14th July, Auditório Verde e Branco, Instituto Butantan, São Paulo

08:30 - Registration and welcome refreshment

SESSION 1

09:00 - 10:15

In silico tools: accelerating development with better-informed decisions

- Greetings from Butantan
- Latest updates from SBTox, Dr Rafael Lanaro, SBTox
- There is a way out: reassessing impurity limits in stability studies through qualification approaches, Dr Gabriela Silveira, Lhasa
- Impurity safety assessments from the cohort of concern to non-mutagenic: regulatory perspective, Dr Anja Langenkamp, Swissmedic

Q&A session, coffee break

SESSION 2

10:45 - 12:10

Impurity qualification / Nitrosamines

- Impact of the revision of ICH M7 for the control of *N*-nitrosamines: experience as a Task Force expert, Dr Everson Fialho, Brainfarma
- *In silico* support to an integrated nitrosamines workflow, Dr David Ponting, Lhasa
- A case study on enhancing regulatory acceptance of nitrosamine risk assessment through data sharing initiatives, Dr Daniele Freitas, Aché Laboratórios Farmacêuticos

Q&A session, lunch

SESSION 3

13:30 - 15:00

Nitrosamines – Part 2: Regulatory discussion

- 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, AMMA
- *N*-nitrosamines purge and the science behind it, Dr Andrew Teasdale, Former AstraZeneca

Q&A session, coffee break

SESSION 4

15:30 - 16:30

Extractables and Leachables

- Extractables and Leachables: Using read across to help assess systemic toxicity, Dr Julia Martins, Lhasa
- ICH Q3E - an ELSIE perspective on the use of read-across, MSc Patricia Parris, Pfizer
- Round table: Extractables and Leachables
- MSc Patricia Parris, Pfizer
- Dr Adrian Fowkes, Lhasa
- Dr Mariah Ultramari, Spektra Consultoria, a Consult Lhasa company

Q&A session

SESSION 5

16:30 - 17:40

Degradation, compatibility and RDC 964/2025

- *In silico* compatibility study in light of the new RDC 964/2025, MSc Diego Gomes, Lhasa
- Considerations on scientific justifications to comply with the new RDC 964/2025, Juçara Ribeiro Franca, ANVISA

Q&A session

17:40 - 18:00

Wrap up and close

- Back to the future – The role of AI and *in silico* tools, Dr Chris Barber, Lhasa

18:30 onwards - Networking

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