



# 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**

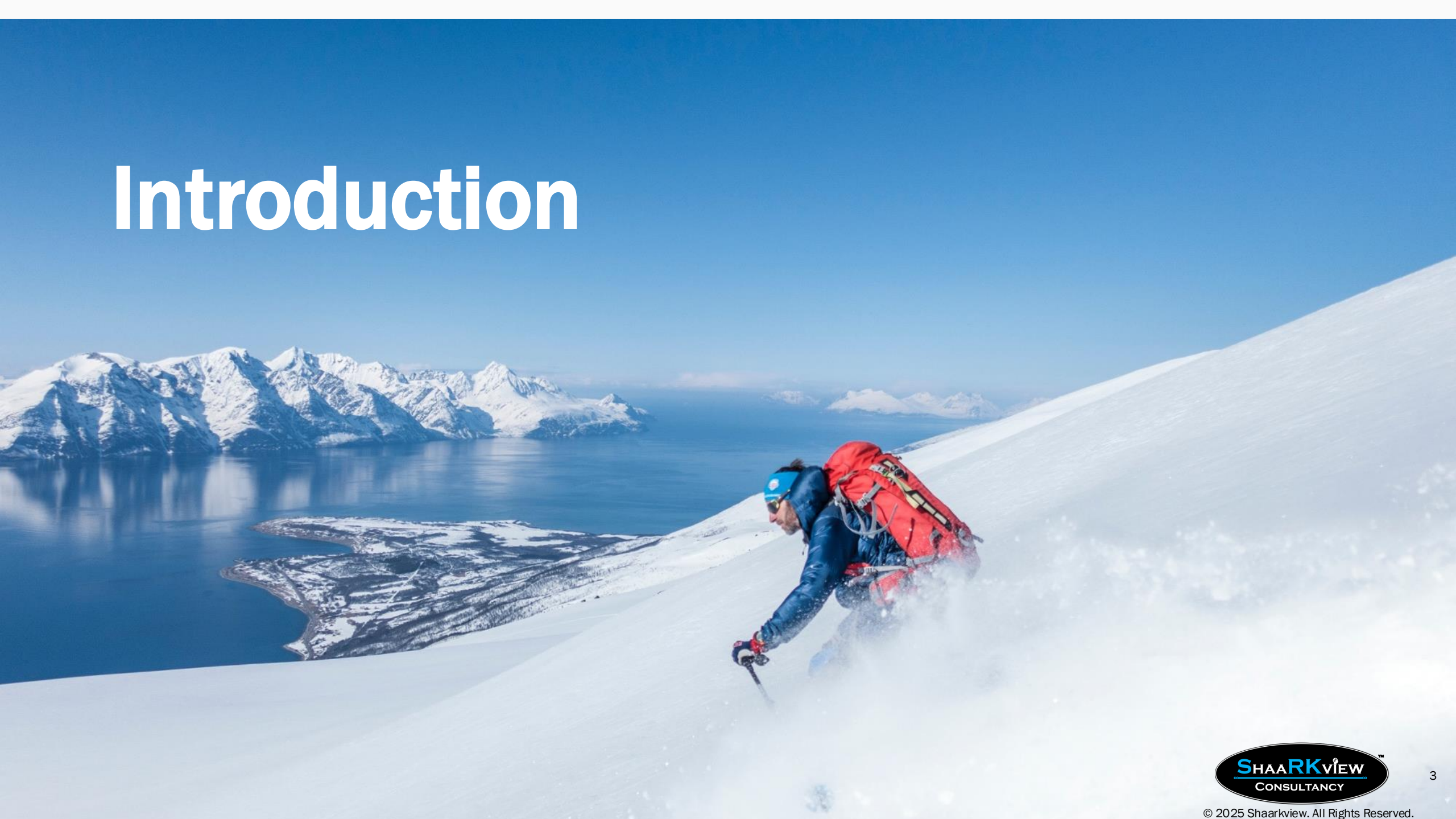
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# Introduction



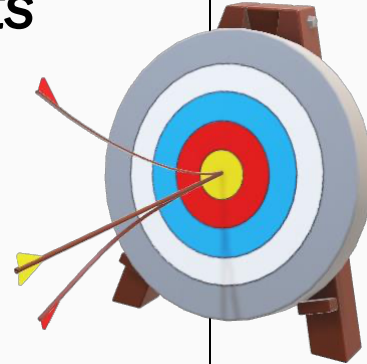
# Introduction

- **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](mailto:seetharam.kandarpa@shaarkview.com)

[www.shaarkview.com](http://www.shaarkview.com)



- A seasoned professional, Trainer, Auditor, Data Scientist and Consultant providing consulting services to Pharmaceutical/ Medical Devices/ Food Products/ Other industries.
- **ASQConnex Expert, CMO/OE, CPGP, COA, CMDA, CSQE and CSSGB** by American Society for Quality (ASQ).
- Vice Chair (VC) Member eNgage - 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).
- 22+ years of experience in the areas of Production & Quality Assurance in GxP Industry. Previously worked with Abbott, Ipca, Dr. Reddy's, Mylan (Viatrix), 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

# Introduction of Trainer



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- We, at Shaarkview Consultancy, provide consulting services to Pharmaceutical/ Medical Devices/ Food Products/ Other industries majorly aiming on:
  - Quality Strategy/ Quality Culture
  - GxP Training / Coaching for ASQ/ RAC certifications
  - Quality Audits (manufacturing sites/ vendors/ warehouses/ distribution centres etc.)
  - Inspection/ Audit Readiness, Inspection Response and Remediation Support
  - Quality Management Systems: Quality Risk Management, Change management, Deviation Management, CAPA, Vendor Management, Qualification & Validation, Software Quality Engineering etc.
  - Compliance consultation
  - Quality Improvements/ Lean Management/ Cost of Quality
  - Project Management
  - Regulatory Affairs Strategies
  - Data Science and Analytics
  - Others as needed by Clients
- Our services are available across Asia, North America, Europe, Australia, Latin America and Africa.



