SHAARKVIEW CONSULTANCY™

Overview of "Pharmaceutical GMP Professional Certification (CPGP) Program"

Seetharam Kandarpa,

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

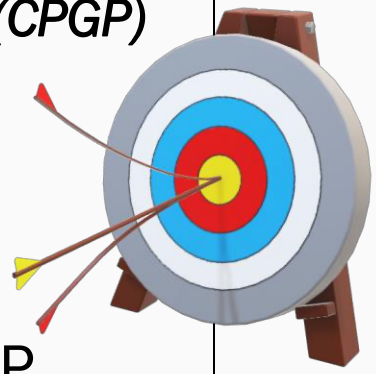
Founder & Director- Shaarkview Consultancy

Contents

Introduction

Welcome

- **Objective**
  - To provide a brief overview of
    - ***Pharmaceutical GMP Professional Certification (CPGP)*** Program (*WHAT, WHY, WHERE, WHEN, WHO and HOW*).
    - Training Course on ***"Certified Pharmaceutical GMP Professional Certification (CPGP) Preparation Course"***



- **Scope**
  - This presentation is useful to those who are aspiring to attempt CPGP exam to become Certified Pharmaceutical GMP Professional Certification.

Introduction of Trainer

Seetharam Kandarpa
Founder & Director-
Shaarkview Consultancy (OPC) Private Limited
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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).
- 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/

Purpose of Career:

Learning Unknown, Helping Community & Earning Respect

ASQ Certifications

ASQ Certifications

ASQ Certifications

RAPS Certifications

PMP & Other Certifications

Project Management Institute

THIS IS TO CERTIFY THAT

Seetharam Kandarpa

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 CREDENTIAL

Project Management Professional (PMP)®

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

Jennifer Tharp | Chair, Board of Directors

Mike DePrisco | Interim President & CEO

PMP® Number: 3263387

PMP® Original Grant Date: 30 June 2022

PMP® Expiration Date: 30 June 2025

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

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Overview of Pharmaceutical GMP Professional Certification (CPGP) Program

Overview of CPGP Certification Program

- **Basics**

  - The Certified Pharmaceutical GMP Professional Certification (ASQ CPGP) [1]
    - Understands the ***good manufacturing practices (GMP)*** as regulated and guided by national and international agencies for the pharmaceutical industry.
    - Covers finished human and veterinary drugs and biologics, ectoparasiticides, and dietary supplements (alternatively called nutraceuticals) where regulated as ***drug products,*** as well as their ***component raw materials*** (includes active pharmaceutical ingredients (APIs) and excipients), and ***packaging, and labeling operations***.

  - Pharmaceutical GMP Professional Certification Body of Knowledge (BoK) (PDF)
  - Pharmaceutical GMP Professional Certification Fact Sheet (PDF)

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq,* https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.

Overview of CPGP Certification Program

- Requirements and Education

REQUIREMENTS

5

Years of on-the-job experience in one or more areas of the Certified Pharmaceutical GMP Body of Knowledge.

3

***Years of on-the-job experience must be in a "Decision-making" position.**

Candidates must have worked in a full-time, paid role.

*A "Decision-making" position is defined as the authority to define, execute, or control projects/processes and to be responsible for the outcome. This may or may not include management or supervisory positions.

EDUCATION

- **There are no Education waivers for this exam.**

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.

Overview of CPGP Certification Program

- Body of Knowledge

Topic	Questions	Weightage %
I. Regulatory Agency Governance (17 Questions)	17	11.33
II. Quality Systems (26 Questions)	26	17.33
III. Laboratory Systems (20 Questions)	20	13.33
IV. Infrastructure: Facilities, Utilities, Equipment (17 Questions)	17	11.33
V. Materials and Supply Chain Management (17 Questions)	17	11.33
VI. Sterile and Nonsterile Manufacturing Systems (22 Questions)	22	14.67
VII. Filling, Packaging, Labeling (18 Questions)	18	12.00
VIII. Product Development and Technology Transfer (13 Questions)	13	8.67
Total	150	100.00

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.

