LIFE SCIENCES

DRUG DEVELOPMENT SERVICES

LIFE INSPIRED, QUALITY DRIVEN

SGS

YOUR GLOBAL DRUG DEVELOPMENT ORGANIZATION FOR ANALYTICAL LABORATORY TESTING AND CLINICAL RESEARCH

Bringing a compound from the laboratory to the market is a long and winding road with a great number of scientific, safety and regulatory challenges. SGS has been offering high quality analytical testing and clinical research services to support drug research, registration and production.

SGS leverages its conveniently located network of laboratories and clinical trial facilities present in North America, Europe and Asia-Pacific, to deliver harmonized solutions to large pharmaceutical and biotechnology firms.

Our experts provide effective and efficient testing solutions for analytical development, biologics characterization, biosafety and quality control, as well as clinical research services. We perform a variety of tests that are bespoke, client-specific and support the full clinical development, from Phase I First-in-Human trials in our Clinical Pharmacology Units to Phase II and Phase III studies in patients.

ABOUT SGS

SGS is the world's leading inspection, verification, testing and certification company. We are recognized as the global benchmark for quality and integrity. With more than 97,000 employees, we operate a network of more than 2,600 offices and laboratories around the world.

WHY WORK WITH SGS LIFE SCIENCES?

SGS HAS OVER 40 YEARS OF EXPERIENCE AS A GLOBAL CONTRACT RESEARCH ORGANIZATION

RELIABLE & ACCURATE RESULTS

When it comes to the pursuit of developing life-changing solutions, there's no such thing as one size fits all; our studies are engineered to your unique needs. We guarantee reliable and accurate testing using state-of-the-art facilities, equipment and techniques and offer integrated advanced drug development solutions.

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 activities while reducing errors and potentially costly mistakes that can delay bringing your product to market.

PARTNERSHIP & GROWTH

Our conveniently located network of laboratories and clinical trial facilities 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 sites and qualified partners.
- Size and diverse testing capabilities matching biologics and small molecules needs
- International network across America, Europe and Asia-Pacific

ANALYTICAL TESTING AND QC SERVICES

METHOD DEVELOPMENT & VALIDATION

- Method development for identity, assay and purity of drug products, APIs and degradation products
- Method validation according to ICH guidelines and/or customer requirements
- Verification of accuracy and suitability of the developed method
- Development and validation of stability indicating methods
- Transfer lab to lab validation
- Re-validation

ANALYTICAL CHEMISTRY

- Assay and purity (e.g. chromatography, titration, limit tests)
- Identity (e.g. spectroscopy, chromatography)
- Dissolution test (on line / off line)
- Pharmaceutical water analysis (e.g. TOC)
- Water content (loss on drying, KF titration)
- Disintegration
- Appearance (e.g. clarity, opalescence)
- pH and conductivity
- Osmolality, osmolarity
- Melting point, boiling point etc.
- Viscosity, rheology
- Uniformity of mass

MICROBIOLOGY TESTING

- Microbial limits tests
- Sterility testing
- Microbial contaminant identification
- Preservatives testing and microbial challenges
- Microbiological assessment of antibiotics
- Bacterial endotoxins
- Environmental monitoring
- Water systems validation
- Production facility qualification
- Cleaning validation

STABILITY TESTING

- Long term stability studies
- Short term, accelerated studies
- Follow-up stabilities
- Photostability testing
- All ICH conditions + specific conditions
- Fully controlled and monitored
  - All systems with 24 H / 7D - monitoring and alert system
- Validated monitoring system, 21 CFR part 11 compliant
- Back-up chambers available
- Comprehensive documentation

IN-VITRO TOXICOLOGY

- Skin corrosion, irritation and sensitization
- Cytotoxicity USP <87> ISO 10993-5
- Genotoxicity OECD 471
- Phototoxicity OECD 432
- Pyrogenicity monocyte activation test EP 2.6.30
- Bioavailability CACO-2 permeability assay

EXTRACTABLES & LEACHABLES TESTING

- Comprehensive testing for extractables in:
  - Container testing (glass, plastic, rubber...)
  - Packaging
  - Single-use systems (SUS)
  - Medical devices
  - Migration studies
- Leachables in final products

MEDICAL DEVICE TESTING

- Determination of bioburden before sterilization
- Sterility testing according to USP and EP of products and biological indicators
- Test for endotoxins
- Cytotoxicity testing
- Hygiene monitoring for the qualification and control of production zones
- Test for ethylene oxide residues din En ISO 10993-7

