

# TWO DAYS TRAINING PROGRAM ON GOOD MANUFACTURING PRACTICES WITH GLOBAL APPROACH TO RISK MANAGEMENT & CONTINUAL IMPROVEMENT

**Faculty: Dr. Milind Pathak** 



### **QUALITY CIRCLE FORUM OF INDIA**

**Ankleshwar Chapter & Surat Sub Chapter** 

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Mobile: 93774 34079 (Dr. Milind Pathak)

:: Venue

Hotel Lords Plaza, Station Road, Surat.

19th & 20th August - 2016

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



# **INTRODUCTION:**

Good Manufacturing Practices intended to provide guidance regarding cGMP for manufacturing of API and intermediates.

Considering the needs of system for 21st century, this guideline should be implemented in accordance with the current approaches of Risk Management, Life cycle approach and system promoting continual improvement.

### **OBJECTIVE:**

An objective of this training program is to explain this guideline in Global Approach.

### **CERTIFICATE:**

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

### **FACULTY**

Dr. Milind Pathak - (©) 09377434079, Email: niketan35@yahoo.co.in

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

# DATE & TIME:

19th & 20th August - 2016: 9.00 A.M. to 5.00 P.M.

### **VENUE**

Hotel Lords Plaza, Station Road, Surat., Gujarat.

SCHEDULE : Day 1		SCHEDULE : Day 2	
9.00 AM	Registration	9.00 AM	Storage & distribution
9.15 AM	Inauguration / Prayer	9.15 AM	Laboratory controls (Data Integrity)
9.30 AM	Introduction	10.30 AM	Qualification of equipment
9.45 AM	Scope, Application & Principle	11.00 AM	Tea Break
10.00 AM	Responsibilities	11.15 AM	Validations : Life cycle approach
	(All the concerned departments)	1.00 AM	Lunch
11.15 AM	Tea Break	1.45 PM	Validations (contd.)
11.30 AM	Product Quality Review	2.15 PM	change Control & Deviations
	(Use of Statistical Inputs and tools for continual improvement)	2.101	(Risk based approach)
12.45 PM	Building & Facility	3.00 PM	Tea Break
	(Risk based approach).	3.15 PM	Complaints & Recalls
1.00 PM	Lunch		(Investigation for improvement)
1.45 PM	Calibrations, Documents & Records	3.45 PM	Summary
	(Data Integrity)	4.00 PM	Evaluation Test
3.15 PM	Tea Break	4.15 PM	Valedictory Function
3.30 PM	Materials Management &		Distribution of certificates
5.00 PM	Manufacturing controls (PAT)  Day off	5.00 PM	Closure.

### FEES:

Training charges: 4,500/- Rs. per participant + Service Tax 15% (675/- Rs.). Total: 5175/- Rs.

### **DISCOUNT**

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

### **SPECIAL OFFER**

5% Special discount on training charges will be offered for early birds, registration and payment of charges on or before 9th August - 2016.

# **ENROLLMENT**

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