# **LIFE SCIENCE SERVICES & SITES**







POCKET MAP - 2014



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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.



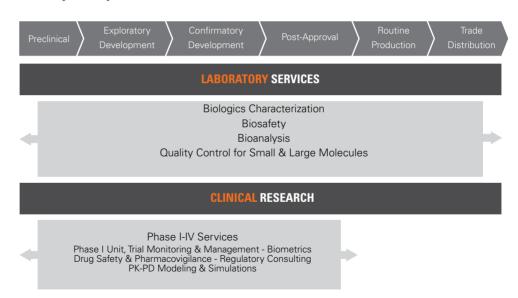






#### **SERVICES**

### **GMP, GLP, GCP - FROM MOLECULE TO MARKET**









### WORLD MAP OF SGS LIFE SCIENCE SERVICES **FACILITIES**

#### **NORTH AMERICA EUROPE ITALY CHINA** CANADA **RFI GIIIM** Toronto (Mississauga, ON) Antwerp Florence (Livorno) Shanghai Brussels (Wavre) USA **POLAND** INDIA Brussels (Mechelen) Warsaw Chennai Chicago (Lincolnshire, IL) CZECH REPRUITC New York (Fairfield, NJ) Mumbai (Navi) **SPAIN** • Prague Philadelphia SINGAPORE Madrid (West Chester, PA) FRANCE Singapore **SWITZERLAND** Washington, DC Paris (Clichy) Geneva TAIWAN (Germantown, MD) Paris (Arcueil) Kaohsiung UNITED KINGDOM Los Angeles (Carson, CA) Poitiers Taipei London (Thurrock) **GFRMANY** Glasgow Berlin London (Wokingham) Frankfurt (Taunusstein) Freiburg

 NEW Laboratory in 2014 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.

control for smal	ll and large	molecules laboratory network.				
SERVI	CES	Preclinical Exploratory Development Post-Approval Production Trade Development				
		Method Development, Optimization & Validation				
	ge	GMP Analytical Chemistry – Quality Control Batch Release				
	& La	Microbiological Testing				
	mall	Extractables & Leachables - Container Testing				
	trol for Sm Molecules	Stability Studies (ICH) & Storage				
<b>&gt;</b>	Mol	Pre formulation				
<u>ဗ</u> ုတ္လ	Quality Control for Small & Large Molecules	Utilities Qualification & Monitoring (Gas, Air, Water & Surface)				
NBORATOF SERVICES	Qual	Facilities / Equipment Qualification and Calibration				
<b>\$</b> \$	-34	Biologics Safety Testing – Endotoxin, Virus, Mycoplasma				
<u> </u>	tion 8	Virology – Cell Bank and Virus Seeds Characterization				
S	erizat :Y	Cell & Molecular Biology – qPCR Assays				
<b>3</b>	Biologics Characterization & Biosafety	Protein, Peptide Analysis & Quantification (PPB)				
	S Ch Bis	Product Characterization				
	ologic	Host Cell Impurity Testing & Identification				
	ä	Cell-Based Assays, Cytotoxicity (ADCC)				
	Sis	Biomarkers – Immunogenicity and Neutralizing Antibody Testing				
	Bio analysis	Bioanalysis – PK/PD Mass Spectrometry – Large & Small Molecules – ADME-14C Trials				











