TECHNICAL FACT SHEET

Medical & Regulatory Support

Health Inspired, Quality Driven.

Development, registration and post-authorization services

SGS boasts over 40 years of experience as a global Contract Research Organization (CRO), providing a range of services from preclinical activities to Phase I, II and III clinical trials, including pre-and post-approval medical and regulatory activities. Our customer-centricity and unparalleled experience will ensure your projects' success.

Medical and regulatory staff

Our Medical Writing, Regulatory Affairs, and Medical Safety departments provide extensive medical and regulatory expertise. Our multilingual teams include MDs, PhDs, pharmaceutical scientists and MScs, all of whom are familiar with ICH-GCP, GVP, national guidelines.

Quality from start to finish

Our large, flexible team provides an array of medical and regulatory support throughout the whole product lifecycle. This includes drafting and developing regulatory documents and other clinical research documentation for Phase I through to Phase III of clinical development. We can even support clients who do not have in-house templates by using our own set of ICH-compliant templates.

Our team adapts its services and approach according to each client's specifications. We are well versed in collaborating closely with all types of teams – whether they are small and local or global and cross-functional. By following our rigorous quality control standard operating procedures (SOPs), we provide total accuracy and clarity at all times.

Our coordinators act as central points of contact throughout the entire product lifecycle. This not only aids communication but also enables us to foster a close, mutually beneficial working relationship with all our clients.

Areas of regulatory and scientific expertise

- Strategic regulatory advice
- Scientific advice stemming from discussions with the EMA/European health authorities
- Clinical trial submissions (CTA, IND)
- Pediatric investigation plans (PIP)
- Orphan drug designations (ODD)
- Responding to regulatory authorities' requests
- Preparation of Marketing Authorization Applications (MAA) in Europe (MRP, DCP, CP)
- Product license maintenance (variations, line extensions, renewals)
- Preparation and review of Drug/Active Substance Master File
- Good PharmacoVigilance Practices (GVP)
- Eudract/Eudravigilance registration and submission and maintaining your clinical trial in the clinical information system (CTIS)

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)
- Overall quality summary
- Clinical Overview (CO)/Addendum to Clinical Overview (ACO)
- Clinical summary, including efficacy and safety summaries
- Clinical Study Reports (CSR)

Other regulatory and scientific documents

- Development of risk minimization materials (educational materials)
- Protocol writing
- Preparation and review of the Investigator's Brochure (IB)
- Preparation and review of Chemistry Manufacturing and Controls (CMC) documentation
- Investigational Medicinal Product Dossier (IMPD) review writing
- Company Core Data Sheets (CCDS)
- Development Safety Update Reports (DSUR)
- Periodic Benefit Risk Evaluation Reports (PBRER)/ Periodic Safety Update Reports (PSUR)
- Individual Case Safety Reports (ICSR)
- Case narratives, including company assessments
- Signal detection/management
- Scientific articles and poster presentations

Medical Support

- Expert drug safety physicians team
- Medical support for medical and regulatory writing

Contact us

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WHEN YOU NEED TO BE SURE