

Capability Statement

Company Overview

Shaarkview Consultancy is a global consulting firm providing professional services to Pharmaceutical, Medical Device, Food Products, Banking, and other regulated and quality-driven industries.

The organization focuses on enabling clients to achieve sustainable **Quality Excellence, Quality Strategy, and Quality Culture**, while ensuring regulatory compliance and operational efficiency.

Our approach combines **practical industry experience, regulatory expertise, data-driven decision making, and leadership-focused quality transformation** to support organizations across the product and service lifecycle.

Company Information

- **Company Name:** Shaarkview Consultancy (OPC) Private Limited
- **Services:** Consulting | Auditing | Training | Coaching | Project Management | Data Science
- **Industries Served:** Pharmaceuticals | Medical Devices | Food Products | Banking | Other Industries
- **Delivery Model:** Global (Remote Hybrid & On-site)



Differentiators

- Strong focus on **Quality Excellence, Strategy, and Culture**
- Combination of **industry experience, regulatory knowledge, and data science capability**
- **Practical and implementation-oriented** consulting approach
- Experience across **multiple regulated industries**
- **Global delivery capability** with flexible engagement models
- **Training and consulting** aligned with real-world operational challenges

Regulatory & Standards Expertise

- US FDA 21 CFR regulations
- ICH Guidelines
- WHO GMP
- EMA and PIC/S requirements
- Health Canada GMP
- CDSCO requirements
- TGA requirements
- ISPE
- ISO 9001, ISO 13485, ISO 14001
- ISO 19011 auditing guidelines
- IPEC requirements
- **Inspections' Exposure:** USFDA, WHO, EU, MHRA, TGA, Canada, CDSCO etc.

Geographic Coverage

- Provides services **globally across Asia, North America, Europe, Australia, Latin America & Africa**
- Services are delivered through **remote, hybrid, and on-site** engagement models based on client requirements

Core Competencies

Training & Coaching

- GxP/ Quality/ compliance
- ASQ/ RAC professional certifications
- Lean Six Sigma Yellow, Green, and Black Belt
- Quality cultural excellence
- Auditor training

Quality Auditing

- Manufacturing site audits
- Supplier and vendor audits
- Warehouse/ distribution center audits
- Internal audits
- Independent third-party compliance audits

Quality Excellence & Quality Strategy

- Quality transformation and quality maturity programs
- Development and deployment of Quality Strategy
- Quality Culture assessment and implementation
- Leadership engagement and quality governance frameworks

Inspection & Audit Readiness

- Regulatory inspection readiness programs
- Mock inspections and gap assessments
- Inspection response and remediation support
- CAPA effectiveness and sustainable compliance solutions

Consulting

- Quality Management Systems (QMS)
- Compliance & Regulatory Consulting
- Operational Excellence & Improvement
- Project Management
- Data Science
- Others, as needed by clients

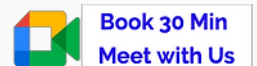


Contact Information

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Capability Statement

Leadership Profile



- A seasoned **professional, Trainer, Auditor, Data Scientist, Lean Six Sigma Practitioner and Consultant** providing consulting services to Pharmaceutical/ Medical Devices/ Food Products/ Other industries.
- **ASQConnex Expert, CMQ/OE, CPGP, CQA, CQE, CMDA, CSQE** and **CSSGB** by American Society for Quality (ASQ).
- Vice Chair (VC) Member eEngagement - ASQ Quality Management Division Community.
- VoC Chair- ASQ Customer-Supplier Division Community.
- Leader of Community of Excellence, Drugs- ASQ Food, Drug, and Cosmetic Division
- **RAC-Drugs** and **RAC- Devices** holder from Regulatory Affairs Professional Society (RAPS).
- **PMP** by Project Management Institute (PMI).
- Certified Lean Six Sigma Black Belt (**LSSBB**) by The Council for Six Sigma Certification (CSSC).
- **Certified ISO 13485 Internal Auditor** by DQS (Deutsch Quality Systems).
- 23+ years of experience in the areas of Production & Quality Assurance in GxP Industry. Previously worked with Abbott, Ipca, Dr. Reddy's, Mylan (Viatris), Alembic and Aurobindo.
- MS in Data Science from Eastern University, USA in 2024; M. Sc. in Chemistry from MP Bhoj (Open) University, India in 2006; and B. Sc. in Chemistry from Andhra University, India in 2002.
- LinkedIn : <https://www.linkedin.com/in/seetharamkandarpa/>

Purpose of Career: Learning Unknown, Helping Community & Earning Respect

Seetharam (Ram) Kandarpa,

ASQ ConnEx Expert, ASQ CMQ/OE, ASQ CQA, ASQ CQE, ASQ CMDA, ASQ CSQE, ASQ CPGP, ASQ CSSGB, RAC Drugs, RAC Devices, PMP, LSSGB



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