

Capability Statement

Company Overview	Company Information	Differentiators	Regulatory & Standards Expertise	Geographic Coverage	
<p>Shaarkview Consultancy is a global consulting firm providing professional services to Pharmaceutical, Medical Device, Food Products, Banking, and other regulated and quality-driven industries.</p> <p>The organization focuses on enabling clients to achieve sustainable Quality Excellence, Quality Strategy, and Quality Culture, while ensuring regulatory compliance and operational efficiency.</p> <p>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.</p>	<ul style="list-style-type: none">Company Name: Shaarkview Consultancy (OPC) Private LimitedServices: Consulting Auditing Training Coaching Project Management Data ScienceIndustries Served: Pharmaceuticals Medical Devices Food Products Banking Other IndustriesDelivery Model: Global (Remote Hybrid & On-site) 	<ul style="list-style-type: none">Strong focus on Quality Excellence, Strategy, and CultureCombination of Industry experience, regulatory knowledge, and data science capabilityPractical and implementation-oriented consulting approachExperience across multiple regulated industriesGlobal delivery capability with flexible engagement modelsTraining and consulting aligned with real-world operational challenges	<ul style="list-style-type: none">US FDA 21 CFR regulationsICH GuidelinesWHO GMPEMA and PIC/S requirementsHealth Canada GMPCDSCO requirementsTGA requirementsISPEISO 9001, ISO 13485, ISO 14001ISO 19011 auditing guidelinesIPEC requirementsInspections' Exposure: USFDA, WHO, EU, MHRA, TGA, Canada, CDSCO etc.	<ul style="list-style-type: none">Provides services globally across Asia, North America, Europe, Australia, Latin America & AfricaServices are delivered through remote, hybrid, and on-site engagement models based on client requirements	
Core Competencies					
	Training & Coaching <ul style="list-style-type: none">GxP/ Quality/ complianceASQ/ RAC professional certificationsLean Six Sigma Yellow, Green, and Black BeltQuality cultural excellenceAuditor training	Quality Auditing <ul style="list-style-type: none">Manufacturing site auditsSupplier and vendor auditsWarehouse/ distribution center auditsInternal auditsIndependent third-party compliance audits	Quality Excellence & Quality Strategy <ul style="list-style-type: none">Quality transformation and quality maturity programsDevelopment and deployment of Quality StrategyQuality Culture assessment and implementationLeadership engagement and quality governance frameworks	Inspection & Audit Readiness <ul style="list-style-type: none">Regulatory inspection readiness programsMock inspections and gap assessmentsInspection response and remediation supportCAPA effectiveness and sustainable compliance solutions	Consulting <ul style="list-style-type: none">Quality Management Systems (QMS)Compliance & Regulatory ConsultingOperational Excellence & ImprovementProject ManagementData ScienceOthers, as needed by clients



Contact Information

Seetharam Kandarpa
Founder & Director

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Capability Statement



Seetharam Kandarpa,

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

Leadership Profile

- A seasoned **professional, Trainer, Auditor, Data Scientist and Consultant** providing consulting services to Pharmaceutical/ Medical Devices/ Food Products/ Other industries.
- **ASQConnex Expert, CMQ/OE, CPGP, CQA, CMDA, 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 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, Ipcra, 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



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