

Summary - Application of Quality Risk Management to Periodic Review of SOPs

Each GMP site should define the responsibilities and the processes for preparing, approving, maintaining, and archiving GMP-related documents and records. Pursuant to this requirement many sites employ a default frequency for periodic review of SOPs. Since processes and procedures have varying impact on product this practice may unnecessarily consume resources in an attempt to maintain compliance with the stated review policy. This document provides guidance on how to apply quality risk management to periodic review of SOPs utilizing the risk assessment tool known as risk ranking and filtering.

The risk is the likelihood (PROBABILITY) of having non-compliant or deficient procedures which have the potential to impact product quality or regulatory compliance attributed to lack of timely document review and that could remain unchecked or undetected. In addition, the greater potential of an SOP to impact product quality and regulatory compliance directly corresponds to a greater likelihood of that SOP being reviewed during an inspection. The potential undesired consequence (OUTCOME) under such circumstances is a negative impact on product quality and a regulatory citation from having an SOP in a non-compliant status. Considering the number of SOPs that could be subject of periodic review at a site, a more practical approach is to categorize the SOPs on the basis of potential impact to product quality and regulatory compliance.

After agreement is reached on the risk associated with each procedure or type of procedure, a site should then define the level of risk it is willing to accept. This again, will depend on several factors such as the regulatory environment, type of products produced, etc. For the working example, four (4) separate frequencies of review have been proposed for implementation. Formal acceptance of these established risks occurs when the procedure defining the new risk-based approach is approved by the relevant site management.

The use of a risk management approach will allow sites to reach a balance between benefits, risks, and resources as they are now able to set priorities and effectively use available resources to address the review/revision of SOPs. After reaching a well-informed decision, a suitable SOP review period can be assigned for each SOP with a frequency that is reasonable and relevant to the site's own experiences.

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