Nitrosamines – Risk Assessment Creation

Services created to develop comprehensive Risk Assessments within Nitrosamines ICH M7 adaptation projects. We specialize in identifying and evaluating potential risks associated with nitrosamine impurities in pharmaceutical products, adhering to ICH M7 guidelines

Comprehensive Data Collection

We gather detailed information on the manufacturing process, including raw materials, intermediates, and final products, to identify potential sources of nitrosamine formation.
We review historical data, analytical results, and relevant literature to assess the presence and levels of nitrosamines in pharmaceutical products.

Hazard Identification and Characterization

Our experts assess the genotoxicity and carcinogenicity of nitrosamine impurities based on available toxicological data and regulatory guidelines.
We characterize the potential risks associated with nitrosamine exposure, considering factors such as dose, duration, and route of administration.

Risk Evaluation and Prioritization

Using scientific principles and risk assessment tools, we evaluate the likelihood and severity of nitrosamine contamination in pharmaceutical products.
We prioritize risks based on their potential impact on patient safety and regulatory compliance, guiding the development of targeted risk mitigation strategies.

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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