SMART CONSULTING GROUP

Life. Science.

Pharmaceutical Consultants Providing Insight, Strategy and Analysis
for the Advancement of Medical Products

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Smart Consulting Group
West Chester, Pennsylvania
www.smartconsultinggroup.com
610-344-9218
POC email: dsmart@smartconsultinggroup.com

NAICS Codes

541611 541690 541990 541618

CAGE Code: 304U6 DUNS: 167069082

GSA Contract: GS10F0273V: Schedule 874-1

WBENC and SBA-Certified **Woman-Owned Small Business**

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Who We Are

Founded by
Denise F. Smart, M.Mgmt., Esq.,

A medical product industry professional with more that 30 years medical product CMC and regulatory experience.

Established in 1999

Providing scientific, regulatory, process analysis and advisory services.

Subject Matter Experts

Complex regulatory challenges

- Application of regulations and guidance to new technologies
- Risk analysis and mitigation strategy
- Forensic data integrity analysis

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Smart Consulting Group Capabilities

- Analysis – Conduct complex data analysis of FDA regulatory submissions to identify data integrity, quality, process issues
- Transactions/Technology Transfer – Technology evaluation, monitoring and due diligence of acquisitions and divestitures of medical products
- Surveillance – Plan, conduct and report GxP audits and regulatory compliance monitoring
- Regulatory Strategy – Analyze regulatory data and recommend regulatory strategy to meet client goals
- Process Design – Design and Implement Quality Systems and Processes
- Manufacturing – Conduct product and cross functional process analysis to improve inefficiencies and product quality
- Product Strategy – Includes analysis of alternatives, regulatory, clinical and business strategies
- Subject Matter Expert Staffing Support – Provide highly qualified and experienced professionals supporting medical product development

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SPECIALIZED OFFERINGS

Remote and Virtual Presence inspection and training support

Using SmartGlass Technology

Enabling remote and team supported inspections

Enabling remote coaching and training

Technology Readiness Level Assessments

Using Department of Defense technology maturity scale for evaluating medical products

Complex regulatory data analysis

Using medical product expertise combined with applied statistics such as DOE, RSM, Variance Decomposition, Regression Modeling, Process Capability, Contingency Analysis, Predictive Models, Logistic Regression

Past Performance Examples

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Past Performance (FDA)

Development of Strategy in Managing High Profile Consent Decree With AIP (Contract: HHSF223201210242C and 75F40121F80457)

Exceptional CPARs ratings across contracts. Currently on 12th year of supporting FDA, CDER, Office of Compliance, Office of Manufacturing Quality and affiliated organizations.

Tasks included

- Analysis of Establishment Inspection Reports (EIR) and responses to determine whether a pattern violations of GMP regulations demonstrated a systematic failure of multiple quality system elements at each site.
- Forensic analysis of Validity Assessment Reports from third party Data Integrity consultant.
    - Technical and regulatory data review
    - Determination whether data substantiated findings within the audit report.
- Reviewed specific analyses mentioned in FDA-483 observations along with the EIR to determine if there were data integrity issues. SCG was provided comment on whether the company responses were credible, had rational basis and could be supported by the scientific evidence provided.
- Provided independent expert review and analysis of a high-profile Pharmaceutical Consent Decree to advise FDA on the firm's efforts to gain the compliance with the AIP provisions and to evaluate the Firm's third-party proposals, scope and execution of data gathering and auditing and strategic oversight. Provided analysis the firm's data integrity in view of Consent Decree obligations.

Past Performance (FDA)

Training Needs Assessment and Delivery of Adopted and/or Adapted Advanced Manufacturing Training (Current Subcontract)

Current Tasks include

- Analysis of the medical products scientific, technical and regulatory landscape to identify applicable innovative product technologies, manufacturing platforms, and testing methods for medical products regulated by FDA developed in recent years, as well as those that are likely to emerge in the next five to ten years.
- Assess skills needed to equip FDA staff to effectively oversee this growing sector of industry and protect public health.
- Assess the current training available to ORA staff and determine gaps in the training needs.
- Topics of consideration include techniques used to manufacture medical products, including essential medical products used in the diagnoses, treatment and prevention of COVID-19 and other potential pandemic causing pathogens, advanced manufacturing processes and platforms and include the regulatory and inspectional perspective for oversight.

