

LIFE SCIENCE SERVICES & SITES



POCKET MAP – 2015



LABORATORY



R & D



CLINICAL

SGS

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SGS Life Science Services has over 35 years of experience as a global bio/pharmaceutical contract service organization. We provide integrated solutions from preclinical activities to phase I-IV clinical trials, pharmaceutical development, bioanalytical, protein characterization, biosafety and quality control testing of small and large molecules, raw materials, finished products, containers and utilities. With over 1,600 employees, a state-of-the-art clinical unit and the world's largest wholly owned network of GMP/GLP/GCP 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 thereby creating value for our clients, employees, shareholders and benefits for patients worldwide.



SERVICES

GMP, GLP, GCP – FROM MOLECULE TO MARKET



LABORATORY SERVICES

Biologics Characterization
Biosafety
Bioanalysis
Quality Control for Small & Large Molecules

CLINICAL RESEARCH

Phase I-IV Services
Phase I Unit, Trial Monitoring & Management - Biometrics
Drug Safety & Pharmacovigilance - Regulatory Consulting
PK-PD Modeling & Simulations



SGS LIFE SCIENCE SERVICES

FACILITIES BY REGION



NORTH AMERICA

CANADA

- Toronto (Mississauga, ON)

USA

- Chicago (Lincolnshire, IL)
- New Jersey (Fairfield, NJ)
- Philadelphia (West Chester, PA)
- Washington, DC (Germantown, MD)
- Los Angeles (Carson, CA)

EUROPE

BELGIUM

- Antwerp
- Brussels (Wavre)
- Brussels (Mechelen)

CZECH REPUBLIC

- Prague

FRANCE

- Paris (Villeneuve)
- Paris (Arcueil)
- Poitiers

GERMANY

- Berlin
- Frankfurt (Taunusstein)
- Hamburg

ITALY

- Florence (Livorno)

POLAND

- Warsaw

SPAIN

- Madrid

SWITZERLAND

- Geneva

UNITED KINGDOM

- London (Thurrock)
- Glasgow
- London (Wokingham)

ASIA

CHINA

- Shanghai

INDIA

- Chennai
- Mumbai (Navi)

SINGAPORE

- Singapore

- Laboratory Services
- Clinical Pharmacology Unit
- Clinical Trial Management



LABORATORY SERVICES

SGS's laboratory team provides complete pharmaceutical development and analytical services with its international, harmonized, and wholly-owned GLP/GMP/GCP bioanalytical, biosafety, characterization and quality control for small and large molecules laboratory network.

SERVICES		Preclinical	Exploratory Development	Confirmatory Development	Post-Approval	Routine Production	Trade Distribution
LABORATORY SERVICES	Quality Control for Small & Large Molecules	Method Development, Optimization & Validation					
		GMP Analytical Chemistry – Quality Control Batch Release					
		Microbiological Testing – Process- and Process-Related Impurities					
		Extractables & Leachables – Container Testing					
		Stability Studies (ICH) & Storage					
	Pre/Formulation Development						
	Utilities Qualification & Monitoring (Gas, Air, Water & Surface)						
	Facilities / Equipment Qualification and Calibration						
	Biologics Characterization & Biosafety	Biologics Safety Testing – Endotoxin, Virus, Mycoplasma					
		Virology – Cell Bank and Virus Seeds Characterization					
Cell & Molecular Biology – qPCR Assays							
Protein, Peptide Analysis & Quantification							
Biotherapeutic Characterization (Primary to Quaternary Structure)							
Bio analysis	Host Cell Impurity Testing & Identification						
	Cell-Based Assays, Cytotoxicity (ADCC)						
	Biomarkers – Immunogenicity and Neutralizing Antibody Testing						
Bioanalysis – PK/PD MS & Immunoassay – Large & Small Molecules – ADME ¹⁴ C Trials							

July 2015



LABORATORY SERVICES

BIOLOGICS CHARACTERIZATION AND BIOSAFETY

SGS has unrivaled expertise in glycoprotein analysis, gained from over 30 years experience in peptides, proteins, glycoproteins (including antibodies and biosimilars), oligonucleotides and vaccines. SGS's offering for biopharmaceuticals is complemented by extensive experience in the biosafety testing ensuring drug products are free of contaminants. Our biopharmaceutical services portfolio is available at all stages of development, from GLP discovery to GMP manufacturing. All analyses are designed to conform with the global regulatory guidelines (FDA/USP/EMA/Ph.Eur./ICH).

