



**SGS Biopharma**

**SGS Lab Simon**

## *Drug Development Services*

### **A SINGLE SOURCE MULTIDISCIPLINARY RESOURCE**

*SGS Biopharma - SGS Lab Simon is a European leader in the provision of a full spectrum of contract drug development services to the global healthcare industry. The company offers over 30 years of experience, the dynamism and flexibility of a medium size organisation with the scientific and Quality standards of the world's largest companies. Our location at the heart of Europe (20 minutes from Brussels), the professionalism of its multilingual staff, and the synergistic network of services are highly appreciated by our clients from Europe, USA and Japan, as well as by International Regulatory Authorities.*

**Phase I studies**, including first administration to man, pharmacokinetic, pharmacodynamic, and 14C ADME studies in a hospital-based GCP-compliant, AICRC-approved, 78-bed facility. Database of over 3,500 healthy volunteers and special populations (renally impaired, hepatically impaired, asthmatics, hypertensives, post-menopausal, sterilised women, elderly, slow metabolisers..). Studies can be initiated and completed rapidly.

**Phase II, III & IV studies** throughout Europe, with experience in a large number of therapeutic areas, and a particularly strong network of GPs. This department is staffed by a dynamic team of monitors and project managers who offer a personalised and expert service.

A GMP packaging and storage facility (approved by National Authority) offers full management of **clinical supplies**.

An experienced **data management and statistics** department supports all in-house as well as external project needs for clinical trials (human and veterinary), health economics, pharmacokinetics, biometrics and ICH format reporting.



**Healthcare and Biosciences Services**



## SGS Biopharma

### SGS Lab Simon

A GLP certified, FDA inspected **bioanalytical laboratory** with an international reputation for method development, validation and assay of drugs in biological fluids.

The laboratory, which utilises the most modern equipment (including LC-MS/MS, other instrumental and immunoanalytical techniques) and robots for automated sample preparation, is increasingly recognised as a central bioanalytical laboratory for international drug development. The immuno-analytical laboratory also specialises in **esoteric testing** of therapeutic markers.

A **veterinary trials** department performs efficacy, safety, residue and PK studies in most small and large animals according to GCP/GLP regulations.

The pharmaceutical development division provides a range of **pre-clinical services**. **Analytical chemistry and microbiology** departments develop analytical (HPLC, GC, LC-MS/MS, IR...) or microbiological methods validated according to EU requirements; their area of expertise also includes the preparation of a Drug Master File, content-container interactions etc...

An experienced team of scientists provide assistance in **formulation development**, including feasibility studies, preformulation, formulation, analytical development, manufacture of dosage forms, scaling up and transfer of technology.

A GLP certified laboratory conducts all the **stability studies**. A purpose-built storage facility combined with a validated computer and alarm system satisfies ICH requirements for the storage of stability samples.

In vivo short term **safety and toxicology testing** on 4 animal species (mice, rat, rabbit, guinea pig) combined with new developments in in-vitro toxicology (**alternative methods** in cell cultures, permeation in reconstructed skin, LAL...) completes the activities of our **QC laboratory**, which performs chemical, biological and microbiological testing of raw materials and finished products. This QC laboratory is EN45001 certified and nationally accredited for testing products imported in the EU.

A **Regulatory Affairs** department offers consultancy in Europe-wide registration of pharmaceuticals, veterinary products and medical devices. Moreover, SGS Biopharma and regulatory specialists from other European countries have combined their strengths to offer a pan-European registration network in accordance with the regulatory procedures in force since January 1998.

For further information, contact our Business Development department :

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