



REGULATORY AFFAIRS

SGS Life Science Services has 30 years of experience as a global Contract Research Organization (CRO) with US, European and Asian operations and offices, providing a large range of services from preclinical activities to Phase I-IV trials. With over 3.800 trials performed, SGS has served the pharmaceutical and biotechnology industries with a focus on Integrity, Quality and Flexibility.

SGS Life Science Services provides Regulatory support and expertise for:

- **CLINICAL TRIALS**
- **DEVELOPMENT AND REGISTRATION**

STRONG REGULATORY INTELLIGENCE COUNTRY-BY-COUNTRY

- Regulatory intelligence and dedicated team of experts in place for 76 countries
- Drug import regulations and procedures by country for every country in Europe, established contacts with authorities
- Regulatory submission experience in Europe (Eastern/EU), Canada and USA
- FDA and Canadian health authorities inspections

REGULATORY SUPPORT FOR CLINICAL TRIALS

- Scientific advice request to authorities (including EMEA)
- IMPD writing and review
- Preparation and review of clinical trial applications, inclusive EudraCT
- Preparation of country-specific submission packages
- Regulatory submission - liaison with Regulatory Authorities
- Initiation and management of insurance certificate
- Import licenses for IMP - qualified person for GMP certification
- Specific authorisation request for GMO products
- Advice in regulatory submission strategy
- FDA IND submission

REGULATORY SUPPORT FOR DEVELOPMENT AND REGISTRATION

- Protocol and Scientific Advice request
- Preparation, review and editing of CTD files
- Preparation, review and submission of Marketing Authorisation Applications in Europe
- Liaise with all European Health Authorities
- Product licence maintenance (variations and renewal)
- Evaluation, assessment and expert advice on the preparation of the CMC part
- Preparation and review of Drug Master File and Eur. Ph. Certificate of Suitability file
- Bibliographic On Line research
- National Pharmacovigilance services
- MRL file
- Ecotoxicological assessment
- Regulatory services for other products as medical devices, biocides, diagnostics, cosmetics and nutriments
- Preparation and conducting of Readability User Tests on Package Leaflet in French and Dutch

DID YOU KNOW THAT...

- SGS has filed more than 225 dossiers in 17 countries, and has close links with the European regulatory agencies (EMA inclusive)

CONTACT US

EUROPE

t +33 1 53 78 18 79

NORTH AMERICA

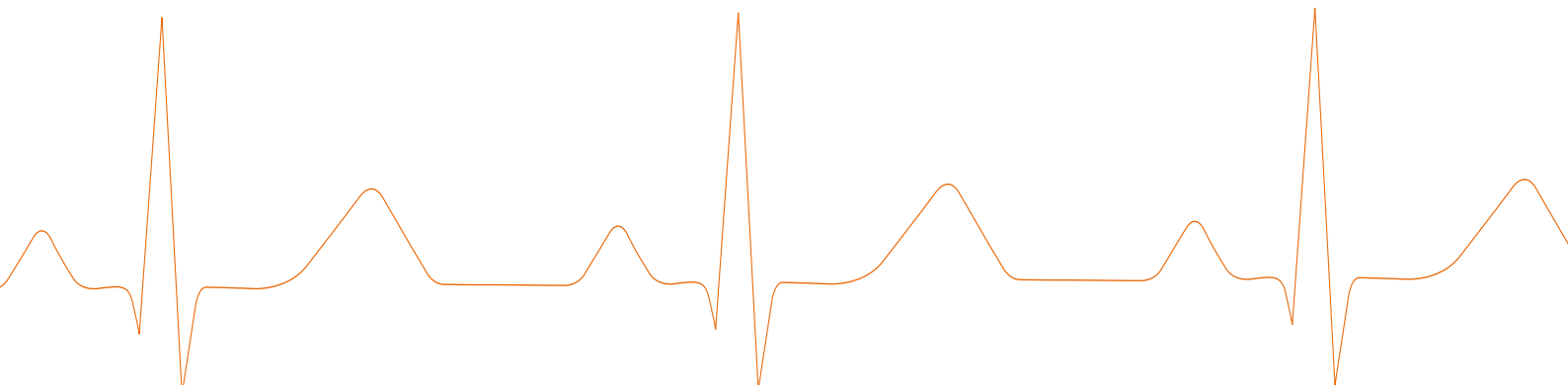
t +1 877 677 26 67

ASIA

t +65 98 26 25 98

WWW.SGS.COM/CRO

E-MAIL: CLINICALRESEARCH@SGS.COM



WHEN YOU NEED TO BE SURE

SGS