

# 2023 Pharmaceutical Industry and Regulators Symposium:

## 17<sup>th</sup> May 2023 – Day 1

08:30 Registration

09:00 Session 1

- **Introduction from ANVISA (10 mins)**
- **What is our purpose and why are we here? (10 mins)**  
Dr. Chris Barber, CEO and Dr. Crina Heghes, Director of Applied Sciences, Lhasa Limited.
- **Application of *in silico* tools for incremental innovation (20 min)**  
Margarita M. M. Henao, Senior Application Scientist, Lhasa Limited.
- **Challenges in ICH M7 expert review (30 mins) - interactive session with poll questions and answers from the audience**  
Gabriela Silveira, Senior Application Scientist, Lhasa Limited.
- **Q&A (10 mins)**

10:20 Coffee break

10:40 Session 2

- **Practical use cases from an industry perspective using *in silico* tools within ICH M7 – Part I (15 mins)**  
Elenilson Figueiredo da Silva, Pesquisador Pleno, Established Pharmaceuticals, Abbott Laboratórios do Brasil LTDA.
- **Practical use cases from an industry perspective using *in silico* tools within ICH M7 – Part II (15 mins)**  
Julia Martins, Analista de Desenvolvimento, Libbs Farmacêutica.
- **GESEF's vision of frequent deficiencies in ICH M7 assessments (20 mins)**  
ANVISA
- **Q&A (20 mins)**

11:50 Lunch

13:20 Session 3

- **Strategies for Assessing Acceptable Intakes for Novel N-Nitrosamines Derived from Active Pharmaceutical Ingredients (20 mins)**  
David Ponting, Principal Scientist, Lhasa Limited.
- **N-Nitrosamines – Remarks after concluding step 1 - where is the real risk (20 mins)**  
Dr. Andrew Teasdale, Senior Principal Scientist - Impurity Management & External Advocacy, Chair AZ Impurities Advisory Group, AstraZeneca.
- **N-Nitrosamines: Ongoing Development and Initiatives at Lhasa (20 mins)**  
Anax Oliveira, Director of Science, Lhasa Limited.
- **Q&A (10 mins)**

### 14:30 Coffee break

#### 14:50 Session 4

- **Updates on RDC N° 677: Transitional Provisions (20 mins)**  
ANVISA
- **Challenges on Nitrosamine risk assessment for solid formulations – a chemical perspective (20 mins)**  
Natanael Segretti, COO, Spektra Consultoria
- **Round table discussion on N-Nitrosamines: an industry perspective and challenges (30 mins)**  
Chair: Anax Oliveira, Director of Science, Lhasa Limited  
Participants: Andre Luiz Desidera, Especialista de DMF, Grupo CIMED.  
                  Mariah Ultramari, CEO, Spektra Consultoria  
                  Ana Lucia Borges Shimada, Coordenador de Desenvolvimento Analítico, Aché Laboratórios Farmacêuticos
- **Q&A (20 mins)**

### 16:20 Wrap up and close

## 18<sup>th</sup> May 2023 – Day 2

#### 09:00 Session 5

- **Purge factors as part of M7 Assessment of mutagenic impurity risk – using Mirabilis to assist in control strategies(20 mins)**  
Michael Burns, Principal Scientist, Lhasa Limited
- **Management of N-Nitrosamines and their risk assessment within GSK R&D (20 mins)**  
Mike Urquhart, Scientific Director at GlaxoSmithKline
- **Common challenges of establishing control strategies (20 mins)**  
Dr. Diego da Silva Padilha, Pesquisador, Nortec Química
- **Q&A (10 min)**

### 10:10 – Coffee break

#### 10:30 Session 6

- **Qualification of non-mutagenic impurities using in-silico tools (20 mins)**  
Margarita M. M. Henao, Senior Application Scientist, Lhasa Limited.
- **Application of read across approaches for safety assessments (30 mins)**  
David Ponting, Principal Scientist, Lhasa Limited.
- **GESEF's experience and expectations on qualifications of non-mutagenic impurities (use cases) (20 mins)**  
ANVISA
- **Q&A (20 mins)**



## 12:00 – Lunch

## 13:30 Session 7

- **Degradation predictions in analytical development: compatibility study, RDC 53 and packaging (20 min)**  
Diego Gomes, Senior Global Alliances Manager, Lhasa Limited.
- **Q&A (5 min)**
- **Perspectives on the oncoming ICH Q3E Guideline on Extractables and Leachables (20 mins)**  
Anax Oliveira, Director of Science, Lhasa Limited.
- **Q&A (5 min)**

## 14:20 – Closing remarks

- **Anvisa's trajectory in Brazil: Lessons from Latin America's pioneer agency (15 mins)**  
ANVISA
- **Lhasa's closing remarks (15 mins)**  
Chris Barber, CEO, Lhasa Limited.

## 14:50 Wrap up and close

