

# LIFE SCIENCE SERVICES & SITES



POCKET MAP – 2013

**SGS**



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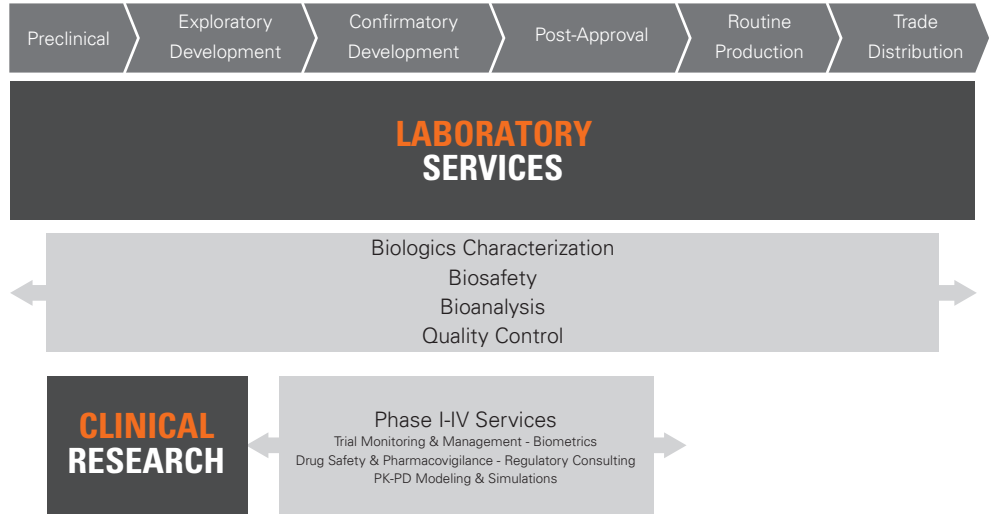
SGS's Life Science Services has over 35 years of experience as a global bio/pharmaceutical contract service organization providing integrated solutions from preclinical activities to phase I–IV clinical trials, bioanalytical, R&D, protein characterization, biosafety and quality control testing of small and large molecules, raw materials, finished products and containers. With 1,400 employees, state-of-the-art clinical pharmacology units and the world's largest network of GMP compliant laboratories, SGS serves the pharmaceutical, biotechnology and medical device industries across Europe, the Americas and Asia with 28 facilities located in 15 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.

Dr. Anne Hays



# SERVICES FROM MOLECULE TO MARKET



# WORLD MAP OF SGS LIFE SCIENCE SERVICES FACILITIES

## NORTH AMERICA

### CANADA

- Toronto (Mississauga, ON)

### USA

- Chicago (Lincolnshire, IL)
- New York (Fairfield, NJ)
- Philadelphia (West Chester, PA)
- Washington, DC (Gaithersburg, MD)

## EUROPE

### BELGIUM

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

### CZECH REPUBLIC

- Prague

### FRANCE

- Paris (Clichy)
- Paris
- Poitiers

### GERMANY

- Berlin
- Frankfurt (Taunusstein)
- Freiburg

### ITALY

- Livorno

### POLAND

- Warsaw

### SPAIN

- Madrid

### SWITZERLAND

- Geneva

### UNITED KINGDOM

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

## ASIA

### CHINA

- Shanghai

### INDIA

- Chennai
- Mumbai (Navi)

