



Training Course on "Corrective and Preventive Action (ASQ ConnEx Course)"

Seetharam Kandarpa,

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

Founder & Director- Shaarkview Consultancy (OPC) Private Limited

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• Overview of Training Course on "Corrective and Preventive Action (ASQ ConnEx Course)"





Introduction

Objective

 To provide a brief overview of Training Course on "Corrective And Preventive Action" (ASQ ConnEx Course)

Scope

 This course is useful to the organizations that are intending to enrich competencies of their employees on Corrective and Preventive Action.

Introduction of Trainer



Seetharam Kandarpa
Founder & DirectorShaarkview Consultancy
(OPC) Private Limited
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seetharam.kandarpa@shaarkview.com

in



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, 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).
- 22+ 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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Introduction of Trainer



Founder & Director-Shaarkview Consultancy (OPC) Private Limited

Ph: +91-9892968049 seetharam.kandarpa@shaarkview.com www.shaarkview.com









- 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



1 / ASQConnEx / Find an Expert / Seetharam Kandarpa



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

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



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







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

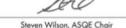






VERIFIED CERTIFICATE

Certificate Number: 381





ASQ Certifications

Seetharam Kandarpa

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



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







VERIFIED CERTIFICATE

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









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 Comily Destitle

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

Comily Destitl

Emily Nesbitt RACB Chair

PMP & Other Certifications





Overview of Training Course on "Corrective and Preventive Action (ASQ ConnEx Course)"



Training Course by Seetharam Kandarpa, Shaarkview [1]

Format: Live Virtual/ Face-to-Face



- Get an in-depth understanding of how to conduct corrective & preventive action (CAPA) in response to non-conforming product or services.
- Learn how to define the problem, assess conditions for root causes, define proper actions to contain and prevent the problem, and then develop a plan to deploy those actions. Common methods, including the 8D approach, are covered and tools for performing incident and root cause analysis, and the use of various CAPA checklists, are provided.
- Use both case studies and participant situations to apply the methods, tools and checklists during the course. Go away with a thorough understanding of a systematic, tool-based CAPA system.

Training Course by Seetharam Kandarpa, Shaarkview [1]

Learning Objectives:



- Learn the vital quality principles that drive proper CAPA.
- Determine when to initiate formal corrective action, and when not to.
- Write clear and actionable problem statements.
- Explore sample CAPA systems and records for best practices, and for potential weaknesses.
- Learn how to use a team approach to CAPA.
- Use various tools to perform process-based root cause analysis.
- Develop detailed actions to contain and prevent the problem.
- Identify opportunities for improvement in the participant's organization that can be acted upon after the course.

Who Should Attend:

• This course is designed for quality managers, production supervisors, account managers, purchasing staff, quality technicians, and owners of a company's CAPA system.



• Training Course by Seetharam Kandarpa, Shaarkview [1]



Course Outline:

- I. Introductions & Goal Setting
- II. Taking a "quality-in" approach
 - 1. Benefits and key principles
 - 2. Self-assessment on "quality-in" behaviors
- III. Key concepts of CAPA
 - 1. What is the root cause standard?
 - 2. 5 Whys
 - 3. Poka Yoke
 - 4. Selecting proper root cause countermeasures
 - 5. Getting buy-in from others for CAPA discipline

IV. Using the 8D approach to CAPA

- 1. Main steps of 8D
- 2. Checklists for key stages
- 3. When to close an open CAPA
- 4. Tips and recommendations for success

V. Application

- 1. Case studies
- 2. Participant situations



• Training Course by Seetharam Kandarpa, Shaarkview [1]

Format: Live Virtual/ Face-to-Face

ASQ CONNEX*

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 (ASQConnex Expert)

ASQ RU (Recertification Units): under Continuing Education

- 0.7 RU for Face-to-Face training
- 0.7 RU for Live Virtual training

Training Fee for Organization specific training (of 6-15 students) for Face-to-Face or Live Virtual training program: <u>Contact Us</u>

• Training Course by Seetharam Kandarpa, Shaarkview [1]

Procedure for Training program:



- 1. Purchase agreement between Shaarkview and the Organization.
- 2. Finalization of training dates and list of students (name, mail id etc.)
- Details of students will be shared by Shaarkview with ASQ, USA for processing the training request.
- 4. Students will receive instructions to receive/ download the training material from ASQ, USA team through mail before 1 week of training class
- 5. Students will attend the training class (all sessions without fail).
- 6. Students will download training completion certificate from ASQ website after getting clearance from ASQ, USA team.



Thank You



Seetharam Kandarpa,

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