•	–	–	–	–
Geneva	Switzerland	•	–	–	•	–	•	–	•	–
Florence (Livorno)	Italy	•	•	•	•	–	–	–	–	•
London (Wokingham)	UK	•	–	•	•	•	•	–	–	–
Glasgow	UK	•	•	–	•	–	•	•	–	–
Shanghai	China	•	•	•	•	–	–	–	–	–
Chennai	India	•	•	•	•	•	–	–	–	–
Mumbai (Navi)	India	•	•	•	•	•	–	–	–	–
Singapore	Singapore	•	•	•	•	–	–	–	–	–

ANALYTICAL DEVELOPMENT AND QUALITY CONTROL OF PHARMACEUTICALS

SGS Life Science Services has been offering high quality analytical testing services to the pharmaceutical industry for decades. We offer a wide range of quality control testing services to support drug research, registration, and production. Biopharmaceutical companies also use many of the same services, and SGS has also added new services to accommodate their unique needs (detailed in the following section).

We perform a variety of tests that are client-specific, particularly in the area of analytical chemistry. Please enquire for more information about additional tests we perform that may not be listed in this brochure.



ANALYTICAL CHEMISTRY

SGS provides the professional expertise and regulatory qualifications necessary to perform analytical testing of raw materials, APIs, finished products, packaging material and medical devices. Well-equipped state-of-the-art laboratories offer comprehensive testing services according to the pharmacopoeia (e.g. EP, USP, BP, JP) and to customer specifications.

CHEMICAL AND PHYSICO-CHEMICAL TESTING

- Assays (e.g. UV/Vis, IR, AAS, etc.)
- Chromatographic tests (e.g. HPLC, GC, IC, ICP-MS)
- Identification of active ingredients and impurities
- Physical and physico-chemical determinations (e.g. pH, viscosity, melting point, particle size, osmolality and osmolarity, flash point, loss on drying)
- Limit tests (e.g. heavy metals, ash, anions)
- Residual solvents (volatile organic compounds [VOC], organic volatile impurities [OVI])
- Solid oral dosage QC tests (e.g. disintegration, dissolution, hardness, friability)
- Sampling and analyses of water for pharmaceutical purpose and controlled process environments (e.g. TOC, conductivity)

MICROBIOLOGICAL TESTING

SGS is a leader in Microbiology Quality Control testing, providing a complete array of services for the bio/pharmaceutical industry. SGS' scientists are published and active on the scientific committees of several organizations. Capabilities range from assessment of microbial contamination to confirmation of antimicrobial activity. SGS' facilities meet the demanding cleanliness and engineering requirements of microbiological testing programs. Class 100 hoods, clean rooms and isolators are available for microbial evaluation.

BIOLOGICAL AND MICROBIOLOGICAL SERVICES

- Microbial limits tests
- Sterility testing
- Microbial contaminant identification
- Mycoplasma testing
- Preservatives testing and microbial challenges
- Microbiological assessment of antibiotics
- Bacterial endotoxins
- Sampling and analysis of water for pharmaceutical purposes
- Chemical disinfectant testing and cleaning studies
- Environmental monitoring
- Microbiological attribute studies (barrier testing: packaging, condoms, medical gloves; hygienic and antibacterial test: contact lenses, personal care products, etc.)
- Particulate testing
- Closure integrity testing

CONTAINER TESTING

SGS Life Science Services is an industry leader in Container Testing (USP, EP, JP, BP), providing full packaging testing for the drug industry. The safety and efficacy of any pharmaceutical product is inextricably linked to its packaging. Containers or closures that do not meet the physical, chemical, or biological specifications of the major compendia will compromise the quality of the drug product.

TESTS INCLUDE MATERIALS USED FOR THE MANUFACTURE OF CONTAINERS

- Identification
- Limit tests
- Impurities
- Assays

CONTAINER TESTING (GLASS, PLASTICS, RUBBER CLOSURE…)

- Classification
- Identification
- Limit tests
- Biological tests
- Heavy metals
- Physicochemical tests
- Water vapor permeation
- Extractable studies
- Others

CONTAINER / CONTENT INTERACTION

- 25°C / 40% r.h.
- 23°C / 75% r.h.
- Leachables
- Extractables studies
- Migration studies
- Others

EXTRACTABLES & LEACHABLES TESTING

The assessment of Extractables and Leachables in bio/pharmaceutical products is an important step in drug product development. Processing equipment, as well as, primary and secondary container closures are potential vectors for chemical contaminants.

