

QUALITY CIRCLE FORUM OF INDIA

ANKLESHWAR CHAPTER
PHARMACEUTICAL WING



Three days workshop on:

Date: 9th Nov. to 11th Nov. 2017

"A ROAD MAP TO MITIGATE FAILURES AND A JOURNEY TOWARDS CONTINUAL IMPROVEMENT IN PHARMACEUTICAL INDUSTRIES"

Experts: Dr. Milind Pathak

Mr. Milan Sheth

Organized By:

QUALITY CIRCLE FORUM OF INDIA

Ankleshwar chapter - Pharmaceutical Wing

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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.

This vision can be fulfilled if manufacturer closely monitor the processes using tools to identify potential risk, identify area for improvements and thus continually improve the operations and system to minimize errors and defects in processes and system.

This workshop focuses to deliver methodology to establish road map for continual improvement and minimizing of errors and defects.

Methodology of Workshop:

- It will be a participatory workshop encouraging questions and sharing experiences between experts and participants.
- Last session on each day will be devoted for workshop activity.
- Performance of participants will be evaluated based on workshop activities.
- Participants will be awarded certificates from "Quality Circle Forum of India" after successful participation in workshop activities.

Schedule and Venue of Workshop:

- **Date:** 9th November, 2017 to 11th November, 2017 (Total 3 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 workshop is just 5 minutes walking distance from the premises of Ankleshwar Railway Station (East side).



Course Agenda:

Day – 1 (09.11.17)				
8:45 to 9:00 am	Registration and Breakfast			
	Inauguration, Introduction and			
9:00 to 9:45 am	blessing speech by Chief Guest			
9:45 to 10:15 am	Introduction of Subject			
10:15 to 10:30 am	What are Problem Solving Tools?			
10:30 to 11:30 am	FMEA			
11:30 to 11:45 am	Tea-Break			
11:45 to 12: 15 pm	FMEA continued and FMECA			
12:15 to 1:15 pm	FTA			
1:15 to 2:15 pm	Lunch - Break			
2:15 to 3:30 pm	НАССР			
3:30 to 3:45 pm	Tea - Break			
3:45 to 5:15 pm	Workshop Activity			
5:15 to 5:30 pm	Open discussion			

	Day - 2 (10.11.17)
8:45 to 9:00 am	Breakfast
9:00 to 11:00 am	HAZOP
11:00 to 11:30 am	PHA
11:30 to 11:45 am	Tea - Break
11:45 to 12:00 pm	PHA Continued
12:00 to 1:15 pm	Fish Bone Diagram
1:15 to 2:15 pm	Lunch - Break
	Statistical Tools:
2:15 to 3:30 pm	Shewhart Control Chart
3:30 to 3:45 pm	Tea - Break
3:45 to 4:15 pm	DoE
4:15 to 5:30 pm	Workshop Activity

	Day	y – 3 (11.11.17)	
8:45 to 9:00 am	Breakfast	2:15 to 2:45 pm	Process Capability Continued
			General Tools:
			Flow Chart, Check sheet,
9:00 to 10:00 am	Pareto Diagram	2:45 to 3:30 pm	Stratification, Belt Graph
10:00 to 10:45 am	Radar Chart	3:30 to 3:45 pm	Tea – Break
10:45 to 11:30 am	Scatter Graph	3:45 to 4:30 pm	Workshop Activity
			Valedictory Ceremony and
11:30 to 11:45 am	Tea - Break	4:30 to 5:30 pm	Certificate Distribution
11:45 to 12:45 pm	Histogram		
12:45 to 1:15 pm	Process Capability		
1:15 to 2:15 pm	Lunch - Break		

Workshop Charges:

- INR 11,000/- per participant + 18 % GST (Total 12,980 /- INR).
- 5% discount will be awarded to each participant for the registration of 3 or more participants from single organization.
- Special discount of 5 % will be awarded for the registration and payment before 25th October, 2017.
- Course fee includes training material, tea-snacks and working lunch.
- This workshop is a non-residential event.

Registration Procedure:

- Registration can be acknowledged on niketan35@yahoo.co.in or milan_sheth1@yahoo.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 and Bank details shall be provided for payment through NEFT at niketan35@yahoo.co.in , if requested.
- Call on +91 0937434079 for any additional information related to workshop, if required.

Workshop Experts:

Dr. Milind Pathak:

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 programs on various topics on Pharmaceutical Quality Systems.

He has conducted more than 250 training programs covering around 3000 professionals at different locations and deeply involved with around 50 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.

Mr. Milan Sheth:

Mr. Milan has more than 15 years experience in various pharmaceutical organizations at various levels up to the Plant-Head position. He has rich experience of manufacturing, design, audits, compliance and monitoring quality metrics of organization.

He has been associated with QCFI contributing a lead role in pharmaceutical wing. He has delivered more than 100 lectures on various topics on Pharmaceutical Quality System. Writing articles on Pharmaceutical Quality System has been a passion of Mr. Milan.

Also actively involved as a faculty in a six months coaching course on Pharmaceutical Quality System and Regulatory Guidelines.



