2024 Pharmaceutical Industry and Regulators Symposium:

7th May 2024 – Day 1

08:30 Registration

09:00 Session 1 – Greetings | ICH M7

- **Greetings from CFF (5 min)**
- **40 years of supporting decisions on chemical safety (30 mins)**
  Dr. Chris Barber, CEO and Dr. Philip Judson, Lhasa Limited co-founder.
- **Using in silico tools to support safety assessments under ICH M7 (15 min)**
  Laura Johnston, Associate Director at Lhasa Limited and Director of Business Operations at Consult Lhasa.
- **Case Study – example of overcoming an ICH M7 challenge using silico tools (20 min)**
  Julia Martins, Libbs Farmacêutica.
- **Q&A (10 mins)**

10:20 Coffee break

10:50 Session 2 – ICH M7

- **Challenges in ICH M7 expert review – interactive session with poll questions (30 mins)**
  Gabriela Silveira, Senior Application Scientist, Lhasa Limited.
- **Who is responsible for purge calculations? (20 mins)**
  ** Speaker to be confirmed.*
- **Regulatory considerations for ICH M7 option 4 control strategies (30 mins)**
  Barbara Scott, US FDA.
- **Q&A (20 mins)**

12:30 Lunch

14:00 Session 3 – Nitrosamines

- **Latest EMA nitrosamines updates (20 min)**
  Dr Martin Walter, Non-Clinical Assessor at the Austrian Medicines and Medical Devices Agency, representant of EMA's nitrosamine safety operational expert group (NS OEG).
- **Using *in vivo* mutagenicity data to set AIs for NDSRIs (20 mins)**
  Raphael Nudelman, Ph.D, Registered Toxicologist (ERT), Senior Director Impurity Expert R&D Operations, Teva.
- **Q&A (20 mins)**

15:00 Coffee break

15:30 Session 4 - Nitrosamines

- **Novel nitrosamine science in existing in silico frameworks (20 mins)**
  David Ponting, Principal Scientist; Roberta Drekener, Senior Application Scientist, Lhasa Limited.

- **Nitrites data sharing: Case Study (20 mins)**
  Eder Lorenzato, Organic Chemist, Althaia.

- **Q&A (20 mins)**

17:30-19:30 Networking event

8th May 2024 – Day 2

09:00 Session 5 – Nitrosamines

- **N-nitrosamines: oversight of regulatory guidance (20 min)**
  Dr. Andrew Teasdale, Senior Principal Scientist - Impurity Management & External Advocacy, Chair AZ Impurities Advisory Group, AstraZeneca.

- **Using read-across to set AIs for NDSRIs (20 min)**
  David Ponting, Principal Scientist, Lhasa Limited.

- **Case studies for nitrosamines purge (20 min)**
  Michael Burns, Principal Scientist, Lhasa Limited.

- **Q&A (20 min)**

10:20 – Coffee break
10:50 Session 6 – Degradation, compatibility and RDC 53

- **What to expect from RDC 53's Revision (20 min)**
  Natanael Segretti, COO, Spektra.

- **Early-Stage Theoretical Compatibility: Case Study (20 min)**
  Angel Acevedo, Senior Researcher, Abbott – Chile.

- **Degradation pathway study – Regulatory deficiency use case (20 min)**
  Diego Gomes, Lead Scientific Consultant, Consult Lhasa.

- **Round table: Perspective on RDC 53, in silico degradation and compatibility study. (30 min)**
  Chair:
  Diego Gomes, Senior Global Alliances Manager, Lhasa Limited.
  Participants:
  João Pelissari, Senior Analitical Development Analist, Santisa
  Mariah Ultramari, CEO, Spektra
  Caroline Lima de Oliveira, Analitical Development Coordinator, Blau Farmacêutica

- **Q&A (20 min)**

12:40 – Lunch

14:10 Session 7 - Extractables and Leachables

- **Application of in silico tools to assess skin sensitization (20 min)**
  Adrian Fowkes, Director of Science, Lhasa Limited.
- **ICH Q3E - an ELSIE perspective (20 min)**
  Patricia Parris, Global Risk Assessment Services Toxicologist – Pfizer.
- **E&L regulatory perspective (20 mins)**
  ** Speaker to be confirmed.*
- **Q&A (20 mins)**

16:00 Wrap up and close