

Guidelines For Initiating Events And Independent Protection Layers In Layer Of Protection Analysis

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serves as a foundation or resource document that is independent of, yet supports, other ICH Quality documents and complements existing quality practices, requirements, standards, and

QUALITY RISK MANAGEMENT - ICH

protection of the patient by managing the risk to quality should be considered of prime importance. The manufacturing and use of a drug (medicinal) product, including its components, necessarily entail some degree of risk. The risk to its quality is just one component of the overall risk. It is important to understand that product should be quality

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management. It serves as a foundation or resource document that is independent of, yet supports, other ICH Quality documents and complements existing quality practices, requirements, standards, and guidelines within the pharmaceutical industry and regulatory environment. It specifically provides guidance on the

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recommendations it contains are, unless labelled as 'expert opinion', based on independent review of the available evidence. Interpretation of this document by those without appropriate medical and/or clinical training is not recommended, other than at ...