Overview of CPGP Certification Program

I. Regulatory Agency Governance (17 Questions)

A. Global regulatory framework
B. Regulations and guidances
C. Mutual recognition agreements
D. Regulatory inspections
E. Enforcement actions
F. Regulatory agency reporting
G. Site Master File (SMF), Validation Master Plan (VMP), Drug Master File (DMF), and Site Reference File (SRF)

II. Quality Systems (26 Questions)

A. Quality management system (QMS)
B. Quality unit (site) management
C. Risk management and assessment
D. Training and personnel qualification
E. Change control and management
F. Investigations and corrective and preventive action (CAPA)
G. Audits and self-inspections
H. Documents and records management
I. Product complaints and adverse event reports
J. Product trend requirements
K. Supplier and contractor quality management

III. Laboratory Systems (20 Questions)

A. Compendia (United States, Europe, and Japan)
B. Laboratory investigations of atypical results
C. Instrument management
D. Specifications
E. Laboratory record-keeping and data requirements
F. Laboratory handling controls
G. Stability programs

IV. Infrastructure: Facilities, Utilities, and Equipment (17 Questions)

A. Facilities
B. Utilities
C. Equipment
D. Qualification and validation
E. Maintenance and metrology systems
F. General cleaning, sanitization, and sterilization systems
G. Automated or computerized systems
H. Business continuity and disaster recovery planning

Source:
[1] “Pharmaceutical GMP Professional Certification CPGP”, *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.

Overview of CPGP Certification Program

V. Materials and Supply Chain Management (17 Questions)

A. Receipt of materials
B. Sampling processes
C. Material storage, identification, and rotation
D. Shipping and distribution
E. Traceability and sourcing
F. Salvaged/returned goods and destruction

VI. Sterile and Nonsterile Manufacturing Systems (22 Questions)

A. Master batch and completed batch records
B. Production operations
C. In-process controls
D. Dispensing and weighing controls
E. Requirements for critical unit processes
F. Contamination and cross-contamination
G. Reprocessed and reworked materials

VII. Filling, Packaging, and Labeling (18 Questions)

A. Filling operations and controls
B. Environmental monitoring
C. In-process and finished goods inspections
D. Product inspection
E. Packaging operations and controls
F. Labeling operations and controls
G. Filling and packaging records

VIII. Product Development and Technology Transfer (13 Questions)

A. Quality by design concepts
B. Phase-appropriate Good Manufacturing Practices (GMP) requirements
C. Raw materials, packaging, and infrastructure for product development
D. New product development studies and reports
E. Scale-up and transfer activities

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.

Overview of CPGP Certification Program

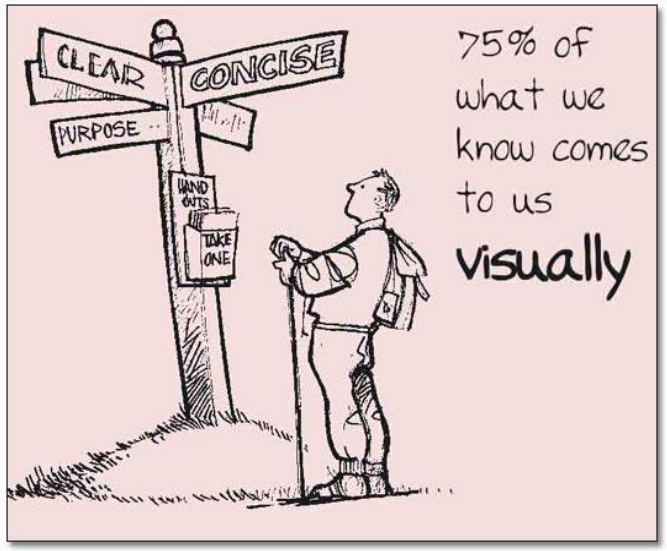
- Examination
  - Each certification candidate is required to pass an examination that consists of multiple-choice questions that measure comprehension of the Body of Knowledge.
  - **Computer Delivered** - The CPGP examination is a one-part, 165- multiple choice question exam, and is offered in English only. 150 multiple choice questions are scored and 15 are unscored. Total appointment time is four-and-a-half-hours, exam time is 4 hours and 18 minutes.
  - Paper and Pencil - The CPGP examination is a one-part, 150- multiple choice question, four-hour exam and is offered in English only.
  - All examinations are **open book**. Each participant must bring his or her own reference materials. Use of reference materials and calculators is explained in the **FAQs** [2].

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.
[2] "General FAQs", *asq*, https://www.asq.org/cert/faq. Accessed on 19 Oct 2024.

Overview of CPGP Certification Program

- Examination
  - Is Exam tough or easy?

Exam is neither tough nor easy



Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.
[2] "General FAQs", *asq*, https://www.asq.org/cert/faq. Accessed on 19 Oct 2024.

Overview of CPGP Certification Program

- Computer-Based Testing Dates

ASQ certification examinations are delivered by ASQ's testing partner, Prometric.