#### **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 d	esigned to	conform with the global regulatory guidelines (FDA/USP/EMA/Ph.Eur./ICH).		
SERVIC	CES	Preclinical Exploratory Confirmatory Post-Approval Routine Trade Development Development		
		Method Development, Optimization & Validation		
		Amino Acid Sequencing and Analysis (Edman, MS/MS)		
		Peptide Mapping by MS		
	afe	Disulfide Analysis		
	Biosafety	Glycosylation - Monosaccharides, Sialic Acid, Linkage, Glycan Profile, and Site Analysis		
		Post-Translational Modification Analysis		
<b>≥</b>	and	Isoform and Electrophoretic Patterns		
ဗ္ဗလ္	.io	Extinction Coefficient		
三岩	izat	LC Patterns (SEC, RP, IEX)		
<b>₹</b> 5	teri	FTR and Fluorescence to Spectrometric Profile (CD, DSC, NMR)		
	rac	Aggregation Analysis (AUC, SEC-MALS, DLS)		
ABORATOR Services	Characterization	Characterization of Process and Product-Related Impurities		
5		Stability and Pre/Formulation		
_	Stability and Pre/Formulation  Biosafety Testing  Cell Bank and Virus Seeds Characterization - Electron Microscopy Studies			
	jois	Cell Bank and Virus Seeds Characterization - Electron Microscopy Studies		
	ш	Raw Material and Bulk Harvest Testing (Sterility, Mycoplasma, Viruses)		
		Final Product Testing for Residual DNA and Host Cell Protein		









#### 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 York (Fairfield)	USA	•	•	•	•	•	•	•	-	-
Philadelphia (West Chester)	USA	•	-	-	•	•	•	-	-	-
Los Angeles (Carson)*	USA	-	•	-	•	-	-	-	•	-
Brussels (Wavre)	Belgium	•	•	•	•	•	•	-	•	-
Paris (Clichy)	France	•	•	•	•	•	-	-	-	-
Poitiers	France	-	-	•	•	-	•	-	•	-
Berlin	Germany	•	-	•	•	•	-	-	-	-
Frankfurt (Taunusstein)	Germany	•	•	-	•	•	-	-	-	-
Freiburg	Germany	•	-	-	•	-	•	-	-	-
Geneva	Switzerland	•	-	-	•	-	•	-	•	-
Florence (Livorno)*	Italy	•	•	•	•	-	-	-	-	•
London (Wokingham)	UK	•	-	•	•	•	•	-	-	-
Glasgow	UK	•	•	-	•	-	•	•	-	-
Shanghai	China	•	•	•	•	-	-	-	-	-
Chennai	India	•	•	•	•	•	-	-	-	-
Mumbai (Navi)	India	•	•	•	•	•	-	-	-	-
Singapore	Singapore	•	•	•	•	-	-	-	-	-
Kaohsiung	Taiwan	•	-	-	-	-	-	-	-	-
Taipei	Taiwan	•	•	-	_	-	_	-	_	-









#### **REGULATORY AND QUALITY MANAGEMENT OVERVIEW**

LABORATORIES	COUNTRY	QUALITY MANAGE- MENT SYSTEM	ISO STANDARD	US-FDA REGISTERED	US-FDA INSPECTED
Toronto (Mississauga)	Canada	GMP	9001/13485	•	•
Chicago (Lincolnshire)	USA	GMP/GLP	9001	•	•
New York (Fairfield)	USA	GMP	9001	•	•
Philadelphia (West Chester)	USA	GMP	-	•	•
Los Angeles (Carson)*	USA	GMP/GLP	-	•	-
Brussels (Wavre)	Belgium	GMP/GLP/GCP	17025	•	•
Paris (Clichy)	France	GMP	-	•	•
Poitiers	France	GMP/GLP/GCP	-	•	•
Berlin	Germany	GMP	-	•	•
Frankfurt (Taunusstein)	Germany	GMP	17025	•	•
Freiburg	Germany	GMP/GLP	-	•	•
Geneva	Switzerland	GMP/GLP	-	•	•
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	•	•
Kaohsiung	Taiwan	-	17025	-	-
Taipei	Taiwan	-	17025	-	-









### SGS WAVRE, BRUSSELS AREA – BELGIUM



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

Size: 8,400 m<sup>2</sup> 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



### SGS M-SCAN WOKINGHAM, LONDON AREA - UK



SERVICES	
Method Development & Validation	Protein and Peptide Analysis and Quantification
Stability and Pre/Formulation	Proteomics
Biophysical Analysis	Antibody Drug Conjugate Analysis
Peptide, Protein, Glycoprotein & Antibody Characterization	Aggregation Analysis
Glycosylation (Monosaccharide,	Pharmaceutical Analysis
Sialic Acid & Linkage Analyses)	Extractables & Leachables
Glycan Profiling Analysis	Product and Process-related
Post-Translational Modification	Impurity Determination and Quantification
Analysis	Residual Solvent Analysis

