



TWO DAYS TRAINING PROGRAM ON Quality Risk Management With Statistical and Problem Solving Tools.

Faculty : Dr. Milind Pathak

Organized By:

QUALITY CIRCLE FORUM OF INDIA

Ankleshwar Chapter

Opp. State Bank of India (Main Branch)

Station Road, ANKLESHWAR - 393 001

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:: Venue

Hotel **Dev Corporate**,

Opp. Bawarchi Restaurant,

Girish Coldrink cross Road,

Off. C.G.Road,

Navarangpura, Ahmedabad.

28th & 29th September - 2016

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



INTRODUCTION :

Risk Management principles are effectively utilized in many areas of business including finance, insurance, occupational safety, public health and pharmaceutical industries and by agencies regulating these industries.

An effective Quality Risk Management approach can ensure the high quality of the products to the stakeholders, customers and patients by providing a proactive means to identify and control potential quality issues during development and manufacturing.

In addition, use of Quality Risk Management can improve the decision making if a quality problem arises.

ICH Q9 offers a systematic approach to Quality Risk Management to industries providing guidance and tools that can enable more effective and consistent risk based decisions.

OBJECTIVE :

An objective of this training program is to explain FDA's expectation regarding Quality Risk Management methodology and tools.

CERTIFICATE :

Certificates will be awarded to the participants at the end of the training programme.

METHODOLOGY :

A Quality Risk Management approach (ICH-Q9) guidance will be explained in detail with suitable examples and rationale. It will be a participatory session followed by an evaluation on second day.

FACULTY

Dr. Milind Pathak - (M) 9377434079, email : nikan35@yahoo.co.in

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

SCHEDULE : DAY-1

8.45 AM	Breakfast
9.00 AM	Registration
9.30 AM	Inauguration/Prayer
9.45 AM	Introduction of Participants
10.00 AM	Introduction of QRM What is Risk Management Role of ICH Q9 Scope Principles of QRM QRM Process Responsibility
11.30 AM	Tea-Break
11.45 AM	Risk Assessment Risk control
1.00 PM	Lunch Break
1.45 PM	Risk Communication Risk Review Risk Management Methodology Risk Management Tools Cause & Effect diagram Workshop exercise
3.15 PM	Tea Break
3.30 PM	FMEA FMECA
5.00 PM	Day off

SCHEDULE : DAY-2

8.45 AM	Break Fast
9.00 AM	FTA (Faut Tree Analysis) HACCP HAZOP PHA Supporting Statistical Tools
11.00 AM	Tea Break
11.15 AM	Shewart Control Charts Design of Experiments Pareto Diagram Integration of QRM and Regulatory operations Documentation Training and Education Quality Defects
1.00 PM	Lunch Break
1.45 PM	Auditing and Inspection Change Control Design Space Design of facility & equipment QRM in Production
3.00 PM	Tea Break
3.15 PM	QRM in Materials Management Laboratory Controls Packaging & Labeling Conclusion
3.45 PM	Evaluation Test
4.15 PM	Valedictory Function
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 15th September - 2016.

ENROLLMENT

Registration can be acknowledged on ✉ niketan35@yahoo.co.in or qcfi.ank@gmail.com or milan_sheth1@yahoo.com
Cash or Draft or Cheque can be sent in favor of "**Quality Circle Forum of India**" and can be submitted at following address

QUALITY CIRCLE FORUM OF INDIA

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Opp. State Bank of India (Main Branch), Chauta Naka, Station Road, ANKLESHWAR - 393 001