BIOLOGICS TESTING SERVICES

BIOLOGICS CHARACTERIZATION

- Aggregation analysis (AUC, SEC-MALS, DLS)
- Amino acid sequencing & analysis (Edman, MS/MS) - Extinction Coefficient
- Product characterization
- Comparability studies
- Cell line characterization
- Cell-based assays
- Protein analysis
- Host cell impurity testing - Residual DNA / host cell proteins (Immunoassay & mass spectrometry)
- FTIR & fluorescence to spectrometric profile (CD, DS)
- Glycosylation - monosaccharides, sialic acid, linkage, glycan profile, and site analysis
- Higher Order Structures analysis (HOS)
- Isoform & electrophoretic patterns
- LC patterns (SEC, RP, IEX)
- Method development, optimization & validation
- Peptide mapping by MS - Disulphide bridge analysis
- Stability studies

BIOSAFETY TESTING

- Sterility
  - Direct inoculation (ep 2.6.1)
  - Filtration method (ep 2.6.1)
  - Alternative automatised method
- Endotoxins detection (ep 2.6.14, USP <85>)
- Cytotoxicity testing (iso 10993-5, USP <87>)
- Pyrogen detection (ep 2.6.30, In vitro testing)
- Bacterial identification
  - Vitek2
  - Apigallery
- Virus testing (EP 2.6.16, 5.2.3, ICH Q5A)
- In vitro adventitious virus assays
- Mycoplasma testing (ep 2.6.7, FDA)
- Cell banks and raw materials
- Cell-derived harvests and final product
- Viral seeds and harvests
- Animal tissue and cell-derived products
- Purified drug substances for "PRP"
- Supporting manufacture of biologicals:
  - Recombinant protein
  - Monoclonal antibodies
  - Viral vaccines
  - Cell therapies
  - Gene therapies

BIOANALYSIS SERVICES

- Method transfer, development and validation for small molecules, biologics, biosimilars and biomarkers.
- PK bioanalysis (small molecules, biologics, biosimilars)
- PD bioanalysis (soluble and cellular biomarkers)
- Immunogenicity testing (screening, confirmatory, titration characterization and neutralizing anti-drug antibody assays)
- ELISA and Multiplex assays for parent, metabolites, biomarkers
- Cell-based assays (cellular biomarkers, receptor occupancy, neutralizing anti-drug antibody assays, immunophenotyping)
- Hybrid approach LBA/LC-MS/MS

LABORATORY AND CLINICAL SERVICES SYNERGIES

- Services for small and large molecule testing in TK, PK and PD
- Online clinical samples dosing with CPU's
- Discovery biomarkers translated in clinical research
- Immune function testing
  - Immunogenicity, flow cytometry, cytokine multiplexed elisa

CLINICAL DEVELOPMENT SOLUTIONS
FROM STAND ALONE TO FULL SERVICE

DRUG DEVELOPMENT CONSULTANCY

SGS comprehensive range of services includes:

- Early phase development strategy and tactics
- Validation of strategy with regulators
- Development and redaction of official health authorities' trial documents
- Scientific and medical input

EARLY PHASE DEVELOPMENT

SGS has a wealth of expertise in First-In-Human studies, QT/QTc prolongation, Human Challenge Testing, and complex trials. Clients can benefit of 30% reduction in development timelines thanks to:

- Fast study start-up with shortest EU regulatory timelines in Belgium
- Solid expertise in complex trials & fast track development (Combined / Adaptive Design protocols)
- Rapid access to healthy volunteers and patients

Early adaptors of new techniques to follow the drug in the human body

- Challenge studies with viruses
- Specific sampling techniques (brain fluid, lung, bowels, …)
- We have our own Clinical Pharmacology Unit in Belgium (GCP, ICH) and we manage 3 Phase I Patient Units in Belgium and in Hungary
- Access to patient networks in EU and in the US

BIOMETRICS AND SUPPORT SERVICES

Early adopters of integrated IT solutions such as E-source or Argus safety database and pioneer in full EDC application with multi EDC systems, SGS is a CDISC registered solution provider and has successfully completed full electronic FDA submissions for several candidate drugs.