### SINGAPORE

- Singapore

### TAIWAN

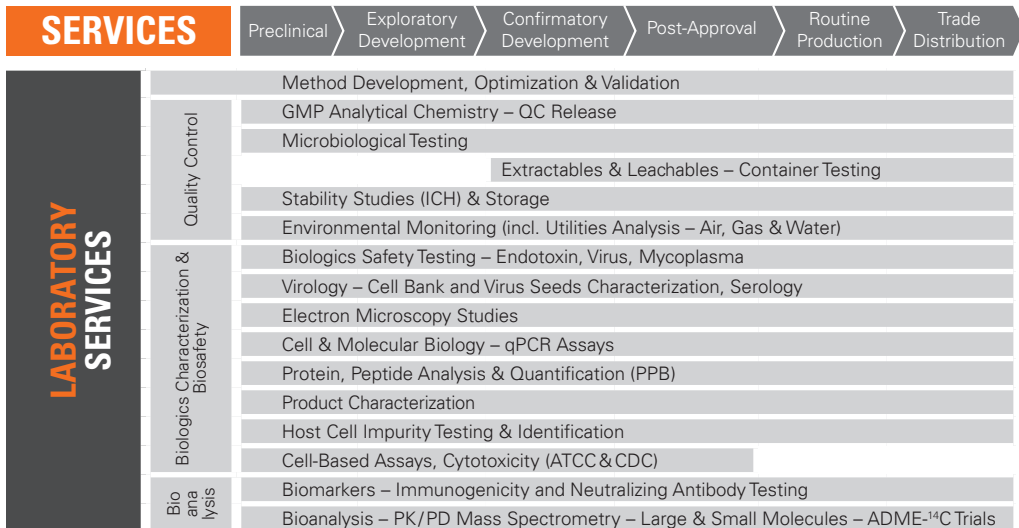
- Kaohsiung
- Taipei

- Laboratory Services
- Clinical Pharmacology Unit
- Clinical Trial Management



## LABORATORY SERVICES

With GLP/GCP bioanalytical centers in Europe featuring mass spectrometry & immunoassays as well as an international, harmonized network of cGMP, R&D, characterization, biosafety and quality control laboratories in Europe, the Americas and Asia, SGS's laboratory services team provides complete analytical services for drug development.



## BIOLOGICS CHARACTERIZATION AND BIOSAFETY

SGS M-Scan 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 SGS Vitrology's over 20 year experience in the biosafety testing ensuring drug products are free of contaminants. Our biopharmaceutical services portfolio is available at all stages of development, from 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 (Edman, MS/MS)

Amino Acid Analysis

N- and C-terminal Sequencing

Peptide Mapping by MS

Disulfide Analysis

Glycosylation - Monosaccharide, Sialic Acid, Linkage, Glycan Profile, and Site Analysis

Post-Translational Modification Analysis

Isoform and Electrophoretic Patterns

Extinction Coefficient

LC Patterns (SEC, RP, IEX)

Spectroscopic Profiles (CD, DSC, NMR)

Aggregation Analysis (AUC, SEC-MALS)

Characterization of Process and Product-Related Impurities

Biosafety Testing

Cell Bank and Virus Seeds Characterization

Raw Material and Bulk Harvest Testing (Sterility, Mycoplasma, Viruses)

Final Product Testing for Residual DNA and Host Cell Protein

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 VALIDATION |
|--|-------------|----------------------|---------------|-------------------|--------------------------|-------------------|-------------------|------------|--------------|--------------------------|
| Toronto (Mississauga)                    | Canada      | •                    | •             | •                 | •                        | •                 | •                 |            |              |                          |
| Chicago (Lincolnshire)                   | USA         | •                    | •             | •                 | •                        | •                 |                   |            |              |                          |
| New York (Fairfield)                     | USA         | •                    | •             | •                 | •                        | •                 |                   |            |              |                          |
| Philadelphia (West Chester) <sup>1</sup> | USA         | •                    |               |                   | •                        | •                 | •                 |            |              |                          |
| Brussels (Wavre)                         | Belgium     | •                    | •             | •                 | •                        | •                 | •                 | •          |              |                          |
| Paris (Clichy)                           | France      | •                    | •             | •                 | •                        | •                 |                   |            |              |                          |
| Poitiers                                 | France      |                      |               |                   | •                        |                   | •                 |            | •            |                          |
| Berlin                                   | Germany     | •                    |               | •                 | •                        | •                 |                   |            |              |                          |
| Frankfurt (Taunusstein)                  | Germany     | •                    | •             |                   | •                        | •                 |                   |            |              |                          |
| Freiburg <sup>1</sup>                    | Germany     | •                    |               |                   | •                        |                   | •                 |            |              |                          |
| Geneva <sup>1</sup>                      | Switzerland | •                    |               |                   | •                        |                   | •                 |            | •            |                          |
| Livorno <sup>3</sup>                     | Italy       |                      |               |                   |                          |                   |                   |            |              | •                        |
| London (Wokingham) <sup>1</sup>          | UK          | •                    |               |                   | •                        | •                 | •                 |            |              |                          |
| Glasgow <sup>2</sup>                     | UK          | •                    | •             |                   | •                        |                   | •                 | •          |              |                          |
| Shanghai                                 | China       | •                    | •             | •                 | •                        | –                 | –                 | –          | –            | –                        |
| Chennai                                  | India       | •                    | •             | •                 | •                        | •                 | –                 | –          | –            | –                        |
| Mumbai (Navi)                            | India       | •                    | •             | •                 | •                        | •                 | –                 | –          | –            | –                        |
| Singapore                                | Singapore   | •                    | •             | •                 | •                        | –                 | –                 | –          | –            | –                        |
| Kaohsiung                                | Taiwan      | •                    | –             | –                 | –                        | –                 | –                 | –          | –            | –                        |
| Taipei                                   | Taiwan      | •                    | •             | –                 | –                        | –                 | –                 | –          | –            | –                        |

