

Hyderabad Science Symposium

17th July 2024, The Park Hotel, Hyderabad

08:00 – 09:00 Registration & welcome refreshment

Session 1

09:00 – 09:05 Opening session to introduce speakers and Lhasa chairpersons Manya Arora, Application Scientist, Lhasa Limited

09:05 – 09:35 40 years of supporting decisions on chemical safety – developing science that allows you to take confident decisions Dr Chris Barber, CEO, Lhasa Limited Dr Crina Heghes, Director of Applied Sciences, Lhasa Limited

09:35 – 09:55 Application of *in silico* tools for accelerated innovation during pharmaceutical drug development

Mitali Kamat, Application Scientist, Lhasa Limited

09:55 – 10:15 Using *in silico* tools to support safety assessments under ICH M7 Laura Johnston, Associate Director, Lhasa Limited

Q&A session (10 mins)

Coffee break and networking

10:25 - 10:40



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Session 2

10:40 - 11:10 Challenges in ICH M7 expert review – Interactive session Dr Roberta Drekener, Senior Application Scientist, Lhasa Limited

11:10 - 11:30

Practical use cases from an industry perspective using in *silico* tools within ICH M7

Dr Muzaffar Khan, Senior General Manager, Laurus Labs

11:30 - 11:50

Regulatory considerations for ICH M7 Option 4 control strategies

Dr Barbara Scott, Chemist at the Office of Translational Sciences, US FDA

11:50-12:10

Purge factors as part of M7 assessment of mutagenic impurity risk – Using Mirabilis to assist in control strategies Manya Arora, Application Scientist, Lhasa Limited

Q&A Session (20 mins)

12:30 - 13:50 Lunch break



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Session 3

13:50 - 14:10

Using *in vivo* mutagenicity data to set acceptable intakes for NDSRIs

Dr Raphael Nudelman, Senior Director Impurity Expert R&D Operations, Teva

14:10 - 14:30

Latest EMA nitrosamine updates

Dr Martin Walter, Representant of EMA's nitrosamine safety operational expert group (NS OEG)

14:30-15:30

N-Nitrosamines risk assessment: Practical strategies to meet regulatory needs

Dr David Ponting, Principal Scientist, Lhasa Limited Dr Roberta Drekener, Senior Application Scientist, Lhasa Limited

15:30 - 15:50

Challenges on nitrosamine risk assessment for solid formulations – a chemical perspective via degradation pathways

Dr Natanael Segretti, Director of Scientific and Innovation, Consult Lhasa

Q&A Session (30 mins)

16:20– 16:30 Closing of the symposium and invitation to network to network Dr Chris Barber, CEO, Lhasa Limited

16:30 - 18:00 Networking and goodbye