Size: 2,100m<sup>2</sup> Established: 1979 Employees: 72

Certifications: cGMP/GLP, US-FDA and MHRA

registered & inspected

Site Manager: Dr. Chris Cox

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

Nearby: Heathrow Airport Tel: +44 118 912 1190

email: uk.m-scan@sgs.com www.sgs.com/biopharma

August 2014

### SGS VITROLOGY GLASGOW - UK



SERVICES		
Assay Development & Tech. Transfer	Regulatory Consultancy Services	
Virology – <i>In Vitro</i> Adventitious Virus Assays and Cell Biology Assays	Cell & Virus Banks Characterization	
Assays and Cell Biology Assays	Raw Material and Bulk Harvest Testing	
Electron Microscopy – Virus Particle Quantification & Identification	Drug Substance & Vaccine Batch Release Testing (Residual DNA & other residual process components)	
RT Assays (FPERT & qPERT)	Cell Line Induction Studies with	
Retrovirus Infectivity Assays	customized end-points	
Custom Biosafety Assay Design	Cell Line & Virus Identity & Genetic	
Mycoplasma, Mycobacteria, Spiroplasma & Virus Detection by qPCR	Stability Testing, Massive Parallel Sequencing	
Bioanalytical Analysis	Stability Testing	

Size: 1,124 m<sup>2</sup> Established: 2007 Employees: 48

Certifications: cGMP/GLP, MHRA; US-FDA registered

Site Manager: Margaret Temple

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 CLICHY, PARIS AREA – FRANCE



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

Size: 2,500 m<sup>2</sup> Established: 1994 Employees: 60

Certifications: cGMP, ANSM/ANSES inspected

US-FDA registered & inspected

Site Manager: Dr. Paul Beyou

Address: 20–22 rue Charles Paradinas 92583 Clichy cedex, France

Nearby: Paris Airports Tel: +33 141 06 95 85

email: fr.pharmaqc@sgs.com www.sgsgroup.fr/lifescience







### **SGS POITIERS – FRANCE**



#### **SERVICES**

Immunoassay and LC-MS/MS Assay
Development and Validation

PK Bioanalysis (Small and Large Molecules)

Biomarkers Testing (simplex and multiplex, cell-based assays and Cobas®6000)

Bioanalytical Testing For Biosimilars

Potency assays for characterisation, batch release and stability testing

Immunogenicity

Enzymatic Activity Assays

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

Size: 3,200 m<sup>2</sup> 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 TAUNUSSTEIN, FRANKFURT AREA – GERMANY



# Method Development & Validation Analytical Chemistry – Batch Release Microbiological Testing

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

Biologics Safety Testing

Extractables & Leachables

(Endotoxin, Virus, Mycoplasma...)

Elemental Impuriities Testing

Medical Device Testing

Size: 1,040 m<sup>2</sup> Established: 1978 Employees: 60

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 Extractables & Leachables

Analytical Chemistry – Batch Release Cleaning Validation

Stability Studies Elemental Impurities Testing

Container Testing Particle Analysis

Size: 2,100 m<sup>2</sup> Established: 1985 Employees: 61 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 M-SCAN FREIBURG - GERMANY



SERVICES	
Method Development & Validation	Protein and Peptide Analysis and Quantification
Peptide, Protein, Glycoprotein & Antibody Characterization	Proteomics
Glycan Profiling Analysis	Aggregation Analysis
Post-Translational Modification Analysis	Product and Process-Related Impurity Determination

