

# Nitrosamines – Data Management Strategy Creation

Zamann Pharma Support provide service dedicated to develop robust Data Management strategies customized to meet ICH M7 and FDA requirements. We provide essential background documentation, including SOPs and internal guidelines, to enable clients to effectively manage data related to nitrosamine analysis and control

## SOP Development

Crafting detailed SOPs outlining procedures for data collection, storage, analysis, and reporting in accordance with regulatory guidelines.

Customizing SOPs to align with the specific needs and processes of the client's organization, ensuring clarity and compliance.

## Data Governance Framework Establishment

Designing a comprehensive data governance framework to define roles, responsibilities, and processes for managing nitrosamine-related data.

Implementing protocols for data quality assurance, validation, and traceability to maintain the integrity and reliability of the information.

## Compliance Assessment and GAP Analysis

Conducting a thorough assessment of existing Data Management practices to identify gaps and areas of non-compliance with regulatory requirements. Providing recommendations for enhancements and corrective actions to ensure alignment with ICH M7 and FDA standards. Collaborating with the client to develop and implement remediation plans to address deficiencies and data management capabilities.

