2019 Pharmaceutical Industry and Regulators Symposium*:

29th May 2019 – Day 1

08.30 – Registration

09.00 Session 1

- Introduction from Lhasa - Applying ICH M7 – What defines an expert? (15 min)
  Dr. Chris Barber, CEO, Lhasa Limited
- Introduction from ANVISA – Q&As regarding documents submitted to ANVISA for qualification of impurities (20 min)
  Lívia Carolina de Abreu Ribeiro, Gerência de Avaliação de Segurança e Eficácia, GESEF Gerêncial Geral de Medicamentos – GGMED Agência Nacional de Vigilância Sanitária – ANVISA
- Use of *in silico* tools for toxicity predictions within ICH M7 (40 min)
  Dr. Alex Cayley, Senior Scientist, Lhasa Limited

10.30 – Coffee break

11.00 Session 2

- Valsartan – Implications (40 min)
  Dr. Andy Teasdale, Senior Principal Scientist – Impurity Management & External Advocacy, Chair AZ Impurities Advisory Group (IAG), Astra Zeneca
- Expectations regarding ICH M7 from an industry perspective (40 min)
  Antonio Anax, Ph.D., Principal Toxicologist for Latin America and Mexico, Global Product Safety, Kimberly-Clark Corporation

12.30 – Lunch

13.30 Session 3

- ICH M7 Expert review examples (40 min)
  Scott McDonald, Director of Member Services, Lhasa Limited
- ICH M7 Knowledge and data sources management (30 min)
  Dr. Liz Covey-Crump, Director of Global Alliances, Lhasa Limited

14.50 – Coffee break

15.20 Session 4

- (Q)SAR Evaluation of drug impurities from the US FDA scientific perspective (40 min)
  Dr. Naomi Kruhlak, Scientific Lead, Computational Toxicology Consultation Service Division of Applied Regulatory Science Office of Clinical Pharmacology Office of Translational Sciences, FDA's Centre for Drug Evaluation and Research

- Round table discussion and concluding remarks on ICH M7
  Chairs: Dr. Chris Barber, Antonio Oliveira, Ph.D

17.00 - Wrap up and close

30th May 2019 – Day 2

09.00 Session 5

- Supporting purge arguments under ICH M7 (30 min)
  Dr. Michael Burns, Senior Scientist, Lhasa Limited
- Case study of a risk assessment for ICH M7 control of impurities (30 min)
  Scott McDonald, Director of Member Services, Lhasa Limited

10.15 – Coffee break

10.45 Session 6

- Mutagenic impurity control: an industry case study (40 min)
  Dr Mike Urquhart, Scientific Director, GSK
- Toxicity evaluation of degradation products – an industry perspective (40 min)
  Dr. Mariah de Almeida Ultramari, Spektra Consultoria

12.30 – Lunch

13.30 Session 7

- RDC nº53/2015: challenges on impurities qualification (40 min)
  Maria Augusta Carvalho Rodrigues, Gerência de Avaliação de Segurança e Eficácia, GESEF Gerêncial Geral de Medicamentos – GGMED Agência Nacional de Vigilância Sanitária – ANVISA
- Round table discussion and concluding remarks on degradation assessments (30 min)
  Chairs: Maria Augusta Carvalho Rodrigues, Dr. Mariah de Almeida Ultramari

14.45 – Coffee break

15.15 Session 8

- Introduction to Elemental Impurities data sharing initiative (10 min)
  Dr. Crina Heghes, Principal Global Alliance Manager, Lhasa Limited
- ICH Q3D; current state and the use of published data-driven risk assessments (35 min)
  Dr. Helmut Rockstroh, Head Pharmacopoeial Affairs, Pharmaceuticals Division, Global QC Business Support and Improvement, F. Hoffmann-La Roche Ltd.
- Q3D Regulatory Case Study – Database vs Experimental (30 mins)
  Diego Zulkiewicz Gomes, Analytical Development Specialist, Analytical Department, Aché Laboratórios Farmacêuticos S.A.

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16.30 – Wrap up and close *Details subject to change

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