



6 Novemeber, Hyderabad, India

08:00 - Registration and welcome refreshments

09:00-09:20

Greetings

- Symposium Overview and Agenda, [Mitali Kamat, Lhasa Limited | Consult Lhasa](#)
- Leveraging Innovation to Inform Chemical Safety Decisions, [Dr Adrian Fowkes, Lhasa Limited](#)

SESSION 1

09:20-10:50

Informing Chemical Safety Decisions for ICH M7: A Practical Approach

- Using *in silico* Tools to Support Safety Assessments Under ICH M7: Overcoming Challenges in Expert Review [Interactive session], [Mitali Kamat, Lhasa Limited | Consult Lhasa](#)
- Practical Use Cases from an Industry Perspective: Using *in silico* Tools Within ICH M7, [Muzaffar Khan, Laurus Labs](#)

Q&A session, Coffee break & Networking

SESSION 2

11:05-12:25

Comprehensive Strategies for Potentially Mutagenic Impurity Formation and Control: Nitrosamines and Beyond

- Purge Factors as Part of ICH M7 Assessment of Mutagenic Impurity Risk, [Dr Daniel O'Connor, Lhasa Limited](#)
- Applying purge argumentation to N-Nitrosamines, [Dr Andrew Teasdale, recently retired former Chair of AstraZeneca impurities advisory group](#)
- Identifying the risk of nitrosamine formations via degradation pathways, [Manya Arora, Lhasa Limited | Consult Lhasa](#)

Q&A session, lunch

SESSION 3

14:00-15:45

Nitrosamine Risk Assessment: Industry and Regulatory Perspectives

- CPCA: From Concept to Regulatory Application - Mechanisms, Methods, and Practical Insights, [Dr Naomi Kruhlak, US FDA](#)
- EMA's current projects to establish a read-across framework for nitrosamines and NDSRIs, [Dr Martin Walter, Austrian Medicines and Medical Devices Agency](#)
- How do experts evaluate nitrosamine read-across? A discussion of key factors to consider, [Dr David Ponting, Lhasa Limited | Consult Lhasa](#)

Q&A session, coffee break

SESSION 4

16:00-17:00

What does the future hold for the management of impurities?

- Impurity safety assessments from the cohort of concern to non-mutagenic: regulatory perspective, [Dr Anja Langenkamp, Swissmedic](#)
- Navigating Data Gaps in E&L Toxicology: Leveraging *In Silico* Tools for Safety Assessment, [Dr Ravichandra Bhadravathi Vedamurthy, Amneal Pharmaceuticals](#)
- Assessing E&L Risk Through the Lens of Drug Degradation, [Luccas Sanches, Consult Lhasa/ Spektra](#)

17:00-17:20

Round table: Impurities

Chair: [Dr Adrian Fowkes, Lhasa Limited](#)

- [Dr David Ponting, Lhasa Limited | Consult Lhasa](#)
- [Samuel Odebamowo, Lhasa Limited](#)
- [Luccas Sanches, Consult Lhasa/ Spektra](#)

17:20-17:30

- Closing remarks, [Dr Adrian Fowkes, Lhasa Limited](#)

17:30 - Networking refreshments

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