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Data integrity issues

Mohammad Iqbal Hossain

Novartis Ltd., Bangladesh

Abstract

Data Integrity issues have got extreme focuses immediate after the incidents identified by FDA to some Prominent Pharmaceutical Companies. Everything was fine through data collection to data presentation to regulatory bodies but few queries at the same time on how electronic book keeping are maintained by those companies, blast the real situation about the processes practice over there and companies faced too horrible image issue. The issues were rather very simple but so far there was a misunderstanding on how to perform and how to document them and in some cases there might be even an intentional deviation to generate factious data having no archival evidence of electronic raw data or even if any there was much more dissimilarities on data generation date or electronic system logging date. This was the scenario first identified by FDA Audit for few companies across the world and concern raised on how to check those points and which types of remedial actions are in fact to be fruitful to ensure medicines expected level of quality, efficacy & safety. That was really a major concern, no doubt.

Consequently, what is the current situation for mid-size Pharmaceutical companies who still carry poor understanding level about data integrity issues & FDA requirements and what initiative should they need to take to avoid the recurrence of incidents for which many reputed Pharmaceutical Companies received warning letter many times in the past? So far, electronic devices being used in a compliant lab should have some definite features that would finally be the key indicators for claiming data authenticity usually generated by those devices for any testing in any time.

Biography

Mohammad Iqbal Hossain has completed M.Sc. in Chemistry from the University of Chittagong followed by an MBA degree in Marketing from another University. He has more than 10 years of practical experiences in Pharma analytical field and working with Sandoz from the very beginning of his career to till date. He successfully led a project
'Quality Transformation Program' to make fine tuning Sandoz's quality issues specially
Data Integrity & lab in- control to improve. He is a Senior Executive & Team Leader for Analytical Method Development, Validation of Analytical Procedures & Tech Transfer issues. He is responsible for dealing Registration activities for Sandoz Bangladesh Tech Ops.