SERVICES

Preclinical

Exploratory
Development

Confirmatory
Development

Post-Approval

Routine
Production

Trade
Distribution

Method Development, Optimization & Validation

Amino Acid Sequencing and Analysis (Edman, MS/MS) – Extinction 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 Quantification 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)

LABORATORY
SERVICES

Biologics Characterization and Biosafety



LABORATORY SERVICES

LABORATORY CAPABILITIES PER SITE

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 (Tausenstein)	Germany	•	•	–	•	•	–	–	–	–
Geneva	Switzerland	•	–	–	•	–	•	–	•	–
Florence (Livorno)	Italy	•	•	•	•	–	–	–	–	•
London (Wokingham)	UK	•	–	•	•	•	•	–	–	–
Glasgow	UK	•	•	–	•	–	•	•	–	–
Shanghai	China	•	•	•	•	–	–	–	–	–
Chennai	India	•	•	•	•	•	–	–	–	–
Mumbai (Navi)	India	•	•	•	•	•	–	–	–	–
Singapore	Singapore	•	•	•	•	–	–	–	–	–



REGULATORY AND QUALITY MANAGEMENT OVERVIEW

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 BRUSSELS – BELGIUM



SERVICES

Method Development & Validation	Biologics Safety Testing (Endotoxin, Virus, Mycoplasma ...)
Analytical Chemistry – Batch Release	
Microbiological Testing	Potency Assays
Stability Studies	
Host Cell Impurity Testing	PK Bioanalysis (Small Molecules)
Cell-Based Assays	Protein, Peptide Analysis & Quantification
Cell Line Characterization	

Size : 8,400 m²

Established : 1971

Employees : 121

Certifications : GLP/GCP/cGMP, ISO 17025

US-FDA registered & inspected

Site Manager : Wim Van Immerseel

Address : 10 Vieux Chemin du Poète

1301 Wavre, Belgium

Nearby : Brussels Airport

Tel : +32 10 42 11 11

email : be.pharmaqc@sgs.com

www.sgs.be/lifescience



SGS LONDON – UK



SERVICES

Method Development & Validation	Post-Translational Modification Analysis
Biologics Pre/Formulation Services	Proteomics
Biologics Stability Studies	Analytical Chemistry – QC Release
Biophysical Analysis	Extractables & Leachables Studies
Peptide, Protein, Glycoprotein & Antibody Analysis	Product- & Process-Related Impurity Analysis
Monosaccharide, Sialic Acid, Linkage & Glycan Profiling Analysis	Characterization of Unknowns

Size : 2,100m²

Established: 1979

Employees: 64

Certifications: cGMP/GLP, US-FDA and MHRA
registered & inspected

Site Manager: Dr. Chris Harbach

Address: 2–3 Millars Business Centre, Fishponds Close
Wokingham, Berkshire RG41 2TZ, UK

Nearby: Heathrow Airport

Tel: +44 118 912 1190

email: uk.biopharma@sgs.com

www.sgs.com/biopharma



SGS GLASGOW – UK



SERVICES

Assay Development & Tech.Transfer	SPR Biacore Assays
Virology – <i>In Vitro</i> Adventitious Virus Assays and Cell Biology Assays	Regulatory Consultancy Services
Electron Microscopy – Virus Particle Quantification & Identification	Cell & Virus Banks Characterization
RT Assays (FPERT & qPERT)	Raw Material and Bulk Harvest Testing
Retrovirus Infectivity Assays	Batch Release (residual impurities)
Custom Biosafety Assay Design	Cell line Induction Studies
Mycoplasma, Mycobacteria, Spiroplasma & Virus Detection by qPCR	Cell Line & Virus Identity & Genetic Stability Testing, Massive Parallel Sequencing
	Stability Testing

Size: 1,124 m²

Established: 2007

Employees: 52

Certifications: cGMP / GLP, MHRA;

US-FDA registered & inspected

Site Manager: Dr. Archie Lovatt

Address: 5 South Avenue, Clydebank Business Park
Glasgow, G81 2LG, UK

Nearby: Glasgow Airport

Tel: +44 141 952 0022

email: biosafety@sgs.com

www.sgs.com/biopharma



SGS PARIS – FRANCE



SERVICES

Method Development & Validation	Utilities Testing and Monitoring (Gas, Air, Water & Surface)
Analytical Chemistry – Batch Release	
Microbiological Testing	Cleaning Validation (Atomic Absorption)
Stability Studies	Container Testing
Mycoplasma Testing	Extractables & Leachables
CMR Products Testing	Medical Device Testing
Amino Acid Analysis	Elemental Impurities Testing

