

**TWO DAYS TRAINING PROGRAMME  
(NON RESIDENTIAL)  
ON  
A New Approach To Process Validation  
(Inlight of ICH Q8-011)**

**Faculty : Dr. Milind Pathak**



**Organized By:**

**QUALITY CIRCLE FORUM OF INDIA**

Ankleshwar Chapter & Proposed Ahmedabad Sub Chapter.

Opp. State Bank of India (Main Branch)

Station Road, ANKLESHWAR - 393 001

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Tel. : 02646 - 247461

Mobile : 098794 77357 (Mr. Milan Sheth)

Mobile : 093774 34079 (Dr. Milind Pathak)

**:: Venue**

**Hotel Dev Corporate,**

**Opp. Bawarchi Restaurant,**

**Off.C.G.Road,**

**Nr.Girish Coldrink Cross Road,**

**Navarangpura Ahmedabad.**

**29th - 30th, APRIL - 2016**

**Time : 9:00 A.M. to 5.00 P.M.**

## **INTRODUCTION :**

A revised guidance on A New Approach to Process Validation published in Jan. 2011, provides recommendations that reflect some of goals of FDA's initiatives entitled "Pharmaceuticals GMP for the 21st Century, A Risk-Based Approach", particularly with regard to the use of.

- \* Technological advances in Pharmaceutical manufacturing.
- \* Implementation of a
  - Risk Management
  - Quality System tools and management.

A New approach to Process Validation has been linked with a "Product life cycle concept" which includes stages,

- Process Design
- Process Performance Qualification
- Continued Process/Quality Verification.

## **OBJECTIVE :**

An objective of this training program is to explain FDA's expectation regarding new approach of process validation.

## **CERTIFICATE :**

Certificate will be awarded to the participants after successful compliance of the test at the end of the training programme.

## **METHODOLOGY :**

A New Approach to Process Validation (Inlight of ICHQ8-Q11) guidance will be explained in detail with suitable examples and rationale. It will be a participatory session and followed by an evaluation on second day.

## SCHEDULE :

### DAY-1

8.45 AM	Breakfast
9.00 AM	Registration
9.30 AM	Inauguration/Prayer
10.00 AM	Introduction of Participants
10.15 AM	Glossary
	Introduction of Process Validation
	Requirement of Process Validation
11.30 AM	Tea-Break
11.45 AM	Traditional Approach
	New Approach
	General Consideration for process validation
	Process Validation and Product Quality
1.00 PM	Lunch Break
1.30 PM	Ethics
	Stage I : Process Design
3.00 PM	Tea Break
3.15 PM	Stage II : Process Qualification
	Stage III : Continued Process Verification
5.00 PM	Day Off

### DAY-2

8.45 AM	Break Fast
9.00 AM	Continued Process Verification (contd.)
	Concurrent Release of PPQ batches
	Documentation
	Analytical Methodology
	Statistical Analysis to Monitor Stage III
	Parato Diagram
11.00 AM	Tea Break
11.15 AM	Fish Bone Diagram
	DoE
1.00 PM	Lunch Break
1.30 PM	Shewart Control Charts
	Radar Charts
	Spread Sheets
	Scatter Graph
3.00 PM	Tea Break
3.15 PM	Q & A
3.45 PM	Evaluation Test
4.15 PM	Valedictory Function
5.00 PM	Closure

## **FACULTY**

**Dr. Milind Pathak - (M) 09377434079**

\* Having 29 years of experience in reputed APIs manufacturing industries at various capacities in QA and Regulatory Department.

**DATE, TIME & VENUE :** 29th - 30th, April - 2016 : 9.00 A.M. to 5.00 P.M. Hotel Dev Corporate, Opp. Bawarchi Restaurant, Off.C.G.Road, Nr.Girish Coldrink Cross Road, Navarangpura, Ahmedabad.

## **FEES :**

Rs. 4000/- per participant + Service Tax @ 14.00 + 0.5 % SBC = Rs. 4580/- Course Fee includes training material, Tea / Snacks and working Lunch.

## **DISCOUNT**

10% Discount for QCFI-Life Members. 5% Discount for 3 or more participants from QCFI - Institutional Member organizations.

## **ENROLLMENT**

Please e-mail the list of names of participants along with local cheque/Demand Draft in favour of “**Quality Circle Forum of India**” at

Mr. Milan Sheth, QCFI, Proposed Ahmedabad sub Chapter: Mo. **098794 77357**, E-mail : **milan\_sheth1@yahoo.com**

Dr.Milind Pathak, Joint Secretary & Faculty, QCFI, Ankleshwar Chapter: Mo.**9377434079**, E-mail : **niketan35@yahoo.co.in**

QCFI, Ankleshwar Chapter: Ph.**02646 - 247461**, E-mail : **qcfi.ank@gmail.com**

Last Date For Registration : **18th April - 2016**

**REGISTRATION FORM**

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**29<sup>th</sup> - 30<sup>th</sup> APRIL - 2016**

**The Honorary Secretary**  
**Quality Circle Forum of India, Ankleshwar Chapter**  
 Opp. State Bank of India (Main Branch) Station Road, ANKLESHWAR - 393 001  
 Tel. : 02646 - 247461 Mobile : 9377434079 / 9974062641

Sr.No.	Name	Designation	Mobile

Name of Organization : .....

Address : .....

.....

Tel. .... Fax :..... E-mail :.....

Cheque/Demand Draft No. .... Date :.....

Amount ..... Rs. (in words) :.....

Bank : .....

Branch : .....

Name : .....

Designation : .....

Date : ..... Signature :.....