



QUALITY CIRCLE FORUM OF INDIA

Ankleshwar Chapter

Organizing



Two days Training Program

on

CAPA through Investigation of Changes, Deviations & Failure using Problem Solving and Statistical Tools

Organized By

QUALITY CIRCLE FORUM OF INDIA

Ankleshwar chapter - Pharmaceutical Wing

Opp. State Bank of India (Main Branch),

Station Road, Chauta-Naka,

Ankleshwar – 393001.

Mobile: 93774 34079, 9375233039

Email: qcfi.ank@gmail.com www.qcfi.in

Date : 12th & 13th November, 2025

Time : 9 am to 5 pm

Venue : Hotel Mastiff, Station Road, Ankleshwar - 393002

**Experts : Dr. Milind Pathak
Mr. Jagdish Jain
Ms. Alka Kale**

INTRODUCTION :

In Pharmaceutical Quality Management, change management, deviations and failure handling, conducting investigation and planning corrective and preventive actions using tools are inter connected processes. Efforts and implementation of this system leads organization on the pathway of continual improvement ensuring successful regulatory audits.

PROGRAM DELIVERY THROUGH :

Workshop Activity; Audio-visual Presentation; Industry case studies and Group discussion.

BRIEF DETAILS OF EXPERTS :

Dr. Milind Pathak

- ☛ Has 32 years of experience in Pharmaceutical industries.
- ☛ Associated with QCFI since 2012 as an Auditor and Faculty
- ☛ Core Area - Quality and Regulatory Compliance

Mr. Jagdish Jain

- ☛ Has 32 years of experience in reputed pharmaceutical industries at Senior Management Level.
- ☛ Core Area - Quality and Regulatory Compliance

Mrs. Alka Kale

- ☛ Has 32 years of experience in pharmaceutical & chemical industries.
- ☛ Associated with QCFI since 2012 as an Auditor and Faculty
- ☛ Core Area – Quality, Safety, TQM

SCHEDULE

DAY 1

Session I : 9.00 am – 9.30 am Registration Tea/Coffee & Snacks.

- Introduction of participants
- Importance of Change Control System
- Relevance of Change Control System with QbD .
- Definition and classification

11. 15 am - 11.30 am Tea/Coffee Break

Session II

- Risk Management
- Formality in QRM during changes
 - Uncertainty
 - Complexity
 - Tools
- Pre-evaluation before implementation of change (DoE)
- Post implementation effectiveness evaluation during change.

1 pm to 2 pm Lunch Session

Session: III

- Post implementation effectiveness evaluation during change (Continue)
- Shewhart Control Charts
- Histogram
- Process Capability

3:15 pm to 3:30 pm Tea break

Session: IV

- Radar Chart (Workshop)
- Expectation of Regulatory to manage changes
- Deviation Management
- QRM during handling of deviations
- Categories of deviation

DAY 2

Session I : 9.00 am – 9.30am Tea/Coffee & Snacks.

- FMEA to manage deviation
- What is CAPA?
- Correction, Corrective Actions and Preventive Actions

11. 15 am - 11.30 am Tea/Coffee Break

Session: II

- Management of CAPA
- 7 Step process of CAPA
 - Identification
 - Evaluation
 - Investigation Strategy

1 pm to 2 pm Lunch Session

Session: III

- Analysis (Identification of root cause)
- Implementation Strategy
- Implementation
- Follow up & Review

3:15 pm to 3:30 pm Tea break

Session: IV

- Problem Solving Techniques for Root Cause Identification
 - Fishbone Diagram
 - Why Why Analysis (Workshop)
- Evaluation test (MCQ)
- Certification

CERTIFICATES :

Certificates shall be awarded for the participation to every participant on behalf of **Quality Circle Forum of India, Ankleshwar Chapter**.

FEES :

- INR 7500/- per participant + 18% GST applicable.
- Course fee includes training material, Tea-snacks, working lunch.
- This is a non-residential training program.

REGISTRATION :

- Registration can be acknowledged on qcfi.ank@gmail.com.
- Request to prepare Demand draft or Cheque 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 and Bank details shall be provided for payment through NEFT at qcfi.ank@gmail.com, if requested.
- Call on 9377434079 / 9375233039 for any additional information and registration.

