FULLY GMP COMPLIANT PHASE I UNIT PHARMACY

SGS CLINICAL PHARMACOLOGY UNIT – FIRST PHASE I SITE WITH FULL GMP AUTHORIZATION IN BELGIUM

Dose flexibility, cost reduction, and meeting short timelines are key features that distinguish one phase I clinical trial from another.

To meet the needs of pharmaceutical companies worldwide, SGS Life Science Services has completed the construction and validation of a fully compliant GMP pharmacy at its clinical pharmacology unit in Antwerp, Belgium. This GMP designation for the pharmacy demonstrates SGS's commitment to global regulatory compliance. The new pharmacy has undergone a successful inspection by the Belgian Health Authority to confirm full GMP compliance.

As the first phase I site holder of a full GMP authorization in Belgium, SGS now delivers extended pharmacy services to its clients, managing the Investigational Medicinal Product (IMP) manufacturing process during the set-up of the clinical trial in the most efficient way. This facilitates ordering and production of the small IMP volumes inherent to phase I clinical trials.

With this full GMP Manufacturing Authorization granted by the Belgian Health Authority, SGS has the necessary approval to perform a variety of manufacturing activities within the pharmacy, including:

- Manufacturing of non-sterile products (including API weighing):
  - Hard capsules (filling with powder or with liquid)
  - Solutions, to be used internally
  - Semi-solid products
  - Other: liposomes, gel
- Primary packaging of:
  - Hard capsules
  - Solutions, to be used internally
  - Semi-solid products
  - Other: liposomes, gel
- Secondary packaging including labeling
- Batch release of imported IMP (from outside EU) (by SGS Qualified Person)
  - Sterile products
  - Non-sterile products

The SGS pharmacy has been expanded to include a state-of-the-art validated GMP clean-room which is fully temperature and humidity monitored, in overpressure against the preparation room, and particulate and microbiologically controlled. In addition, SGS can manufacture IMP for distribution to other sites for multi-center clinical trials.

An SGS Qualified person, as required by the implementation of the EU Clinical Trial Directive, ensures that both manufacturing site and imported batches meet the European Union standards of GMP prior to release.

The SGS phase I pharmacy manufacturing services are supported by the SGS quality system enabling continuous improvement, protection of subjects' safety and well-being, data quality, and added value for our customers.

ABOUT SGS

SGS Life Science Services is a leading contract service organization providing clinical research, analytical development, biologics characterization, biosafety, and quality control testing. Delivering solutions for bio-pharmaceutical companies, SGS provides Phase I-IV clinical trial management services encompassing clinical project management and monitoring, data management, biostatistics, and regulatory consultancy. SGS's clinical units located in Antwerp, Belgium, and in Paris, France, with a total of 172 hospitalization beds have successfully passed several US FDA inspections during recent years. For optimized early phase clinical trials, SGS features sample tracking for safety lab data interfaced with Oracle for PK samples, full eSource clinic automation (EDC), a GMP pharmacy for on-site formulation, and a Biosafety Level 2 quarantine facility.

SGS has a wealth of expertise in: First-In-Human studies, QT/QTc prolongation, radio-labeled 14C ADME & PET scan trials, viral challenge testing, biosimilars, and complex PK/PD studies. For a qualitative and faster patient recruitment

across Americas and Europe, clients can also count on SGS's large database of investigators and key opinion leaders with therapeutic expertise in Infectious Disease & HIV/HCV, Vaccines, Oncology and Respiratory. Clients benefit from the favorable regulatory environment in the two countries with very short phase I trial approval.

SGS also offers GMP/GLP contract laboratory services that include analytical chemistry, microbiology, stability studies, bioanalysis, virology, and protein characterization.

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