

Nitrosamines – Analytical Strategy Creation

Zamann Pharma Support offers services meticulously designed to provide clients with the requisite background documentation, particularly SOPs, to execute the essential analytical steps for nitrosamines in pharmaceutical products, aligning with the stringent requirements outlined in ICH M7 and FDA regulations

SOP Development

Our team works closely with clients to understand their specific analytical requirements and challenges, ensuring that the SOPs are tailored to their unique needs.

We develop detailed SOPs covering all aspects of the analytical process, including sample preparation, instrumental analysis, data interpretation, and reporting. Our SOPs are meticulously crafted to align with the latest regulatory guidelines from ICH M7 and FDA, ensuring that clients remain compliant with industry standards.

Method Validation Guidance

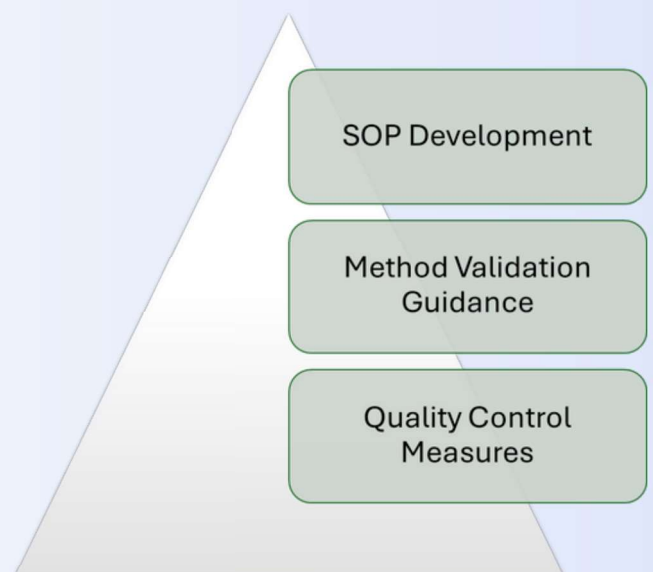
We assist clients in designing validation protocols that are tailored to their analytical methods and instrumentation, taking into account factors such as matrix complexity and detection limits. Our team provides guidance on conducting method validation studies with a focus on demonstrating accuracy, precision, specificity, and robustness, as required by ICH M7. We emphasize the importance of data integrity throughout the validation process, advising clients on best practices for documenting and evaluating validation results.

Quality Control Measures

We help clients implement risk-based quality control measures to prioritize critical parameters and ensure the reliability of analytical data.

Our team assists in establishing procedures for ongoing monitoring of analytical performance, including regular calibration and maintenance of analytical instruments.

We support clients in establishing a culture of continual improvement by providing guidance on performance metrics, trend analysis, and corrective action implementation to enhance the quality of analytical results.



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

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