Preliminary Agenda, 20 - 22 September 2016

userBridge.16
LORENZ USER CONFERENCE

Register for Hotel

Register for Conference

Location: Hotel Atlantic Kempinski, An der Alster 72-79, 20099 Hamburg, Germany

Presentation Highlights will include:

- Adapting the docuBridge Settings to Accommodate Business Needs for Non-Standard Submission Formats, **Magda Andritoiu**, Alvogen Romania S.R.L.
- Connecting SaaS Solutions: Evolution or Revolution?, **Paul Attridge**, Veeva Vault R&D EU
- NDS Submissions to Health Canada, **Karen Chiang**, Intrinsik Health Sciences Inc.
- Document Intelligence, **Susana De Abrew**, Foxit Software Inc.
- RIM replacement and IDMP readiness – How we Manage the Double Challenge, **Alice Ebel,** Grünenthal GmbH
- Automator Solutions in Regulatory Affairs – How To Eliminate Boring Process Steps, **Xiaojing Fan**, Bayer HealthCare AG
- Initial eCTD v4.0 Industry-Agency Field Test, **Dr. Andreas Franken**, BAH
- EMA's Policy 70: Practical Questions and Challenges, **Claire Holmes**, Accenture R& D Services
- What's New in LORENZ docuBridge 5.9, **Christian Hapke & Elsmari Eggers**, LORENZ Life Sciences Group
- Product Development Update, **Christian Kaas**, LORENZ Life Sciences Group
- RPS & eCTD v4.0: The Path To Implementation, **Jared Lantzy**, LORENZ Life Sciences Group
- The South African eCTD: Lessons Learned, **Don Lebitsa**, Adcock Ingram Limited
- IDMP Implementation in the EU and its Impact upon Industry, **Dr. Andrew Marr**, Marr Consultancy Ltd.
- Update on EU – IT Initiatives for Regulated Markets (eCTD v4.0 Implementation Guideline), **Dr. med. Klaus Menges**, BfArM
- A Product is a Product is a Product…. or is it?, **André Mellies & Stefan Fischer Rivera**, Bayer Business Services GmbH
- Efficient Dossier and Submission Process: Leveraging Today's & the Future's Possibilities, **Timm Pauli,** PharmaLex GmbH
- Gateways, Portals and Repositories: Challenges for an NCA like BfArM, **Harald von Aschen**, BfArM
- Comparison of eCTD by Regions and the Outlook for eCTD, **Akira Yamaguchi**, LORENZ Life Sciences Group v4.0,
- and more ...

Table Tutorial Highlights will include:

- Agency Round Table Q&A Session, **Kent Briggs**, VECTOR Life Sciences (Pty) Ltd.
- Getting Documents Submission Ready, **Marta Estruch**, InvoFarma S.L.
- What's New in LORENZ docuBridge 5.9, **Christian Hapke**, LORENZ Life Sciences Group
- Medical Devices, **Tim Ivani**□, LORENZ Life Sciences Group
- From Science to Submission, **Dr. Michael Klein**, mikle-pharm GmbH
- US Module 1 version 3.3, **Jared Lantzy**, LORENZ Life Sciences Group
- New EU Module 1 version 3.0, **Karl-Heinz Loebel**, PharmaLex GmbH
- IDMP, **Markus Pfahlert**, LORENZ Life Sciences Group
- eAF or PSUR-Repository and/or CESP Submission, **Anna Rubik**, Arac GmbH
- What's New in LORENZ drugTrack version 5.x, **Nicole Sagner**, LORENZ Life Sciences Group
- LORENZ Automator, **Katharina Schmitz**, LORENZ Life Sciences Group
- LORENZ docuBridge Configuration, **Frank Schroer**, LORENZ Life Sciences Group
- and more ...

Learn - Discuss - Interact:

Presentations: Learn & discuss about challenges, trends & case studies regarding regulatory operations & strategies.
Table Tutorials: Interact in multiple, parallel sessions: share your experiences and receive many in return.

Day 1 - 20 September	Day 2 - 21 September	Day 3 - 22 September
8:00 - 9:00 Registration		
9:00 - 12:15 Presentations	8:30 - 12:15 Table Tutorials	8:30 - 12:15 Presentations
13:30 - 17:00 Presentations	13:30 - 17:00 Presentations	12:15 - 12:30 Closing Remarks

Contact LORENZ: www.lorenz.cc/email - Tel. +49 69 78991-901

Please note that LORENZ reserves the right to modify the agenda and/or list of speakers.