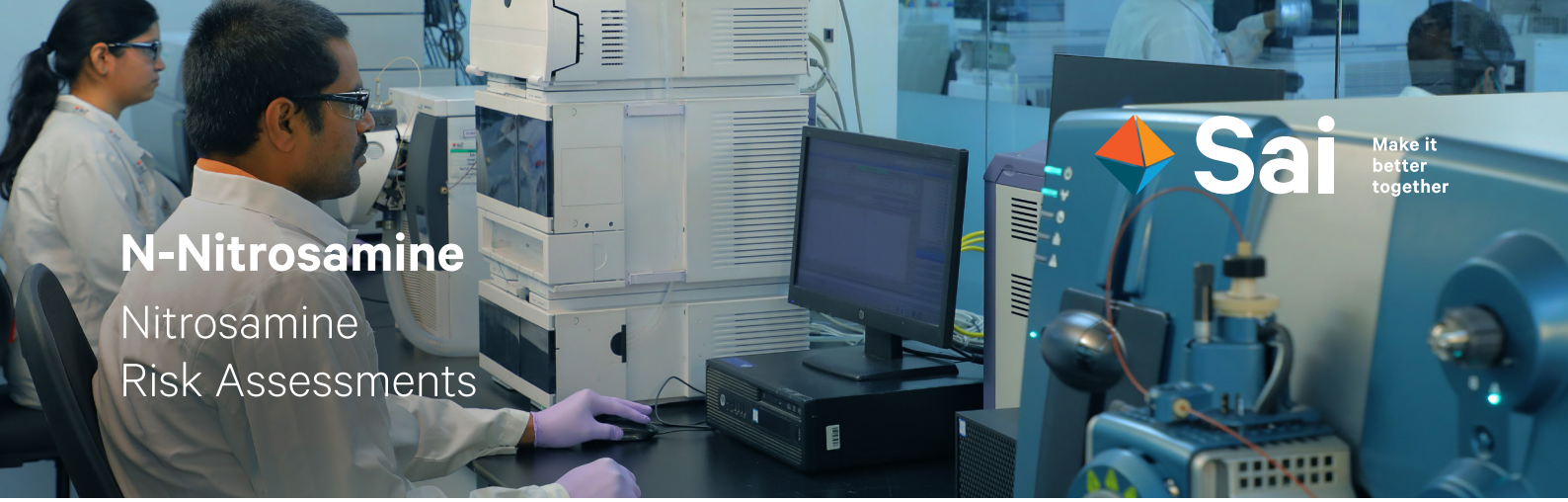

# N-Nitrosamine

## Nitrosamine Risk Assessments

Sai Make it better together

**The understanding of the process chemistry with respect to the risk of API containing N-Nitrosamines as impurities is essential to ensure patient safety and meet regulatory requirements. Sai Life Sciences has a robust end to end process to assess risk and support customers in the development of control strategies.**


### Highlights

- Robust risk assessment process as part of the quotation, manufacture and lifecycle management stages
- Vendor assessment process covering raw materials and starting materials
- Ongoing risk assessment process to mitigate any risk of N-Nitrosamine contamination as a result of the utilisation of process equipment
- Expertise in process chemistry to understand and mitigate the risk of N-Nitrosamine formation
- Expertise in the utilisation of in-silico purge calculations and spiking/purge studies to support control strategy development
- State of the art analytical instrumentation and expertise capable of meeting regulatory requirements for the control of N-Nitrosamines
- Capability to carry out Mutagenicity testing (Non-GLP Studies such as; Ames, In Vitro Chromosome Aberration Assay, and In Vivo Micronucleus Test)

### Achievements

- 100+ projects (RM, KSM, intermediates and API) were assessed and evaluated by Expert Panel Team at Sai and provided N-Nitrosamine Assessment reports for regulatory requirement as per client request
- Synthetic route designs which minimise the risk of N-nitrosamine formation
- Utilisation of purge calculations to inform the approach to regulatory control strategies

### State of the art analytical Instrumentation

- Sciex LC-MS/MS ion trap
- Shimadzu GC-MS/MS ion trap
- Methodology has been established for a number of the N-Nitrosamines with ADIs approved by the regulatory authorities with a limit of quantification of 10ppb
- Flexibility to extend the approach to other N-Nitrosamines of interest

For more information contact: **contact@sailife.com**