<sup>1</sup>SGS M-Scan <sup>2</sup>SGS Vitrology <sup>3</sup>SGS Sertec

Jan. 2013 **CLICK ON A SPECIFIC SERVICE OR SITE TO VIEW MORE DETAILS.**





## REGULATORY AND QUALITY MANAGEMENT OVERVIEW

| LABORATORIES                             | COUNTRY     | QUALITY MANAGEMENT SYSTEM | ISO STANDARD | US-FDA REGISTERED | US-FDA INSPECTED |
|--|-------------|---------------------------|--------------|-------------------|------------------|
| Toronto (Mississauga)                    | Canada      | GMP/GLP                   | 9001/13485   | •                 | •                |
| Chicago (Lincolnshire)                   | USA         | GMP/GLP                   | 9001         | •                 | •                |
| New York (Fairfield)                     | USA         | GMP/GLP                   | 9001         | •                 | •                |
| Philadelphia (West Chester) <sup>1</sup> | USA         | GMP                       |              | •                 | •                |
| Brussels (Wavre)                         | Belgium     | GMP/GLP                   | 17025        | •                 | •                |
| Paris (Clichy)                           | France      | GMP                       |              | •                 | •                |
| Poitiers                                 | France      | GLP / GCP                 |              | •                 |                  |
| Berlin                                   | Germany     | GMP                       |              | •                 | •                |
| Frankfurt (Taunusstein)                  | Germany     | GMP/GLP                   | 17025        | •                 | •                |
| Freiburg <sup>1</sup>                    | Germany     | GMP/GLP                   |              | •                 | •                |
| Geneva <sup>1</sup>                      | Switzerland | GMP/GLP                   |              | •                 | •                |
| London (Wokingham) <sup>1</sup>          | UK          | GMP/GLP                   |              | •                 | •                |
| Glasgow <sup>2</sup>                     | UK          | GMP/GLP                   |              | •                 |                  |
| Livorno <sup>3</sup>                     | Italy       |                           | 9001/17025   |                   |                  |
| Shanghai                                 | China       | GMP                       | 17025        | •                 | –                |
| Chennai                                  | India       | GMP                       | 17025        | •                 | •                |
| Mumbai (Navi)                            | India       | GMP                       | 17025        | •                 | –                |
| Singapore                                | Singapore   | GMP                       | 17025        | •                 | –                |
| Kaohsiung                                | Taiwan      | –                         | 17025        | –                 | –                |
| Taipei                                   | Taiwan      | –                         | 17025        | –                 | –                |

