SHABAS
Advise • Act • Achieve

EDWOSB CERTIFIED

9001:2015

ISO 9001:2015 CERTIFIED

CORPORATE OVERVIEW

Shabas Solutions, LLC ("Shabas") is a Virginia (USA)-based, specialist provider of **Quality Management Maturity (QMM)** Services to the Pharmaceutical Industry. As a scientific and management consulting provider, Shabas brings deep expertise in drug development R&D, drug manufacturing, stockpiling and distribution, quality assurance, and regulatory compliance. Our approach is informed by our experience leading the FDA QMM Pilot for Foreign API Manufacturers and complemented by the collective experience of SMEs who have extensive past affiliation with Big 4 Global Management Consulting firms, US and International Regulatory Authorities, Biologic and Small Molecule Drug Substance/Drug Product companies and Medical Device manufacturers.

Corporate Overview

- Headquartered in Fairfax, Virginia, USA
- US Government Approved Accounting System
- ISO 9001:2015 Certified Quality Management System
- DUNS: 178149998
- Primary NAICS: 541611
- Self-Funded and No Debt

Functional Domains

- Pharmaceutical Quality Management Maturity – Drug Product/Drug Substance (Small Molecule, Biologics) Manufacturers, CDMOs, Repackagers
- Pharma Quality and Regulatory Consulting

NAICS CODES

- 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
- 611430 – Professional Training Development

CORE SERVICE OFFERINGS – GOING BEYOND GMP

Quality Management Maturity Assessment Services

- Assessment Planning and Communication
- Assessment Execution
- Site Assessment Reporting
- Cross-Site Benchmarking
- Corporate Management Reporting

Quality Management Maturity Development Services

- Strategy and Planning Support
- Site Quality Management Process Re-engineering
- Site Business Management Process Re-engineering
- Policy and Procedure Development
- Quality Risk Management and Integration
- Training Development and Delivery
- Organizational Change Management
- Vendor Selection, Audits and Qualification
- Supplier and Customer Relationship Management
- Quality Compliance and Regulatory Consulting

FDA QMM PILOT EXPERIENCE

- US FDA engaged Shabas through a competitive selection process as a prime contractor to lead the QMM Pilot for API Manufacturers (non-US).
- Eight API manufacturers from South America, Europe and Asia volunteered for this initiative.
- Under FDA's guidance, Shabas conceptualized, developed and administered a QMM Assessment tool specifically designed for facilitated assessment of the API Manufacturers.
- Shabas facilitated assessments using its comprehensive QMM Assessment tool was well received by the pilot participants and was a factor in their positive views of the QMM program.

FDA QMM PILOT PARTICIPANT FEEDBACK

Examples of Participant Feedback

FDA

Pilot participant feedback shows positive sentiment for the program

The assessment results will be used for the improvement of processes and programs and for communication within the corporate organization.	*In the same way that QMM data is useful in assessing a potential API* supplier, the data could be useful in assessing a contract lab or other contract facility.*
We could envisage using the QMM score to reduce the frequency, content, and time spent on vendor audits.	*We will look at various behaviors/actions listed in each maturity level and strive to move to the next level.*

*API – Active Pharmaceutical Inaredient

www.fda.gov

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QMM RELATED PUBLICATION

- **Introduction to Pharmaceutical QMM Model: QMM Assessment to Promote Pharmaceutical Operational Excellence** *Published on: December 2, 2022, Somnath Mishra, William Hauck, Zachary Royal, Robert Michalik* ***Pharmaceutical Technology****, Pharmaceutical Technology, December 2022, Volume 46, Issue 12 Pages: 30–33*
- ***QMM for Pharmaceutical Manufacturers– Implications for Drug Manufacturers, API Suppliers and Contract Manufacturers*** *Published May 2,2023, Somnath Mishra, William Hauck , Zachary Royal, Robert Michalik*
- ***QMM Podcast,*** *August 9, 2023, Somnath Mishra, William Hauck , Zachary Royal, Robert Michali, www.shabas.net*

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