SHABAS
Advise • Act • Achieve

www.shabas.net
www.linkedin.com/company/shabas-solutions-llc

EDWOSB CERTIFIED

9001:2015

ISO 9001:2015 CERTIFIED

CORPORATE OVERVIEW – QMM Services

Shabas Solutions, LLC ("Shabas") is a Virginia-based provider of **Quality Management Maturity (QMM) services for the pharmaceutical industry**. Shabas brings deep scientific and management expertise in R&D, drug manufacturing, distribution, quality assurance, and regulatory compliance to our clients through consulting services. Our guidance is informed by experience leading the FDA QMM Pilot for Foreign API Manufacturers and complemented by the collective expertise of SMEs with extensive backgrounds in global management consulting firms, US/global regulatory authorities, small molecule drug, biologic, and medical device development and manufacturing.

Corporate Overview

- Headquarters in Fairfax, Virginia, USA
- Federally Approved Accounting System
- ISO 9001:2015 Certified QMS
- UEI Number: ZGLHPDKK5GP9
- CAGE: 4PAR3
- NAICS: 541611, 541614, 541690, 541990
- Privately owned and self-funded

Functional Domains

- Pharmaceutical QMM
  - Drug Product/Drug Substance (Small Molecule, Biologics) Manufacturers
  - CDMOs
  - Re-packagers
- Pharma Quality and Regulatory Consulting

CORE SERVICE OFFERINGS – GOING BEYOND COMPLIANCE!

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

QUALITY MANAGEMENT MATURITY EXPERIENCE

- US FDA engaged Shabas through competitive selection as a prime contractor to lead a QMM Pilot Program for 8 API manufacturing sites located globally in South America, Europe and Asia.
  - Shabas conceptualized, developed and administered a QMM Assessment Tool under FDA guidance designed for facilitated assessment of API Manufacturers.
  - Assessments were well received by the pilot participants, driving positive views of the QMM program and its benefits.
- QMM engagements with large-pharma clients including a top-ten global generic drug manufacturer.

RELATED PUBLICATIONS AND PRESENTATIONS

- *Michalik, R. & Hauck, W. (2024).* ***The FDA's Quality Management Maturity Program.*** *Regulatory Focus, A RAPS Publication. https://media.raps.org/m/3433e82ee0098c95/original/24-7_Michalik-et-al.pdf*
- *Mishra, S., Hauck, W., Schultz, C., Royal, Z., Michalik, R.* ***QMM for Pharmaceutical Manufacturers– Implications for Drug Manufacturers, API Suppliers and Contract Manufacturers.*** *Pharmaceutical Technology 2023 47 (5)*
- *Mishra, S., Hauck, W., Royal, Z., Michalik, R.* ***Introduction to Pharmaceutical QMM Model: QMM Assessment to Promote Pharmaceutical Operational Excellence.*** *Pharmaceutical Technology 46 (12) pp. 30–33 (2022)*
- ***QMM Podcast,*** *August 9, 2023, Somnath Mishra, William Hauck , Zachary Royal, Robert Michalik, www.shabas.net*
- ***QMM Presentation at Quality Innovations Summit,*** *American Society for Quality (Sep 21,2023) W. Hauck/S. Mishra*

POC: Somnath Mishra, 11166 Fairfax Blvd # 310 | Fairfax, VA 22030 | 703.763.7685 Ex.101| Somnath.Mishra@Shabas.net