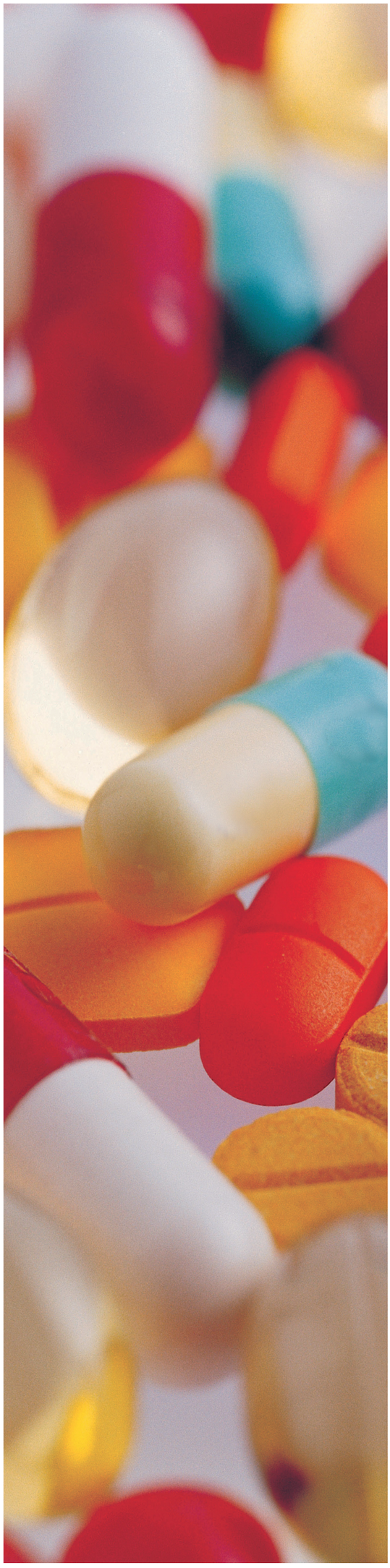

MEDICAL & REGULATORY AFFAIRS

DEVELOPMENT, REGISTRATION AND POST AUTHORISATION

SGS Life Science Services has 30 years of experience as a global 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.

MEDICAL AND REGULATORY STAFF

The department includes MDs, PhDs and Pharmaceutical scientists, all familiar with ICH-GCP, EMEA/CHMP and national guidelines and FDA rules, and management support for data entry and administrative tasks. The team is multilingual (English, French, Dutch, German, Spanish, Polish, Russian), and works closely with Regulatory Agencies worldwide. Temporary staff is available for short-term projects.

QUALITY FROM START TO FINISH

- REGULATORY SUPPORT:
  - Protocol Assistance and Scientific Advice
  - Regulatory submission strategy guidance
  - Consultancy on medicinal products in development, generics, biosimilars, bibliographic submissions, orphan drugs, medical devices, herbal medicines
  - Advice on guideline interpretation
  - Preparation and review of IMPD and IB
  - Preparation, review and submission of Marketing Authorization Applications in Europe (MRP, DCP, CP)
  - Liaise with all European Health Authorities (NCAs and EMEA)
  - Product licence maintenance (variations, line extensions, renewals, PSUR submissions)
  - Response to Regulatory Authorities requests
  - Converting of old files into CTD format
  - Preparation and review of the CMC section
  - Preparation and review of Drug Master File and Eur. Ph. Certificate of Suitability file
  - Regulatory services for herbal medicines, medical devices, biocides, diagnostics, cosmetics and nutriments
  - Preparation and conducting of Readability Tests on Package Leaflet in French and Dutch
  - Artwork review
  - Handling of product information documents (e.g. QRD formatting, creation of labelling)
  - Writing of articles

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- QUALIFIED PERSON (QP) SERVICES:
  - (Deputy) Local QP and deputy EU QP for PharmacoVigilance
  - QP for batch release
  - QP for advertising and information
  - SOP writing
  - Audits

- POSTMARKETING PHARMACOVIGILANCE:
  - 24/7 Medical support and safety coverage

  - Case management support:
    - In-house processing and expedited reporting of (Serious) Adverse Drugs Reactions (SADR), pregnancy cases and other safety reports
    - Setup and maintenance of in-house validated E2B compliant safety database
    - Accurate MedDRA and WHO-drug coding
    - Quality and Medical review of safety reports
    - Query management to the reporter

  - Report writing:
    - Case narrative writing, including company assessment
    - Product-related Expert Reports/Clinical overviews
    - Periodic Safety Update Reports (PSUR)/Bridging Reports/Addendum Reports
    - Risk Management Plan
    - Reference safety information (e.g. core label, SPC, PI)

  - Literature search and evaluation:
    - Search and alerts
    - Screening/review of search results
    - Processing and expediting reporting of serious literature cases

  - Signal detection and ongoing safety evaluation :
    - ADR review and causality assessment (case level and cumulative review)
    - Signal detection ad review of new data
    - Signal evaluation
    - Risk/benefit assessment

  - Submission Support:
    - Regulatory submission – liaise with Regulatory Authorities
    - Expedited reporting to Authorities (CIOMS I reports)
    - Eudravigilance Registration Consultancy
    - E2B compliant electronic reporting in EU through Eudravigilance
    - PSUR submission
    - Submission Compliance tracking

  - Pharmacovigilance system:
    - Detail description of the pharmacovigilance system
    - Standard Operating Procedures
    - Pharmacovigilance training of non-pharmacovigilance staff and staff working specifically with pharmacovigilance

  - Pharmacovigilance audits

CONTACT US

EUROPE
t +33 1 53 78 18 79

NORTH AMERICA
t +1 877 677 26 67

WWW.SGS.COM/CRO
E-MAIL: CLINICALRESEARCH@SGS.COM

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WHEN YOU NEED TO BE SURE

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