REGISTRATION PROCEDURE

Secretary
Quality Circle Forum of India,
Hyderabad Chapter

S.No.	Name	Designation

Name of organization: _____

_____

Address: _____

_____

TEL: E-Mail:

Demand Draft No.:_____ Date:_____

Cheque No.: _____Date:_____

for Rs._____ Bank: _____

For Online transaction Bank details : Indian Overseas Bank, Secunderabad Branch (Code : 0200) Savings Bank Account No: 020001000011579 IFS Code : IOBA0000200

Our GST No : 36AAAAQ0008P1ZK

A ONE DAY WORKSHOP
on

A Way to Successfully Face a Regulatory Audit for PHARMA/BULK DRUG INDUSTRIES

DATE: on 21st MAY 2018

VENUE :
YOSHODA HOSPITAL, CONFERENCE HALL, SECUNDERABAD
(NON - RESIDENTIAL)

ORGANISED BY

QUALITY CIRCLE FORUM OF INDIA
Hyderabad Chapter
206, 2nd Floor, Navketan Chambers, Opp. Clock Tower
Secunderabad - 500 003

Introduction:

Auditing has become one of the important key for the success of a pharmaceutical company. Regulatory agencies play a very important role in the pharmaceutical companies by assuring the good quality so that safe and effective products can be delivered to the public.

Worldwide, the expectation of a quality product is the same for regulatory agencies. Quality is determined by whether the firm complies with GMP requirements and makes scientifically justified decisions.

The purpose of the Audits conducting by the Regulatory Authorities is:

1. To determine that the rights, safety and welfare of patients have been protected.
2. To assess adherence to regulations and statutory requirements.
3. To determine the quality and integrity of data submitted in support of healthcare products registration.
4. To ensure that the facility is in compliance with regulatory rules and regulations.
5. To know that product development was done appropriately and the cGMP is up to regulatory standards.

Methodology of Training:

- It will be a participatory event encouraging questions and sharing experiences between experts and participants.
- Participants will be awarded certificates from "Quality Circle Forum of India" at the end of event.

Who should attend

Professionals involved with managing day to operations , Manger Hr & Marketing, Frontline production supervisors, Sr. Executives & Pharmacists engaged in Quality Assurance including Sales will benefit this course immensely .

Mode of Language : Mainly English & Hindi wherever required.

Course Agenda:

8:45 to 9:15	Registration /Tea	14:30 to 14:45	Discussion in Inspection room after Plant tour
9:15 to 09:30	Types of audit Benefits of audit Internal Vs External Audit	14:45 to 15:15	Closure meeting Site wash up meeting
09:30 to 09:50	Audit preparation Pre-audit preparation Team selection	15:15 to 15:30	Tea-Break
09:50 to 11:15	Responsibility of team	15:30 to 16:00	Post Audit activities: Analysis of Audit findings Analysis of existing procedures Response of Audit report
11:15 to 11:30	Tea - Break		
11:30 to 12:15	Responsibility of team cont.. Auditor's interested areas	16:00 to 16:15	Dos and Don'ts
12:15 to 13:15	Activities during Audit: Arrival on the day Reception Beginning	16:15 to 16:30	Cultural Differences of Auditee and Auditor
		16:30 to 16:45	Conclusion
13:15 to 14:00	Lunch Break	16:45 to 17:00	Certificate Distribution
14:00 to 14:30	System Approach Plant Tour	17:00	Closure

Programme Tariff: Rs. 2000/- Plus GST @ 18% Per Person

For details contact Programme Co-ordinator: D.K. Bhattacharya (Phone: 040-27801668 Mobile: 9346004244 & 9676720717)

Training 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 3500 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.