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Importance of data integrity in pharmaceuticals

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As per USFDA, data integrity refers to the completeness, consistency and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA).World Health Organization (WHO) defines data integrity as the degree to which a collection of data is complete, consistent and accurate throughout the data lifecycle. The collected data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices. USFDA expects data to be reliable and accurate, necessary to have flexible and risk-based strategies to prevent and detect data integrity issues, implement meaningful and effective strategies to manage their data integrity risks. The expectation of MHRA with respect to data integrity is the governance system should be integral to the pharmaceutical quality system. Data integrity is related to many stakeholders like patients, regulators and organization. Data integrity is applied at all stages of product life cycle from discovery to distribution and applied on GXP systems, facilities, quality system, data functions and regulatory submissions. Data integrity does matter because it is necessary to establish confidence that the quality related activities are being performed effectively and regulatory decisions depends on accurate data across product lifecycle. Data integrity lapses lead to prosecution, injunction, penalty, warning letters and import alerts affecting the overall business of the organization.

Biography

Raghunandan H V is currently working as Professor of Pharmaceutics JSSCP and worked as Pharmacist with over 23+ years of progressive experience in pharmaceutical quality assurance, quality control, regulatory affairs, manufacturing of formulations/API's/biologicals, contract manufacturing and pharmaceutical technical consultation (reg. affairs, product development and quality). He has good understanding of the audits and risk management in pharmaceuticals/bio pharmaceuticals, consumer health care products like OTC/OHC/nutritional health care. He is an experienced Quality Auditor and has good experience in auditing and site quality management.

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