22nd July, BelAir Unique a Wyndham Hotel, Ciudad de México

08:30 - Registration and welcome refreshment

SESSION 1

09:00 - 11:10

Classifying impurities under ICH M7: Expert insights

- Welcome remarks, Rubén A. Manuel Briceño, CTR Scientific
- Why are we here, Dr Chris Barber, Lhasa
- Using in silico tools to support safety assessments under ICH M7: Overcoming challenges in expert review, MSc Lucía Toscano, Lhasa
- Defining acceptable intakes for NDSRIs within the ICH M7 framework, Dr David Ponting, Lhasa

Q&A session, coffee break

SESSION 2

11:10 - 14:15

Comprehensive strategies for potentially mutagenic impurity formation and control: Nitrosamines and beyond

- Learning from nitrites: A safer tomorrow in nitrosamine research, Dr María Celeste Del Fueyo, Lhasa
- Applying purge argumentation to *N*-nitrosamines, Dr Andrew Teasdale, Former AstraZeneca

Demonstrations – Focused overview of *in silico* tools

Q&A session, lunch

SESSION 3

14:15 - 16:00

Nitrosamine risk assessment: Industry and regulatory perspectives

- Common pitfalls in regulatory submissions for nitrosamines risk assessments , Dr Mariah Ultramari, Spektra Consultoria, a Consult Lhasa company
- CPCA: From concept to regulatory application - Mechanisms, methods, and practical insights, Dr Naomi Kruhlak, US FDA
- Advancing Pharmaceutical Regulation: ANMAT's Integration into ICH, MSc Melina Dal Mas, ANMAT

Q&A session, coffee break

SESSION 4

16:00 - 17:20

Degradation, compatibility and strategies on impurities assessment

- *In silico* compatibility study: Comprehensive assessment for informed decision making , MSc Diego Gomes, Lhasa
- Pharmaceutical Impurities: Current Challenges and Strategies for Effective Assessment , Dr Natanael Segretti, Spektra Consultoria, a Consult Lhasa company
- An Industry Perspective: Nitrosamines: Strategies During Pharmaceutical Product Development, Mary Carmen Del Moral Hernández, Laboratorios Carnot

Q&A session

17:20 - 17:30

Wrap up and close

- How can I help?, Dr Crina Heghes, Consult Lhasa

17:30 onwards - Networking

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