Nitrosamines – GAP Assessment regarding ICH M7

Services created to evaluate the existing strategies implemented by clients concerning nitrosamines and assess their compliance with ICH M7 and FDA regulations. We meticulously review SOPs, internal guidelines, and risk management practices to identify any GAPs or deficiencies and provide recommendations for improvement

Comprehensive Documentation Review

Conducting a thorough examination of SOPs, internal guidelines, and other relevant documents pertaining to nitrosamine risk management.

Assessing the adequacy and completeness of documentation in addressing ICH M7 and FDA requirements for nitrosamines.

Risk Assessment Analysis

Performing a detailed analysis of the risk assessment methodologies employed by the client to evaluate nitrosamine risks in pharmaceutical products.

Reviewing risk assessment criteria, data sources, and decision-making processes to ensure alignment with ICH M7 and FDA guidelines.

Compliance GAP Identification

Identifying any discrepancies or non-compliance issues in the client's nitrosamine risk management strategy concerning ICH M7 and FDA standards.

Highlighting areas where improvements or corrective actions are needed to enhance compliance and mitigate risks associated with nitrosamines.

- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS

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