



QUALITY CIRCLE FORUM OF INDIA
ANKLESHWAR CHAPTER
PHARMACEUTICAL WING

Two days' Seminar on:

COMPREHENSIVE cGMP MODEL
FOR 21ST CENTURY

Date: 5th and 6th May, 2023



Expert: Dr. Milind Pathak

Program Facilitator:
Mrs. Alka Kale

Organized By:

QUALITY CIRCLE FORUM OF INDIA
Ankleshwar chapter - Pharmaceutical Wing

Opp. State Bank of India (Main Branch), Station Road, Chauta-Naka, Ankleshwar – 393001.
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Background:

In August, 2002, FDA announced the vision for pharmaceutical industries for 21st century. In this announcement, FDA explained the agency's intention to initiate Quality System to be integrated with risk management and science based knowledge. To integrate science based knowledge, ICH has published ICH Q8 & Q11 and to integrate this concept with Quality System ICH Q10 was published which focuses on objectives like Product realization, Establishing and maintaining State of Control for manufacturing processes, and Facilitate continual improvement.

FDA expects that Comprehensive Quality System Model for 21st century should allow manufacturers to support and sustain robust modern Quality System which stresses on "Quality should be built in to the product and testing alone cannot be relied on to ensure product quality".

A need to redress at a cGMP is emphasized by FDA in guidance published in 2006 on "Quality System Approach to Pharmaceutical cGMP regulations " to guide industries.

Methodology of Seminar:

- It will be a participatory seminar encouraging questions and sharing experiences between expert and participants.
- Performance of participants will be evaluated based on evaluation test.
- Participants will be awarded certificates from "Quality Circle Forum of India".

Schedule and Venue of Seminar:

Date: 5th May, 2023 & 6th May, 2023 (Total 2 days)

- **Time:** 09:00 am to 05:30 pm
- **Venue:** Hotel **Lords Plaza**, Station Road, Ankleshwar (East),
Dist.: Bharuch -393001, Gujarat.

Information for Participant's convenience:

Venue of seminar is just 5 minutes walking distance from the premises of Ankleshwar Railway Station (East side).



Course Agenda:

Day – 1 (05.05.2023)

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|--------------------|--|
| 8:45 to 9:00 am | Registration and Breakfast, |
| 9:00 to 9:45 am | Inauguration, Introduction Speech by Chief Guest |
| 9:45 to 10:15 am | Introduction of cGMP |
| 10:15 to 10:30 am | Goal of cGMP Guideline |
| 10:30 to 11:30 am | Concept of Modern Quality System: Quality, QbD Concept, QRM, CAPA, Change Control |
| 11:30 to 11:45 am | Tea-Break |
| 11:45 to 12: 15 pm | Concept of Modern Quality System: The Quality Unit, 6 System Inspection Model |
| 12:15 to 1:15 pm | Quality System Model for 21 st Century: Management Responsibilities: 1. Provide Leadership 2. Structure of Organization |
| 1:15 to 2:15 pm | Lunch – Break |
| 2:15 to 3:30 pm | Management Responsibilities: 3. Building Quality System 4. Policies, Objectives and Plans 5. Review |
| 3:30 to 3:45 pm | Tea - Break |
| 3:45 to 5:30 pm | Resources: 1. General Arrangements 2. Personnel Development 3. Facilities and Equipment 4. Control of Outsourcing |



Day – 2 (06.05.2023)

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|-------------------|--|
| 8:45 to 9:00 am | Breakfast |
| 9:00 to 11:30 am | Manufacturing: 1. Design & Development 2. Examine Inputs |
| 11:30 to 11:45 am | Tea - Break |
| 11:45 to 1:15 pm | Manufacturing: 3. Perform and Monitor Operations 4. Address Nonconformities Evaluation Activities: 1. Analysis Data for Trends 2. Internal Audits |
| 1:15 to 2:15 pm | Lunch - Break |
| 2:15 to 3:30 pm | Evaluation Activities: 3. Quality Risk Management 4. Corrective Action 5. Preventive Action 6. Continual Improvement |
| 3:30 to 3:45 pm | Tea - Break |
| 3:45 to 4:00 pm | Conclusion |
| 4:00 to 4:30 pm | Evaluation Test |
| 4:30 to 5:30 pm | Valedictory Function (certificate distribution) |



Seminar Charges:

- INR 8,000/- per participant + 18 % GST (Total 9,440 /- INR).
- Course fee includes reading material, tea-snacks and working lunch.
- This seminar is a non-residential event.

Registration Procedure:

- Registration can be acknowledged on alkakale.65@gmail.com or qcfi.ank@gmail.com
- Demand draft or Cheque are requested in favour of “**Quality Circle Forum of India**” and can be submitted at following address.

“QUALITY CIRCLE FORUM OF INDIA,

Ankleshwar Chapter

Opp. State Bank of India (Main Branch), Station Road, ANKLESHWAR-393001, Dist.: Bharuch (Gujarat)”

- GST number & Bank details shall be provided for payment through NEFT at qcfi.ank@gmail.com , if requested.
- Call on **+91 93774 34079** or **+91 93752 33039** for any additional information related to seminar, if required.

Profile

- **Dr. Milind Pathak (Expert):**

- Dr. Milind has rich experience of more than 3 decades to his credit at various levels in reputed pharmaceutical organizations in Quality, Manufacturing and Regulatory compliance during his professional assignment. He successfully faced several regulatory audits during this tenure.
- Presently, representing Quality Circle Forum of India as an expert to deliver training program on various topics on Pharmaceutical Quality Systems.
- He has conducted more than 500 training programs covering around 10,000 professionals at different locations and deeply involved with around 80 organizations to train their professionals.
- He also conducts six month duration coaching on Pharmaceutical Quality System and Regulatory Guidelines for professionals involved in pharmaceutical manufacturing.



- **Mrs. Alka Kale (Event Facilitator) :**

- Mrs. Alka has more than 25 years' experience in chemicals and pharmaceutical organizations.
- She has been associated with QCFI since 2012 contributing a major role in pharmaceutical wing. Her core subjects are Industrial Safety in Pharmaceutical industries and 5S – Workplace Management System in Life Science Industries.