Past Performance (FTC/Industry)

- Monitoring/ Due Diligence
  - Interim Monitor for the divestiture of pharmaceutical products pursuant to a Federal Trade Commission Consent Order.
    - Verification of Compliance with Consent Order
    - Facilitator to Aid with Smooth Transition and Technology Transfer
    - Report Observations to Commission
    - Aid Commission with Understanding Complexities and Challenges of Divestiture
  - Divestitures monitored: Cephalon/Cima, Teva/Ivax, Actavis/Abrika, Akorn/Hi-Tech

Past Performance (DoD/MilTech)

Assisted Montana State University/MilTech with FDA regulatory and product analysis for multiple medical products to support the Department of Defense (AFMSA)

- Regulatory Strategy
  - Provide TRL level assessments for a range of medical products including:
    - Antivenin
    - Endovascular Variable Aortic Control Catheter,
    - Multi-channel infusion pump and other medical products.
- Medical Device GMP Compliance
    - Provide GMP compliance assessment and product analysis for an Oxygen Generating Field Portable device

Past Performance (HHS/ASPR/BARDA)

Medical Countermeasure Subject Matter Expert staffing support to BARDA as a subcontractor to Tunnell Government Services and Conceptual Mindworks (HHSO100201100003I)

Provided Medical Countermeasure Subject Matter Experts for

- Regulatory and Quality Affairs
- Small Molecule Pharmaceutical Product Development
- Respiratory Medical Device
- Blood Products

Provided recruiting and medical product talent acquisition strategy and support for a full range of medical product Subject Matter Experts

Assisted the Prime Contractor with Program Management to achieve successful contract performance.

Past Performance (Industry)

- Manufacturing Compliance (Generic pharma)
  - Conducted audits and remediation of manufacturing operations of generic pharma company under Warning Letter
  - Assessment and remediation of generic pharma company under Warning Letter and exhibiting data integrity issues associated with QC Laboratory.
  - Data integrity assessment of Manufacturing and Quality Control Laboratories under Warning Letter and exhibiting Data Integrity and Compliance issues.
  - Identified data integrity issues and remediation of Quality Control Laboratories.

Past Performance (Industry)

- Regulatory Compliance
  - Provide training in the Drug Supply Chain Security Act, Product Recalls and Reverse Distribution
  - Total design of Quality Systems for production of Bulk Drug Substance.
  - Remediation of Quality System for multiple global companies under Consent Decrees
  - Application Integrity audit for company suspected of data integrity and application errors.
  - Assessment and redesign of pharmacovigilance systems for major pharma companies
  - Process mapping and design of unified GMP, GLP and GCP Quality Systems.
  - Development of Policies and Training Materials for Implementation.
  - Conducting GMP, GLP and GCP Audits of Contractors and Suppliers (CONUS and OCONUS)
  - Provide GMP, GLP and GCP training
  - Assistance with re-launch of a seized medical countermeasure vaccine during public emergency.

Past Performance (Industry)

- Manufacturing Strategy

  Pharma
  - Lean strategy and operational design for QC Laboratory and manufacturing for major API supplier
  - Lean Laboratory re-design for Pharmaceutical QC Laboratory

  Medical Device
  - Lean analysis of manufacturing and compliance approach for an optical medical device company
  - Lean Manufacturing strategy for Medical Device/ Drug combination product

Questions?

Thank you for this opportunity to share our capabilities with you.

For more information, visit:

www.smartconsultinggroup.com

or

Contact dsmart@smartconsultinggroup.com

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