The examination scheduling instructions in your eligibility letter will direct you to a section of Prometric's website, where you can select and schedule your examination date and location.

APPLY NOW

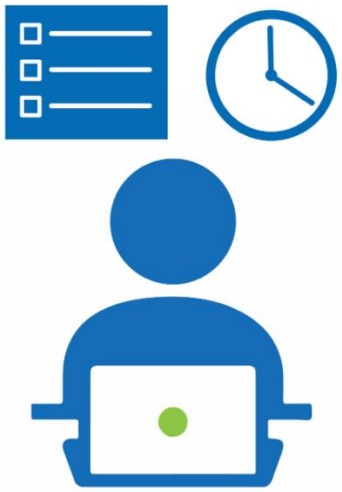
TESTING WINDOW	TESTING WINDOW	TESTING WINDOW	TESTING WINDOW
FEBRUARY 1 - 28, 2025	**APRIL 1 - 30, 2025**	**JUNE 1 - 30, 2025**	**AUGUST 1 - 31, 2025**
Application Deadline:	**Application Deadline:**	**Application Deadline:**	**Application Deadline:**
Deadline Passed	March 10, 2025	May 12, 2025	July 14, 2025

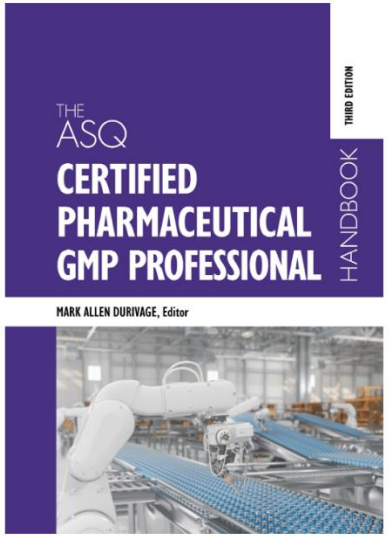
Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.
[2] "General FAQs", *asq*, https://www.asq.org/cert/faq. Accessed on 19 Oct 2024.

Overview of CPGP Certification Program

- **Prepare for the exam**

Review a list of references that provide the basis for the exam questions. These items give you a better idea of the material covered in the exam.





CPGP Question Bank

The CPGP Question Bank provides sample exam questions based on the CPGP Body of Knowledge. Includes simulated timed exam and review modes.

CPGP Handbook

The Certified Pharmaceutical GMP Professional Handbook, Third Edition is a companion guide to your exam's Body of Knowledge. The handbook can be used during your open-book exam!

CPGP Question Bank [3]

CPGP Handbook [4]

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.
[3] "Certified Pharmaceutical GMP Professional Question Bank", *asq*, https://asq.org/training/certified-pharmaceutical-gmp-professional-question-bank-qbcpgp2016asq. Accessed on 12 Mar 2025.
[4] "The ASQ Certified Pharmaceutical GMP Professional Handbook, Third Edition", *asq*, https://asq.org/quality-press/display-item?item=H1634. Accessed on 12 Mar 2025.

Overview of CPGP Certification Program

- **Exam Results** [5]
  - Computer-Based Tests
    - You will be presented with your test results at the Prometric testing center on your screen as well as a follow-up email with your test results (from Prometric).
    - In approximately seven days, you will receive your official ASQ results email notification as well as a short survey about your exam experience.
  - ASQE uses procedures that meet the *Standards for Educational and Psychological Testing*, which were developed jointly by the American Educational Research Association (AERA), the American Psychological Association (APA) and the National Council on Measurement in Education (NCME).

Click here to view full details of exam grading process [6].

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.
[5] "Exam Results FAQs", *asq*, https://www.asq.org/cert/faq/faq-exam-results#results-top. Accessed on 19 Oct 2024.
[6] "Frequently Asked Questions", *asq*, https://www.asq.org/cert/faq/exam-grading-process . Accessed on 19 Oct 2024.

Overview of CPGP Certification Program

- **Exam Results** [5]
  - ASQ passing rate for CPGP exam [6]

Pass Rates by Exam

Exam	2022	2023	2024
CCT	64%	64%	61%
CFSQA	64%	57%	62%
CMQ/OE	54%	60%	67%
CMDA	73%	63%	75%
CPGP	48%	47%	42%
CQA	70%	73%	72%
CQE	69%	78%	69%
CQI	60%	64%	60%
CQIA	73%	74%	76%
CQPA	68%	68%	66%
CQT	64%	60%	69%
CRE	58%	73%	70%
CSQE	72%	64%	64%
CSQP	61%	60%	68%
CSSBB	76%	75%	73%
CSSGB	69%	76%	77%
CSSYB	80%	81%	83%
CMBB	65%	76%	89%

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025.
[5] "Exam Results FAQs", *asq*, https://www.asq.org/cert/faq/faq-exam-results#results-top. Accessed on 19 Oct 2024.
[6] "Frequently Asked Questions", *asq*, https://www.asq.org/cert/faq/exam-grading-process . Accessed on 04 Mar 2025.