Size: 400 m<sup>2</sup> Established: 2006 Employees: 9

Certifications: cGMP/GLP, US-FDA registered and

inspected

Site Manager: Christian Wandschneider

Address: Engesserstr. 4a

79108 Freiburg i.Br., Germany

Nearby: Basel Airport Tel: +49 761 611 677 60 email: de.m-scan@sgs.com www.sgs.com/biopharma

### SGS M-SCAN GENEVA - SWITZERLAND



Method Development & Validation

Peptide, Protein, Glycoprotein & Antibody Characterization

PK Bioanalysis (Small Molecules, Peptides, Biopharmaceuticals)

Glycan Profiling Analysis

Glycosylation, incl.

Monosaccharides, Sialic Acid and Linkage Analyses

Post-Translational Modification Analysis

Protein and Peptide Analysis and Quantification

**Proteomics** 

Product and Process-Related Impurity
Determination and Quantification

Size: 600 m² Established: 1991 Employees: 15

Certifications: cGMP/GLP

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.m-scan@sgs.com www.sgs.com/bjopharma





August 2014

### **SGS LIVORNO, FLORENCE AREA - ITALY**



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

Size: 1,085 m<sup>2</sup>

Established: Sept 2013

Employees: 25

Certifications: ISO 9001, cGMP Site Manager: Marco Benvenuti Address: Via Cimarosa, 95/105, Livorno, Italy

Nearby: Florence and Pisa Airports

email: it.pharmaqc@sgs.com www.sgsgroup.it/lifescience

Tel: +39 0586 852591

#### LABORATORY SERVICES - NORTH AMERICA

### SGS MISSISSAUGA, TORONTO AREA – CANADA



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

Size: 4,300 m<sup>2</sup> Established: 1984 Employees: 125

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.pharmagc@sgs.com

www.sqs.ca/lifescience







### SGS LINCOLNSHIRE, CHICAGO AREA – USA



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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 m<sup>2</sup> Established: 1972 Employees: 95

Certifications: cGMP/GLP, ISO 9001

US-FDA registered & inspected

Site Manager: Richard Bunnell August 2014

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 FAIRFIELD, NEW YORK AREA – USA



SERVICES	
Method Development & Validation	Safety Studies in vitro
Analytical Chemistry – Batch Release	Medical Device Testing
Stability Studies, Formulation/ Preformulation	Bioanalytical Testing of Biosimilars/ Proteins/Peptides
Microbiological Testing	Immuno/Enzymatic/Potency/Bio
Container Testing	Assays
Extractables & Leachables	Utilities Qualification and
Biologics Safety Testing (Endotoxin)	Monitoring (Gas, Air, Water & Surface)

Size: 3,345 m<sup>2</sup> Established: 1995 Employees: 50

Certifications: cGMP, ISO 9001

US-FDA registered & inspected

Site Manager: Richard Bunnell

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









#### **LABORATORY SERVICES – NORTH AMERICA**

### SGS M-SCAN WEST CHESTER, PHILADELPHIA AREA – USA



SERVICES			
Method Development & Validation	Proteomics		
Peptide, Protein, Glycoprotein &	Oligonucleotide Analysis		
Antibody Characterization	Pharmaceutical Analysis		
Glycosylation, including Monosaccharide and Sialic Acid Analysis	Unknown Identification		
Glycan Profiling Analysis	Product and Process-related		
Post-Translational Modification	Impurity Determination		
Analysis	Residual Analysis		
Protein and Peptide Sequencing & Quantification Analysis	Quantitative Mass Spectrometric Analysis		

Size: 1,200 m<sup>2</sup> Established: 1984 Employees: 16

Certifications: cGMP, US-FDA registered & inspected

DEA licensed

Site Manager: Dr. Mark Rogers

Address: 606 Brandywine Parkway

West Chester, PA 19380, USA Nearby: Philadelphia International Airport

Tel: +1 610 696 8210/8240 email: us.m-scan@sgs.com www.sgs.com/biopharma



#### LABORATORY SERVICES - NORTH AMERICA

### SGS CARSON, LOS ANGELES AREA - USA



### **SERVICES**

Immunoassay Method Transfer, Development, Validation and Sample Analysis

Large Molecule Bioanalysis

PK bioanalysis (Large Molecules)

