

Agenda

Time (MDT) September 30, 2025

8:00 - 9:00 am REGISTRATION & CONTINENTAL BREAKFAST

9:00 - 10:00 am **LORENZ Keynote**
LORENZ Life Sciences Group

10:00 - 10:30 am BREAK

10:30 - 11:00 am **RegOps 2030: How will the function evolve?**
Steve Gens, Gens & Associates

11:00 - 11:30 am **Cloud transformation through Trusted Regulatory Spaces (TRS)**
Omar Serang, DNAnexus

11:30 - 12:00 pm **Transforming regulatory landscapes: Driving regulatory innovation toward global regulatory reliance**
Dr. Vada A. Perkins, Boehringer Ingelheim

12:00 - 1:30 pm LUNCH

1:30 - 2:10 pm TABLE TUTORIALS

- 1 **eCTD 4.0 in Europe: Challenges, progress and effortless integration with LORENZ**
Anna Kispál & Maximilian Muth,
LORENZ Life Sciences Group
- 2 **Beyond submission management: Building a digitally agile regulatory operations function**
Kehinde Bakin, Novavax
- 3 **Submission-level review using LORENZ Web Access**
Danielle Minner-Vosburgh,
Accenture Accelerated R&D Services
- 4 **Automated hyperlink setting integrated within LORENZ docuBridge's submission assembling process**
Akira Yamaguchi, LORENZ Life Sciences Group

2:10 - 2:20 pm BREAK

2:20 - 3:00 pm TABLE TUTORIALS

- 1 **AI powered content validation - Automating document review**
Anna Kispál, LORENZ Life Sciences Group &
Rainer Schwarz, KlearDoc/LORENZ Life Sciences Group
- 2 **Health Canada compliance made easy: SPL & eCTD submissions**
Robin Schilling, LexisNexis Reed Tech
- 3 **Drivers ed: Learn how to take the wheel of eCTD 4.0**
Jessica Lemley & Adam Burgess,
LORENZ Life Sciences Group
- 4 **What's new in LORENZ docuBridge 25.1**
Maximilian Muth, LORENZ Life Sciences Group

3:00 - 3:30 pm BREAK

3:30 - 4:00 pm **Regulatory evolution in Africa: Harmonization meets digital innovation**
Charle Leibbrandt & Dr. Madelein Terblanche, VECTOR

4:00 - 4:30 pm **Co-operation of regulatory authorities and its role for global drug development - ACCESS, ORBIS and how they are speeding up approvals processes**
Dr. Ulrich Granzer,
Granzer Regulatory Consulting Services

4:30 pm END OF CONFERENCE DAY 1

Agenda

Time (MDT) October 1, 2025

8:00 - 8:30 am CONTINENTAL BREAKFAST

8:30 - 9:00 am **Innovative approaches to regulatory operations: New markets, docuBridge Viewer, and generative AI**
Rob Pers & Ameen Dattoo, Regeneron

9:00 - 9:30 am **Mastering grouped submissions in LORENZ docuBridge: Risks, benefits & development opportunities**
Walt Goldman, Merck

9:30 - 10:00 am **LORENZ verifAI – eCTD document validation: lessons from early testing**
Harald von Aschen, BfArM

10:00 - 10:30 am BREAK

10:30 - 11:10 am TABLE TUTORIALS

- 1 **AI governance and regulations: An approach to controlling this technology**
Cary Smithson, LeapAhead Solutions
- 2 **What's new in LORENZ docuBridge 25.1**
Maximilian Muth, LORENZ Life Sciences Group
- 3 **Drivers ed: Learn how to take the wheel of eCTD 4.0**
Jessica Lemley & Adam Burgess, LORENZ Life Sciences Group
- 4 **Regulatory content management custom procedures and issue resolution using the annotation feature**
Anthony Skiles, Accenture

11:10 - 11:20 am BREAK

11:20 - 12:00 pm TABLE TUTORIALS

- 1 **Veeva integration and assisted compilation**
Emma Feickert & Calyn Stanfill, Gilead
- 2 **Overview of the Singapore eCTD: From portal submission to eCTD validation**
Eric Vestal, VRG
- 3 **Content preparation, conversion & enrichment - Benefits of using DocShifter with LORENZ docuBridge**
Paul Ireland, DocShifter
- 4 **End-to-end lifecycle control within the LORENZ RIM solution**
Mathias Spiller, LORENZ Life Sciences Group

12:00 - 1:30 pm LUNCH

1:30 - 2:00 pm **Evolution of eCTD in China: A unique regulatory landscape**
Sophia Huang, Beijing BrilliantMed Pharma Tech

2:00 - 2:30 pm **Regulatory initiatives and their potential impacts on submission processes**
Mark Gray, LORENZ Life Sciences Group

2:30 - 2:45 pm **Closing remarks**
Yaprak Eisinger & Raoul-A. Lorenz, LORENZ Life Sciences Group

2:45 pm END OF CONFERENCE DAY 2

3:00 - 4:00 pm **LORENZ docuBridge userGroup meeting**
(Optional)
Philip Hall