
Data Integrity Considerations for the Pharmaceutical Microbiology Laboratory

By **Tim Sandle** Nov 21, 2016 9:50 am PST

Data integrity refers to maintaining and assuring the accuracy and consistency of data over its entire life-cycle, and is a critical aspect to the design, implementation and usage of any system which stores, processes, or retrieves data. Data integrity is a key regulatory concern and guidance documents have been produced by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Moreover, data integrity in relation to the microbiology laboratory features in several FDA warning letters, especially in relation to sample handling and reading.

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