Nitrosamines – General Strategy Creation

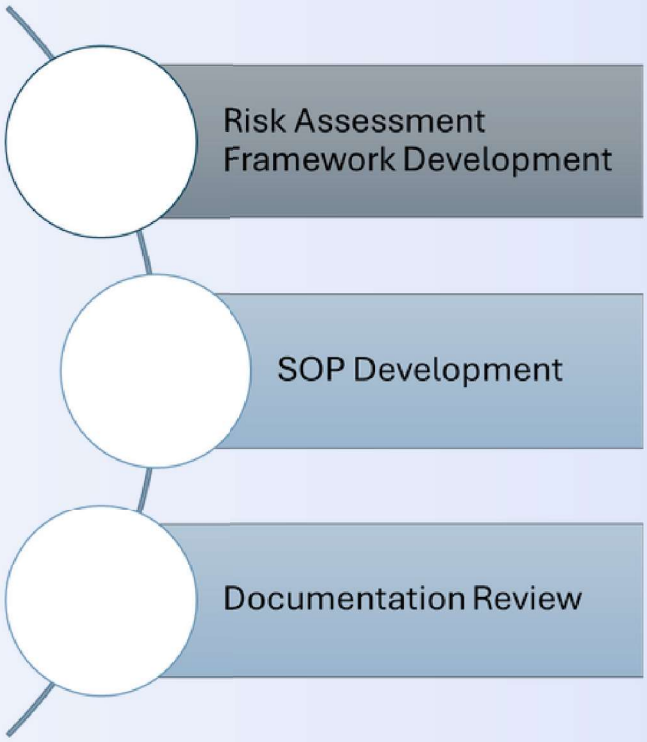
We offer services designed to equip clients with a comprehensive strategy for addressing Nitrosamine impurities in pharmaceutical products. We provide essential background documentation, including SOPs and internal guidelines, created to enable clients to meet the stringent requirements outlined by ICH M7 and the FDA.

Risk Assessment Framework Development

We utilize established methodologies such as the ICH M7 guideline to develop a comprehensive risk assessment framework.
Tailoring the framework to the specific manufacturing processes, raw materials, and drug formulations of the client's products. Incorporating industry best practices and scientific principles to ensure thorough identification and evaluation of nitrosamine risks.

SOP Development and Implementation

Creating detailed SOPs that outline step-by-step procedures for detecting, quantifying, and mitigating nitrosamine impurities. Ensuring SOPs are clear, concise, and compliant with regulatory requirements, including those set forth by ICH M7 and the FDA. Collaborating with the client's Quality Assurance and Regulatory Affairs teams to facilitate the smooth implementation of SOPs across manufacturing facilities.



Documentation Review and Compliance Check

Conducting a comprehensive review of existing documentation, including SOPs, validation reports, and analytical methods, to assess compliance with nitrosamine-related regulations. Identifying inconsistencies in documentation and recommending corrective actions to address deficiencies. We provide guidance on documentation updates and revisions to ensure alignment with regulatory requirements.

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

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