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 | Date 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 17025
- 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

SHAARKVIEW™ CONSULTANCY

Contact Information

Dr. Seetharam (Ram) Kandarpa
Founder & Director

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Capability Statement

Leadership Profile



Dr. Seetharam (Ram) Kandarpa,

DBA, MS Data Science, ASQ ConnEx Expert, ASQ Instructor, ASQ CMQ/OE, ASQ CQE, ASQ CQA, ASQ CMDA, ASQ CPGP, ASQ CFSQA, ASQ CSQP, ASQ CSQE, ASQ CSSGB, PMP, RAC Drugs, RAC Devices, LSSBB

- 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, ASQ Instructor, CMQ/OE, CPGP, CQA, CMDA, CFSQA, CQE, CSQP, CSQE and CSSGB by American Society for Quality (ASQ).
  - Vice Chair (VC) Member eNgagement - 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.
- Holds Doctorate in Business Administration (DBA) from The European Institute of Management and Technology (EIMT), Switzerland, MS in Data Science from Eastern University, USA, M. Sc. in Chemistry from MP Bhoj (Open) University, India and B. Sc. in Chemistry from Andhra University, India.
- LinkedIn : https://www.linkedin.com/in/seetharamkandarpa/

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

ASQ ConnEx | ASQ Certified Manager of Quality/ Organizational Excellence | ASQ Certified Quality Auditor | ASQ Certified Medical Device Auditor | ASQ Certified Pharmaceutical GMP Professional | ASQ Certified Food Safety and Quality Auditor | ASQ Certified Quality Engineer | ASQ Certified Software Quality Engineer | ASQ Certified Supplier Quality Professional | ASQ Certified Six Sigma Green Belt | Black Belt Certified | PMP Professional Certification | RAPS RAC Devices | RAPS RAC Drugs

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