Jan. 2013

<sup>1</sup>SGS M-Scan    <sup>2</sup>SGS Vitrology    <sup>3</sup>SGS Sertec



## SGS WAVRE, BRUSSELS AREA – BELGIUM



### SERVICES

|                                   |  |
|-----------------------------------|--|
| Method Development & Validation   | Biologics Safety Testing<br>(Endotoxin, Virus, Mycoplasma ...) |
| Analytical Chemistry – QC Release |  |
| Microbiological Testing           | Potency Assays   |
| Stability Studies                 | PK Bioanalysis (Small Molecules)                               |
| Host Cell Impurity Testing        | Protein, Peptide Analysis<br>& Quantification (PPB)            |
| Cell-Based Assays                 |  |
| Cell Line Characterization        | Serology Testing – ELISA,<br>LUMINEX, Flow Cytometry ...       |

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](mailto:be.pharmaqc@sgs.com)

[www.sgs.be/lifescience](http://www.sgs.be/lifescience)

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



### SERVICES

|  |   |
|--|---|
| Method Development & Validation  | Protein and Peptide Analysis and Quantification                       |
| Biophysical Analysis   | Proteomics  |
| Peptide, Protein, Glycoprotein & Antibody Characterization                 | Aggregation Analysis  |
| Glycosylation, including Mono-saccharide, Sialic Acid and Linkage Analyses | Pharmaceutical Analysis   |
| Glycan Profiling Analysis  | Extractables & Leachables   |
| Post-Translational Modification Analysis                                   | Product and Process-related Impurity Determination and Quantification |
|  | Residual Solvent Analysis   |

Size: 1,200 m<sup>2</sup>

Established: 1979

Employees: 45

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

Site Manager: Dr. Andrew Reason

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

Nearby: Heathrow Airport

Tel: +44 118 989 6940

email: [uk.m-scan@sgs.com](mailto:uk.m-scan@sgs.com)

[www.sgs.com/biopharma](http://www.sgs.com/biopharma)

## 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   |
|  | 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 customized end-points  |
| Retrovirus Infectivity Assays  |   |
| Custom Biosafety Assay Design  | Cell Line & Virus Identity & Genetic Stability Testing, Massive Parallel Sequencing               |
| Mycoplasma, Mycobacteria, Spiroplasma & Virus Detection by qPCR              |   |

Size : 625 m<sup>2</sup>

Established : 2007

Employees : 39

Certifications : cGMP/GLP, 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](mailto:biosafety@sgs.com)

[www.sgs.com/biopharma](http://www.sgs.com/biopharma)



## SGS CLICHY, PARIS AREA – FRANCE



### SERVICES

|                                   |  |
|-----------------------------------|--|
| Method Development & Validation   | Utilities Testing (Air, Gas and Water) |
| Analytical Chemistry – QC Release | Cleaning Validation                    |
| Microbiological Testing           | Container Testing                      |
| Stability Studies                 | Medical Device Testing                 |
| Extractables & Leachables         | Heavy Metals Testing                   |

Size : 2,500 m<sup>2</sup>

Established : 1994

Employees : 70

Certifications : cGMP

US-FDA registered & inspected

Site Manager : Dr. Paul Beyou

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

Nearby : Paris Airports

Tel : +33 1 41 06 95 85

email : [fr.pharmaqc@sgs.com](mailto:fr.pharmaqc@sgs.com)

[www.sgsgroup.fr/lifescience](http://www.sgsgroup.fr/lifescience)

## SGS POITIERS – FRANCE



### SERVICES

Immunoassay and LC-MS/MS Assay  
Development and Validation

PK and PD Bioanalysis

Biomarkers Testing

Multiplexed Biomarkers Analysis

Bioanalytical Testing For Biosimilars

Peptide and Protein Quantification

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 : 85

Certifications : GLP/GCP, US-FDA registered

Site Manager : Alain Renoux

Address : 30 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](mailto:fr.pharmaqc@sgs.com)

[www.sgs.com/biopharma](http://www.sgs.com/biopharma)

