

Nitrosamines – QMS Life Cycle Integration

We offer a service to seamlessly integrate Nitrosamines ICH M7 adaption projects into existing Quality Management Systems (QMS), with minimal disruption to routine operations. By focusing on these aspects, our service goes beyond mere integration, offering a holistic approach to QMS alignment that drives continuous compliance and operational excellence

GAP Analysis and Assessment

Comprehensive review of QMS documentation, including SOPs, policies, and procedures, to identify areas requiring alignment with Nitrosamines requirements.

Assessment of existing risk management processes to ensure they encompass Nitrosamines-related risks and mitigation strategies.

Customized Integration Plan Development

Tailored development of integration milestones and deliverables, considering the specific requirements of Nitrosamines adaptation projects and the QMS.

Identification of key performance indicators (KPIs) and metrics to track progress and ensure successful integration within the established timelines.

Stakeholder Engagement and Training

Collaboration with cross-functional teams to gather insights and perspectives on the integration process, fostering a collaborative approach.

Provision of targeted training sessions on Nitrosamines regulations and their implications for different departments within the organization.



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