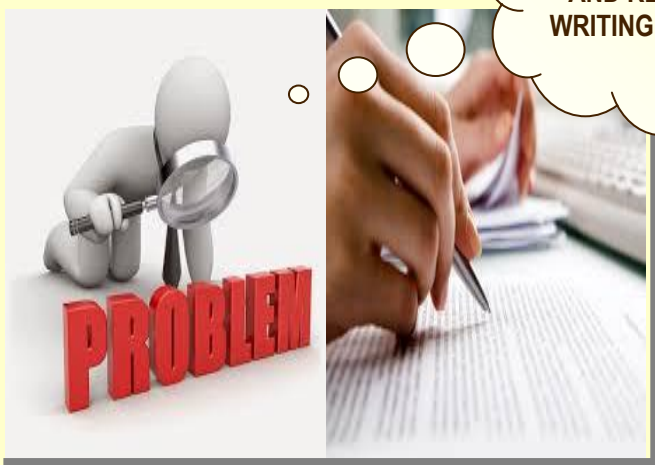
EMPHASIS ON DEVELOPING INVESTIGATION AND REPORT WRITING SKILLS



EFFECTIVE INVESTIGATION OF GMP FAILURES AND DEVIATIONS

A RISK BASED APPROACH TO GMP FOR COMPLIANCE AND PERFORMANCE

A two days, practical, value loaded training programme !

Venue : Hotel Satkar Residency, Pokhran Road No 1, Next to Cadbury, Opposite Raymonds, Thane (West) Pin - 400606

On December 4 & 5, 2015.
Timings : 10 : am to 5 : 00 pm.

....Course Director - Atul Shirgaonkar....

Introduction :

With the emphasis now heavily placed on implementing Pharmaceutical Quality Systems (PQS) and with ongoing changes to GMP Regulations and Guidelines, a recurring deviation is not considered as an outcome of implementing a robust quality system. Operator error or human error as an easy way out is not an acceptable root cause of Deviations and GMP Failures. All Deviations and GMP failures hence need to be investigated effectively leading to a proper Root Cause Analysis (RCA) and further resulting into Corrective and Preventive Actions (CAPA). In addition, these need to be documented properly, correctly and effectively to meet the needs of all the stake holders including regulatory inspectors.

Understanding this need of the industry, we are pleased to announce a two days training programme on the above topic. In line with our mission 'synergy for success', this programme also like our previous training programmes shall be practical and result oriented.

…. MEET YOUR COURSE DIRECTOR ….

Atul Shirgaonkar

Completed Masters in Pharmacy from Haffkine Institute Mumbai in regulatory toxicology supported with Diploma in Business and Marketing Management from IITC, Mumbai.

Also completed Diploma in Training and Development from ISTD, Delhi and carries a rich experience of working in the Pharmaceutical industry in various disciplines and capacities for nineteen years.

Conducted more than one thousand nine hundred fifty plus (1950+) training programmes till date in functional, technical and behavioural aspects of management and more than 100 GMP audits.

A popular trainer and has traveled all over the country and overseas to train more than 50,000 participants (from nineteen countries as well) as on date. Presented views on pharmaceutical quality aspects at different national and international symposia.

Also, a meticulous and in-depth auditor, documentation and GMP resource to various leading multinational firms in India and overseas.

…. COURSE CONTENTS ….

- **What do the terms deviation, failures, changes and CAPA mean**
- **Regulatory requirements for the above three GMP drivers**
- **Steps in deviation management and failure investigations**
- **Root cause analysis – what it means and its relevance and importance**
- **Logical steps in RCA and most probable and non assignable causes**
- **Tools and techniques as brain storming, cause and effect diagrams, 5 why analysis and HAZOP**
- **Findings, observations and documentation of investigation reports**
- **Expectations, requirements and responsibilities of investigators, reviewers and approvers of investigation reports**
- **Use of language proficiency, reasoning, coherence, structure, grammar to write meaningful investigation reports**
- **Linkages of deviation management, failure investigations and CAPA**
- **Non compliances reported by various regulatory agencies in investigation and its documentation**

…. WHO SHOULD ATTEND ….

Individuals from different working sections as QA, QC, Production, R&D, Compliance and Regulatory sections, Regulatory affairs, Validation teams, Hygiene & Sanitation, MR's, and personnel responsible for GMP Compliance and performance.

…. LEARNING OBJECTIVES ….

Upon completion of the course, the participants shall be familiar with the Basic and Advance GMP requirements in the area of Deviation Management, Failure investigations and CAPA. The participants shall be able to apply the techniques learnt for conducting and writing effective investigations and its reports to meet current GMPs. Achieving confidence in facing GMP audits shall be a value added advantage.

….REGISTRATION DETAILS….

Kindly confirm your nominations **with a DD of Rs.16986/-** (14,900 + 2086 service tax,) this includes, stationery, tea and lunch expenses) drawn in favour of **" Insight Systems Inc.", payable at Pune,** on the address mentioned below :

Insight Systems Inc.,
'SADHANA', Plot No. 13, Mangaldham Society, Near Ekalavya Polytechnic, S. No. 52, Kothrud, Pune 411038. Tel : (020) 25368620, 25361165 (telefax) Cell : 9822208197
e mail :**insight.shirgaonkar@insightcgmp.com**, **insight.shirgaonkar@gmail.com**
Do visit us at : www.insightcgmp.com
(For Group discounts refer registration Form attached separately)