## SGS TAUNUSSTEIN, FRANKFURT AREA – GERMANY



### SERVICES

|  |  |
|--|--|
| Method Development & Validation        | Biologics Safety Testing<br>(Endotoxin, Virus, Mycoplasma ...) |
| Analytical Chemistry – QC Release      |  |
| Microbiological Testing                | Medical Device Testing   |
| Extractables & Leachables              | Heavy Metals Testing   |
| Utilities Testing (Air, Gas and Water) |  |

Size: 1,040 m<sup>2</sup>

Established: 1978

Employees: 52

Certifications: cGMP/GLP, 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](mailto:de.pharmaqc@sgs.com)

[www.de.sgs.com/lifescience](http://www.de.sgs.com/lifescience)



## SGS BERLIN – GERMANY



### SERVICES

Method Development & Validation

Analytical Chemistry – QC Release

Stability Studies

Extractables & Leachables

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](mailto:de.pharmaqc@sgs.com)

[www.de.sgs.com/lifescience](http://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: 7

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](mailto:de.m-scan@sgs.com)

[www.sgs.com/biopharma](http://www.sgs.com/biopharma)

## SGS M-SCAN, GENEVA – SWITZERLAND



### SERVICES

|  |  |
|--|--|
| Method Development & Validation                                | Glycosylation, incl. Mono-saccharide, Sialic Acid and Linkage Analyses |
| Peptide, Protein, Glycoprotein & Antibody Characterization     | Post-Translational Modification Analysis                               |
| PK Bioanalysis (Small Molecules, Peptides, Biopharmaceuticals) | Protein and Peptide Analysis and Quantification                        |
|  | Proteomics   |
| Glycan Profiling Analysis                                      | Product and Process-Related Impurity Determination and Quantification  |

Size: 450 m<sup>2</sup>

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](mailto:ch.m-scan@sgs.com)

[www.sgs.com/biopharma](http://www.sgs.com/biopharma)



## SGS MISSISSAUGA, TORONTO AREA – CANADA



### SERVICES

|   |  |
|---|--|
| Method Development & Validation                   | Cell Bank/Line Characterization (Molecular Biology, Phenotypic ...)                          |
| Cleaning Validation                               | Biologics Safety Testing (Endotoxin, Mycoplasma, Host Cell Protein & Host Cell DNA Analysis) |
| Analytical Chemistry – QC Release                 |  |
| 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)                | Immunoligand Assays  |
| Microbial Disinfectant Efficacy Studies           |  |

Size: 4,300 m<sup>2</sup>

Established: 1984

Employees: 125

Certifications: cGMP/GLP, 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](mailto:ca.pharmaqc@sgs.com)

[www.sgs.ca/lifescience](http://www.sgs.ca/lifescience)



## SGS LINCOLNSHIRE, CHICAGO AREA – USA



### SERVICES

|                                   |  |
|-----------------------------------|--|
| Method Development & Validation   | Environmental Monitoring                   |
| Analytical Chemistry – QC 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

Address : 616 Heathrow Drive

Lincolnshire, IL 60069, USA

Nearby : Chicago O'Hare Airport

Tel : +1 847 821 8900

email : [us.pharmaqc@sgs.com](mailto:us.pharmaqc@sgs.com)

[www.sgsgroup.us.com/lifescience](http://www.sgsgroup.us.com/lifescience)

## SGS FAIRFIELD, NEW YORK AREA – USA



### SERVICES

|                                      |                                |
|--------------------------------------|--------------------------------|
| Method Development & Validation      | Safety Studies <i>in vitro</i> |
| Analytical Chemistry – QC Release    | Medical Device Testing         |
| Microbiological Testing              | Water System Validation        |
| Stability Studies                    | Container Testing              |
| Extractables & Leachables            | Environmental Monitoring       |
| Biologics Safety Testing (Endotoxin) |                                |

Size : 3,345 m<sup>2</sup>

Established : 1995

Employees : 50

Certifications : cGMP/GLP, 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](mailto:us.pharmaqc@sgs.com)

[www.sgsgroup.us.com/lifescience](http://www.sgsgroup.us.com/lifescience)

