ScientiaBio
FORTIFYING YOUR KNOWLEDGE ROOTS

Pharma Quality Workshop

Quality Risk Assessment ICH Q9 & WHO TRS -981(QRM)

28th February, 2020 (Friday)
Hotel Trinity Isle, Bangalore
9:30am to 5:30pm
Registration Fee: 7000 INR net (+GST)
(5% discount for a group of 3 or more)

GMP Auditor / Lead Auditor Training

29th February, 2020 (Saturday)
Hotel Trinity Isle, Bangalore
9:30am to 5:30pm
Registration Fee: 6000 INR (+GST)
(5% discount for a group of 3 or more)

Participant's comments from previous Lead Auditor training

"Training was excellent and full of knowledge. All guidelines highlights ae very clear & helpful to our day to day activity. So many new information also added by the trainer"- **Nidhi, Head-QA Analytical Lab, Par Formulations**

"I really like the way training was managed. Its not only taught new update and new things but also gave huge learning material for reference" **– Ravindra, Assistant Manager CQA, Flamingo Pharmaceuticals**

"It is good training session. It will be useful for us while working on auditing our system. After attending this training program, my knowledge in this subject get polished" **– Megha, Officer Quality Assurance, Embio Limited**

Email: admin@scientiabio.com with subject line "Pharma Quality Workshop"
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Quality Risk Assessment

Risk Management Plan Development and Implementation

The QRM Process

- Risk Identification
- Risk Assessment
- Risk Evaluation
- Risk Control
- Ranking and Trending
- Reports and outputs

QRM Tool
Practice Risk Assessment -Group Study-Application Orientation-one OOS case; one deviation case, one data integrity QRM

Risk decision tree / matrix
Breakout – Application of a risk decision tree
QRM-Qualitative approaches

QRM Across the product lifecycle
Implementation of QRM from Design to Decommissioning-By Qbd (Quality by design) way

Group Study-Examples from Regulatory Inspections observations and citing correct QRM application

Details about QRM SOP-A new model SOP Template Discussion

GMP Auditor / Lead Auditor Training

Audit Methods, Tools And Techniques

The Audit Process

Audit Plan for the opening meeting

Internal audit and improving the audit systems

How to Audit CAPA, OOS, OOT & QRM-PQS systems

Auditing Product manufactures

Data Integrity audits

Auditing for Approval of Suppliers / Contractors

Auditing API

Classifications of Observations

Plan for closing meeting and audit closure

BONUS Session:
At the end a small exam will be conducted to access understanding of Audit process

Meet the faculty:

G. Sundar

Our faculty has guided more than 6000 of individuals through effective training and conducted many effective Audit Process. He was also trained by USFDA. With more than 28 years of experience in GMP and Investigation Training, he has seen every problem and answered almost every questions you may have.

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