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On-site audits approach: A tool for Quality Risk Management

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On-site Audits is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. It is an important part of organization's quality management system and is a key tool for measuring Quality risks associated with products. Use of Quality Risk Management (QRM) can improve the decision making processes from development, technical transfer, manufacturing, post approval changes and throughout the entire product life cycle to ensure regulatory compliance. On-site Audits are typically performed at predefined agenda and ensure that the organization has clearly-defined internal quality monitoring procedures linked to effective action. This can help determine if the organization complies with the defined quality system processes and can involve procedural or results-based assessment criteria. In present Quality Systems, the focus of the audits has shifted from purely procedural adherence towards measurement of the actual effectiveness of the Quality Management System (QMS) and the results that have been achieved through the implementation of a QMS. On-site Audits can be an integral part of compliance or regulatory requirements. Quality Audit can save organizations from quality disasters. The goal of this article is to provide brief information regarding on-site audits methodology and how to apply auditing rules effectively to achieve organizational objectives and goals to meet sustainable growth through continuous improvement of any quality system. This article may helpful to understand that how to sharpen on-site auditing skills and apply auditing principles to an appropriate way to influence auditee for better assessment and take risk based decision through proper audit checklists and audit interviews.

Biography

V. Siva Kumar has completed his post-graduate in Organic Chemistry and Master of Business Administration from Anna University. Siva Kumar is a Certified Quality Auditor from American Society for Quality (ASQ CQA) and Trained ICH Q7 Auditor from European Compliance Academy (ECA). He is a senior member of American Society for Quality (ASQ). He is an Expert committee member in Indian Pharmacopeia commission (IPC). Faculty for USP Pharmacopoeia Educational programme for GMP topics.

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