

SGS Life Science Services

Clinical Research & Quality Control Testing

SGS Life Science Services is a leading contract organization providing clinical research services and quality control testing. We serve a variety of Life Science companies including pharmaceutical, biopharmaceutical, biotechnology and medical device manufacturers. SGS provides clinical trial management (Phase I to IV) and services encompassing data management & statistics, bio-analytical assays, and regulatory consultancy. We also offer quality control services that include analytical chemistry, microbiology, stability studies, method development, toxicology, and protein analysis. SGS is the world's leading verification testing, inspection, and certification company.

Our mission is to safeguard the quality of medicines by providing professional and independent services in global drug development and testing of pharmaceuticals, creating value for our clients, employees, shareholders and patients worldwide.



QUALITY CONTROL TESTING

At SGS, we believe that outsourcing quality control testing starts with a trustworthy relationship. You have to be sure about your contract laboratory. Only then can you really benefit from the numerous advantages of outsourcing quality control activities. Outsourcing allows clients to: focus on core competencies, react to fluctuating workload, reduce fixed costs, and minimize investment in capital equipment. SGS has a long track record as a service provider to the pharmaceutical industry. To maintain the strong expertise, to ensure the high quality of our services, and to stay current with regulatory requirements, we conduct extensive training programs with our staff and continuous investment in state-of-the-art laboratories and analytical equipment.



Our portfolio of analytical services include the following:

- Quality control testing of raw materials, APIs and finished products
- Monograph testing (USP, EP, BP, JP)
- Analytical method development and validation
- Container testing
- Environmental testing
- Inspection services
- Medical device testing
- Microbiological testing
- Safety testing (in vivo, in vitro)
- Stability testing according to ICH guidelines or customer specifications
- Water system validation

SGS operates a global network of quality control testing laboratories with facilities in the US, Canada, Belgium, France, Germany, India, Hong Kong, China, Taiwan, Thailand and Singapore. Our customers include large multinational companies as well as midsize and small local enterprises. The Top 20 pharmaceutical and biopharmaceutical companies trust SGS as a partner for their quality control testing needs. Our laboratories operate according to the highest quality standards (cGMP, GLP, ISO 17025, and ISO 9000) and have been inspected by the FDA and/or local regulatory authorities.



SGS Life Science Services Quality Control Testing

Operating in 14 laboratories worldwide, SGS LIFE SCIENCE SERVICES represents the broadest network of contract analytical laboratories, with unmatched geographic coverage serving local as well as global companies. Our facilities are equipped with state-of-the-art instruments such as GC/MS and LC/MS/MS.

SGS provides services for:

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|-------------------------------------|-----------------------------|-----------------------------|
| ■ Analytical Transfer | ■ Raw Materials Testing | ■ Inspection Services |
| ■ Stability Studies | ■ Finished Products Testing | ■ GMP Gap Auditing Services |
| ■ Method Development and Validation | ■ API Testing | |

With vast technical experience and the in-depth knowledge of local and international GMP guidelines, see how we can facilitate your drug development process. Learn more about our **broad portfolio** of Analytical Services.

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



TRUST IS BASED ON FACTS



SGS Life Science Services

Clinical Research

EARLY PHASE

PHASE I-IIA, BIOANALYSIS - INTERNATIONAL TRIAL MANAGEMENT, BIOMETRICS, REGULATORY AFFAIRS

SGS enables clients to improve efficiency in drug development timelines and decision making.

FACTS : 30 years of experience in all therapeutic areas - 800 professionals in 12 offices within 7 countries across 3 continents - 162 beds in 3 clinical research units - 2 000 studies in complex phase I-IIa trials and 1.000 in late phase trials - 28 late generation LC/MS-MS in 4 labs - 700 assay methods - FDA inspected - processing over one million CRF pages/year - experience in EDC & CDISC - Regulatory Intelligence

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CLINICAL RESEARCH

Within SGS' Clinical Research business, SGS state-of-the-art facilities include: three Phase I units with a total of 162 beds, four bioanalytical labs, and a network of Phase II-IV clinical trial management offices throughout Europe, North America and Asia.

In order to streamline our clients' clinical development process, SGS offers the following services:

■ Phase I-IIa clinical trials

Through years of developing and executing complex trials SGS has a wealth of expertise in: QT/QTc prolongation, radio-labeled C14 ADME & PET scan trials. Rapid access to special patient populations provides clients with the recruitment edge to execute time-critical trials, including: pediatric, renal & hepatic impaired, postmenopausal and sterilized women, elderly and slow metabolizer patients.

■ Bioanalysis

SGS offers extensive Bioanalytical capabilities and services, featuring mass spectrometry and immunoanalysis; including R&D capabilities for NCE's, hormones & biomarkers, flow cytometry and a library of over 600 methods.



■ Phase II-IV clinical trials

SGS is also a full provider in international Phase II-IV clinical trial management, throughout Europe and North America. SGS has experience in over 800 projects. These projects are handled by a large pool of experienced CRAs and Project Managers; continuously trained in GCP procedures, regulatory issues and company SOPs.

■ Data Management & Statistics

SGS' data management & statistics team supports Phase I-IV clinical trials, with an emphasis on biostatistics, data management, and medical writing. Clients benefit from a knowledgeable, proactive & flexible staff; experts in working in: Oracle Clinical® & ClinTrial®, CDISC & EDC.

■ Regulatory Affairs

The Regulatory Affairs department offers consulting in EU and US registration of pharmaceuticals and medical devices. Complete pharmacovigilance services are also available.

With over 48,000 employees, the SGS Group is the global leader and innovator in Inspection, Verification, Testing and Certification services. Founded in 1878, SGS is recognized as the global benchmark in quality and integrity.