

Nitrosamines – Strategic Consultancy

We offer services to provide the necessary expertise and strategy to establish a robust background and compliance framework to be compliant with the ICH M7 definitions and FDA requirements. This includes the creation of necessary SOPs to nitrosamine risk assessment and mitigation, or evaluation of existing processes to identify areas for improvement

Development of Background

We work closely with clients to develop a comprehensive documentation framework customized to their specific needs and compliance requirements. This includes the creation of SOPs, work instructions, and protocols for conducting risk assessments, sampling plans, and analytical testing methods for nitrosamine detection. We also assist in drafting guidance documents and templates to streamline the documentation process and ensure consistency across departments and facilities.

GAP Analysis and Process Evaluation

Our experts conduct a thorough evaluation of existing processes, including manufacturing, testing, and quality control procedures, to identify potential sources of nitrosamine contamination. We assess the adequacy of current risk assessment methodologies and control measures in place to mitigate nitrosamine-related risks. Based on the findings, we provide detailed recommendations for process improvements and updates to documentation, such as SOPs and risk management plans.

Strategy Development and Implementation Plan

Our team collaborates with clients to develop a strategic roadmap for achieving and maintaining compliance with ICH M7 guidelines. We help define short-term and long-term goals, establish key performance indicators (KPIs), and develop an actionable implementation plan. This may involve identifying training needs, establishing communication channels, and allocating resources effectively to support ongoing compliance efforts.



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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