

## CORPORATE OVERVIEW

Shabas Solutions, LLC ("Shabas") is a Virginia-based, Woman-Owned, Small Business providing Scientific, Technical Services, Regulatory and Management Consulting Services to Government Agencies. We are recognized for successfully leading large scale, departmental level mission-support operations through our expertise in policy, operations and systems. Our top-notch consulting talent and senior advisors are drawn from the ranks of large management consulting firm professionals, military veterans, federal agency executives, and industry experts.

### Corporate Overview

- SBA Certified Woman-owned Small Business;
- DCAA-Certified Accounting System
- ISO 9001:2015 Certified
- DUNS: 178149998
- UEI: ZGLHPDKK5GP9
- CAGE: 4PAR3
- Primary NAICS: 541611
- Self-funded and No Debt

### Functional Domains

- Medical Supply Chain
- Pharmaceutical Research
- Pharmaceutical Quality and Regulatory
- Financial Management
- Logistics Management

### NAICS CODES

- 541219 – Other Accounting Services
- 541511 – Custom Computer Programming Services
- 541512 – Computer Design and Integration
- 541611 – Administrative & General Management Consulting
- 541614 – Process, Physical Distribution, & Logistics Consulting Svcs
- 541690 – Other Scientific and Technical Consulting Services
- 541990 – All other Professional, Scientific & Technical Consult Svcs
- 561110 – Office Administrative Services
- 611430 – Professional Training Development

### SELECTED PRIME VEHICLES

- GSA MAS Professional Services Schedule (GS-00F-110GA)
- GSA OASIS Plus Small Business and WOSB
- Selected Agency-wide Contracts
  - NIH-wide Office of Research Services (Scientific Cluster) Staffing BPA (\$45M/5-year)
  - NIH-wide Personal Property Services BPA (OLAO) (\$30M/5-year)

### GOVERNMENT CONSULTING CORE SERVICE OFFERINGS

#### Quality Assurance (cGMP) Consulting

- Regulatory Guidance at a Federal Organization – cGMP, DSCSA, Controlled Substances, Transportation, HAZMAT
- NDC Registration, SLEP
- Quality Investigations/ Root Cause Analysis/ CAPA
- Risk Assessment
- Equipment Qualification, Warehouse & Cold Chain Temperature Mapping, Shipping Studies & Computerized System Validation (21 CFR Parts 11, 211)
- Supplier Qualification and Audits
- Regulatory & Customer Audit Support
- Quality Manual, Policy & SOP Development, Training
- Quality Management Review Meetings
- QC Inspection & Release

### CORE SERVICE OFFERINGS (CONTINUED)

#### Product Development and R&D Support Services

- Product Strategy Development & Planning
- Product Development Lifecycle Support (Drug Substance/Drug Product)
- Small Molecules/API Support (Pharmaceuticals /Formulation/CMC, Scalability & Process Chemistry)
- Biologics Support (Process Development, CMC, GMP Manufacturing, & QA) for Product Development & Clinical Evaluation of Vaccines/Biotherapeutics
- Clinical Trial Support & Logistics
- Sample Repository & Stability Management
- Pre-Clinical/Clinical Immunoassay Development & Validation
- Laboratory Concordance Studies
- Correlates of Protection Analysis
- Medical Affairs
- Regulatory Affairs Support & Health Authority Filings
- Scientific Staffing

#### Program Leadership and Management Services

- Strategic Planning
- PMO Design and Operationalization
- Studies & Analysis
- Policy Development, Implementation, Administration
- Regulatory Helpdesk Support
- Survey and Benchmarking
- Integrated Planning
- Performance Management
- External and Internal Communications & Outreach
- Program Reporting
- Knowledge Management
- Process Improvement
- Financial Management

#### Logistics and Supply Chain Management

- Full Lifecycle Asset Management
- Warehouse Management - Requisitioning, Receiving, Shipping & Inventory
- Cold Chain Storage & Temperature Monitoring
- Pharmaceutical Repackaging
- Medical Kitting/Co-Packaging
- Recall Management Support
- Customer Services/Help Desk
- Records Management and Administrative Operations
- Logistics System Business Operations, & O&M
- Logistics Training
- Financials & Acquisition Support
- Business Analytics