Nitrosamines – Data Management Activities Execution

Managing nitrosamine compliance requires the collection and maintenance of a large volume of product, manufacturing, supplier, analytical and regulatory information. Zamann supports pharmaceutical companies by establishing and maintaining structured datasets that consolidate critical information from multiple sources, enabling efficient decision-making, regulatory compliance and lifecycle management.

Data Collection and Integrity

We support the collection, verification and organization of critical nitrosamine data from multiple internal and external sources. This includes product identifiers (e.g. GMIDs), manufacturing sites, API suppliers, marketed countries, analytical results, acceptable intake limits, risk assessment outcomes and regulatory information. Bringing these data together creates a complete and reliable product overview.

Data Management and Critical Evaluation

Our structured data management approach links product information with analytical testing strategies, acceptable intake limits, supplier changes and lifecycle activities. By maintaining consistent, traceable datasets, we enable efficient evaluation of product-specific risks, support scientific decision-making and ensure that critical information remains current throughout the project lifecycle..

Lifecycle Tracking & Reporting

Zamann continuously maintains nitrosamine datasets to reflect changes in API suppliers, manufacturing processes, marketed countries, analytical testing programmes and regulatory requirements. Standardized reporting and tracking tools provide clients with a clear overview of product status, outstanding activities and compliance priorities, supporting timely project execution and regulatory readiness.

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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