

LIFE SCIENCES

BIOANALYSIS SOLUTIONS

LIFE INSPIRED, QUALITY DRIVEN



SGS



YOUR GLOBAL DRUG DEVELOPMENT ORGANIZATION FOR BIOANALYTICAL TESTING

With over 30 years of experience and operating out of our GLP/GCP compliant laboratories.

SGS has the expertise to both develop assays from scratch (including LC-MS/MS, immunoassays and cell-based assays) and to support large scale routine sample analyses, from regulatory pre-clinical (toxicology) to early and late clinical studies (Phase I to IV).

SERVICES

SGS Life Sciences can provide bioanalytical testings for drug development from regulatory preclinical to early and late clinical phases

- 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 characterisation and neutralising anti-drug antibody assays)
- ELISA and multiplex assays for parent, metabolites, biomarkers
- Cell-based assays (cellular biomarkers, receptor occupancy, neutralising anti-drug antibody assays, immunophenotyping)
- Hybrid approach LBA/LC-MS/MS

CONTINUOUS FOCUS ON DEVELOPMENT

A dedicated group evaluates assay requests from a strategic and scientific point of view. SGS offers more than 700 validated methods that are ready for use with very short lead time.

Validation criteria follow guidelines from FDA

- 2018: Bioanalytical method validation & 2019: Immunogenicity
- EMA (2011) for GLP compliance
- European Reflection Paper (2012) for the GCP compliance.

BIOMARKERS

SGS has also actively pursued the assay development & validation of innovative biomarkers, with the support of our clinical teams. SGS has the expertise to both develop assays from scratch (including LC-MS/MS, immunoassays and cell-based assays) and to support large scale routine sample analyses, from regulatory pre-clinical (toxicology) to early and late clinical studies (Phase I to IV). In parallel, SGS has validated several multiplex inflammatory panels

(cytokines/chemokines) in human matrices, methods readily available for clinical sample analysis.

SGS provides a large list of biomarkers. SGS doubled its capacity (lab space, equipment and staff) within the last two years to develop multiplex immunoassays for biomarkers screening by therapeutic area (Mesoscale, Luminex 200 platforms). SGS also invested in the COBAS®6000 platform for biomarkers analysis under GLP/GCP environment, in the ELLA/SimplePlex and the latest Meso Scale Discovery platforms (S600).

ELISA, RIA, ECLIA, cell-based assay, flow cytometry

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.

LARGE CAPACITIES FOR ON-TIME DELIVERY

In order to support the bioanalysis of various classes of compounds, SGS offers a large range of techniques and methods, providing rapid high volume bioanalysis:

- Mass spectrometry: 31 LC-MS/MS (Sciex API 4000 to API6500)
- Waters equipment (Xevo TQ-S)
- Immunoanalysis: ELISA, RIA, ECLIA measurements for routine analysis of a variety of molecules including therapeutic proteins, monoclonal antibodies (mAb), antibody-drug conjugates (ADCs), peptides and biosimilars.
- Automated sample preparation using robotics (Multiprobe/TECAN) or turbulent flow technology (Cohesive)
- Large sample storage capacity combined with bar code system for sample tracking (400 000 samples storage and equivalent backup)

INNOVATIVE TECHNOLOGIES

- Customized immunoassay development and validation for New Biological Entities (NBEs) for Pharmacokinetics (PK) and Immunogenicity (ADA)
- Biomarkers development and screening by Multiplex Immunoassays
- Peptide quantification and LLOQ improvement
- Complex LC-MS/MS methods for several biomarkers detection in a single sample
- Fast LC analysis and plasma protein binding determination by rapid equilibrium dialysis
- Dried blood spot filter paper technology combined with LC-MS/MS
- Hybrid approach LBA/LC-MS-MS for NBEs

- Flow cytometry capabilities operating in a GCP environment (FACS CANTO & Verse)
- Clotting and chromogenic assays (Diagnostica Stago)