Monomers and polymer additives such as antioxidants, plasticisers, stabilizers, dyes, metal catalysts and other harmful chemicals may potentially migrate into the product under storage conditions. SGS provides a complete service for testing Extractables in container materials and Leachables in final products. These tests are conducted in cGMP compliant laboratories using technologies that detect ultra trace levels.

SERVICES

- Test strategy planning and data evaluation based on the available information
- Development of a tailored study design for Extractables and Leachables
- Extractables profiling (inorganic and organic extractables)
- Sequential extractions and alternative extraction techniques for isolating Extractables in container materials
- Characterization of Extractables by chromatographic and spectroscopic investigations
- Determination of the Analytical Estimation Threshold (AET)
- Calculation of the Qualification Threshold based on Safety Concern Threshold (SCT)
- Method development and validation of potential Leachables in pharmaceutical products
- Performing of Leachables studies on pharmaceutical products
- Reporting and evaluation of results within the current guidelines

TECHNOLOGIES

- HPLC-MS/MS, HPLC Q-Tof, HPLC-UV, DAD
- HS-GC, HS-GC-MS
- GC (FID, ECD, FID-NP), GC-MS
- GC-TEA (nitrosamines)
- ICP-OES, ICP-MS, AAS, IR
- FTIR
- TGA, DCS
- X-ray fluorescence analysis
- ASE (accelerated solvent extraction)
- Soxhlet

STABILITY STUDIES

From study design to storage, monitoring, analytical testing and documentation, SGS offers services to your complete satisfaction. With more than 25 years of experience and currently more than 100,000 samples in storage, SGS has the skills and the capacity to handle your stability projects. SGS can provide its customers with the complete bandwidth of storage conditions in numerous climatic walk-in chambers and climatic cabinets with a total storage capacity of over 1,600 m^3. Various refrigerators and freezers are available for storage at lower temperatures. All storage chambers are fully controlled with 24h/7d monitoring and alert systems (21 CFR part 11 compliant). For your safety, SGS operates back up chambers for complete sample retrieval.

SERVICES

- Support in designing studies for real time, stress tests and photo stability studies
- Development and validation of "stability indicating methods"
- Examination of stability-relevant parameters
- Storage and management of stability samples
- Interim reports for every testing period
- Comprehensive final report

CLIMATIC ZONES (ACCORDING TO ICH & WHO)

I. 21°C / 45% r.h.
II. 25°C / 60% r.h.
III. 30°C / 35% r.h.
IVa. 30°C / 65% r.h.
IVb. 30°C / 75% r.h.

LONG-TERM, INTERMEDIATE AND ACCELERATED STORAGE

- 25°C / 40% r.h. (semi-permeable container study)
- 25°C / 60% r.h.
- 30°C / 65% r.h.
- 30°C / 70% r.h.
- 30°C / 75% r.h.
- 40°C / 75% r.h.
- 40°C / not more than (NMT) 25% r.h.
- +5°C
- –20°C
- –80°C
- Photostability
- Transport stability (freeze and thaw, cycle test)
- In-use stability
- Customer-specific conditions

METHOD DEVELOPMENT & VALIDATION

SGS Life Science Services laboratories have extensive knowledge and expertise in developing and validating methods for raw materials, API's, finished products and cleaning validation.

SGS offers development and documentation of analytical protocols and reports for proprietary and nonproprietary test methods and manufacturing processes in compliance with the ICH Q2 (R1) guideline "Validation of Analytical Procedures : Text and Methodology" and FDA guidelines.

Once a method is validated, it may require transfer. Method transfer may involve comparative testing, co-validation between two sites (Lab-to-Lab), complete or partial revalidation and comprehensive documentation (Transfer Plan, Protocol, Report). Whether SGS' Life Science Services is the developing or the receiving laboratory, we can assist you with your method transfer requirements.

