

Nitrosamines – Routine Support

Our service focuses on hands-on execution of the project, including conducting risk analyses, document creation, and project follow-up. With our expertise in pharmaceutical quality and regulatory compliance, we ensure efficient and compliant execution of activities to be compliant with ICH M7 requirements

Project Execution

We take care of executing all tasks outlined in the project plan, including conducting risk assessments, generating reports, and implementing risk mitigation strategies. Our team ensures meticulous attention to detail and adherence to established protocols to effectively address nitrosamine-related risks and safeguard product quality.

We can also conduct thorough risk analyses to identify potential sources of nitrosamine contamination throughout the product lifecycle. This involves assessing factors such as raw materials, manufacturing processes, packaging materials, and storage conditions to pinpoint potential areas of concern.

Execution of Risk Mitigation Strategies

Based on the findings of the risk analysis, we develop customized risk mitigation strategies to the specific needs and circumstances of the client.

This may involve implementing changes to manufacturing processes, such as adjusting reaction conditions or modifying cleaning procedures to minimize the risk of nitrosamine formation. We also assist in sourcing alternative raw materials or suppliers that meet stringent quality standards and have lower risks of nitrosamine contamination.

Project Follow-up and Monitoring

We provide ongoing support and monitoring to ensure the successful implementation of risk mitigation strategies. This includes regular follow-up assessments to track the effectiveness of implemented measures and identify any emerging risks or issues.