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



### SERVICES

|   |  |
|---|--|
| Method Development & Validation                                   | Proteomics   |
| Peptide, Protein, Glycoprotein & Antibody Characterization        | Oligonucleotide Analysis                           |
|   | Pharmaceutical Analysis                            |
| Glycosylation, including Mono-saccharide and Sialic Acid Analysis | Extractables & Leachables                          |
| Glycan Profiling Analysis   | Product and Process-related Impurity Determination |
| Post-Translational Modification Analysis                          | Residual Solvent 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

E-mail: [us.m-scan@sgs.com](mailto:us.m-scan@sgs.com)

[www.sgs.com/biopharma](http://www.sgs.com/biopharma)

## SGS SHANGHAI – CHINA



### SERVICES

Method Development and Validation

Analytical Chemistry – QC Release

Healthcare Product/Healthcare Supplement Testing

Medical Device Testing

Microbiological Testing

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](mailto:cn.pharmaqc@sgs.com)

[www.cn.sgs.com/lifescience](http://www.cn.sgs.com/lifescience)

## SGS CHENNAI – INDIA



### SERVICES

Method Development and Validation

Analytical Chemistry – QC Release

Environmental Monitoring

Extractables and Leachables

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](mailto:in.pharmaqc@sgs.com)

[www.sgsgroup.in/lifescience](http://www.sgsgroup.in/lifescience)



## SGS MUMBAI (NAVI) – INDIA



### SERVICES

|                                   |                                   |
|-----------------------------------|-----------------------------------|
| Method Development & Validation   | Stability Studies (ICH) & Storage |
| Analytical Chemistry – QC Release | Residual Solvent Analysis         |
| Environmental Monitoring          | Cleaning Validation               |
| Extractables and Leachables       | Water System Validation           |
| Microbiological Testing           |                                   |

Size: 1,393 m<sup>2</sup>

Established: 2012

Employees: 30

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](mailto:in.pharmaqc@sgs.com)

[www.sgsgroup.in/lifescience](http://www.sgsgroup.in/lifescience)

## SGS SINGAPORE – SINGAPORE



### SERVICES

Method Development and Validation

Analytical Chemistry – QC Release

Environmental Monitoring

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

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](mailto:sg.pharmaqc@sgs.com)

[www.sgs.sg/lifescience](http://www.sgs.sg/lifescience)

## SGS TAIPEI & KAOHSIUNG – TAIWAN



### SERVICES

|  |  |
|--|--|
| Method Development and Validation                | Medical Device Testing   |
| Analytical Chemistry – QC Release                | Microbiological Testing  |
| Container Testing                                | Stability Studies  |
| Drug Abuse Testing                               | Bioassay Services ( <i>in vitro</i> toxicology, Endotoxin ...) |
| Extractables and Leachables                      |  |
| Cosmetic Testing                                 |  |
| Healthcare Product/Healthcare Supplement 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

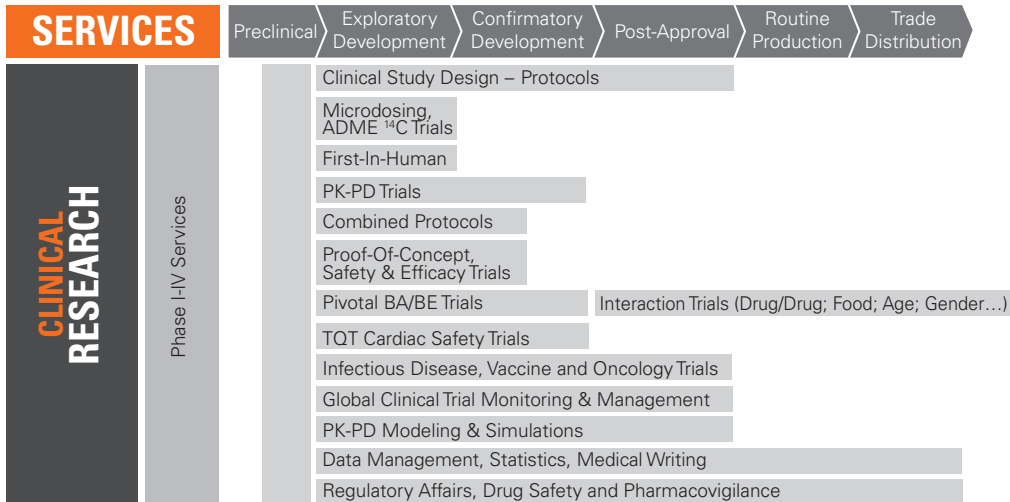
email: [tw.pharmaqc@sgs.com](mailto:tw.pharmaqc@sgs.com)

