SMART CONSULTING GROUP

Life Science Solutions

INSIGHT | STRATEGY | ANALYSIS | STAFFING

Since 1999, **SMART CONSULTING GROUP** has provided expert consulting and staffing support offering scientific, technical, quality and regulatory assistance to the medical products industry. SCG provides unique insight, analysis and solutions to the complex world of medical product development and licensure.

"I commend you for the great job you did. You showed a high level of professionalism. This type of outcome proves we chose the right company to work with." -Director, US FDA Center for Drug Evaluation and Research (CDER)

DENISE SMART
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Founder & President

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SMART CONSULTING GROUP
PO Box 884
West Chester, PA 19381

CAPABILITIES

- FDA Regulatory Support:
  - Manufacturing analysis and strategy
  - FDA Application review
  - Data integrity audits
- Scientific and regulatory professional / SME Staffing
- Scientific and regulatory due diligence
- Technology transfer strategy and oversight
- Technology Readiness Assessments
- Quality Management System strategy and implementation
- FDA GMP compliance assessment
- Audits - GMP, GLP, GCP and ISO
- Market Research and Analysis
- Training: FDA GMP and Inspections

EXPERTISE

- **Subject Matter Expert Staffing Support** – Provide highly qualified and experienced professionals supporting medical product development
- **Quality** – Design and Implement FDA-compliant Quality Systems and Processes for R&D and Commercial manufacturing organizations
- **Audits** – Plan, conduct and report GMP, GLP, GCP and ISO audits
- **Regulatory Affairs** – Analyzing regulatory data and recommend regulatory strategy to meet client goals
- **Monitoring and Verification** – Conduct complex data analysis of FDA regulatory submissions to identify data integrity, quality, process issues
- **Product Development/Manufacturing** – Conduct product and cross functional process analysis to improve inefficiencies and product quality
- **Technology Transfer** – Technology evaluation, monitoring and due diligence of acquisitions and divestitures of medical products
- **Product Strategy** – Including analysis of alternatives, regulatory, clinical and business strategies

CODES | CERTIFICATIONS

NAICS: 541611 541618 541690 541790 541990

CAGE Code: 304U6

UEI: EAZXL6WGGEN5

GSA Contract: GS10F0273V
SIN 541611

Certified SBA WOSB Woman Owned Small Business FEDERAL CONTRACTING PROGRAM

GSA Advantage! www.gsaadvantage.gov

WOMEN OWNED CERTIFIED BY | WOMEN'S BUSINESS ENTERPRISE NATIONAL COUNCIL

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CAPABILITIES - EXPERTISE - ACCOMPLISHMENTS

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PAST PERFORMANCE (GOVERNMENT)

- Medical Countermeasure Subject Matter Expert staffing support to BARDA as a subcontractor to Tunnell Government Services and Conceptual Mindworks (HHSO100201100003I) (2011-2018)
- Development of Strategies in Handling High Profile Consent Decrees (2012-Present, 4 contract awards) Exceptional CPARS rating.
  - HHSF223201620432G, HHSF223201510572G, HHSF223201210242C, 75F40121F80457. Development of a Strategy, Goals, Recommendations and Providing Assistance in managing FDA's Implementation of a Consent Decree, with a Focus on Application Integrity Policy (AIP). Evaluated complex drug manufacturing and testing data associated with FDA GMP compliance enforcement actions.
- FDA Training Needs Assessment and Delivery of Adopted and/or Adapted Advanced Manufacturing Training (Current Subcontract)
- Montana State University MilTech: Provided FDA and Medical Product Subject Matter Expert support including FDA regulatory and product development strategy.

PAST PERFORMANCE (INDUSTRY)

- Technology Transfer Monitor of FTC-ordered drug product divestitures Dosage forms: solid, sterile/non-sterile liquids and ointments
  - ANI-Novitium, Akorn, Actavis, Teva, Cephalon
- FDA Consent Decree Monitoring and Remediation
  - Strategy, FDA Interactions, Warning Letter Responses
  - Quality System Gap Analysis, Interim Controls, Design, Implementation and Verification
  - Third Party Verification
  - Batch record review and release
  - Laboratory Data Analysis
- Quality System Design and Implementation
  - Global, Multi-site harmonization
  - Assessments, Process Design, Prepare Quality Manual, Policies, Procedures, Implementation Plans and Training
  - eQMS System selection and validation
- Audits: GMP, GLP and GCP: 21CFR211; 820; ISO 9001, 13485, 14971; IEC 62304; ICH Q9)
- Biotechnology Product/Process Troubleshooting, Capability Analysis
- CMC Regulatory Strategy and FDA submission support
- Software validation, Validation Master Plans