

Nitrosamines – Drug Product Risk Management Strategy Creation for NDSRI

Zamann Pharma Support offers services created to assist clients in developing comprehensive strategies for managing nitrosamine risks specifically for new drug substance reference standards (NDSRIs). We provide essential background documentation, including SOPs and internal guidelines, to guide clients in creating effective risk management plans in compliance with ICH M7 and FDA requirements

Risk Assessment Framework Development for NDSRIs

Designing a specialized risk assessment framework specifically tailored to evaluate nitrosamine risks associated with new drug substance reference standards.

Defining risk assessment criteria and methodologies unique to NDSRIs to systematically identify and assess potential nitrosamine impurities.

Mitigation Strategy Formulation for NDSRIs

Collaborating with clients to develop targeted mitigation strategies for managing nitrosamine risks in new drug substance reference standards.

Implementing risk control measures and preventive actions specific to NDSRIs to minimize the risk of nitrosamine contamination during manufacturing and storage.

Compliance GAP Analysis for NDSRIs

Conducting a thorough analysis of existing risk management practices related to new drug substance reference standards to assess compliance with ICH M7 and FDA guidelines.

Identifying any GAPs or deficiencies in current risk management processes for NDSRIs and providing recommendations for enhancement.

Assisting clients in implementing corrective actions and improvements to ensure alignment with regulatory requirements and industry standards for NDSRIs.

