

General Services

**SMART
Pharmaceutical
Consulting**





Services We Provide

Compliance and Quality Systems

- Compliance auditing (GMP, GLP, GCP, ISO and QSR)
- Compliance Risk Assessment and Corrective Action Plan Evaluation
- Regulatory Mock Inspections
- Identification and Management of Clinical Suppliers and Contract Manufacturer's Laboratories
- Quality Assurance Support
- Quality control and Analytical Support
- QP Support
- Analytical Methods and Validation
- Design Control and Quality Systems
- Strategic Compliance Advice
- Documentation for Validation
- Development and Implementation of Corrective Action Plans
- Remedial Solutions
- Regulatory action Strategic Solutions
- Data Integrity Assessment/Mitigation
- Procedures Development

Clinical Support

- Project Management
- Packaging and labeling
- Biostatistical Consulting Service
- Clinical Monitoring
- Clinical QA Auditing
- Clinical Pharmacology Support
- Clinical Research training
- Clinical Supply services
- Data Management
- IRB/Ethical review Committee Assessment
- Phase I Clinical Services
- Phase II - III Clinical Services
- Service Provider Assessment
- Regulatory Readiness Audits
- Submission Review and Assessment
- Design and Implementation of clinical Quality Systems
- SOP development and Training

Regulatory Affairs

- Preparation and Review of Regulatory Submissions including INDs, CTAs, eCTDs, CTXs, IDEs, CTNs, NDAs, ANDAs, MAAs, BLAs, PMAs and 510Ks
- CTM Services and Document Submission

- Document Control System Assessment
- eCTD Vendor Audits
- Review and Preparation of Drug master Files (DMFs) and EDMFs
- FDA 483/Warning Letter/ Consent Decree Response
- NDC numbers filing and acquisition
- Mock FDA/EMEA/MHRA Inspection and Assessments/GAP analysis

Inspections/Mock Inspections

- Pre-approval Inspection Preparedness (PA PREP)
- Third Party Audits/ Assessments/GAP Analysis (GMP/GLP/QSR/ISO)
- Third Party Certification
- Mock FDA Inspections
- Due Diligence Audits and Assessments

Product Development and Manufacturing

- Clinical and Commercial Manufacturing Support
- Formulation Development
- Supply chain management
- Facility Design
- Facility, Utility and Equipment Validation
- Facility, Utility and Equipment Validation
- Computer Validation (21CFR Part 11)
- Cleaning Validation
- Process Validation
- Product Development Strategy
- Lean Manufacturing Strategy and Design

INTEG

The SMART Team

- Spans several continents, including America, Asia, Europe and Australia.
- Brings a global perspective and consistency to the services we offer.
- Provides you with an established network of highly experienced and geographically diverse Associates.
- Is structured to support your business goals and ensure the success of your project.
- Has the insight, integrity and ingenuity to assist you in the design and execution of sound and effective programs.
- Continues to provide our clients with the necessary support and capabilities to ensure the successful, timely and cost-effective realization of their goals.
- Has a track record of success in the Pharma/Biotech/Medical Device industries.
- Bases this success on our network of experienced Associates who provide, not only their technical capabilities, but the reality that they've successfully done it before.
- Understand that the need for flexibility, reasonable solutions to problems, a sense of urgency, and teamwork are the keys to cooperation and mutual support with our clients.
- Will do whatever is required to allow you to focus on your business.
- Will not only provide you with the correct resources and solutions to meet and exceed your needs, but will provide you with the collective resources of the entire organization.

SMART Pharmaceutical Consulting is an international consulting organization dedicated to offering its clients highly personalized service by enabling both effective and efficient solutions to your company's needs. We work with small, medium and large pharmaceutical, biologic and medical device organizations to achieve your company's goals. As a broad multidisciplinary organization, we offer clear and obvious solutions based on both novel and proven principles.



SMART Pharmaceutical Consulting

20 E Market Street
West Chester, PA 19380, USA

TEL: 610.422.1097
FAX: 610.344.9219

1-833-GMP-LEAN

