South Korea Symposium 2025

25th November 2025

Lhasa Limited

주식회사 바이텍켐스
BITEK CHEMS Inc.

09:00 Registration

Greetings
09:30

***In silico* tools: Accelerating development with better-informed decisions**

Introduction to Symposium overview and agenda, BITEK Team

Introduction to BITEK, BITEK Team

Welcome to Lhasa: Working together for safer decisions, Nik Marchetti, *Lhasa Limited*

Session 1
09:50

Degradation, compatibility and strategies on impurities assessment

Identifying the risk of nitrosamine formations via degradation pathways,
Lawrence Tam, *Lhasa Limited*

***In silico* compatibility study: Comprehensive assessment for informed decision making**,
Natan Segretti, *Spektra/Consult Lhasa* (dial in)

Q&A

10:35 Coffee Break

Session 2
10:45

Classifying mutagenic impurities under ICH M7: Expert Insights

Recorded presentation on checklist for submitting ICH M7 assessments to the US FDA
Franny SwederGold, *Lhasa Limited*

Classification of genotoxic impurities in pharmaceuticals: Case-based insights,
Yeongsuk Yoo, *CMG Pharm*

Using *in silico* tools to support safety assessments under ICH M7: Overcoming challenges in expert review (interactive), Jessica Halliday, *Lhasa Limited*

11:50 Lunch Break and Q&A

Session 3
13:30

Nitrosamine risk assessment: Industry and regulatory perspectives

Recorded presentation on CPCA: Mechanistic foundations and regulatory applications,
Naomi Kruhlak, *FDA*

Discovery to distribution: Leveraging Lhasa's tools for nitrosamine risk assessment and read-across strategy, Jessica Halliday, *Lhasa Limited*

Q&A

14:30 Coffee Break

Session 4
14:45

Comprehensive strategies for potentially mutagenic impurity formation and control

Re-defining purge assessments across pharmaceutical development,
Michael Burns, *Lhasa Limited*

Applying purge arguments to *N*-nitrosamines, Andrew Teasdale, *AT CMC solutions*

Q&A

16:00 Demonstrations & Networking