CLINICAL

REGULATORY AFFAIRS

DRUG DEVELOPMENT SOLUTIONS

SGS

SGS has over 30 years of experience as a global, life science contract research organization (CRO with US and European operations and offices, providing a large range of services from preclinical activities to Phase I-IV trials and including also pre and post approval medical and regulatory activities. With over 3,800 trials performed, SGS has served the pharmaceutical and biotechnology industries with a focus on Integrity, Quality and Flexibility.

LEADERS IN REGULATORY AFFAIRS

Our consulting team, a combination of highly skilled, multilingual industry experts and ex-Health Authority officials, offers a full-scope of Regulatory solutions, enhancing the development of your drug from molecule to market and beyond.

- Regulatory requirements expertise, technical and operational excellence
- Sound Regulatory strategy for optimal drug development
- Tailor-made, cost-effective solutions, including functional outsourcing
- Training programs
- Quality system compliant with international regulatory requirements to international regulatory requirements

Supported by team of highly experienced medical writers and an in-house translation agency, the regulatory affairs team at SGS offers you the personalized service of a boutique Regulatory firm, with the advantages of a full-service CRO.

CLINICAL DEVELOPMENT	MARKET AUTHORIZATION	POST MARKETING SUPPORT
• Regulatory Strategy	• Registration processes	• Licence variations, renewals and line extensions
• SME Office	• eCTD	• Artwork review
• Non-Clinical Guidance	• Readability testing	• Product Information
• IB & IMPD	• Pricing & reimbursement	• eCTD Life Cycle Management
• Scientific Advice	• CMC Writing	• QP services for batch release operations & Responsible Person for Distribution
• Pediatric Investigation Plan	• DMF files	• QP Advertising & Information
• Orphan Drug Designation	• Advice on guidelines	• SOP writing and audits
• Advanced Therapy Medicinal Products	• Clinical and non-clinical | overviews	• PSUR submissions & Pharmacovigilance services
• Clinical Trial Applications	• Writing all CTD modules	• Other products

CLINICAL DEVELOPMENT

During the development of your compound, an appropriate regulatory strategy is essential to avoid costly delays and loss market share. The regulatory team at SGS, provides you with tailored regulatory support at every stage of development:

REGULATORY STRATEGY

With in-depth understanding of the complex regulatory environment. We provide a map for how the existing process works (in practice not in theory), including individual functional contributions and perceived bottlenecks, a sound regulatory strategy plan, and help optimizing the use of the various incentives to drug development

NON-CLINICAL GUIDANCE

Performing the correct non-clinical studies before the First-in-Human (FIH) and exploratory trials is essential. Our 30 year experience supporting our phase I unit, has given us a unique insight in Agency's view on animal studies. Our Regulatory group advises you on the required non-clinical studies, and supports you in interactions with Health Authorities

SME OFFICE

The EMA and the FDA have implemented the micro, small, and medium-sized enterprises (SMEs) offices to provide incentives. This office offers incentives to SME such as fee reductions and protocol assistance. SGS helps clients to obtain SME status.

INVESTIGATOR'S BROCHURE (IB) AND INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD) WRITING

The SGS regulatory department writes and reviews IB's and IMPD's. Our dedicated team has extensive experience with a broad range of compounds, including biotech products, cell therapy, and radiolabeled products.

SCIENTIFIC ADVICE

Scientific Advice can be of great value for drug development and can speed up the regulatory approval. SGS guides you in

selecting the most appropriate Authority (national authority or EMA). We prepare high-quality briefing books and attend the Scientific Advice meetings.

PEDIATRIC INVESTIGATIONAL PLAN (PIP)

All European marketing authorization applications (MAA) for new medicines have to include the results of studies carried out in children of different ages, unless a deferral or a waiver has been granted. The timely submission of a PIP and a successful PIP procedure are therefore of key importance for the filing of both adult and pediatric applications in the EU. SGS develops waivers, deferrals, initial PIPs and modifications to agreed PIPs.

ORPHAN DRUG DESIGNATION (ODD)

Incentives, such as 10 year market exclusivity, are offered to companies developing medication for rare diseases. SGS obtains Orphan Drug Designation for your compound and maintains the ODD status.

ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP)

Advanced-therapy medicinal products (ATMPs) are medicines for human use that are based on gene therapy, somatic-cell therapy or tissue engineering. SGS obtains ATMP classification for your therapy.

CLINICAL TRIAL SUBMISSIONS

SGS prepares and submits clinical trial packages for your Investigational New Drug (IND), Clinical Trial Applications (CTA), and Voluntary Harmonised Procedure (VHP). We prepare a tactical submission plan for your trial optimizing your approval pathway.

MARKET AUTHORIZATION

The SGS Regulatory team prepares and submits your MAA package.

- Extensive experience in writing and expert input on all modules including: Risk Management Plans (RMP), Summary of Product Characteristics (SmPC) and Package Leaflets (PL), supporting overviews, etc
- Compilation of full MAA package
- Conversion of legacy trials
- Formatting to eCTD format
- Submission pathway: Centralized Procedure (CP), Decentralized Procedure (DCP), Mutual Recognition Procedure (MRP), National Procedure (NP) including liaising with EMA and national competent authorities
- Strategic advice on selected application pathway in Europe
- In-house translation Agency for translation of SmPC and PL from master to local version Preparation, coordination and conducting of Readability testing PL
- Preparation of Drug Master Files
- Preparation of submission dossiers
- for veterinary products, food supplements, herbal products, cosmetics, and biocides

POSTMARKETING SUPPORT

SGS helps you with the administrative burden of post-approval licence maintenance. We work to coordinate variations and license maintenance in a cost-efficient manner.

LIFE CYCLE MAINTENANCE

- Type I A/B and II (analytical and clinical) variations, line extensions and renewals
- Periodic Safety Update Report (PSUR) writing & submission.
- Coordination with agencies, and responses to regulatory authorities
- Artwork review
- Handling of product information documents such as QRD formatting, creation of labelling, declaration of conformity …
- Grouping approach for variation
- Handling pricing & reimbursement dossiers

ECTD MANAGEMENT

- Technical eCTD related support towards creation of compliant eCTD dossiers ready for submission
- eSubmission management consultancy
- Product Life Cycle management
- For National Procedures: core dossier versus local submission strategy country per country

QUALITY SERVICES

- Qualified Person for batch release (Marketed Products, IMP's)
- Qualified Person for Pharmacovigilance
- Qualified Person for advertising and information
- SOP writing
- Audits

CONTACT INFORMATION

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WHEN YOU NEED TO BE SURE

SGS