WITH THE RIGHT QUALITY

- GLP/GCP compliant bioanalytical sites
- Each site is periodically inspected by the relevant local agency
- Inspected by FDA
- 21 CFR Part 11 compliance program
- Independent QA group (project and facility audits and GLP training)



HARMONIZED REGULATORY & QUALITY MANAGEMENT SYSTEM BASED ON GCP/GLP

| CAPABILITIES | | | | |
|---------------------------|-------------|---------|-------------|---------------|
| | EUROPE | | | NORTH AMERICA |
| COUNTRY | BELGIUM | FRANCE | SWITZERLAND | CANADA |
| Quality Management System | GMP/GLP/GCP | GLP/GCP | GMP/GLP/GCP | GMP |
| ISO Standard | 17025 | - | - | 9001/13485 |
| US-FDA Registered | • | • | • | • |
| US-FDA Inspected | • | • | • | • |

QUALITY MANAGEMENT

SGS complies with the requirements of all global regulatory authorities necessary for approval.

OUR 6 LAYER SYSTEM:

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

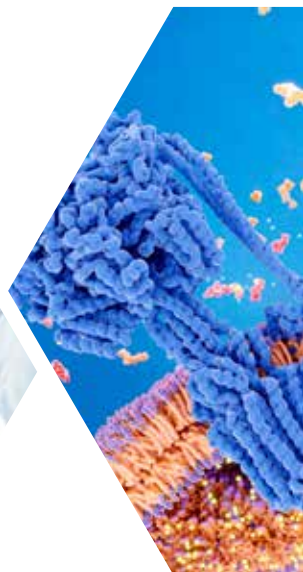
BASED ON GXP PRINCIPLES:

Incorporates additional certifications on local levels

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

GLOBAL REGULATORY AUTHORITIES WE WORK WITH INCLUDE:

- US FDA
- EMA/MHRA
- Health Canada
- Swiss Medic
- ANSM
- PDMA (Japan)



| CAPABILITIES | | | | |
|--|---------|--------|-------------|---------------|
| COUNTRY | EUROPE | | | NORTH AMERICA |
| | BELGIUM | FRANCE | SWITZERLAND | CANADA |
| Method development/transfer | • | • | • | • |
| Method validation | • | • | • | • |
| PK Bioanalysis | • | • | | • |
| PD Bioanalysis (soluble and cellular biomarkers) | • | • | | • |
| Immunogenicity testing | | • | | • |
| Cell-based assays | | • | | • |
| Hybrid approach LBA/LC-MS/MS | • | • | | • |
| Discovery (PK, ADA, Immunotox) | | • | | |



FIND US HERE

BELGIUM

- Brussels (Wavre)
- +32 10 42 11 11

SWITZERLAND

- Geneva (Plan-les-Ouates)
- +41 22 794 83 74

FRANCE

- Poitiers
- +33 5 49 57 04 04

CANADA

- Toronto (Mississauga, ON)
- +1 905 364 3757

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With a harmonized network of laboratories across Europe, North America and Asia, the Laboratory Services Team provides regulatory compliant (GLP/GMP and/or ISO) analytical services including: analytical chemistry, microbiology, stability studies, extractables & leachables, biosafety and protein characterization testing.



DELIVERING SUSTAINED EXCELLENCE ACROSS OUR ENTIRE GLOBAL NETWORK

SGS has always been at the forefront of bringing excellence into the business environment. With OneVision, our global digitalization initiative to create a single, integrated network of testing laboratories, the SGS Life Sciences global network of laboratories delivers a more comprehensive service to their customers, adding value and delivering faster turnaround times.

Utilizing the latest technologies, OneVision implements standardized record-keeping processes in all offices and laboratories around the globe. This means, wherever a customer is in the world, they are guaranteed the same high-quality service.



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.

GET TO MARKET QUICKLY, SAFELY & EFFICIENTLY

We provide the highest quality services, reliable expertise and guidance through our network of laboratories conveniently located around the globe.



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WHEN YOU NEED TO BE SURE

