



*A Woman Owned Small Business*

# CAPABILITIES STATEMENT

Smart Consulting Group  
*a Woman Owned Small Business*

**COMPANY NAME:**

Smart Consulting Group

**BUSINESS ADDRESS:**

20 E. Market Street  
West Chester, PA 19382

**BUSINESS SUMMARY:**

Providing premier pharmaceutical services to an international client base, we are a life sciences firm with the goal of making our clients the leaders in their business centers. As a small business, we recognize the importance of establishing a strong relationship with each one of our clients. This strong relationship enhances our capability to create effective, yet unique solutions to meet our client's goals.

Employing a combination of seasoned industry professionals and former FDA professionals, SCG has developed the capability to provide efficient, cost effective solutions to current public and private sector problems, on budget, on time and Right-First-Time.

Our company's mission is to provide outstanding technical and regulatory compliance assistance to enable our clients to meet their objectives. In fulfilling this mission, we act as a bridge from our clients problems to great solutions, developed in partnership.

**CAPABILITIES:**

- Quality Program Assessment, Design and Implementation
- Life Science Product Regulatory Strategy
- Training
- Life Science Product Development Analysis
- Laboratory Management and Operations Support
- Project Management
- Monitoring and Review of Compliance Obligations
- Consent Decree Consulting for FDA
- Divestiture Monitoring for FTC
- Subject Matter Expert Support for Complex Life Science Product Development and Licensure



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**FACILITIES AND EQUIPMENT:**

Smart Consulting Group offices are located in West Chester, Pa. SCG consultants are available to provide on-site at our clients' offices.

**EXPERTISE:**

Smart Consulting Group's internal core team is led by founders Denise and Nigel Smart, who have 31 and 35 years, respectively, of industry-specific lab and manufacturing experience with such companies as SmithKline Beecham, DuPont Pharma, Sterling Winthrop, and Allelix BioPharmaceuticals. Combined with our other team members, who average 20 - 25 years of industry experience, our team has a strong talent base to provide solutions that are timely, focused and can be implemented immediately.

**CUSTOMERS:**

FDA  
FTC  
BARDA  
Medimmune  
Regeneron  
Abbott Vascular  
Targacept  
Teleflex Medical  
Endo Health Solutions

GSA MOBIS:  
GS-10F-0273V

PSC:  
NAICS:

541690  
541611  
541614  
541618

Cage Code:  
304U6

D&B:  
167069082

**CERTIFICATIONS:**

WBENC

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