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Corrective action & preventive action (capa system) and regulatory inspection

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CAPA system is the IMPROVEMENTS to be made in PRODUCT, PROCESS or QUALITY SYSTEMS to eliminate non conformities and other undesirable situation. CAPA is a REGULATORY concept that focuses on systematic INVESTIGATIONS to find out the ROOT CAUSE, understanding and correcting discrepancies while attempting to prevent their REOCCURANCE. Regulatory Inspections gives more importance for CAPA, for the reason, it will high light the systems followed in the company as well as the technical capability of the people concerned. CAPA investigation is set in motion by an event either in manufacturing inconsistency, complaint or regulatory/internal audit. During investigation, it is important that there be system to make sure that the problems are tracked and corrective actions are taken ensuring the quality of the product. Identify the problem and understand its impact on product and reputation of the company.Investigate scientifically to find out the potential cause and arrive at root cause. Extensive documents are required to be checked. All activities and results, in detail, are required to be documented. Once the root cause is identified, analyze the results of findings and confirm. Evaluate the impact of findings in earlier batches of the product. Changes proposed are to be verified and validated to ensure the effectiveness and quality attribution. Inform the details to Management and implement the changes in presence of all concerned in shop floor with proper training. The CAPA system investigation document will give a clear picture of how the QUALITY SYSTEMS works and hence, Regulatory Inspectors give lot of importance to audit this system.

REAL ROOT CAUSE IS TO BE IDENTIFIED WITH SCIENTIFIC PROOF AND SHOULD NOT BE GENERATED.

Biography

S N KILIKAR has completed his graduation in Chemistry from Kerala University, India in the year 1973. He is having an experience in Pharmaceutical Industry for more than 37 years in the field of QC, PRODUCTION and GMP Implementation including Validation. Now he is working as a CONSULTANT to support Pharmaceutical units to develop new Facilities, Documentation, Validations and other cGMP requirements. He is conducting many Training programmes including for sterile manufacturing. Technical audits are conducted to rectify and upgrade the systems to cGMP level. Three AYURVEDA manufacturing units are set up in Kerala conforming to cGMP standards.

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