



Training Course on "Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits"

## Seetharam Kandarpa,

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

Founder & Director- Shaarkview Consultancy (OPC) Private Limited

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## Introduction

## Objective

 To provide a brief overview of Training Course on "Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits"

## Scope

• This course is useful to the organizations that are intending to enrich their employees' competencies related to ISO 19011:2018 to achieve auditing excellence.

## Introduction of Trainer



Seetharam Kandarpa Founder & Director-Shaarkview Consultancy (OPC) Private Limited Ph: +91-9892968049 seetharam.kandarpa@shaarkview.com www.shaarkview.com









- A seasoned professional, Trainer, Auditor, Data Scientist and Consultant providing consulting services to Pharmaceutical/ Medical Devices/ Food Products/ Other industries.
- ASOConnex Expert, CMO/OE, CPGP, COA, CMDA, CSOE and CSSGB by American Society for Quality (ASQ).
- CMC Lead for Customer Focused Organizations- ASQ Quality Management Division Community
- VoC Chair- ASQ Customer-Supplier Division Community
- Education Committee Member- ASQ Human Development & Leadership 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)
- 21+ 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/























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## **ASQConnex Expert Profile**

## **About ASQ ConnEx:**



ASQConnEx is an education delivery system and network that vets, designates, and connects quality subject matter experts with organizations to advance their excellence journey. Organizations can build competencies needed to achieve strategic objectives by engaging a vast network of ASQ-authorized subject matter experts in the field of quality. Experts gain a professional advantage by aligning with the world's leading quality association and gaining access to ASQ-licensed education and certification preparation content. The end result- Empowering individuals, organizations, and communities to achieve excellence through quality.

For more details, refer <a href="https://asq.org/asqconnex">https://asq.org/asqconnex</a>

# **ASQConnex Expert Profile**



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## SEETHARAM KANDARPA CPGP, CQA, CMQ/OE, CSSGB, CMDA, CSQE



#### REQUEST PROPOSAL

#### ADD TO COMPARISON LIST

#### Education

M. Sc.

Madhya Pradesh Bhoj (Open) University Bhopal, India

B. Sc.

Andhra University Kakinada, India

Master of Science (MS) Eastern University Philadelphia, USA

#### Industries

Business & Professional Services - Consulting, Engineering, Human

Hesources

Healthcare - Medical Devices/Pharmaceuticals
Healthcare - Services, Providers, Supplies
Technology, Equipment/Software & Services

Technology - Equipment/Software & Services

#### Languages

English

#### Travel Preferences

Internationa

ASQConnEx Credentials & Certifications



#### Professional Experience

Seetharam Kandarpa is a seasoned Professional, Trainer, Auditor, Data Scientist and Consultant providing consulting services to Pharmaceutical/ Medical Devices/ Other GxP industries. Seetharam is Founder & Director of SHAARKVIEW CONSULTANCY (www.shaarkview.com).

Seetharam did 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. He holds various professional certifications such as CMQ/OE, CPGP, CQA, CMDA, CSQE, CSSGB from ASQ; Regulatory Affairs Certified (RAC-Drugs and RAC- Devices) from Regulatory Affairs Professional Society (RAPS); Certified Project Management Professional (PMP) by Project Management Institute (PMI) and Certified ISO 13485 Internal Auditor by DQS (Deutsch Quality Systems).

Seetharam has over 21 years of industrial experience in the areas of Production & Quality Assurance in GxP Industry in various leadership positions with major companies such as Abbott, Ipca, Dr. Reddy's, Mylan (Viatris), Alembic and Aurobindo. He has a versatile experience in complying various regulations/ standards such as 21 CFR, ICH, IVHO, EMA, PIC/S, Canada GMP, TGA, GAMP5, ISO 9001, ISO 13485 and ISO 19011 etc. He has experience in conducting, as Lead Auditor, audits of GxP sites, dealing with quality system elements such as personnel training, quality risk management, deviation, change control, internal audits, supplier management, management review, complaints, recall, CAPA etc. and working with GXP software applications such as TrackWise, ISOtrain, SumTotal, myProcess, API VR training programs.

Seetharam has a rich experience in conducting training programs & presenting in professional seminars/ conferences across the world. He has proven expertise in dealing with large geographically and culturally diverse teams.

Seetharam's Purpose of Career: "Learning Unknown, Helping Community & Earning Respect".

