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Review Article

Risk Assessment and Management Tools in Quality Assurance

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Abstract: *The aim of this article is to provide better understanding in the application of the International Conference on Harmonization Q9 guideline. This paper reflects the need of quality risk management in pharmaceutical industry to improve and consistently working with quality. Quality risk management (QRM) can be applied at various stages in the industry consisting of manufacturing, distribution, inspection, and review of pharmaceutical products and any biological product throughout its lifecycle. QRM includes risk evaluation, risk control, and risk review. The risk evaluation provides regulator brief information about the severity of the risk and depending on severity of the risk appropriate risk management tool. The various risk management tools are described in this paper. Risk pertaining in the quality of product declining the firm's growth so as to maintain the market response firm has to be consistent with the product quality. QRM shows how to implement, evaluate, control, and review the risk.*

Keywords: Failure mode effect analysis, hazard management, international conference on harmonization guidelines, quality risk management, risk management