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Effective integration of quality risk management into the CAPA system

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Effective integration of quality risk management (QRM) into CAPA systems is the complete system implantation in pharmaceutical life cycle process. CAPA requirements in GxP environment and how they relate to quality risk management. QRM establishment involves a multi-level assessment process which enables CAPA process to meets the requirements. Using integrated risk management system to allocate CAPA resources and priorities. Quality risk management integrates with recall decisions and health hazard evaluations. QRM helps risk management of vendors, audits and supplier corrective actions.

CAPA findings in Regulatory inspections continue to be among the highest observations cited by investigators. FDA has provided information explaining that risk is an important consideration in the CAPA process. They do not however provide any guidance on how risk is included in this important process. Additionally, more information is flowing out of FDA indicating that risk is becoming an additional focus of the agency, such as in the recent report on risk communication. Manufacturers need to understand what FDA expects in incorporating risk in the CAPA process, what strategies can be used to assign resources to CAPA activities, and how to manage multi-level CAPA processes, so that they will not run afoul of the FDA during inspections.

Biography

Sundar Ganesan has completed his master's in Chemistry at the age of 25 years from Annamali University and post graduate diploma from Alagappa University. He was the head of QA-GMP compliance, Alkem Laboratories Ltd., Daman, India. He has published more than 10 papers in reputed journals and serving in pharma industry more than 18 years in quality, regulatory departments.

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