METHOD DEVELOPMENT

- Identification
- Assay testing
- Dissolution
- Particle size distribution
- Testing for impurities
- Stability indicating methods
  - Humidity/temperature
  - Temperature
  - pH variation
  - Oxidative and reductive stress
  - Light stressing
  - Microbial testing

VALIDATION

- Accuracy
- Precision
  - Repeatability
  - Intermediate precision
  - Reproducibility
- Specificity
- Detection limit
- Quantitation limit
- Linearity
- Range
- Robustness
- System suitability test

ENVIRONMENTAL MONITORING

In addition to acceptance tests for the installation of clean rooms in production facilities, SGS can perform routine monitoring of viable and nonviable contamination of production facilities.

SGS offers a broad range of monitoring services for clean rooms and can also provide you with customized hygiene-monitoring programs that suit your needs.

SERVICES INCLUDE

- Viable and nonviable particle counting of air sample in manufacturing, packaging and testing sites
- Microbial sampling and enumeration of surfaces
- Cleaning validation studies
- Disinfectant efficacy studies
- Microbiological tests on individual process media (air, water, technical gases)
- Determination of bacterial count in air under all operating conditions
- Particle measurement
- Determination of TOC (total organic carbon)
- Media Control (e.g. humidity, particle, oil and organic residues in gases)
- Testing surfaces, consumables and primary packaging
- Qualification of production facilities after installation, reconstruction, standstill, etc.
- Confirmation of personal hygiene, determination of microbiological exposure on clothing and hands of production personnel

MEDICAL DEVICE TESTING

SGS supports its partners in the medical device industry with a broad range of services. SGS performs hygienic qualification of the production facilities, microbiological tests on the products before and after sterilization, and screening for possible residual contaminants from the sterilization process (endotoxins, ethylene oxide). SGS also conducts studies for migration of substances from packaging material (leachables).

SERVICES INCLUDE

- Determination of bioburden before sterilization
- Sterility testing according to USP and EP of products and biological indicators
- Method development and validation
- Endotoxin testing
  - Gel clot, kinetic, and chromogenic
- Residual ethylene oxide testing according to EN ISO 10993-7
- Environmental monitoring of production zones
  - Viable and nonviable particulate analysis
  - RODAC and swab analysis of surfaces
- Cytoxicity bioassay
- Polymer identification
  - FTIP, TGA, DSC
- Container Closure Permeation
  - Dye and microbial ingress studies
- Test for leachable substances according to EN ISO 10993-17

These services are complimented by capabilities in other SGS divisions, including CE mark, electrical testing, package integrity testing and Medical Device ISO certification and audits. SGS is the Medical Device industry's single source provider.

REGULATORY AND QUALITY MANAGEMENT SYSTEMS

LABORATORIES	COUNTRY	QUALITY MANAGEMENT SYSTEM	ISO STANDARD	US-FDA REGISTERED	US-FDA INSPECTED
Toronto (Mississauga)	Canada	GMP	9001/13485	•	•
Chicago (Lincolnshire)	USA	GMP/GLP	9001	•	•
New Jersey (Fairfield)	USA	GMP	9001	•	•
Philadelphia (West Chester)	USA	GMP	–	•	•
Los Angeles (Carson)	USA	GMP/GLP	–	•	–
Brussels (Wavre)	Belgium	GMP/GLP/GCP	17025	•	•
Paris (Villeneuve La Garenne)	France	GMP	–	•	•*
Poitiers	France	GMP/GLP/GCP	–	•	•
Berlin	Germany	GMP	–	•	•
Frankfurt (Taunusstein)	Germany	GMP	17025	•	•
Geneva	Switzerland	GMP/GLP/GCP	–	•	•
London (Wokingham)	UK	GMP/GLP	–	•	•
Glasgow	UK	GMP/GLP	–	•	•
Florence (Livorno)	Italy	GMP	9001	•	–
Shanghai	China	GMP	17025	•	•
Chennai	India	GMP	17025	•	•
Mumbai (Navi)	India	GMP	17025	•	–
Singapore	Singapore	GMP	17025	•	•