#### **Current Courses**

Auditing for Improved Supplier Performance

Corrective and Preventive Action

Certified Manager of Quality/Organizational Excellence Certification Preparation

Certified Quality Auditor Certification Preparation

Introduction to Supplier Management

Quality/Engineering Tools for Supplier Management

Supplier Quality Professional: An Introduction



# **ASQ Certifications**

#### Seetharam Kandarpa

has satisfactorily fulfilled the requirements established by ASQE for professional attainment of the

CERTIFIED MANAGER OF QUALITY/ ORGANIZATIONAL EXCELLENCE

Date Issued: **September 12, 2017** Expiration Date: **June 30, 2027** 







**VERIFIED CERTIFICATE** 

Certificate Number: 54772



### **Seetharam Kandarpa**

has satisfactorily fulfilled the requirements established by ASQE for professional attainment of the

CERTIFIED PHARMACEUTICAL GMP PROFESSIONAL

Date Issued: June 7, 2014

Expiration Date: June 30, 2027







VERIFIED CERTIFICATE

Certificate Number: 381







# **ASQ Certifications**

#### **Seetharam Kandarpa**

has satisfactorily fulfilled the requirements established by ASQE for professional attainment of the

#### **CERTIFIED QUALITY AUDITOR**

Date Issued: December 6, 2014 Expiration Date: June 30, 2027







Certificate Number: 49009



### **Seetharam Kandarpa**

has satisfactorily fulfilled the requirements established by ASQE for professional attainment of the

#### CERTIFIED MEDICAL DEVICE AUDITOR

Date Issued: November 24, 2021 Expiration Date: June 30, 2027







**VERIFIED CERTIFICATE** 

Certificate Number: 2130



Steven Wilson, ASQE Chair

# **ASQ Certifications**

#### Seetharam Kandarpa

has satisfactorily fulfilled the requirements established by ASQE for professional attainment of the

## CERTIFIED SOFTWARE QUALITY ENGINEER

Date Issued: October 27, 2023

Expiration Date: December 31, 2027







VERIFIED CERTIFICATE

Certificate Number: 6871



### **Seetharam Kandarpa**

has satisfactorily fulfilled the requirements established by ASQE for professional attainment of the



Date Issued: December 10, 2018









## **RAPS Certifications**





## **PMP & Other Certifications**





# Overview of Training Course on "Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits"



# "Auditing Excellence: Navigating ISO 19011:2018" by Shaarkview Consultancy

• Training Course by Seetharam Kandarpa, Shaarkview [1]

Format: Live Virtual/ Face-to-Face



### **Learning Objectives:**

- Audit Principles: The principles that form the basis for effective auditing (internal and external audit)
- Managing an Audit Program: Guidelines for establishing and managing an audit program.
- Conducting Audits: Steps and procedures for planning, executing, and reporting audits.
- Competence and Evaluation of Auditors: Criteria for auditor competence and evaluation.

#### Who Should Attend:

- All stakeholders involve in audit programme- Auditor (internal or external auditor), Auditee, Client,
   Observer, Technical Expert, Guide & others.
- QA, QC, Production, Engineering, Warehouse & Others.

Training class size: Not more than 15 persons (internal auditors/ external auditors/ auditees)



# "Auditing Excellence: Navigating ISO 19011:2018" by Shaarkview Consultancy

• Training Course by Seetharam Kandarpa, Shaarkview [1]

#### **Course Outline:**

- This course covers majorly:
  - Brief introduction of ISO 19011:2018
  - Different Types of Audits (1st/2nd/3rd party)
  - Terms and Definitions
  - Principles of Auditing
  - Managing an Audit Programme
  - Conducting an Audit
  - Competence and Evaluation of Auditors

## **Training methodology:**



- Highly interactive and practical learning with case studies & group activities
- Post test to assess the attendees' learning at the end of the course
- Issuance of training completion certificate to attendees (with Shaarkview and Customer's management signatures).

At the end of the course, students can be able to have a decent understanding on the usage and application of ISO 19011:2018 standard into their routine area of audit programme to achieve organizational excellence.

# "Auditing Excellence: Navigating ISO 19011:2018" by Shaarkview Consultancy

Training Course by Seetharam Kandarpa, Shaarkview [1]

Format: Live Virtual/ Face-to-Face

Course Duration: 8 hours (1 day)

Training Days: 1- Weekday (Mon/Tue/Wed/Thu/Fri), 09.00 to 18.00 Hr

Language of Instruction: English

Instructor: Seetharam Kandarpa

Training Fee for Organization specific training (not more than 15 students) for Face-to-Face or Live Virtual training program: <u>Contact Us</u>

# "CQA Certification Preparation (ASQ ConnEx Course)" by Shaarkview Consultancy

## Training Course by Seetharam Kandarpa, Shaarkview [1]

#### **Procedure for Training program:**

- 1. Purchase agreement between Shaarkview and the Organization.
- 2. Finalization of training date and list of students (name, mail id etc.)
- 3. Training material: PDF copy of training presentation, case studies, training exam questionnaire, training completion certificate etc. will be shared before the commencement of training session to organize printed copy to attendees as training material.
- 4. Conduiting training program as agreed.
- 5. Post test to assess the attendees' learning at the end of the course.
- 6. Issuance of training completion certificate to attendees (with Shaarkview and Customer's management signatures).









# Thank You



## Seetharam Kandarpa,

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

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