

# Nitrosamines – Workshop and Trainings

In our "Nitrosamines – Workshop and Trainings" service, we offer comprehensive training sessions and workshops customized to meet the specific needs of pharmaceutical companies in addressing Nitrosamine impurities and complying with ICH M7 guidelines

## Regulatory Landscape Exploration

In-depth exploration of global regulatory requirements and expectations regarding nitrosamines in pharmaceutical products, including recent updates and emerging trends.

Analysis of regulatory guidance from authorities such as the FDA, EMA, and other relevant regulatory bodies to ensure a thorough understanding of compliance obligations.

## Risk Assessment Techniques

Detailed training on risk assessment methodologies specific to nitrosamines, covering hazard identification, risk evaluation, and risk control strategies.

Practical exercises and case studies designed to reinforce understanding and application of risk assessment principles in the context of nitrosamine impurity management.

## Implementation Strategies and Case Studies

Guidance on implementing risk mitigation strategies and control measures to prevent or minimize nitrosamine contamination in drug products.

Examination of real-world case studies and best practices from the industry to illustrate effective approaches to nitrosamine risk management and regulatory compliance.



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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