Two days seminar on:

GENOTOXIC IMPURITIES

Date:

12th & 13th, June - 2018

Program Facilitator:

Mr. Milan Sheth

Experts:

Dr. Milind Pathak

& Dr. Nikhil Bhatt

PARTICIPATION FOR PROGRESS

QUALITY CIRCLE FORUM OF INDIA

Ankleshwar chapter - Pharmaceutical Wing

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

Ph.: 02646 247461, **Mobile:** 093774 34079 / 082003 56803

Email: Faculty: niketan35@yahoo.co.in / nikhilbhatt86@hotmail.com

Organizer: qcfi.ank@gmail.com

Introduction:

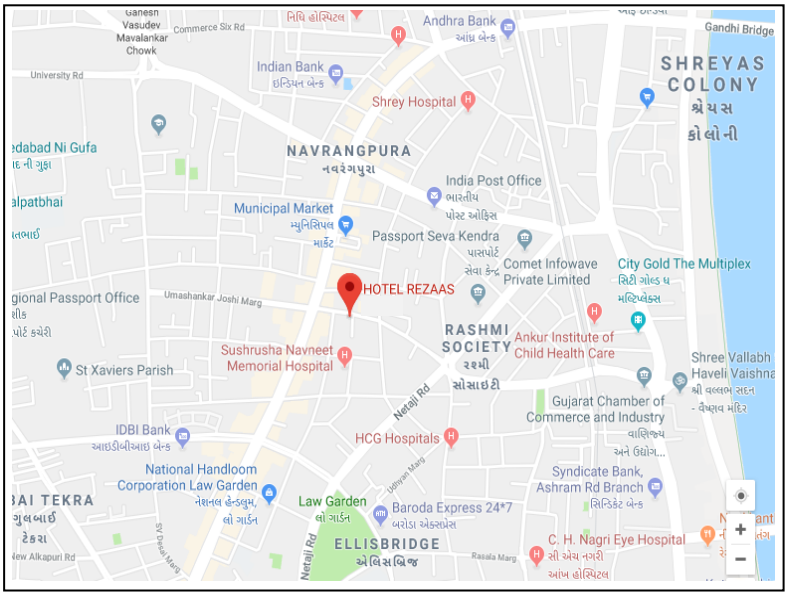
Genotoxic impurities (GTIs) in drug substances are mainly the consequence of using electrophilic reagents for building up the molecular structure. If they don't react completely, they can persist in the reaction mixture and may be carried onward in the synthesis. Due to their high reactivity they can also react with DNA and potentially induce genetic mutations. For this reason regulatory agencies established standards which assure that unavoidable impurities are limited to have no or acceptable levels of risk. Identification and control of potential mutagenic / Genotoxic impurities in drug substances or drug products is still a challenging task for pharmaceutical companies.

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 seminar.

Schedule and Venue of Seminar:

- **Date:** 12th & 13th , June - 2018
  (Total 2 days)
- **Time:** 09:00 am to 05:00 pm
- **Venue:** Hotel **Rezaa's , Near Girish Cold Drink ,**
  Opp. Induben Khakhrawala ,
  Off. C.G.Road/Mithakhali ; AHMEDABAD



Information for Participant's convenience:

Venue of seminar is just 10 minutes walking distance from the Municipal Market, C.G.Road, Navarangpura, Ahmedabad.

Course Agenda:

Day – 1	
8:45 to 9:00 am	Registration and Breakfast
9:00 to 9:30 am	Inauguration, Introduction and blessing speech by Chief Guest
9:30 to 9:45 am	Introduction of Genotoxic Impurities (GTI)
9:45 to 10:15 am	Rational Approach regarding Genotoxic Impurities (GTI)
10:15 to 11:30 am	Introduction to ICH M7
11:30 to 11:45 am	Tea-Break
11:45 to 12: 00 pm	Scope of ICH M7
12:00 to 1:00 pm	General Principles , TTC , Ames test
1:15 to 2:00 pm	Lunch - Break
2:00 to 2:30 pm	Consideration to marketed products
2:30 to 3:00 pm	Drug Substance & Drug Product Impurity Assessment , Synthetic & degradation impurities
3:00 to 3:30 pm	Hazard Assessment elements for GTI
3:30 to 3:45 pm	Tea – Break
3:45 to 4:15 pm	Prediction Softwares
4:15 to 5:30	Risk Characterization of GTI
5:30 pm	Closure

Day – 2	
9:00 to 9:30 am	Compound specific & TTC based AI
9:30 to 10:00 am	Control of process related GTI
10:00 to 11:00 am	Fate & purge factor ; Reactivity , Solubility , Volatility , Ionizability
11:00 to 11:15 am	Tea-Break
11:15 to 1:00 pm	Calculation of purge factor , Control approaches , Examples
1:00 to 2:00 pm	Lunch - Break
2:00 to 2:30 pm	Analytical challenges
2:30 to 3:00 pm	Life cycle management
3:00 to 3:15 pm	Tea-Break
3:15 to 4:00 pm	Case Study
4:00 to 4:15 pm	Summary
4:15 to 5:15 pm	Valedictory Function
5:15 pm	Closure

Seminar Charges:

- INR 8,000/- per participant + 18 % GST (Total 9,440 /- INR).
- 5% discount will be awarded to each participant for the registration of 3 or more participants from single organization.
- Last day to submit cheque / draft to confirm registration : 4th, June – 2018.
- 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 or nikhilbhatt86@hotmail.com or qcfi.ank@gmail.com by mail mentioning list of participants , designation , name of organization and contact detail of participants .
- 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.

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 4000 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.