Biomarkers Testing (simplex and multiplex)

Immunogenicity

Microbiological Testing

Biologics Safety Testing (Endotoxin) Sterility Testing /Environmental

Monitoring

Size: 700 m<sup>2</sup> Established: 2014

Employees: 6

Certifications: GMP/GLP, US-FDA registered

Site Manager: Dr. Jihye Jang Lee

Address: 20535 Belshaw Ave,

Carson, CA 90746, USA

Nearby: LAX Airport, Long Beach Airport

Tel: +1 310 885 3792

email: us.pharmaqc@sgs.com www.sqsqroup.us.com/lifescience







#### LABORATORY SERVICES - ASIA

### SGS SHANGHAI – CHINA



#### SERVICES

Method Development and Validation

Analytical Chemistry - Batch Release

Healthcare Product/Healthcare Supplement Testing

Medical Device Testing

Microbiological Testing

Elemental Impurities Testing by ICP-MS

Stability Studies

Traditional Chinese Medicine Testing

Size: 1,500 m<sup>2</sup> Established: 2006 Employees: 75

Certifications: cGMP, ISO 17025

US-FDA registered

Site Manager: Andy Yi

Address: 9/F, 3rd Building No.889, Yishan Road

200233 Shanghai, China

Nearby: Shanghai Hongqiao Airport

Tel: +86 21 6107 2718

email: cn.pharmaqc@sgs.com www.cn.sgs.com/lifescience



#### **LABORATORY SERVICES – ASIA**

### SGS CHENNAI – INDIA



#### **SERVICES**

Method Development and Validation

Analytical Chemistry - Batch Release

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

Healthcare Product/Healthcare Supplement Testing

Medical Device Testing

Microbiological Testing

Safety Studies (in vitro)

Stability Studies

Size: 1,850 m<sup>2</sup> Established: 2005 Employees: 60

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









#### LABORATORY SERVICES - ASIA

### SGS MUMBAI (NAVI) – INDIA



### **SERVICES**

Method Development & Validation

Analytical Chemistry – Batch Release

Utilities Qualification and

Monitoring (Gas, Air, Water & Surface)

Stability Studies (ICH) & Storage Residual Solvent Analysis

Cleaning Validation

Microbiological Testing

Size: 1,393 m<sup>2</sup> Established: 2012 Employees: 65

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



#### LABORATORY SERVICES - ASIA

### **SGS SINGAPORE**



#### **SERVICES**

Method Development and Validation

Analytical Chemistry - Batch Release

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

Healthcare Product/Healthcare Supplement Testing

Medical Device Testing

Microbiological Testing

Stability Studies

Traditional Chinese Medicine Testing

Size: 497 m<sup>2</sup> Established: 2006 Employees: 20

Certifications: cGMP, ISO 17025

US-FDA registered & inspected

Site Manager: Sethu Ragupathy

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

Nearby: Changi Airport

Tel: +65 63790 111

email: sg.pharmaqc@sgs.com

### SGS TAIPEI & KAOHSIUNG – TAIWAN



SERVICES	
Method Development and Validation	Healthcare Product/Healthcare Supplement Testing
Analytical Chemistry	Medical Device Testing
Microbiological Testing	Stability Studies
Container Testing	
Extractables and Leachables Drug Abuse Testing Cosmetic Testing	Traditional Chinese Medicine Testing

Size: 819 m<sup>2</sup> Established: 2003 Employees: 48

Certifications: ISO 17025 Site Manager: Dr. Clark Chu Address: No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku District, New Taipei

City, 24890, Taiwan (R.O.C.)