Size : 2,100 m²

Established : 1994

Employees : 60

Certifications : cGMP, ANSM/ANSES inspected
US-FDA registered,
inspection planned Q3 2015

Site Manager : Dr. Paul Beyou

Address : 4 Rue du Commandant d'Estienne d'Orves
92390 Villeneuve la Garenne, France

Nearby : Paris Airports

Tel : +33 1 41 06 95 85

email : fr.pharmaqc@sgs.com

www.sgsgroup.fr/lifescience



SGS POITIERS – FRANCE



SERVICES

LC-MS/MS, Immunoassay and Cell-Based Assay Development & Validation

PK Bioanalysis (Small and Large Molecules)

Immunogenicity Testing

Biomarkers Testing (ELISA, ECLIA, Luminex, Cell-Based Assays and Cobas®6000)

Bioanalytical Testing For Biosimilars

Cell-Based Assay (Neutralization Bioassays, Potency Assays, Cell Activation and Inhibition and FACS Analysis)

Potency assays (biological activity) for characterisation, batch release, stability testing and Western Blot

Size : 3,200 m²

Established : 1980

Employees : 80

Certifications : GMP/GLP/GCP, US-FDA registered and inspected, ANSM inspected

Site Manager : Alain Renoux

Address : 90 Avenue des Hauts de la Chaume
86281 Saint-Benoit (Poitiers), France

Nearby : Paris Airports, TGV Train Station

Tel : +33 5 49 57 04 04

email : fr.pharmaqc@sgs.com

www.sgs.com/biopharma



SGS FRANKFURT – GERMANY



SERVICES

Method Development & Validation	Utilities Testing and Monitoring (Gas, Air, Water & Surface)
Analytical Chemistry – Batch Release	
Microbiological Testing	Biologics Safety Testing (Endotoxin, Mycoplasma ...)
Extractables & Leachables	
Sterility Testing	Medical Device Testing

Size: 1,010 m²

Established: 1978

Employees: 64

Certifications: cGMP, ISO 17025

US-FDA registered & inspected

Site Managers: Dr. Sheida Hönlinger

Dr. Axel Wehrmann

Address: Im Maisel 14

65232 Taunusstein, Germany

Nearby: Frankfurt Airport

Tel: +49 6128 744 245

email: de.pharmaqc@sgs.com

www.de.sgs.com/lifescience



SGS BERLIN – GERMANY



SERVICES

Method Development & Validation	Leachables Testing
Analytical Chemistry – Batch Release	Cleaning Validation
Stability Studies	Elemental Impurities Testing
Container Testing	Particle Analysis

Size : 2,100 m²

Established : 1985

Employees : 65

Certifications : cGMP

US-FDA registered & inspected

Site Managers : Dr. Sheida Hönlinger

Dr. Hilde Brümmer

Address : Tegeler Weg 33

10589 Berlin, Germany

Nearby : Berlin Tegel Airport

Tel : +49 30 3460 7500

email : de.pharmaqc@sgs.com

www.de.sgs.com/lifescience



SGS GENEVA – SWITZERLAND



SERVICES

Method Development & Validation	Post-Translational Modification Analysis
Peptide, Protein, Glycoprotein & Antibody Characterization	Protein and Peptide Sequencing & Quantification Analyses
PK Bioanalysis (Small Molecules, Peptides, Biopharmaceuticals)	Proteomics
	Oligonucleotide Analysis
Glycosylation – Qualitative and Quantitative Analyses, Monosaccharide, Sialic Acid, Linkage & Glycan Profiling Analysis	Product- and Process-Related Impurity Determination and Quantification
	HCP Qualitative and Quantitative Analysis by MS

Size : 600 m²

Established : 1991

Employees : 15

Certifications : cGMP/GLP/GCP

US-FDA registered & inspected

Site Manager : Dr. Luc-Alain Savoy

Address : 12 Chemin des Aulx

1228 Plan-les-Ouates (Geneva), Switzerland

Nearby : Geneva Airport and TGV Train Station

Tel : +41 22 794 83 74

email : ch.biopharma@sgs.com

www.sgs.com/biopharma



SGS FLORENCE – ITALY



SERVICES

Method Development & Validation	Equipment Validation
Analytical Chemistry – Batch release	Instrument Calibration (ISO 17025)
Microbiological Testing	IT Compliance and Validation
Stability Studies	Process & Quality Support
	Regulatory Affairs