Our comprehensive services include:

- Electronic solutions: Electronic Data Capture (EDC), electronic Clinical Outcome Assessment (eCOA), Interactive Voice/Web Response System (IVRS/IWRS)
- Data management: SDTM compliant, clean clinical database, ready for submission
- Secure data office: handle all data of potentially unblinding nature
- PK/PD data analysis
- Drug-disease modelling & simulation
- Biostatistics: advice on protocol design, SAP development, statistical analysis and delivery of ADaM compliant datasets
- Pharmacovigilance and Drug Safety
- Medical Monitoring
- Medical writing

GLOBAL CLINICAL TRIAL MANAGEMENT

SGS has extensive experience in managing phase I trials (HV and patients) as well as phase II and III across a wide spectrum of therapeutic indications.

For a qualitative and faster patient recruitment, clients can count on SGS':

- Consultative, cross functional trial design
- Large data base of investigators and key opinion leaders
- Robust and reliable study feasibility
- Efficient project start-up and site-activation
- Worldwide recognition for End-to-End Clinical Trial Management
- Consistent, proven success in multiple therapeutic areas, with a focus on:
  - Infectious Diseases
  - Respiratory
  - Diabetes
  - Rare Diseases
  - Women's Health

ONEVISION

DELIVERING SUSTAINED EXCELLENCE ACROSS OUR ENTIRE GLOBAL NETWORK

A global digitalization initiative to create a single, integrated network of testing laboratories. SGS has always been at the forefront of bringing excellence into the business environment.

OneVision brings flexibility to SGS Life Sciences' service delivery systems, by creating a platform that supports continuous development and allows adaptation and evolution to match ever changing global markets.

TRANSFORMATION

Implements a fully digitalized global network that interconnects systems and laboratories to create a modern, forward-looking business structure.

HARMONIZATION

Establishes a standardized digital record-keeping platform across the SGS global network to reinforce our commitment to quality service.

OPTIMIZATION

Standardizes all network data inputting and streamlines processes to generate greater efficiencies, improve turnaround times and deliver better customer service.

DIGITALIZATION

Creates a single, global digitalized laboratory network with improved communications between the SGS network and its customers.

SUSTAINABILITY

Reduces environmental impact through digitalization, lessening the need for paper and storage while delivering greater efficiencies.

BUSINESS EXCELLENCE

Delivers optimal business evolution through high-tech system adoption, enabling continuous network improvements.

HARMONIZED QUALITY MANAGEMENT SYSTEMS

SGS complies with the requirements of all global regulatory authorities necessary for approval, and operates from GMP / GLP / GCP facilities.

OUR 6 LAYER SYSTEM:

- Global quality manual
- Global policies
- Global SOPs
- Local quality manual
- Local SOPs
- Site quality documents

BASED ON GxP PRINCIPLES:

Incorporates additional certifications on local levels

- ISO 17025
- ISO 9001
- WHO (prequalification scheme)

GLOBAL REGULATORY AUTHORITIES WE WORK WITH INCLUDE:

- FDA (US, China, India)
- EMA / MHRA / FAMHP
- Health Canada
- Swiss Medic
- ANSM
- PDMA

FIND US HERE

AMERICAS

LABORATORY SERVICES

CANADA

- Toronto (Markham)

+1 905 305 0998

- Toronto (Mississauga)

+1 905 364 3757

USA

- Chicago (Lincolnshire)

+1 847 821 8900

- New Jersey (Fairfield)

+1 973 244 2435

- Philadelphia (West Chester)

+1 610 696 8210

CLINICAL RESEARCH

- Washington DC (Germantown)

+ 1 877 677 2667

EUROPE

LABORATORY SERVICES

BELGIUM

- Brussels (Wavre)

+32 10 42 11 11

FRANCE

- Paris

+33 1 41 06 95 93

- Poitiers

+33 5 49 57 04 04

GERMANY

- Berlin

+49 30 3460 7500

- Frankfurt (Taunusstein)

+49 6128 744 245

- Frankfurt (Wiesbaden)

+49 611 962 5910

SWITZERLAND

- Geneva

+41 22 794 83 74

UK

- Glasgow

+44 141 952 0022

CLINICAL RESEARCH

BELGIUM

- Brussels (Mechelen)

+32 15 27 32 45

ASIA-PACIFIC

LABORATORY SERVICES

CHINA

- Shanghai

+86 21 6115 2197

INDIA

- Chennai

+91 44 6462 9711

- Mumbai

+91 22 6457 2540-45

lss.info@sgs.com
sgs.com/lifescience
sgs.com/Linkedin-Life

WWW.SGS.COM

WHEN YOU NEED TO BE SURE

SGS