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" (2024/03)

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

What is Data Integrity or DI?

- Refers to data in records with maximum accuracy and consistency with protection of data from unauthorized or unaccountable changes.
- A process of maintenance, and assurance of completeness, accuracy and consistency of data throughout its life-cycle.
- Refers to both paperwork (manual) and electronic data.
- DI has to be followed throughout the drug development process, including research, clinical trials, manufacturing and distribution.
- Involves implementation of robust systems, processes and controls to prevent data manipulation.
- ALCOA and ALCOA+ are acronyms introduced by USFDA to indicate data integrity in relation to pharmaceutical research, manufacturing, testing and supply chain.

What does Data Integrity ensure?

- **Regulatory compliance**
  Helps companies to obtain approvals for drug products from regulatory authorities and maintain market access.
- **Patient safety**
  Inaccurate or incomplete data could lead to incorrect dosage, ineffective treatments, or adverse reactions.
- **Accountability and Traceability**
  Ensures transparency in events of audits or investigations.
- **Quality Assurance**
  Helps to maintain quality and efficacy of the drug with no batch variations.
- **Customer satisfaction**
  Enhances confidence in the safety, efficacy and reliability of drug product, fostering trust among healthcare professionals, regulatory authorities and patients.

Know ALCOA+		Description
1.	**A - Attributable**	Who performed the action and when? If record is changed, who did it and why?
2.	**L – Legible**	Data must be recorded permanently in durable medium and shall be readable.
3.	**C – Contemporaneous**	Data should be recorded at the time work is performed.
4.	**O – Original**	Is the information an original record or certified true copy?
5.	**A – Accurate**	No error or editing performed without documented amendments.
6.	**Complete**	All data including repeat or reanalysis should be recorded.
7.	**Consistent**	Changes made to original data recording should be time stamped.
8.	**Enduring**	Recorded on controlled worksheets or laboratory notebooks.
9.	**Available**	Available/accessible for review/audit for the lifetime of the record.

An example of ALCOA + : Attributable and Legible

ALCOA$^+$: ATTRIBUTABLE **pH of the buffer solution = ~~6.8~~ = 7.2**	
Who made the correction? Why was the correction done? When was the correction done?	NONE of these data are available X
pH of the buffer solution = ~~6.8~~ = 7.2 with Sign/Date **Reason = Type error**	
Who made the correction? Why was the correction done? When was the correction done?	Data available. Hence, data is attributable.

ALCOA$^+$: LEGIBLE
pH of the buffer solution = ■ = 7.2 - Not Acceptable, as the original text matter is totally hidden. **pH of the buffer solution = ~~6.8~~ = 7.2 with Sign/Date – Acceptable** **Reason for correction = Typo error**

ALCOA$^+$: ORIGINAL		
Step 1	Step 2	Step 3
Source document. (Written in paper form)	PRINT OUT TAKEN	Photocopy of source document (Controlled copy)

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