

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

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ICH guideline Q9 on quality risk management - European ...

including patients and medical practitioners as well as government and industry, the 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 ...

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