AGENDA, 18-20 September 2018

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LORENZ USER CONFERENCE

Time	18 September 2018
08:00 - 09:00	**REGISTRATION & WELCOME COFFEE**
09:00 - 10:00	**LORENZ Keynote** Raoul-A. Lorenz & Christian Kaas, LORENZ Life Sciences Group
10:00 - 10:45	**BREAK (45 min)**
10:45 - 11:15	**CESP Application Dataset Module - Implementation of IDMP using SPOR?** Dr. med. Klaus Menges, BfArM - Federal Institute for Drugs and Medical Devices
11:15 - 11:45	**ICH Update IDMP & SPOR** Dr. Andreas Franken, ICH M8 / BAH - German Federal Association of Pharmaceutical Manufacturers
11:45 - 12:15	**Case Study: Meta-data reuse to increase efficiency and consistency - get prepared for eCTD v4.0** Steven Tan & Dr. Ulrike Vollmer, Bayer
12:15 - 13:45	**LUNCH (90 min)**
13:45 - 14:15	**Achieve business goals with transparent compliance** Klavs Esbjerg, Epista Life Sciences
14:15 - 14:45	**RIM – a single system or a happy family?** David Warner, Generis
14:45 - 15:15	**RIM implementation and integration, tailoring the evaluation for the Right Solution** Amara Tonkiss, Accenture
15:15 - 15:45	**BREAK (30 min)**
15:45 - 16:15	**Structured Content Management for CTD** Hans van Bruggen, eCTDconsultancy
16:15 - 16:45	**Content Validation** Dr. Margaret E. Hurley, Hurley Consulting Associates
16:45	**END OF CONFERENCE DAY 1**

Version August 2018

Time	19 September 2018
08:00 - 08:30	**WELCOME COFFEE**
08:30 - 10:00	**Table Tutorials** (see separate Agenda)
10:00 - 10:45	**BREAK (45 min)**
10:45 - 12:15	**Table Tutorials** (see separate Agenda)
12:15 - 13:45	**LUNCH (90 min)**
13:45 - 14:15	**Implications of Brexit for Regulatory Affairs** Dr. Sir Alasdair Breckenridge, Dr. Regenold
14:15 - 14:45	**Update on EMA/HMA developments** Remco Munnik, Asphalion
14:45 - 15:15	**EU Clinical Trial Portal and Database** Harald von Aschen, BfArM - Federal Institute for Drugs and Medical Devices
15:15 - 15:45	**BREAK (30 min)**
15:45 - 16:45	Panel Discussion: **CTA - eCTD a requirement? How to prepare for upcoming challenges?** Dr. Andreas Franken, ICH M8 / BAH - German Federal Association of Pharmaceutical Manufacturers Dr. Barbara Gansewendt, Bayer Dr. med. Klaus Menges, BfArM - Federal Institute for Drugs and Medical Devices Prof. Dr. Burkhard Sträter, STRÄTER Lawyers
16:45	**END OF CONFERENCE DAY 2**

Time	20 September 2018
08:00 - 08:30	**WELCOME COFFEE**
08:30 - 09:00	**Health Canada Updates** Vianney Caron, Health Canada
09:00 - 09:30	**EU Policy 0070 submissions today and in the future** Helle Ainsworth, Novo Nordisk
09:30 - 10:00	**Managed Vocabularies** Gary Wilson, CorrIT
10:00 - 10:45	**BREAK (45 min)**
10:45 - 11:15	**Pharma Regulation in the next decade, how the GCC is leading the way** Mona Al Moussli, Professionals Regulatory Affairs - Middle East
11:15 - 11:45	**Challenges in Supporting Submissions in Asia Pacific** Dr. Philip Hall, AbbVie
11:45 - 12:15	**Submission Migration – A Challenging and Learning Experience** Andrea Fischer, Elke Schydlo & Luka Kovacic, Sandoz
12:15 - 12:30	**Closing Remarks** Raoul-A. Lorenz, LORENZ Life Sciences Group
12:30 - 13:45	**END OF CONFERENCE & LUNCH**