



QUALITY CIRCLE FORUM OF INDIA
ANKLESHWAR CHAPTER
PHARMACEUTICAL WING

Organizing

One day Training Program on:

ROOT CAUSE ANALYSIS

SYMPTOM



ROOT CAUSE

Date: 31st July. 2018

Experts: Dr. Milind Pathak
Dr. Nikhil Bhatt

Organized By:

QUALITY CIRCLE FORUM OF INDIA

Ankleshwar chapter - Pharmaceutical Wing

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

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Background:

Having deviation occur and jumping in to fix it without investigating a root cause is akin to treating the symptoms of medical condition without trying to cure it.

If someone breaks the leg, a request for painkiller may naturally follow. However, painkiller won't heal the broken leg; nor will a "quick fix" approach resolve deviation.

Likewise, if someone addresses only the symptoms of an adverse event, the problem itself will almost certainly reoccur.

Root Cause Analysis (RCA) represents the best "medicine" for any adverse event. It both fixes the symptoms and helps uncover the reason why the event occurred in the first place. The process helps identify the origin of a problem using a specific set of steps and tools to find the problem's primary cause.

Conducting Root Cause Analysis can help to change an organization to reduce the likelihood of such problems ever recurring.

This training session will focus on explaining the methodology to identify root cause of adverse events scientifically with the use of tools to reduce the problems in day to day work.

Methodology of Seminar:

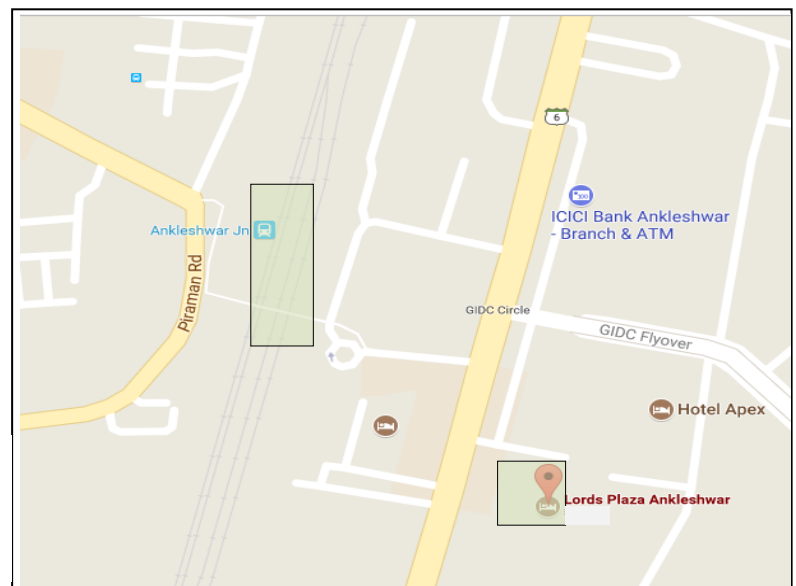
- It will be a participatory seminar encouraging questions and sharing experiences between experts and participants.
- Participants will be awarded certificates from "Quality Circle Forum of India" after successful participation in a training program.

Schedule and Venue of Seminar:

- **Date:** 31st July, 2018 (one day)
- **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 seminar is just 5 minutes walking distance from the premises of Ankleshwar Railway Station (East side).



Course Agenda:

| 8:45 to 9:00 | Breakfast & Registration | 14:30 to 14:45 | Fish Bone Diagram |
|----------------|--|----------------|-------------------------------|
| 9:00 to 09:20 | Introduction of topic | 14:45 to 15:15 | DoE , Shewhardt Control Chart |
| 09:20 to 09:40 | Methodology of root cause analysis | 15:15 to 15:30 | Tea-Break |
| 09:40 to 11:15 | Identification , Evaluation and investigation of problem | 15:30 to 16:00 | FTA |
| 11:15 to 11:30 | Tea - Break | | |
| 11:30 to 12:15 | Analysis of problem & Identification of root cause | 16:00 to 16:15 | Case Study |
| 12:15 to 13:15 | Action Plan | 16:15 to 16:30 | Summary |
| | Action Implementation Follow up of action plan | 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 | Why-Why Strategy , Pareto Diagram | 17:00 | Closure |

Seminar Charges:

- INR 3,000/- per participant + 18 % GST (Total 3,540 /- INR).
- 5% discount will be awarded to each participant for the registration of 3 or more participants from single organization.
- Course fee includes training material, tea-snacks and working lunch.
- This workshop is a non-residential seminar.

Registration Procedure:

- Registration can be acknowledged on niketan35@yahoo.co.in
- 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 09377434079** 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.



- **Dr. Nikhil Bhatt:**

Dr. Bhatt has worked with leading and reputed API manufacturing organization for more than 35 yrs. His core area is development, trouble shooting, optimization, piloting , scale up and smoothly transfer the technology at the commercial level till the completion of validation. During his professional assignment, he represented his organization to Europe, USA, China and Thailand in the area of transfer and commissioning of products. All together he has commissioned around 200 products at commercial scale with the compliance of regulatory expectations.