**US-FDA inspection planned Q3 2015*

SGS MEANS QUALITY

SERVICES

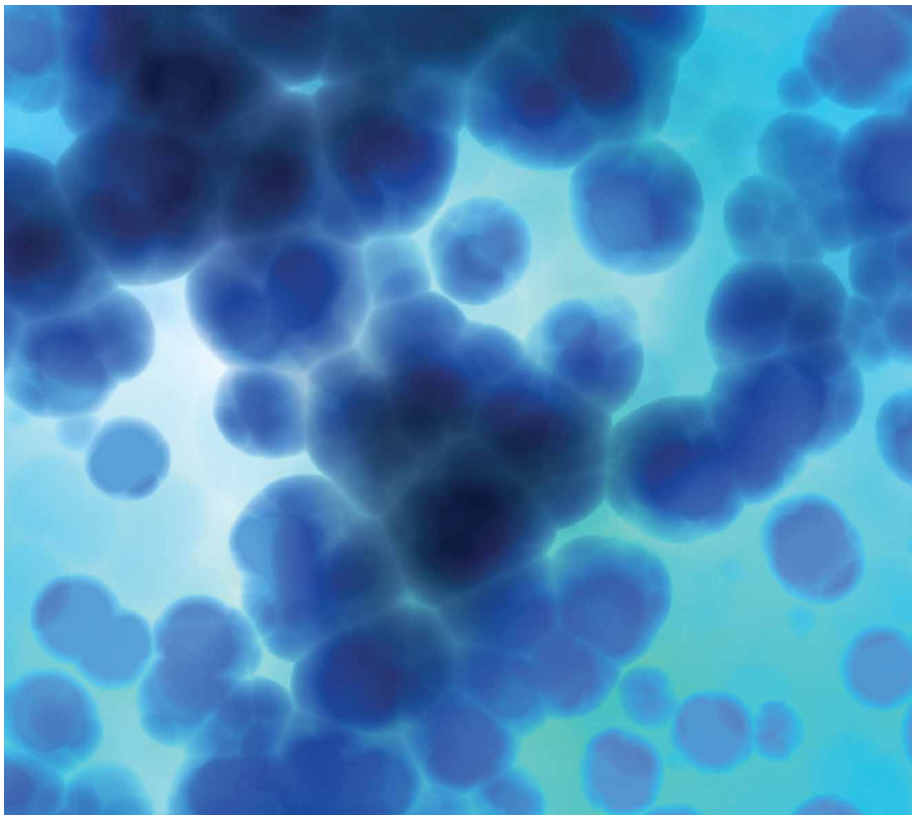
Preclinical › Exploratory Development › Confirmatory Development › Post-Approval › Routine Production › Trade Distribution

LABORATORY SERVICES

Biologics Characterization and Biosafety

- Method Development, Optimization & Validation
- Amino Acid Sequencing and Analysis (Edman, MS/MS) – Exctinction Coefficient
- Peptide Mapping by MS – Disulphide Bridge Analysis
- Glycosylation – Monosaccharides, Sialic Acid, Linkage, Glycan Profile, and Site Analysis
- High Order Structures Analysis
- Post-Translational Modification Analysis
- Isoform and Electrophoretic Patterns
- Comparability Studies
- LC Patterns (SEC, RP, IEX)
- FTIR and Fluorescence to Spectrometric Profile (CD, DSC, NMR)
- Aggregation Analysis (AUC, SEC-MALS, DLS)
- Characterization and Quantitifcation of Process- and Product-Related Impurities
- Stability and Pre/Formulation
- Biosafety Testing
  - Cell Bank and Virus Seeds Characterization – Electron Microscopy Studies
  - Raw Material and Bulk Harvest Testing (Sterility, Mycoplasma, Viruses)
  - Final Product Testing for Residual DNA and Host Cell Protein (by Immunoassay and Mass Spectrometry)

RELATED SERVICES



To support the rapidly developing biopharmaceuticals market, SGS provides a wide range of services to complement our pharmaceutical services and to offer a comprehensive services portfolio.

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 development through characterization and quality control tests, and into clinical trials for safety and efficacy testing.

