



QUALITY CIRCLE FORUM OF INDIA
ANKLESHWAR CHAPTER
Pharmaceutical Wing

Organizing a 5th Session on:

SIX MONTHS COACHING
ON
PHARMACEUTICAL QUALITY SYSTEM
AND
REGULATORY GUIDELINES

April, 2020
TO
September, 2020

Office Address:

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

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PURPOSE:

A purpose to initiate six months evening coaching on "Pharmaceutical Quality System and Regulatory Guidelines" is to impart Quality System and Regulatory Guidelines' knowledge, so the performers can become decision makers instead of sheer followers based on spoon feeding from superiors.

SCOPE:

Organizations can sponsor personnel from QA, QC and production department to make them capable to monitor, review and implement Quality System in their respective area at the level of regulatory compliance.

COURSE DETAILS:

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| 1. Stability Testing of Drug substances and products | ICH Q1 |
| 2. Validation of analytical procedures and methodology | ICH Q2 |
| 3. Impurities in Drug substances and Drug products | ICH Q3 |
| 4. Test procedures and acceptance criteria | ICH Q6 |
| 5. Good manufacturing guidance for Active Pharmaceutical Ingredients | ICH Q7 |
| 6. Development of Drug Products | ICH Q8 |
| 7. Quality Risk Management | ICH Q9 |
| 8. Pharmaceutical Quality System | ICH Q10 |
| 9. A guidance on a new approach to Process Validation (Inlight of ICH Q8 to Q11) | |
| 10. Qualification of equipment and instruments | |
| 11. Cleaning Validation | |
| 12. Preventive Maintenance | |

METHODOLOGY:

- 01. Coaching:** Based on lectures, power point presentations.
Also participation through questions / answers is highly encouraged.
- 02. Assignment:** Question paper from every topic has to be answered by participants in the form of assignments (homework activity).
- 03. Seminars:** Every participant has to deliver minimum one seminar on the topic covered in curriculum . A minimum length of each seminar should be at least one hour.
- 04. Presence:** Minimum 80 %
- 05. Total duration :** 200 hrs.
of Course
- 06. Viva:** At the end, viva will be conducted by external expert to qualify course.

TIME:

3 days in a week from 06:30 pm to 09:00 pm.

CERTIFICATE:

Certificates will be awarded to successful participants based on cumulative performance in periodical evaluation tests, seminars, assignments, compliance of minimum criteria of attendance , established by QCFI and viva conducted by external expert at the end of the course.

VENUE:

A venue for the course shall be QCFI office, Ankleshwar Chapter, Opp. State Bank of India (Main Branch), Chauta Naka, Station Road, Ankleshwar - 393001.

ENROLLMENT PROCEDURE:

An enrollment is requested to be acknowledged with cheque or demand draft in favour of “**Quality Circle Forum of India**”, payable at Ankleshwar, before 15th, March-2020. For further information, contact to –

Dr. Milind Pathak: Mob. 093774 34079,

E-mail: niketan35@yahoo.co.in

Mr. Milan Sheth: Mob. 09879477357

E-mail: milan_sheth1@yahoo.com

FEES:

25000/- Rs. + 18% GST as applicable (Inclusive of course material and all expenses).

EXEMPTIONS:

5% exemption for 3 or more participants from single organization.

FACULTY PROFILE:



Name: **Dr. Milind Pathak**
Qualification: M. Sc., Ph.D.
Experience:
i. Professional: 32 yrs in pharmaceutical industries
ii. Trainer and Faculty: 07 yrs. in Quality Circle Forum of India
Core area: Quality and Regulatory Compliance



Name: **Dr. Nikhil Bhatt**
Qualification: M. Sc., Ph.D.
Experience:
i. Professional: 35 yrs in pharmaceutical industries
ii. Trainer and Faculty: 03 yrs. in Quality Circle Forum of India
Core area: Research & Development, Technology Transfer



Name: **Mr. Bharat Bhamre**
Qualification: DME, B.Tech.
Experience:
i. Professional: 37 yrs in pharmaceutical industries
ii. Trainer and Faculty: 01 yrs. in Quality Circle Forum of India
Core area: Engineering and Technology



Name: **Dr. M.C. Sriraman**
Qualification: M.Sc., Ph.D., P.G.Diploma in Patent Law
Experience:
i. Professional: 38 yrs in pharmaceutical industries
ii. Trainer and Faculty: 1 yrs. in Quality Circle Forum of India
Core area: R & D and Manufacturing of API



Name: **Mr. C. M. Panchal**
Qualification: B. Sc., B.Sc. Technology.
Experience:
i. Professional: 32 yrs in pharmaceutical industries
ii. Trainer and Faculty: 1 yrs. in Quality Circle Forum of India
Core area: Manufacturing API



Name: **Mr. Milan Sheth**
Qualification: Post Graduate- Good Manufacturing Practices.
Experience:
i. Professional: 16 yrs in pharmaceutical industries
ii. Trainer and Faculty: 04 yrs. in Quality Circle Forum of India
Core area: Quality and Regulatory Compliance