Size: 1,161 m²

Established: Sept 2013

Employees: 37

Certifications: ISO 9001, cGMP
US-FDA registered

Site Manager: Marco Benvenuti

Address: Via Cimarosa, 95/105, Livorno, Italy

Nearby: Florence and Pisa Airports

Tel: +39 0586 852591

email: it.pharmaqc@sgs.com

www.sgsgroup.it/lifescience



SGS TORONTO – CANADA



SERVICES

Method Development & Validation	Cell Bank/Line Characterization (Molecular Biology, Phenotypic...)
Cleaning Validation	
Analytical Chemistry – Batch Release GC/MS, LC/MS-MS and ICP-MS	Biologics Safety Testing (Endotoxin, Mycoplasma, Host Cell Protein)
Microbiological Testing	
Stability Studies	Host Cell Impurity Testing
Container/Packaging Testing (Physical, E & L...)	Cell-Based Assays
Cell Banking (including Stability)	Protein/Peptide Characterization & Quantification (HPLC, CE, CEIEF...)
Microbial Disinfectant Efficacy Studies	Immunoligand Assays

Size : 4,300 m²

Established : 1984

Employees : 164

Certifications : cGMP, ISO 9001: 2008 & 13485: 2003

US-FDA registered & inspected

Site Manager : Michael Lindsay

Address : 6490 Vipond Drive

Mississauga, ON, L5T 1W8, Canada

Nearby : Toronto Pearson Airport

Tel : +1 905 364 3757

email : ca.pharmaqc@sgs.com

www.sgs.ca/lifescience



SGS CHICAGO – USA



SERVICES

Method Development & Validation

Utilities Qualification and Monitoring
(Gas, Air, Water & Surface)

Analytical Chemistry – Batch Release

Medical Device Testing

Microbiological Testing

Biologics Safety Testing (Endotoxin)

Stability Studies

Formulation/Pre-formulation
Services

Container Testing

Biosafety Level 2 Sample
Processing Center

Size : 3,700 m²

Established : 1972

Employees : 116

Certifications : cGMP/GLP, ISO 9001

US-FDA registered & inspected

Site Manager : Gayla Velez

Address : 616 Heathrow Drive

Lincolnshire, IL 60069, USA

Nearby : Chicago O'Hare Airport

Tel : +1 847 821 8900

email : us.pharmaqc@sgs.com

www.sgsgroup.us.com/lifescience



SGS NEW JERSEY – USA



SERVICES

Method Development & Validation	Container Testing
Analytical Chemistry – Batch Release	Extractables & Leachables
	Safety Studies <i>in vitro</i>
Stability Studies, Formulation/ Preformulation	Medical Device Testing
	Utilities Qualification and Monitoring (Gas, Air, Water & Surface)
Microbiological Testing	

Size : 3,345 m²

Established : 1995

Employees : 52

Certifications : cGMP, ISO 9001

US-FDA registered & inspected

Site Manager : Theresa Burchfield

Address : 75 Passaic Avenue

Fairfield, NJ 07004, USA

Nearby : Newark Liberty Airport

Tel : +1 973 244 2435

email : us.pharmaqc@sgs.com

www.sgsgroup.us.com/lifescience



SGS PHILADELPHIA – USA



SERVICES

Method Development & Validation	Oligonucleotide Analysis
Peptide, Protein, Glycoprotein & Antibody Characterization	Unknown Identification
Glycosylation – Qualitative and Quantitative Analyses	Product and Process-Related Impurity Determination & Quantification
Post-Translational Modification Analysis	HCP Qualitative and Quantitative Analyses by MS
Protein and Peptide Sequencing & Quantification Analysis	Quantitative Mass Spectrometric Analysis
Proteomics	Biophysical Characterization

Size: 1,200 m²

Established: 1984

Employees: 18

Certifications: cGMP, US-FDA registered & inspected
DEA licensed

Site Manager: Dr. Béragère Tissot

Address: 606 Brandywine Parkway

West Chester, PA 19380, USA

Nearby: Philadelphia International Airport

Tel: +1 610 696 8210/8240

email: us.biopharma@sgs.com

www.sgs.com/biopharma



SGS LOS ANGELES – USA



SERVICES

Immunoassay Method Transfer,
Development, Validation and
Sample Analysis

Biomarkers Testing (simplex and
multiplex)

Immunogenicity

Microbiological Testing

Large Molecule Bioanalysis

Biologics Safety Testing (Endotoxin)