Overview of CPGP Certification Program

- Recertification [7]
  - To maintain the integrity of your CPGP certification, ASQ requires that you recertify **every three** years.
  - Find out the steps you need to take for recertification [7].
  - CREDENTIAL HOLDERS MUST:
    - Obtain 18 recertification units (RUs) within a three-year recertification period.

      Or
    - Retake the certification exam at the end of the 3-year recertification period.

Source:
[1] "Pharmaceutical GMP Professional Certification CPGP", *asq*, https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025..
[7] "Recertification", *asq*, https://www.asq.org/cert/recertification. Accessed on 19 Oct 2024.

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Overview of Training Course on “Pharmaceutical GMP Professional Certification Preparation”

“CPGP Certification Preparation Course” by Shaarkview Consultancy

- **Training Course by Seetharam Kandarpa, Shaarkview [8]**

The Certified Pharmaceutical GMP Professional certification preparation course is presented in a way that reinforces current knowledge, re-introduces applications that may not be used every day, explains the rationale for use, and highlights multiple-choice sample questions. Also, students will receive course materials.

Learning Objectives:

- Review the Body of Knowledge for the Certified Pharmaceutical GMP Professional Examination.
- Attain high scores on practice questions similar to the actual CPGP exam.
- Identify and take remedial action on gaps in your understanding of the CPGP BoK.

Source:
[8] “Certified Pharmaceutical GMP Professional Certification Preparation”, *shaarkview,* https://www.shaarkview.com/pharmaceutical-gmp-professional. Accessed on 04 Mar 2025.

“CPGP Certification Preparation Course” by Shaarkview Consultancy

- Training Course by Seetharam Kandarpa, Shaarkview [8]

ASQ ConnEx™ Advance your Excellence Journey

Course Outline:

I. Regulatory Agency Governance
II. Quality Systems
III. Laboratory Systems
IV. Infrastructure: Facilities, Utilities, Equipment
V. Materials and Supply Chain Management
VI. Sterile and Nonsterile Manufacturing Systems
VII. Filling, Packaging, Labeling
VIII. Product Development and Technology Transfer

Who Should Attend:

Individuals who desire to reinforce their skills, knowledge, and capacity to understand the Certified Pharmaceutical GMP Professional Body of Knowledge in preparation for taking the Certified Pharmaceutical GMP Professional examination.

Note: *Taking this course does not constitute, nor imply, the successful passing of the ASQ Certified Pharmaceutical GMP Professional examination.*

Source:
[8] “Certified Pharmaceutical GMP Professional Certification Preparation”, *shaarkview,* https://www.shaarkview.com/pharmaceutical-gmp-professional. Accessed on 04 Mar 2025.

SHAARKVIEW™ CONSULTANCY

"CPGP Certification Preparation Course" by Shaarkview Consultancy

- **Training Course by Seetharam Kandarpa, Shaarkview [8]**

Format:	Live Virtual/ Face-to-Face
Course Duration:	24 hours (3 days)
Training Days:	3- Weekend days (Sat/Sun), 09.00 am to 06.00 pm *(Time Zone is adjustable as needed by the class)*
Language of Instruction:	English
Instructor:	Seetharam Kandarpa

Organization specific training (of 6-15 students) for Face-to-Face or Live Virtual training program: *Contact Us*

Next Available Public Class Schedule: June/ July 2025

Format: Live Virtual Class
(Online using Google Meet)

Source:
[8] "Certified Pharmaceutical GMP Professional Certification Preparation", *shaarkview,* https://www.shaarkview.com/pharmaceutical-gmp-professional. Accessed on 04 Mar 2025.

