

# DATA INTEGRITY CHALLENGES AND COMPLIANCE REGULATIONS

7<sup>TH</sup> APRIL 2020

TIMINGS: 10-5

UMDC - Behind IoBM,  
korangi Creek. Karachi.

## Overview

Poor documentation practices become a global problem and leads to severe non-compliance of data integrity principles. FDA data integrity warning letters have been increasing over the past few years and also other regulatory agencies of the world concerned about data integrity and bad documentation practices in the companies around the globe.

FDA and MHRA issued guidance on data integrity and documentation. WHO also published guidelines in its Technical Report Series. These guidelines provide provision to data governance and management and help organization to meet the expectation of regulators. In the modern manufacturing era, GMP compliance is based on good documentation and data integrity. The course designed to cater the need to maintain data integrity and learn good documentation practices from basic to the best standards. This course will bring positive impact for pharmaceutical manufacturers in developing confident businesses and compliance with international standards.



## Course Objectives

- The course will enable participants
- Understand the Data Integrity Challenges in emerging pharmaceutical world
- Know why we need Good Documentation Practices in businesses
- Aware of Good Documentation Practices regulations/guidelines worldwide
- Document life cycle and data integrity consideration
- GMP compliant document change management
- Confidently move forward for GDocP and compliance



## Learning Outcomes

- Understanding of Good Documentation Practices
- Enable attendees to find out data integrity issues and build a frame work for Good Documentation Practices.
- Apply knowledge to improve the workplace environment
- Attain knowledge of international standards and guidelines.
- Relate tools learned from the course to structure and implement GDocP
- Able to create a model for monitoring to maintain workplace compliance.



## Previous events



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## Course Outline

The course will broadly cover the topics below using real work scenarios and case studies

- Good documentation practice - need for successful businesses
- Good documentation – general understanding
- Data Integrity and reason behind the issue
- ALCOA – from understanding to application
- FDA WHO guidelines on Documentation
- Electronic records & Electronic Document Management System (EDMS)
- Role of GDocP to make a site GMP compliant
- Data Governance and life cycle management
- Audit trail
- GMP and documentation practices



## Who should attend:

- Industrial pharmacy professionals
- Pharmacist working in Dispensing, Production and Quality functions
- Engineers, Chemists and Microbiologists in pharmaceutical industries
- Regulatory affair professionals
- Quality assurance and quality control professional



## FEE STRUCTURE

**REGULAR COURSE FEE: PKR 18000/- PER DELEGATE EXCLUSIVE OF ANY TAX**

**10% DISCOUNT** ON 3 OR MORE NOMINATIONS FROM SAME ORGANISATION

INCLUDE COURSEWORK, LUNCH, REFRESHMENTS, CERTIFICATE, AND BUSINESS NETWORKING

FOR INDIVIDUAL AND GROUP REGISTRATION(S)-  
PLEASE CONTACT  
BINISH ARSHAD  
MOBILE: 0336 2092 011  
EMAIL: OFFICE@P-IMPACT.PK

OR REGISTER VIA WEBSITE  
[HTTPS://P-IMPACT.PK/REGISTER/](https://p-impact.pk/register/)  
INFO@P-IMPACT.PK  
MOBILE: 0345 202 7552

COURSE INVESTMENT  
**18,000/-**

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## COURSE FACILITATOR



**Dr Tariq Ali, PhD**  
Chairperson & Associate Professor, Department of Pharmaceutics,  
Dow University of Health Sciences

Over 20 years of experience of working in academia, Research, and Manufacturing operations, Dr Ali has authored 27 research publications in international reputed journals. He is also a Program reviewer for graduate & post-graduate level of studies in pharmaceutical and medical sciences for different universities. With his significant contributions in Glaxo SmithKline, Reckitt Benckiser, and Sanofi, he is known for his expertise in Pharmaceutical Manufacturing operations, quality and compliance.

He has been conducting trainings for pharmaceuticals over many years. He is a subject expert on GMP Practices, Halal Pharmaceutical Certifications, Pharmaceutical Quality Management, Industrial Pharmacy, Pharmaceutical Technology, Forensic Pharmacy, Physical Pharmacy and Instrumentation. He has also conducted various trainings in supply chain covering Risk Assessment, Tablet Manufacturing Process and Bioavailability. Some of his training sessions to production staff covers Health and Safety, Uniform Protocols, Accidents and its awareness, Status Labelling and LOTO procedures.

His work in quality management and compliance include ISO compliance Audits, GMP Audits, Regulatory Audits, Model Factory Audits, Micro risk Audits and Health & Safety Audits. He is career advisor and youth counsellor. His work and significant achievements have contributed greatly to the Pharmaceutical industry.

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