MEDICAL & REGULATORY SUPPORT

DEVELOPMENT, REGISTRATION AND POST AUTHORISATION

SGS has over 30 years of experience as a global, life science contract research organization (CRO) with European and US operations and offices, providing a large range of services from preclinical activities to Phase I-IV clinical trials including pre- and post-approval medical and regulatory activities. We are committed to our clients' satisfaction and we will leverage the full strength of our organization and experience to make your projects a success.

MEDICAL AND REGULATORY STAFF

Medical & regulatory expertise is provided through our departments of Medical Writing, Regulatory Affairs, and Medical Affairs. The teams include MDs, PhDs, Pharmaceutical scientists and MScs, all familiar with ICH-GCP, EMEA/CHMP, GVP, national guidelines and FDA rules. The team is multilingual and works closely with Regulatory Agencies worldwide. Temporary staff is available for short-term projects.

QUALITY FROM START TO FINISH

Our large and flexible team can:

- Provide medical and regulatory expertise during the full product life cycle
- Write and develop a wide range of regulatory documents and other clinical research documentation for any phase of clinical development (phase 1 through phase 4)
- Collaborate with and coordinate input from small and large, local and global cross-functional teams of experts
- Adapt to our clients' specifications, including varying operating procedures
- Support clients who do not have in-house templates through our own set of ICH-compliant templates
- Ensure accuracy and clarity through rigorous quality control according to SGS' standard operating procedures (SOPs)
- Deliver coordinators who act as a central point of contact for a client, which allows us to build relationships with our clients, improve efficiency and build up experience with the client

REGULATORY & SCIENTIFIC EXPERTISE

- Consultancy on medicinal products in development, generics, biosimilars, bibliographic submissions, orphan drugs, medical devices, herbal medicines
- Strategic Regulatory Advice
- Non-Clinical Regulatory guidance
- Clinical Trial submissions (CTA / IND)
- Scientific Advice meeting with EMA / European Health Authorities / FDA
- Pediatric Investigational Plan (PIP)
- Orphan Drug Designations (ODD)
- Response to Regulatory Authorities requests
- Preparation of Marketing Authorization Applications in Europe (MRP, DCP, CP)
- Product license maintenance (variations, line extensions, renewals, PSUR/PBRER submissions)
- Preparation and review of Drug Master File and Eur. Ph. Certificate of Suitability file
- Good PharmacoVigilance Practices (GVP)
- Eudract/ Eudravigilance registration & support
- Qualified Person (QP) for batch release and for advertising and information

COMMON TECHNICAL DOSSIER (CTD) WRITING

- Reference Safety Information
  - Summary of Product Characteristics (incl. Article 30 and SPC harmonization)
  - Patient Leaflets
  - Artwork review
  - Handling of product information (e.g. QRD formatting, creation of labeling)
- Pharmacovigilance system
  - Pharmacovigilance Consultancy
  - Pharmacovigilance System Master File
  - Risk Management Plan
  - Standard Operating Procedures
  - Literature search and evaluation
    - Medline and Embase
    - Screening/review of search results
    - Processing of literature cases
  - Safety Data Exchange Agreements (SDEA)
- Quality Overall Summary
- Clinical Overview (CO) / Addendum to Clinical Overview (ACO)
- Clinical Summary, including Efficacy and Safety Summaries
- Clinical Study Reports (CSR)

OTHER REGULATORY & SCIENTIFIC DOCUMENTS

- Development of risk minimisation material (educational material)
- Protocol writing
- Preparation and review of the Investigators Brochure (IB)
- Preparation and review CMC documentation
- Company Core Data Sheets (CCDS)
- Development Safety Update Reports (DSUR)
- Periodic Benefit Risk Evaluation Report (PBRER)/ Periodic Safety Update Reports (PSUR)
- Individual Case Safety Reports (ICSR)
- Case narratives, including company assessment
- Scientific articles and poster presentations

MEDICAL SUPPORT

- Expert Drug Safety Physicians team
- Medical support to Medical & Regulatory Writing team
- Signal detection and review of new data
- ADR review and causality assessment (case level and cumulative review)
- Signal evaluation
- Risk/benefit assessment

CONTACT INFORMATION

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WHEN YOU NEED TO BE SURE