“CPGP Certification Preparation Course” by Shaarkview Consultancy

- **Training Course by Seetharam Kandarpa, Shaarkview [8]**

  Procedure for Reserving Seat for Training Class:

1. **Fill the training enquiry form from our website https://www.shaarkview.com/training-enquiry.**
2. You will receive pro forma invoice with next class schedule (confirmed dates) through mail.
3. Complete the payment through NEFT/ Bank transfer or Payment Gateway (e.g. Payoneer) to Shaarkview Business account.
4. You will receive invoice copy and details of conformation of your seat in training class through mail.
5. Students will receive instructions to receive/ download the training material from Shaarkview through mail before 1 week of training class.
6. Students will attend the training class (all sessions without fail).
7. Students will receive training completion certificate from Shaarkview.
8. Students will prepare for further for their journey towards attempting CPGP exam to get certified.

NOTE: You may seek our support during your journey towards CPGP exam, as needed.

Source:
[8] “Certified Pharmaceutical GMP Professional Certification Preparation”, *shaarkview,* https://www.shaarkview.com/pharmaceutical-gmp-professional. Accessed on 04 Mar 2025.

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Wrap Up

Wrap Up

What New Skills and Techniques Will You Learn?

- A fundamental understanding of regulatory agency governance including global regulatory frameworks, relevant regulations and guidelines, and mutual recognition agreements.
- The elements and requirements of a quality system, various types of audits and self-inspections, and record management systems.
- Factors relating to laboratory systems, including relevant compendia for United States, Europe, and Japan; investigations of aberrant laboratory results; and instrument control and record-keeping.
- Requirements and specifications for construction of facilities, utilities, and equipment; evaluation of automated or computerized systems; and application of business continuity plans and disaster recovery techniques.
- Sampling plans and procedures for shipping and receiving materials; analysis of in-house storage, identification, and rotation of materials; and requirements for materials' traceability and sourcing, including returned goods.
- Sterile and nonsterile manufacturing systems, analysis of master and completed batch records, material control procedures, and contamination controls.
- Product design factors, phase-appropriate GMP requirements, filling and packaging operations and controls, and analysis of technology transfer activities.

What Is the Value to Your Company?

- Good manufacturing practices (GMPs) ensure that pharmaceutical products are safe, efficacious, and pure. Employees who have obtained certification as a Pharmaceutical GMP Professional have a demonstrated, extensive, and proven knowledge of the quality system, ensuring that high-quality products are delivered to the consumer. With their breadth of knowledge, employees holding a CPGP can support nearly any aspect of your company's business and deliver exceptional performance.

What Is the Value to You?

- Improved knowledge, skills, and abilities qualify you for more positions within modern business industries that require demonstrated competency in pharmaceutical GMPs.
- CPGPs with a job title of manager make an average salary of $105k per year; compared to those without certification, who make approximately $93k (national average).*

**Please see the current* Quality Progress *Salary Survey at: asq.org/qualityprogress/ under Tools and Resources.*

- *Do SWOT analysis*
- *Plan your preparation*
- *Prepare well for exam (3-6 months)*
  - *Learn from Shaarkview*
  - *Take other-course*
- *Be confident and apply for exam*
- *Attempt well*
- *Be certified in 1st attempt.*

Think Practically,
Analyze Logically,
Perform Heartfully &
Earn Success Automatically!!!

- Seetharam Kandarpa

SHAARKVIEW CONSULTANCY

References

- [1] “Pharmaceutical GMP Professional Certification CPGP”, *asq,* https://www.asq.org/cert/pharmaceutical-gmp . Accessed on 12 Mar 2025
- [2] “General FAQs”, *asq,* https://www.asq.org/cert/faq. Accessed on 19 Oct 2024.
- [3] “Certified Pharmaceutical GMP Professional Question Bank”, *asq,* https://asq.org/training/certified-pharmaceutical-gmp-professional-question-bank-qbcpgp2016asq. Accessed on 12 Mar 2025.
- [4] “The ASQ Certified Pharmaceutical GMP Professional Handbook, Third Edition”, *asq,* https://asq.org/quality-press/display-item?item=H1634. Accessed on 12 Mar 2025.
- [5] “Exam Results FAQs”, *asq,* https://www.asq.org/cert/faq/faq-exam-results#results-top. Accessed on 19 Oct 2024.
- [6] “Frequently Asked Questions”, *asq,* https://www.asq.org/cert/faq/exam-grading-process . Accessed on 04 Mar 2025.
- [7] “Recertification”, *asq,* https://www.asq.org/cert/recertification. Accessed on 19 Oct 2024.
- [8] “Certified Pharmaceutical GMP Professional Certification Preparation”, *shaarkview,* https://www.shaarkview.com/pharmaceutical-gmp-professional. Accessed on 04 Mar 2025.

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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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Q & A

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