Nearby: Taiwan Taoyuan Airport

Tel: +886 2 2299 3279/7300/7301/7310/7100

email: tw.pharmaqc@sgs.com www.tw.sgs.com/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 92 hospital beds and 8 clinical trial offices, SGS has the expertise to develop, deliver, and support on-time complex trials, screening, and large scale international studies focusing on vaccines, infectious and respiratory diseases.

SERVI	CES	Preclinica	Exploratory \ Development /	Confirmatory Development	Post-Approval	Routine Production	Trade Distribution
	Clinical Study Des			esign – Protoco	ls		
			Microdosing, ADME <sup>14</sup> C Trials				
			First-In-Human				
Ŧ	S		PK-PD Trials				
<u> </u>	vice		Combined Proto	cols			
AB	Phase I-IV Services		Proof-Of-Concep Safety & Efficac	ot, y Trials			
	<u>-</u>		Pivotal BA/BE Tri	als	Interaction Trials	(Drug/Drug; Fo	ood; Age; Gender)
o iji	has		TQT Cardiac Saf	ety Trials			
			Infectious Disease, Vaccine and Oncology Trials				
			Global Clinical Trial Monitoring & Management				
			PK-PD Modeling & Simulations				
			Data Management, Statistics, Medical Writing				
			Regulatory Affai	rs, Drug Safety	and Pharmacovig	ilance	









### SGS ANTWERP (STUIVENBERG) – BELGIUM



SERVICES	
Phase I–IIa, First-In-Human	TQTc Cardiac Safety Trials
PK-PD & ADME <sup>14</sup> C Trials	Pivotal BA/BE Trials
Combined Protocols	Vaccine Trials
Proof Of Concept (POC), POM, POP	Viral Inoculation trials and trials using GMOs - Quarantine Facilities
Interaction Trials	Full GMP Pharmacy for formulation
(Drug/Drug; Food; Age; Gender)	CSF Sampling
Early patients clinical trials – SMO	eSource clinic automation

Hospitalisation area: 92 beds

Size: 3,500 m<sup>2</sup> Established: 1980 Employees: 60

Certifications: GCP, US-FDA inspected,

GMP accredited pharmacy

Site Managers: Annick Van Riel and

Omer Van Schoor

Address: Stuivenberg Hospital,

Lange Beeldekensstraat, 267 2060 Antwerpen, Belgium Nearby: Antwerp Thalys Train Station

Tel: + 32 32 17 25 60

email: clinicalresearch@sgs.com

### SGS ANTWERP (NOORDERLAAN) – BELGIUM



### **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)

Pharmacovigilance Strategies/Safety Database/Report Writing/Case Management

Safety Evaluation and Submission Support

Qualified Person For Pharmacovigilance, Batch Release, Medical Information

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 35 45 44 11

email: clinicalresearch@sgs.com





### SGS MECHELEN, BRUSSELS AREA – BELGIUM



SERVICES			
Full Biometric Services From Phase ITo Post-Approval	Full EDC/IRT Services		
Data Management	CDISC Registered Solution Provider:		
PK/PD Modeling & Simulation Analysis	SDTM, ADaM, CDASH and Define.xn		
Secure Data Office	Clintrial, InForm™ & Central		
Report Writing	Designer™, Rave®, eClinical OSTM, SAS®, WinNonlin®		

Established: 1995 Employees: 220

Compliance: CFR Part 11 FDA/GCP/ICH

Site Managers: Luc Braeken

Eric Snoek

Address: Generaal De Wittelaan 19A Bus 5

2800 Mechelen, Belgium

 ${\it Nearby: Brussels Airport and Thalys Train}$ 

Tel: +32 15 27 32 45

email: clinicalresearch@sgs.com

### SGS GERMANTOWN, WASHINGTON, DC AREA – USA



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

Established: 2000 Employees: 27

Certifications: GCP/ICH

Site Manager: Stefan Comhaire

Address: 20411 Seneca Meadows Parkway

Germantown, MD 20876, USA

Respiratory - Dermatology

Nearby: Washington, DC airports

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