

## 2018 Pharmaceutical Industry and Regulators Symposium\*:

24<sup>th</sup> May 2018 – Day 1

09.00 – Registration and coffee

09.30 Session 1

- **Introduction**  
Dr. Crina Heghes, Lhasa Limited
- **Supporting Lhasa Members in a Regulatory Setting**  
Dr. Chris Barber, Lhasa Limited
- **Improving Toxicity Predictions using Data and Knowledge Sharing**  
Dr. Liz Covey-Crump, Lhasa Limited

11.00 – Coffee break

11.30 Session 2

- **Mutagenicity Predictions using a Statistical System**  
Dr. Crina Heghes, Lhasa Limited
- **Anvisa Expectations Regarding ICH M7, Q3A and Q3B**  
Dr. Gustavo Mendes Lima Santos, Gerência de Avaliação de Segurança e Eficácia, GESEF Gerencial Geral de Medicamentos – GGMed Agência Nacional de Vigilância Sanitária – ANVISA

13.00 – Lunch

14.00 Session 3

- **Miniaturization of the Ames test -MPA – development, advantages and limitations**  
Prof. Dr. Gisela de Aragão Umbuzeiro, Laboratório de Ecotoxicologia e Genotoxicidade LAEG, Faculdade de Tecnologia UNICAMP
- **ICH M7 Use Cases**  
Dr. Chris Barber, Lhasa Limited

15.35 – Coffee break

16.05 Session 4

- **Using Mirabilis to Support Purge Arguments Under ICH M7**  
Dr. Mike Burns, Lhasa Limited
- **Wrap up and close**  
Lhasa Limited

17.30 to 19.00 – Networking drinks

shared **knowledge** • shared **progress**

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# 2018 Pharmaceutical Industry and Regulators Symposium\*:

25<sup>th</sup> May 2018 – Day 2

08.30 – Welcome and coffee

08.45 Session 5

- **Use of in-silico for assessing degradants**  
Dr. Mariah de Almeida Ultramari, Ache Pharmaceuticals
- **How Zeneth Fits Into ICH Q3B**  
Dr. Mike Burns, Lhasa Limited
- **Toxicity Studies for Degradation Impurities – an Industry Perspective**  
Dr. Antonio Anax Falcao de Oliveira, Ache Pharmaceuticals

10.15 – Coffee break

10.45 Session 6

- **Predicting, assessing, and controlling mutagenic impurities from degradation**  
Dr. Steven W. Baertschi, President - Baertschi Consulting LLC
- **Analysis of impurities and pharmaceutical degradation products: advanced tools using mass spectrometry and orthogonal separation techniques**  
Dr. Helio Martins, Sr. Manager, Applications Support, Brazil at SCIEX
- **Round Table Discussion and Concluding Remarks on Degradation Assessments**  
Gustavo Mendes Lima Santos, Gerência de Avaliação de Segurança e Eficácia - GESEF Gerencial

12.40 Wrap up and Close

\* Details subject to change

