AGENDA, 19-21 September, 2017

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LORENZ USER CONFERENCE

Time	19 September 2017
8:00 - 9:00	**REGISTRATION & WELCOME COFFEE**
9:00 - 10:00	**LORENZ Keynote** Raoul-A. Lorenz & Christian Kaas, LORENZ Life Sciences Group
10:00 - 10:45	**BREAK (45 min)**
10:45 - 11:15	**Managing the changes in a global organization** John-Paul Smith, Astellas Europe B.V.
11:15 - 11:45	**Menarini Group and the electronic submission** Giacomo Ridi, Menarini Ricerche S.p.A.
11:45 - 12:15	**See the unseen: across and within applications** Hans van Bruggen, eCTDConsultancy B.V.
12:15 - 13:45	**LUNCH (90 min)**
13:45 - 14:15	**CFDA/CDE'S eCTD program update** Jared Lantzy & Akira Yamaguchi LORENZ Life Sciences Group
14:15 - 14:45	**Inhouse Preparation of eCTDs for SMEs using docuBridge ONE** Dr. Michael Jandke, CO.DON AG
14:45 - 15:15	**Regulatory Strategy – Global vs. Regional Aspects** Marjan Dzeparoski, Bionika Pharmaceuticals
15:15 -15:45	**BREAK (30 min)**
15:45 - 16:15	**Artificial Intelligence in a Regulatory Environment: A Business Case** Christopher Rudolf, Volv Global, Switzerland
16:15 - 16:45	**Evolution of global requirements for Content Management Systems** Sven Harmsen, eDRA Harmsen
16:45	**END OF CONFERENCE DAY 1**

Time	20 September 2017
8:00 - 8:30	WELCOME COFFEE
8:30 - 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	**drugTrack implementation as Product Data Messaging Tool** Ida Jensen, Bayer Consumer Health & Dr. René Jung, Bayer AG
14:15 - 14:45	**Regulatory Landscape: Data in the Regulatory Environment** Vada Perkins, IDENTIFICA LLC
14:45 - 15:15	**Structured (IDMP) data management in context of change control and MA dossier maintenance** Michiel Stam, eCTDConsultancy B.V.
15:15 - 15:45	BREAK (30 min)
15:45 - 16:15	**Standardization Needs and communication of standards** Dr. Andreas Franken, BAH, German Medicines Manufacturer's Association
16:15 - 16:45	**Linking IDMP and the impact of regulatory affairs and RIM solutions** Remco Munnik, Asphalion S.L
16:45	END OF CONFERENCE DAY 2

Time	21 September 2017
8:00 - 8:30	WELCOME COFFEE
8:30 - 9:00	**Progress in EU projects?** Dr. med. Klaus Menges, BfArM, Federal Institute for Drugs and Medical Devices
9:00 - 9:30	**Piloting New Terrain: REMS (Risk Evaluation and Mitigation Strategies) SPL** Sandra Krogulski, Accenture Accelerated R&D Services
9:30 - 10:00	**Regulatory Strategy to Gain SFDA and GCC Approval** Asif Durrani, Saudi Pharmaceutical Industries & Medical Appliances Corporation (SPIMACO)
10:00 - 10:45	BREAK (45 min)
10:45 - 11:15	**Process Automation at Health Canada – Past, Present, and Future** Vianney Caron, Health Canada & Katharina Schmitz, LORENZ Life Sciences Group
11:15 - 11:45	**Support All Submissions – Globally** Philip Hall, AbbVie Ltd.
11:45 - 12:15	**Global Submission Reuse** Jack Daley,Gilead Sciences Ltd.
12:15 - 12:30	**Closing Remarks** Raoul-A. Lorenz, LORENZ Life Sciences Group
12:30 - 13:45	END OF CONFERENCE & LUNCH