PK Bioanalysis (Large Molecules)

Sterility Testing /Environmental
Monitoring

Size : 700 m²

Established : 2014

Employees : 12

Certifications : GMP/GLP, US-FDA registered

Site Manager : Dr. Jihye Jang-Lee

Address : 20535 Belshaw Ave,
Carson, CA 90746, USA

Nearby : LAX, Long Beach and Orange County Airports

Tel : +1 310 885 3792

email: us.pharmaqc@sgs.com

www.sgsgroup.us.com/lifescience



SGS SHANGHAI – CHINA



SERVICES

Method Development and Validation	Microbiological Testing
Analytical Chemistry – Batch Release	Elemental Impurities Testing by ICP-MS
Healthcare Product/Healthcare Supplement Testing	Stability Studies
Medical Device Testing	Traditional Chinese Medicine Testing
	Extractables & Leachables

Size : 2,500m²

Established : 2006

Employees : 110

Certifications : cGMP, ISO 17025

US-FDA registered & inspected

Site Manager : Andy Yi

Address : 7/F and 9/F, 3rd Building, No.889,

Yishan Road, Xuhui District,

Shanghai, China, 200233

Nearby : Shanghai Hongqiao Airport

Tel : +86 21 6107 2718

email : cn.pharmaqc@sgs.com

www.cn.sgs.com/lifescience



SGS CHENNAI – INDIA



SERVICES

Method Development and Validation	Healthcare Product/Healthcare Supplement Testing
Analytical Chemistry – Batch Release	Medical Device Testing
Utilities Qualification and Monitoring (Gas, Air, Water & Surface)	Microbiological Testing
	Stability Studies

Size : 1,675 m²

Established : 2005

Employees : 75

Certifications : cGMP, ISO 17025, WHO-prequalified,
US-FDA registered & inspected

Site Manager : Janakiraman Arun

Address : 2nd Floor, TICEL Bio Park Ltd,
Taramani Road, Chennai 600 113, India

Nearby : Chennai Airport

Tel : +91 44 6462 9711 to 9715

email : in.pharmaqc@sgs.com

www.sgsgroup.in/lifescience



SGS MUMBAI (NAVI) – INDIA



SERVICES

Method Development & Validation	Stability Studies (ICH) & Storage
Analytical Chemistry – Batch Release	Residual Solvent Analysis
Utilities Qualification and Monitoring (Gas, Air, Water & Surface)	Cleaning Validation
	Microbiological Testing

Size : 3,400 m²

Established : 2012

Employees : 115

Certifications : cGMP, ISO 17025, US-FDA
and Local FDA registered

Site Manager : Janakiraman Arun

Address : Plot No. A 773, MIDC, TTC Industrial Area,
Koparkhairane, Navi-Mumbai, 400701, India

Nearby : Mumbai Airport

Tel : +91 22 6457 2540 45

email : in.pharmaqc@sgs.com

www.sgsgroup.in/lifescience



SGS SINGAPORE



SERVICES

Method Development and Validation	Healthcare Product/Healthcare Supplement Testing
Analytical Chemistry – Batch Release	Medical Device Testing
Utilities Qualification and Monitoring (Gas, Air, Water & Surface)	Microbiological Testing
	Stability Studies
	Traditional Chinese Medicine Testing

Size : 497 m²

Established : 2006

Employees : 18

Certifications : cGMP, ISO 17025

US-FDA registered & inspected

Site Manager : Soubhik Banerjee

Address : 3 Toh Tuck Link, #01–02/03,
Singapore 596228, Singapore

Nearby : Singapore-Malaysia Causeway Airport

Tel : +65 6379 0111

email : sg.pharmaqc@sgs.com

www.sgs.sg/lifescience



CLINICAL RESEARCH

SGS is one of Europe's largest First-In-Human clinical pharmacology center and patient trial service provider. With a total capacity of 88 hospital beds and 9 clinical trial offices, SGS has the expertise to develop, deliver, and support on-time complex trials, and large scale international studies focusing on vaccines, oncology, infectious and respiratory diseases.

