

Review Article

DATA INTEGRITY IN PHARMACEUTICAL QUALITY SYSTEM: A REVIEW

Mahaveer Singh *, Hitesh Kothari, Anju Goyal

Department of Pharmaceutical Quality Assurance, Bhupal Nobles' College of Pharmacy, Udaipur
(Rajasthan) 313001, India

Data Integrity, which is data deemed Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available (ALCOA-plus), has been the focus of the pharmaceutical industry in recent years. With the growing use of computerized systems and rising prevalence of outsourcing manufacturing processes, ensuring data integrity is becoming more challenging in an increasingly complex pharmaceutical manufacturing industry. To address this issue, multiple legislation and guidance documents such as 'Data Integrity and Compliance with CGMP Guidance for Industry' from the US Food and Drug Administration (FDA), 'GxP' Data Integrity Guidance and Definitions from the UK Medicines & Healthcare products Regulatory Agency (MHRA), and 'Guidance on Good Data and Record Management Practices' from the World Health Organization (WHO), have been published in recent years. However, with rising data integrity issues observed by FDA, WHO, MHRA and other pharmaceutical inspectors even after these guidance documents have been published, their overall effectiveness is yet to be determined. It appears that these legislation and guidance are insufficient in maintaining data integrity in the industry when used alone. Last, but not least, this paper also reviews other solutions, such as the need for a company culture of integrity, to aid in maintaining data integrity in the manufacturing industry.

KEYWORD: Data integrity, ALCOA, Data, Good documentation practices (GDPs), Regulatory Body, Risk Management.