

Auditing as a Component of a Pharmaceutical Quality System



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By

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The following key elements from ICH Q10 provide strong rationale for conducting both internal and external audits: Include both internal and external audit results as part of the process performance and product quality monitoring system Implement corrective actions and preventive actions (CAPA) as a result of audit observations Include audit results as part of management review of the quality system Consider feedback from periodic internal audits and external audits in con

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