Training Course on "Current Good Manufacturing Practice for Finished Pharmaceuticals: 21 CFR 210 & 211"

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

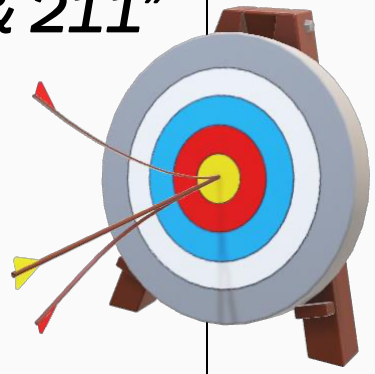
Contents

Introduction

SHAARKVIEW CONSULTANCY

Introduction

- **Objective**
  - To provide a brief overview of Training Course on ***"Current Good Manufacturing Practice for Finished Pharmaceuticals: 21 CFR 210 & 211"***



- **Scope**
  - This course is useful to the organizations that are intending to enrich their employees' competencies related to Current Good Manufacturing Practice for Finished Pharmaceuticals: 21 CFR 210 & 211.

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.
- 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/

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

MENU

/ ASQConnEx / Find an Expert / Seetharam Kandarpa

SEETHARAM KANDARPA

CPGP, CQA, CMQ/OE, CSSGB, CMDA, CSQE

ASQConnEx™

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).

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

SHAARKVIEW CONSULTANCY

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

ASQ Certifications

ASQ Certifications

RAPS Certifications

PMP & Other Certifications

Project Management Institute

THIS IS TO CERTIFY THAT

5GGWJCTCO - 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)®

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

Ike Nwankwo, PMP | Chair, Board of Directors

Pierre Le Manh | President & CEO

Certification Number: 3263387

Original Grant Date: 30 June 2022

Expiration Date: 30 June 2028

DQS MANAGEMENT SYSTEMS SOLUTIONS

Knowledge Solution Centre

... Experience the Global Experience

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 10th & 11th Sep 2020.

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

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

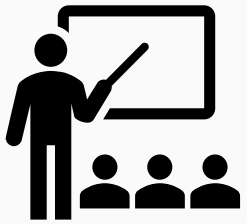
SHAARKVIEW CONSULTANCY

Overview of Training Course on “Current Good Manufacturing Practice for Finished Pharmaceuticals: 21 CFR 210 & 211”

SHAARKVIEW CONSULTANCY

“Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211” by Shaarkview Consultancy

- **Training Course by Seetharam Kandarpa, Shaarkview [1]**



Format: Live Virtual/ Face-to-Face

Learning Objectives:

- Dive deep into the nuances of pharmaceutical manufacturing regulations focused on the USFDA’s 21 CFR 210 & 211.
- Complete breakdown from the general provisions to records and reports.
- Insights into the control of components, packaging, labeling, and more.
- Practical understandings of the regulations.

Who Should Attend:

- All stakeholders involve in cGMP activities in pharmaceutical product manufacturing as per 21 CFR 210 & 211.
- QA, QC, Production, Engineering, Warehouse & Others.

Training class size: *Not more than 15 persons*

Source:
[1] “Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211”, *shaarkview,* https://www.shaarkview.com/cgmp-21cfr210-211. Accessed on 18 Nov 2024.

“Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211” by Shaarkview Consultancy

- Training Course by Seetharam Kandarpa, Shaarkview [1]

Course Outline:

- This course covers majorly:
  - Overview of 21 CFR Part 210 & 211
  - Subpart A – General Provisions
  - Subpart B – Organization and Personnel
  - Subpart C – Buildings and Facilities
  - Subpart D – Equipment
  - Subpart E – Control of Components and Drug Product Containers and Closures
  - Subpart F – Production and Process Controls
  - Subpart G – Packaging and Labeling Control
  - Subpart H – Holding and Distribution
  - Subpart I – Laboratory Controls
  - Subpart J – Records and Reports
  - Subpart K – Returned and Salvaged Drug Products

Source:
[1] “Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211”, *shaarkview,* https://www.shaarkview.com/cgmp-21cfr210-211. Accessed on 18 Nov 2024.

“Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211” by Shaarkview Consultancy

- **Training Course by Seetharam Kandarpa, Shaarkview [1]**

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 requirements of Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211.

Source:
[1] “Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211”, *shaarkview,* https://www.shaarkview.com/cgmp-21cfr210-211. Accessed on 18 Nov 2024.

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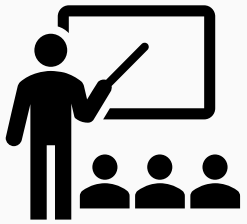

Format: Live Virtual/ Face-to-Face

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: *Contact Us*

Source:
[1] “Current GMP for Finished Pharmaceuticals: 21 CFR 210 & 211”, *shaarkview,* https://www.shaarkview.com/cgmp-21cfr210-211. Accessed on 18 Nov 2024.

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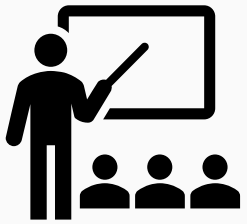
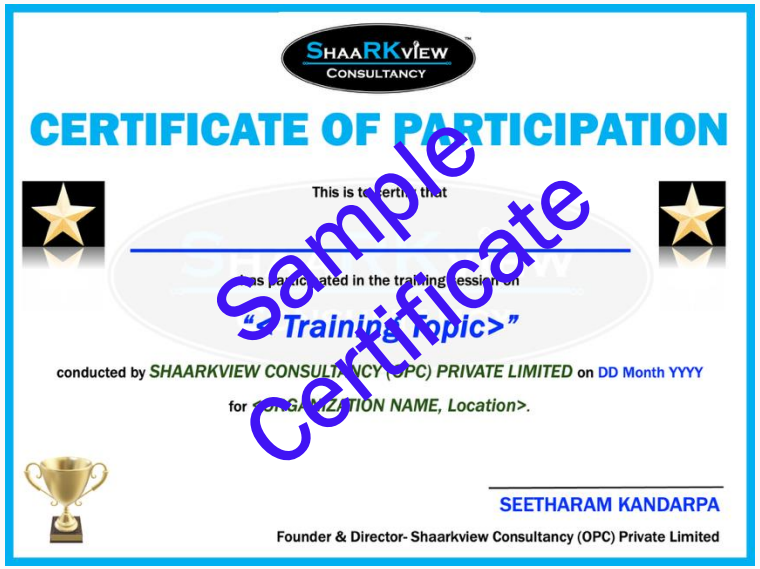


Procedure for Training program:

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).



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Back to Contents

Thank You

Seetharam Kandarpa,

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