Centre for cGMP

PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce & Industry, Govt. of India)

MANIPAL ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

Our Inspiration

Founder : Dr. T M A Pai, Padmashree awardee

**Manipal College of Pharmaceutical Sciences** | **In Association with IDMA and Pharmexcil**

# Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2024/04)

## *THINK cGMP – cGMP is LIFE*

Commitment | Adherence | Creating Quality Culture

3 GOOD HEALTH AND WELL-BEING

## Topic : "Data Integrity" within the Pharmaceutical Sector

4 QUALITY EDUCATION

### Know Data Types

**Data**
Information derived or obtained from raw data.
Examples: A reported analytical result, a reported specification for a finished product.

**Raw data**
Refers to original records and documentation, retained in the format they were originally generated.
Examples: Laboratory worksheet, IPQA sheets etc

**Meta data**
Forms an integral part of data by providing contextual meaning to it.
Example: Provide context with details such as source, type, owner, and other data sets.

### Know Data Terms

**Data Governance**
Strategies implemented to establish clear policies, procedures and controls for managing data.

**Data Lifecycle**
All data should be maintained throughout the record's retention period.
Includes retention of all meta data required to reconstruct cGMP activity.

**Audit trail**
Refers to secure, computer-generated, time-stamped electronic data.

| FDA, EMA, and MHRA – common data integrity guidelines | Common examples of data integrity violations |
|---|---|
| 1.Training all personnel on data storage and processing formats under Good Documentation Practices (GDP). Includes staff such as process operators, supervisors and QA inspectors. | 1.Inattentive documentation leading to potentially missing data during note taking.<br>2.Data transferred from paper to electronic note book is not accept able as it is considered to be data manipulation. |
| 2.All data must be reviewed by QA department. Includes computerised records and physical records. | 1.Incomplete and inaccurately submitted documentation. |
| 3.All data forms must be backed up safely for inspections. Includes printed observations from analytical systems, all meta data and raw data. | 1.Data (raw/processed) unavailable for inspection.<br>2.Manual observations recorded on loose paper.<br>3.Archived copies are not an accurate representation of original record. |
| 4.Audit trails must be checked by QA department. Inspection of data changes such as deletions or backdating. | 1.Backdating results, observations and activities.<br>2.Creating acceptable results to fit with the specifications. |
| 5.Changes to data should be restricted to personnel identifiable in a traceable manner. All personnel should have independent logins and batch ID. | 1.Using shared or common sign in electronic systems. |
| 6.Control strategies must be based on sound scientific basis. To be validated by QA personnel. | 1.Measures in place to maintain and monitor data is non validated. |

### Key points to remember for compliance of data integrity

- Establish robust data management systems
- Implement quality management systems
- Good Documentation Practices
- Training and Education

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