

# Nitrosamines – Drug Product Risk Management Strategy Creation

Service designed to assist clients in developing robust strategies for managing nitrosamine risks in drug products, ensuring compliance with ICH M7 and FDA requirements. We provide essential background documentation, including SOPs and internal guidelines, to guide clients in creating effective Risk Management plans

## Risk Assessment Framework Development

Crafting a comprehensive framework for conducting Risk Assessments to identify potential nitrosamine impurities in drug products. Defining risk assessment criteria, methodologies, and decision-making processes to systematically evaluate and prioritize risks.

## Mitigation Strategy Formulation

Collaborating with clients to develop customized mitigation strategies to control or eliminate nitrosamine impurities in drug products. Implementing risk control measures and preventive actions to minimize the likelihood of nitrosamine contamination during drug manufacturing and storage.

## Compliance GAP Analysis

Conducting a detailed analysis of existing risk management practices to assess compliance with ICH M7 and FDA guidelines. Identifying deficiencies in current Risk Management processes and providing recommendations for improvement. Assisting clients in implementing enhancements to ensure alignment with regulatory requirements and industry best practices.