# ASQConnex Expert Profile

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MENU



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

## Languages

English

## Travel Preferences

International

## 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](http://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, WHO, EMA, PIC/S, Canada GMP, TGA, GAMP5, ISO 9001, ISO14001, 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, AR/ 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



# 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 <https://asq.org/asqconnex>

# 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**



**ASQE™**  
Inspire Excellence

**VERIFIED CERTIFICATE**  
Certificate Number: 54772



Steven Wilson, ASQE Chair

**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**



**ASQE™**  
Inspire Excellence

**VERIFIED CERTIFICATE**  
Certificate Number: 381



Steven Wilson, ASQE Chair

# 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**



**VERIFIED CERTIFICATE**  
Certificate Number: 49009



Steven Wilson, ASQE Chair



**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



Steven Wilson, ASQE Chair



**Seetharam Kandarpa**

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

**CERTIFIED SIX SIGMA GREEN BELT**

Date Issued: **December 10, 2018**



**VERIFIED CERTIFICATE**  
Certificate Number: 19526



Steven Wilson, ASQE Chair



# RAPS Certifications

RAPS Institute  
Regulatory Affairs Certification (RAC)



**Seetharam Kandarpa**

Is hereby recognized as a **RAC-Drugs** certified professional for the three-year period starting on 4/16/2022 and ending on 06/30/2028

Certified since 12/15/2019



Linda Bowen  
RAPS Institute Chair



Emily Nesbitt  
RACB Chair

RAPS Institute  
Regulatory Affairs Certification (RAC)



**Seetharam Kandarpa**

Is hereby recognized as a **RAC-Devices** certified professional for the three-year period starting on 4/16/2022 and ending on 06/30/2028

Certified since 04/16/2022



Linda Bowen  
RAPS Institute Chair



Emily Nesbitt  
RACB Chair

# PMP & Other Certifications



**PMI** Project Management Institute.

THIS IS TO CERTIFY THAT

## 5 GGWJCTOO - CPFCTRC

HAS BEEN FORMALLY EVALUATED FOR DEMONSTRATED EXPERIENCE, KNOWLEDGE AND PERFORMANCE IN ACHIEVING AN ORGANIZATIONAL OBJECTIVE THROUGH DEFINING AND OVERSEEING PROJECTS AND RESOURCES AND IS HEREBY BESTOWED THE GLOBAL PROFESSIONAL CERTIFICATION

### Project Management Professional (PMP)<sup>®</sup>

IN TESTIMONY WHEREOF, WE HAVE SUBSCRIBED OUR SIGNATURES UNDER THE SEAL OF THE INSTITUTE

*Ike Nwankwo*  
Ike Nwankwo, PMP | Chair, Board of Directors



*Pierre Le Manh*  
Pierre Le Manh | President & CEO

Certification Number: 3263387      Original Grant Date: 30 June 2022      Expiration Date: 30 June 2028



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No.: KSC/Q3/0920/06

## Certificate

This is to certify that

### Mr. SEETHARAM KANDARPA

has successfully completed in the two-days session on

### ISO 13485 Internal Auditor Training Program

Conducted by:

**DQS INDIA**  
(an affiliate of DQS Holding GmbH, Germany)

On 10<sup>th</sup> & 11<sup>th</sup> Sep 2020.

*Dr. K. Murugan*  
Dr. K. Murugan  
Managing Director & CEO, DQS India.

\*Registered as: Deutch Quality Systems (India) Private Limited, 5th Floor, Anjaneya Techno Park, 147 HAL Airport Road, Kodihalli, Bengaluru - 560 017, Karnataka, India. www.dqs-india.in

# 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)*

Source:

[1] “Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits”, shaarkview, <https://www.shaarkview.com/auditing-excellence-in-management-systems-audits>. Accessed on 19 Oct 2024.

# “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.*

Source:

[1] “Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits”, shaarkview, <https://www.shaarkview.com/auditing-excellence-in-management-systems-audits>. Accessed on 19 Oct 2024.

# “Auditing Excellence: Navigating ISO 19011:2018” by Shaarkview Consultancy

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



<b>Format:</b>	Live Virtual/ Face-to-Face
<b>Course Duration:</b>	8 hours (1 day)
<b>Training Days:</b>	1- Weekday (Mon/Tue/Wed/Thu/Fri), 09.00 to 18.00 Hr
<b>Language of Instruction:</b>	English
<b>Instructor:</b>	Seetharam Kandarpa

Training Fee for Organization specific training (not more than 15 students) for Face-to-Face or Live Virtual training program: [Contact Us](#)

Source:

[1] “Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits”, shaarkview, <https://www.shaarkview.com/auditing-excellence-in-management-systems-audits>. Accessed on 19 Oct 2024.

# “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. Conducting 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).



Source:

[1] “Auditing Excellence: Navigating ISO 19011:2018 for Effective Management System Audits”, shaarkview, <https://www.shaarkview.com/auditing-excellence-in-management-systems-audits>. Accessed on 19 Oct 2024.

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# Thank You



**Seetharam Kandarpa,**

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