

# 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.

<b>Corporate Overview</b> <ul style="list-style-type: none"> <li>▪ SBA Certified Woman-owned Small Business;</li> <li>▪ DCAA-Certified Accounting System</li> <li>▪ ISO 9001:2015 Certified</li> <li>▪ DUNS: 178149998</li> <li>▪ UEI: ZGLHPDKK5GP9</li> <li>▪ CAGE: 4PAR3</li> <li>▪ Primary NAICS: 541611</li> <li>▪ Self-funded and No Debt</li> </ul>	<b>CORE SERVICE OFFERINGS (CONTINUED)</b> <p><b>Product Development and R&amp;D Support Services</b></p> <ul style="list-style-type: none"> <li>▪ Product Strategy Development &amp; Planning</li> <li>▪ Product Development Lifecycle Support (Drug Substance/Drug Product)</li> <li>▪ Small Molecules/API Support (Pharmaceutics /Formulation/CMC, Scalability &amp; Process Chemistry)</li> <li>▪ Biologics Support (Process Development, CMC, GMP Manufacturing, &amp; QA) for Product Development &amp; Clinical Evaluation of Vaccines/Biotherapeutics</li> <li>▪ Clinical Trial Support &amp; Logistics</li> <li>▪ Sample Repository &amp; Stability Management</li> <li>▪ Pre-Clinical/Clinical Immunoassay Development &amp; Validation</li> <li>▪ Laboratory Concordance Studies</li> <li>▪ Correlates of Protection Analysis</li> <li>▪ Medical Affairs</li> <li>▪ Regulatory Affairs Support &amp; Health Authority Filings</li> <li>▪ Scientific Staffing</li> </ul> <p><b>Program Leadership and Management Services</b></p> <ul style="list-style-type: none"> <li>▪ Strategic Planning</li> <li>▪ PMO Design and Operationalization</li> <li>▪ Studies &amp; Analysis</li> <li>▪ Policy Development, Implementation, Administration</li> <li>▪ Regulatory Helpdesk Support</li> <li>▪ Survey and Benchmarking</li> <li>▪ Integrated Planning</li> <li>▪ Performance Management</li> <li>▪ External and Internal Communications &amp; Outreach</li> <li>▪ Program Reporting</li> <li>▪ Knowledge Management</li> <li>▪ Process Improvement</li> <li>▪ Financial Management</li> </ul>
<b>Functional Domains</b> <ul style="list-style-type: none"> <li>▪ Medical Supply Chain</li> <li>▪ Pharmaceutical Research</li> <li>▪ Pharmaceutical Quality and Regulatory</li> <li>▪ Financial Management</li> <li>▪ Logistics Management</li> </ul>	
<b>NAICS CODES</b> <ul style="list-style-type: none"> <li>▪ 541219 – Other Accounting Services</li> <li>▪ 541511 – Custom Computer Programming Services</li> <li>▪ 541512 – Computer Design and Integration</li> <li>▪ 541611 – Administrative &amp; General Management Consulting</li> <li>▪ 541614 – Process, Physical Distribution, &amp; Logistics Consulting Svcs</li> <li>▪ 541690 – Other Scientific and Technical Consulting Services</li> <li>▪ 541990 – All other Professional, Scientific &amp; Technical Consult Svcs</li> <li>▪ 561110 – Office Administrative Services</li> <li>▪ 611430 – Professional Training Development</li> </ul>	
<b>SELECTED PRIME VEHICLES</b> <ul style="list-style-type: none"> <li>▪ GSA MAS Professional Services Schedule (GS-00F-110GA)</li> <li>▪ GSA OASIS Plus Small Business and WOSB</li> <li>▪ Selected Agency-wide Contracts <ul style="list-style-type: none"> <li>– NIH-wide Office of Research Services (Scientific Cluster) Staffing BPA (\$45M/5-year)</li> <li>– NIH-wide Personal Property Services BPA (OLAO) (\$30M/5-year)</li> </ul> </li> </ul>	

## 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

### 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