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Building a Quality Culture that Supports Data Integrity in the Pharmaceutical Industry

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Abstract

Data integrity is a fundamental regulatory requirement in the pharmaceutical industry, assuring that trustworthy and reliable data are used for decision-making during development, manufacturing, and testing of medicinal products. Complete, consistent, and accurate data throughout the data lifecycle ensures the safety, efficacy, and quality of drugs. However, global regulatory agencies have increasingly cited pharmaceutical organizations for data integrity violations, resulting in product recalls, import bans, drug shortages, and loss of trust from healthcare providers, patients, and regulatory agencies. This paper presents an overview of data integrity, defining the requirements for data reliability, providing a description of data-related issues, potential root causes, and US Food and Drug (FDA) regulatory requirements. Furthermore, this paper explores how a pharmaceutical organization can grow a healthy quality culture that would serve as the foundation in assuring good data management practices, and ultimately providing assurance of data integrity.