SERVICES



CLINICAL RESEARCH

Phase I-IV Services

- Clinical Study Design – Protocols
- ADME ¹⁴C Trials
- First-In-Human
- Viral Challenge Trials
- PK-PD Trials
- Combined Protocols
- Proof-Of-Concept, Safety & Efficacy Trials
- Pivotal BA/BE Trials | Interaction Trials (Drug/Drug; Food; Age; Gender...)
- TQT Cardiac Safety Trials
- Infectious Disease, Vaccine, Oncology, Respiratory Trials
- Global Clinical Trial Monitoring & Management
- PK-PD Modeling & Simulations
- Data Management, Statistics, EDC, Secure Data Office, Medical Writing
- Regulatory Affairs, Drug Safety and Pharmacovigilance



SGS ANTWERP (STUIVENBERG) – BELGIUM



CLINICAL PHARMACOLOGY UNIT SERVICES

Phase I-IIa, First in Human (Healthy Volunteers, Patients, Special Populations)	Challenge Trials using Viruses, Bacteria, Microorganisms or GMO
PK-PD Combined Protocols (SAD, MAD, POC)	Complex Sampling Techniques (CSF, Sputum, Gynaecological, GI, Lung biopsies, ...)
Interaction Trials (Drug-Drug, Food, Age, Gender)	Biosimilar Trials
Cardiac Safety Trials (Telemetric Monitoring)	Respiratory Trials (Bodybox)
Pivotal BA/BE Trials	Vaccine Trials

Hospitalisation area : 88 beds

Size : 3,000 m²

Established : 1980

Employees : 65

Certifications : GCP, US-FDA inspected, CIR, FANC,
GMP accredited pharmacy

Site Manager : Annick van Riel

Address : SGS Clinical Pharmacology Unit

Stuivenberg Hospital,

Lange Beeldekensstraat, 267

2060 Antwerpen, Belgium

Nearby : Antwerp Thalys Train Station

Tel : +32 3 217 25 60

email : clinicalresearch@sgs.com

www.sgs.be/lifescience



SGS ANTWERP (NOORDERLAAN) – BELGIUM



CLINICAL TRIAL MANAGEMENT SERVICES

International & Local Clinical Project Management and Monitoring

Consultancy & Study Design

Country-Specific Feasibility Studies (Europe and CEE)

Clinical Site Evaluation and Selection

Regulatory Support Services from Pre-Clinical to Post-Marketing

Clinical Trial/Marketing Authorization Applications & Product License Maintenance

eCTD (Incl. Creation Of Compliant Dossiers and eSubmission)

Therapeutic Focus: Infectious Disease – Vaccines – Oncology – Respiratory

Established: 1980

Employees: 115

Certifications: GCP/ICH

Site Manager: Jean-Luc Marsat

Address: Noorderlaan 87

2030 Antwerpen, Belgium

Nearby: Antwerp Thalys Train

Tel: +32 3 545 44 11

email: clinicalresearch@sgs.com

www.sgs.be/lifescience



SGS BRUSSELS – BELGIUM



BIOMETRICS & PHARMACOVIGILANCE SERVICES

Full Biometrics Services from Phase I to Post-Approval	Full EDC/IXRS Services: Oracle Inform™, Medidata Rave® and eClinical OS™
Data Management	CDISC registered solution provider for SDTM, ADaM and Define.xml
Secure Data Office	Pharmacovigilance Strategies/Safety Database/Report Writing/Case
Biostatistics	Safety Evaluation and Submission Support
Medical Writing (Protocol, CSR, ...)	Qualified Person for Pharmacovigilance, Batch Release, Medical Information
Pharmacovigilance and Drug Safety	
Medical Monitoring	
PK/PD Analysis	
PK/PD Modeling & Simulation	

Established: 1995

Employees: 220

Compliance: CFR Part 11 FDA/GCP/ICH

Site Manager: Luc Braeken

Address: Generaal De Wittelaan 19A Bus 5
2800 Mechelen, Belgium

Nearby: Brussels Airport and Thalys Train

Tel: +32 1 527 32 45

email: clinicalresearch@sgs.com

www.sgs.be/lifescience



SGS WASHINGTON DC – USA



CLINICAL TRIAL MANAGEMENT SERVICES

International & Local Trial Management and Monitoring	IND Writing, Submission and Management
Consulting & Study Design	Pharmacovigilance Strategies / Safety Database / Report Writing / Case Management / Biometrics PM
Country-Specific Feasibility Studies (North and South America)	
Clinical Site Evaluation and Selection	Therapeutic Focus: Infectious Disease, Vaccines, Oncology, CNS, Respiratory, Dermatology
Full Regulatory Support Services From Pre-Clinical To Post-Marketing	

Established: 2000
Employees: 34
Certifications: GCP/ICH
Site Manager: Stefan Comhaire

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