Good Clinical Practice (GCP) Consultancy Services

Our team of specialist GCP auditors is unparalleled in expertise and training, having successfully completed a multitude of audits across many therapeutic domains. We take pride in our global presence, with a track record that spans over a wide range of countries, underpinned by adherence to both international and national standards.

Navigating the intricacies of GCP quality audits in today's world presents a unique set of challenges, given the intricate nature of clinical trials and the widespread distribution of investigator sites. While sponsor organisations are predominantly based in Europe, the USA, and Japan, their research reaches across the globe, extending to Asia, Africa, South America, the Middle East, and the Far East. Our auditors transcend the mere logistical hurdles of reaching these remote locations; they excel in bridging the gap between diverse cultures with sensitivity and finesse. With SPGL's personnel positioned worldwide, we are strategically placed to overcome language barriers, minimise travel time and expenses, and facilitate seamless audits. Choose SPGL for a partnership that promises not just global reach, but also cost-effectiveness and cultural competency.

Our GCP services

- **Investigator Site Audits**
  - Routine/Targeted/For Cause Investigator Site Audits (Phase I to IV)
- **System Audits**
  - System Audits of Sponsor/CRO Operations
- **Vendor Audits**
  - CROs
  - Phase I units
  - Monitoring & Project Management
  - Data Management, Biostatistics and Medical Writing
  - Clinical Trial Supply
  - Archive Facility
  - Imaging Facilities
  - Statistics
  - Interactive Response Technology
  - Translation services
  - Centralised ECG facilities
- **Computer System Validation Audit**
- **Data Management Audits**
  - Database
  - Data Management System
- **Trial Master File (TMF) Audits**
  - Trial Master File Audit (paper and electronic)
- **Document Audits**
  - Protocol
  - Case Report Forms
  - Informed Consent Forms
  - Investigator's Brochures
  - Clinical Study Reports
  - Development Safety Update Reports
  - Clinical study plans including management, risk management and monitoring plans
- **Mock Inspections**
  - Inspection preparation and training (investigator site/CRO/sponsor)
  - Mock Inspection
  - Inspection facilitation
- **Consultancy services**
  - SOP Development
  - QMS Evaluation
  - Regulatory Intelligence

Reach out to us to explore how we can assist you and tailor our services to meet your unique needs.

For further information:

Website: spgl.eu/services/regulatory-consulting-compliance/
Email: info@spgl.eu

London
SPGL Limited
4th Floor
33 Cannon Street
London EC4M 5SB
United Kingdom
Tel: +44 (0)2070846873

Belgium
SPGL
Posthofbrug 6-8
2600 Berchem
Belgium
Tel: +32(0)33760015

MANAGING QUALITY.
IMPROVING PERFORMANCE.