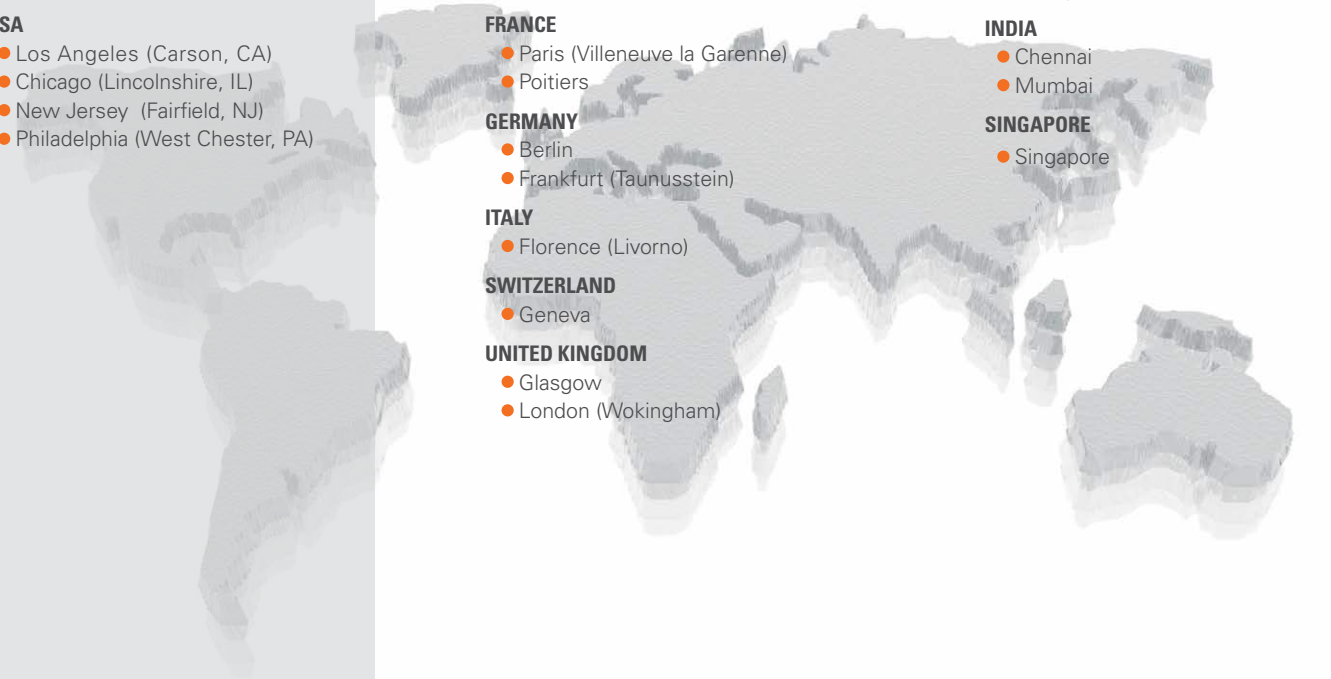
BIOSAFETY TESTING SERVICES

SGS provides a comprehensive range of biosafety services for biologics, including: virology, cell and molecular biology, 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.

BIOANALYSIS

As one of Europe's largest bioanalytical service providers, with three GLP 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. SGS bioanalysis testing is underpinned by a large list of validated methods and biomarkers – over 700 assays to date. We maintain our reputation as an industry pioneer by actively pursuing the assay development and validation of some of the more innovative of these biomarkers.

SGS MEANS PROXIMITY



AMERICAS

CANADA
- Toronto (Mississauga, ON)

USA
- Los Angeles (Carson, CA)
- Chicago (Lincolnshire, IL)
- New Jersey (Fairfield, NJ)
- Philadelphia (West Chester, PA)

EUROPE

BELGIUM
- Brussels (Wavre)

FRANCE
- Paris (Villeneuve la Garenne)
- Poitiers

GERMANY
- Berlin
- Frankfurt (Taunusstein)

ITALY
- Florence (Livorno)

SWITZERLAND
- Geneva

UNITED KINGDOM
- Glasgow
- London (Wokingham)

ASIA

CHINA
- Shanghai

INDIA
- Chennai
- Mumbai

SINGAPORE
- Singapore

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