[www.tw.sgs.com/lifescience](http://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 offices, SGS has the expertise to develop, deliver, and support on-time complex trials, screening, and large scale trials.



## 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 (Drug/Drug; Food; Age; Gender) | Full GMP Pharmacy for formulation                                      |
|   | 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  
Dr. 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](mailto:clinicalresearch@sgs.com)

[www.sgs.be/lifescience](http://www.sgs.be/lifescience)



## SGS ANTWERP (NOORDERLAAN) – BELGIUM



### SERVICES

|   |   |
|---|---|
| International & Local Clinical Project Management and Monitoring                  | eCTD (Incl. Creation Of Compliant Dossiers and eSubmission)                 |
| Consultancy & Study Design  | Pharmacovigilance Strategies/Safety Database/Report Writing/Case Management |
| Country-Specific Feasibility Studies (Europe and CEE)                             | Safety Evaluation and Submission Support                                    |
| Clinical Site Evaluation and Selection  | Qualified Person For Pharmacovigilance, Batch Release, Medical Information  |
| Regulatory Support Services from Pre-Clinical to Post-Marketing                   | Therapeutic Focus : Infectious Disease – Vaccines – Oncology – Respiratory  |
| Clinical Trial/Marketing Authorization Applications & Product License Maintenance |   |

Established: 1980  
Employees: 115  
Certifications: GCP/ICH  
Site Managers: Jean-Luc Marsat  
Luc Braeken

Address: Noorderlaan 87  
2030 Antwerpen, Belgium  
Nearby: Antwerp Thalys Train  
Tel: +32 35 45 44 11  
email: [clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)  
[www.sgs.be/lifescience](http://www.sgs.be/lifescience)



## SGS MECHELEN, BRUSSELS AREA – BELGIUM



### SERVICES

Full Biometric Services  
From Phase I To Post-Approval

Data Management

PK/PD Modeling & Simulation Analysis

Secure Data Office

Report Writing

Full EDC/IRT Services

CDISC Registered Solution Provider:  
STDM, ADaM, CDASH and Define.xml

Systems: Clintrial v 4.7<sup>®</sup>, Oracle  
InForm<sup>®</sup> & Central Designer<sup>®</sup>, Rave<sup>®</sup>,  
SAS<sup>®</sup>, WinNonlin<sup>®</sup>...

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

Nearby: Brussels Airport and Thalys Train

Tel: +32 15 27 32 45

email: [clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)

[www.sgs.be/lifescience](http://www.sgs.be/lifescience)



## SGS GAITHERSBURG, WASHINGTON, DC AREA – USA



### SERVICES

International & Local Trial Management and Monitoring

IND Writing, Submission and Management

Consulting & Study Design

Pharmacovigilance Strategies/  
Safety Database/Report Writing/  
Case Management

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: 27

Certifications: GCP/ICH

Site Manager: Stefan Comhaire

Address: 820 West Diamond Avenue, Suite 100  
Gaithersburg, MD 20878, USA

Nearby: Washington Airports

Tel: +1 877 677 2667

email: [clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)

[www.sgsgroup.us.com/lifescience](http://www.sgsgroup.us.com/lifescience)







# NETWORK AND CENTERS OF EXCELLENCE





[WWW.SGS.COM](http://WWW.SGS.COM)

WHEN YOU NEED TO BE SURE

**SGS**