

## Risk-Based Approach to Internal Quality Auditing



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Auditing is a vital function within the pharmaceutical and healthcare sectors. Audits provide the mechanism to assess the level of compliance and provide an indication of problems that might lead to product adulteration or patient harm. Key areas for the audit process are listed. Relevant audit topics discussed include audit planning, vertical and horizontal audits, audit frequency, trending, regulatory updates, conducting audits, assigning non-compliances, audit responses, and management oversight.

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