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Investigations and CAPA: Quality system for continual improvement in pharmaceutical industry

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Abstract
United States Food and Drug Administration (USFDA) is health regulatory agency responsible for healthcare of the citizens of United State of America (USA). Investigator from the agency perform regulatory audit of drug substance and drug product manufacturing site as a part of verification of cGMP compliance. Regulatory Audit is conducted for any one or combination of three reasons (1) Pre-approval inspection (PAI) before approval of the drug product (2) Regular cGMP inspection and (3) For Cause audit. If any non-compliance is observed during audit, the investigator cites the observation on the form "FDA 483" (that is why the observations are popularly known as 483 observations). The citations related to inadequate investigation and CAPA are always topping among all the observations.
Failures are inevitable in any organization; however, it is important that organization performs a detailed investigation to identify the root cause for the reported non-compliance or failure in order to take an appropriate corrective action to avoid recurrence. Proactive organizations do not wait for the failure to be reported but take preventive action to improve the system. These organizations believe in identifying the potential non-conformity by performing quality risk assessment and taking appropriate preventive action to mitigate the risk and thus avoid the occurrence of non-compliance or failure. Proactive organization not only save money by avoiding these batch failures but also avoid potential questions / observations during regulatory audits. This proactive approach shall improve the quality metrics of the organization and reduce the frequency of regulatory audits as agency determines the audit frequency based on review of the quality metrics of the organizations.

Keywords: pharmaceutical industry, investigation, corrective action and preventive action (CAPA), risk assessment, out of specification (OOS), deviation, good manufacturing practice (GMP)