

Nitrosamines: Compliance with new requirements - Implementation and Improvement

We offer specialized consulting services focused on preparing companies regarding Nitrosamines regulations in accordance with ICH M7 and international standards. Our service encompasses a thorough assessment of existing processes, the development of customized strategies, and the implementation of improvement initiatives to ensure compliance and enhance safety standards

Risk Assessment and GAP Analysis

We conduct detailed risk assessments and GAP analyses to identify potential sources of Nitrosamine contamination in pharmaceutical products, raw materials, and manufacturing processes. Our experts evaluate existing control measures and assess the level of risk to determine necessary corrective actions and preventive measures.

Strategy Development According to ICH M7

Building on the findings from risk assessments, we collaborate with clients to develop Nitrosamine Life Cycle Strategies in compliance with the ICH M7 guidelines. This involves establishing control strategies, defining protocols for testing and monitoring, and implementing measures to prevent nitrosamine formation or contamination.

Implementation Support and Training

We provide comprehensive support and training throughout the implementation of Nitrosamine Life Cycle Strategies, ensuring adherence to ICH M7 guidelines and regulatory requirements. Our experts assist in implementing process changes, conducting training programs for staff members, and establishing robust monitoring systems to maintain compliance over time.



Reckitt | BIONTECH | ratiopharm | SANOFI | Boehringer Ingelheim | Biotest | Heraeus | Takeda



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

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