



Time September 17, 2024

- 8:00 - 9:00 am **REGISTRATION & WELCOME COFFEE**
- 9:00 - 10:00 am **LORENZ Keynote**
Raoul-A. Lorenz, Anna Kispál,
Lorelle Leonienco & Patrick Kunkel,
LORENZ Life Sciences Group
- 10:00 - 10:30 am **BREAK**
- 10:30 - 11:00 am **Update on eCTD v4.0 implementation and outlook into the evolution of eCTD**
Dr. Bernd Misselwitz, Bayer AG
& Tim Powell, Biogen Idec Limited
- 11:00 - 11:30 am **eCTD v4.0 in Japan – History, special requirements and current activities**
Yuki Terauchi, Chugai Pharmaceuticals Co., Ltd.
& Hiroji Emoto, Digital Media System Co., Ltd.
- 11:30 - 12:00 pm **Panel discussion on eCTD v4.0**
Yuki Terauchi, Chugai Pharmaceuticals Co., Ltd.
Dr. Andreas Franken, Pharma Deutschland e.V.
Hiroji Emoto, Digital Media System Co., Ltd.
Dr. Bernd Misselwitz, Bayer AG
Tim Powell, Biogen Idec Limited
- 12:00 - 1:30 pm **LUNCH**
- 1:30 - 2:10 pm Table Tutorials ([see Table Tutorial agenda](#))
- 2:20 - 3:00 pm Table Tutorials ([see Table Tutorial agenda](#))
- 3:00 - 3:30 pm **BREAK**
- 3:30 - 4:00 pm **Update on PRISM**
Vada A. Perkins, Boehringer Ingelheim Pharmaceuticals, Inc.
- 4:00 - 4:30 pm **Trusted Regulatory Spaces in the cloud - Guiding principles**
Omar Serang, DNAnexus, Inc.
- 4:30 - 4:45 pm **Closing remarks**
Raoul-A. Lorenz, LORENZ Life Sciences Group
- 4:45 pm **END OF CONFERENCE DAY 1**



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- 8:00 - 8:30 am WELCOME COFFEE**
- 8:30 - 9:00 am How are regulatory organizations improving their effectiveness through the use of metrics driven continuous improvement?**
Steve Gens, Gens & Associates Inc.
- 9:00 - 9:30 am Collaboration as a global service partner on a central global docuBridge Submission Management System**
Timm Pauli, Cencora PharmaLex GmbH
- 9:30 - 10:00 am Harmonization in Africa through eCTD and reliance**
Hebatallah Ibrahim Abdel-Salam, EDA
Sybil Nana Ama Ossei-Agyeman-Yeboah, SNAAP Access
Don Lebitsa & Dr. Madelein Terblanche
VECTOR Life Sciences
- 10:00 - 10:30 am BREAK**
- 10:30 - 11:10 am Table Tutorials** ([see Table Tutorial agenda](#))
- 11:20 - 12:00 pm Table Tutorials** ([see Table Tutorial agenda](#))
- 12:00 - 1:30 pm LUNCH**
- 1:30 - 2:00 pm eCTD & IDMP – ICH meets ISO**
Dr. Andreas Franken, Pharma Deutschland e.V.
- 2:00 - 2:30 pm Race to be the first with LORENZ docuBridge POC**
Krzysztof Rowiński, Valneva Austria GmbH
- 2:30 - 3:00 pm Collaboration with multiple service partners on one global docuBridge Submission Management System**
Dr. Dietmar Böcker, Bayer AG
Pharmaceuticals
- 3:00 - 3:10 pm Closing remarks**
Raoul-A. Lorenz, LORENZ Life Sciences Group
- 3:10 pm END OF CONFERENCE**
- 3:30 - 4:30 pm LORENZ docuBridge userGroup**
(Optional)
Philip Hall & Theo van der Zee