



BIOANALYTICAL SERVICES

With over 25 years of experience and operating out of two GLP compliant laboratories, SGS Life Science Services is Europe's largest bioanalytical facility (125 staff). Pharma and biotech companies of all sizes have chosen us as their preferred bioanalytical partner. SGS has the expertise to both develop assays from scratch (including immunoassays) and to support large scale routine sample analyses, from pre-clinical to clinical studies.

SERVICES

SGS Life Sciences can provide bioanalytical testings for drug development from early to late phase :

- Cell-based bioassays
- Immunogenicity testing
- Metabolite profiling
- ADME ¹⁴C
- Method Transfer, Development, Optimization and Validation
- PD bioanalysis (biomarkers)
- PK bioanalysis (small molecules, biopharmaceuticals)

CONTINUOUS FOCUS ON DEVELOPMENT

A dedicated group evaluates assay requests from a strategic and scientific point of view. SGS offers more than 600 validated methods that are ready for use with very short lead time. Validation criteria follow guidelines from FDA (May 2001) and the Crystal City Conference (May 2006).

BIOMARKERS

SGS has also actively pursued the assay development & validation of innovative biomarkers, with the support of our clinical teams. SGS has coupled RIA with HPLC to secure further selectivity in biomarker analysis and have developed LC-MS/MS methodologies to measure steroidal and hormonal substances in the low picogram range. SGS provides a large list of biomarkers. SGS doubled his capacities (lab space, equipments and staff) within the last two years to develop multiplex immunoassays for biomarkers screening by therapeutic area (Mesoscale, Luminex Biorad Bioplex 200 platforms).

Complete immunogenicity testing solutions:

- Screening, confirmatory, characterisation and neutralising antibody assays
- ELISA, RIA, ECL, cell-based assay, flow cytometry
- Assays developed and validated according to EMEA guideline and current literature
- Quantification of therapeutic biologicals and associated biomarkers for PK/TK studies across all phases

SGS

BIOPHARMACEUTICALS ANALYSIS

SGS will support you for the analysis of biopharmaceuticals such as recombinant proteins, peptides and monoclonal antibodies or nucleic acid-based drugs. Services:

- In Vitro Safety Testing (endotoxin, mycoplasma)
- Host Cell Impurity Testing (residual DNA/ Host cell proteins)
- Protein Analysis
- Cell Line Characterization
- Stability Studies (ICH Q5C)
- Molecular biology tests
- Cell-Based Assays

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
- Immunoanalysis: RIA, ELISA measurements for routine analysis of a variety of molecules including therapeutic proteins
- UPLC technology: one instrument, equipped with a PDA detector
- Automated sample preparation using robotics (Multiprobe) or turbulent flow technology (Cohesive)
- Large sample storage capacity combined with bar code system for sample tracking (400 000 sample storage and equivalent backup)

INNOVATIVE TECHNOLOGIES

- Customized immunoassay development and validation for New Biological Entities
- Biomarkers screening by Multiplex Immunoassays
- Peptide quantification and LLOQ improvement (API5500 system)
- Complex LCMS 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
- Flow cytometry capabilities operating in a GLP environment (FACs Canto II BD)
- Clotting and chromogenic assays (Diagnostics Stago)

WITH THE RIGHT QUALITY

- Two GLP compliant bioanalytical sites since 1990/91
- Each site is periodically inspected by the relevant local agency
- Audited by FDA
- 21 CFR Part 11 compliance program
- Independent QA group (project and facility audits and GLP training)
- Manufacturing ¹⁴C labeled medication in GMP accredited facilities

OTHER LABORATORY SERVICES

With a harmonized network of 17 laboratories in UK, USA, Canada, Switzerland, Germany, France, Belgium, India, Thailand, Singapore, Taiwan, China, the R&D / Quality Control Services Team provides regulatory compliant (GMP and/or ISO) analytical services including: Analytical Chemistry, Microbiology, Stability Studies, Extractables & Leachables, Biotechnology and Medical Device Testing.

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY

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WHEN YOU NEED TO BE SURE

The logo for SGS, consisting of the letters 'SGS' in a bold, sans-serif font. A vertical orange line is positioned to the right of the letters, and a horizontal orange line is positioned below the letters, forming an L-shape that frames the text.