

# Agenda

**Time September 11, 2023**

**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 (30 min)**

10:30 - 11:00 am **What is the userGroup?**  
Philip Hall, DH Consultants

11:00 - 11:30 am **Business Benefits, Approaches and Insights Gained from Regulatory Intelligent Automation Implementations**  
Cary Smithson, PharmaLex

11:30 - 12:00 pm **Regulatory and Scientific Collaboration via Cloud Platforms**  
Vada A. Perkins, Bayer Pharmaceuticals

**12:00 - 1:30 pm Lunch (90 min)**

**1:30 - 2:10 pm Table Tutorials (Meeting Room 1-4)**  
**Building Grouped Submissions: Tips for Success**  
Allison Steffen, WAYS Pharmaceutical Services

**AI-powered Advances & Automated Submission Assembly**  
Jim Nichols, Phlexglobal

**What's New in LORENZ docuBridge 23.1**  
Jessica Lemley & Parul Patel, LORENZ Life Sciences Group

**LORENZ Regulatory Content Management (RCM)**  
Jakob Schlösinger, LORENZ Life Sciences Group

**Break (10 min)**

**2:20 - 3:00 pm Table Tutorials (Meeting Room 1-4)**  
**How Modern Rendering Can Automate Beyond the Creation of PDFs**  
Paul Ireland, DocShifter

**Simplifying the Publishing and Maintenance of Investigational Medicinal Product Dossiers (IMPDs)**  
Swathi Pandhiti, MMS Holdings Inc.

**Options for Access Restriction**  
Kristina Roberson, LORENZ Life Sciences Group

**Practical Experiences from US FDA eCTD 4.0 Pilot**  
Jessica Lemley, LORENZ Life Sciences Group

**3:00 - 3:15 pm Break (15 min)**

3:15 - 4:00 pm **Regulatory Updates Including eCTD 4.0**  
Akira Yamaguchi, LORENZ Life Sciences Group

**eCTD & Electronic Submissions in Africa**  
Kent Briggs, VECTOR Life Sciences

4:00 - 5:00 pm **Health Canada Updates**  
Tracy Brown & Irena Pastorekova, Health Canada

**5:00 pm End of Conference Day 1**

# Agenda

**Time**      **September 12, 2023**

**8:00 - 9:00 am**      **Continental Breakfast**

9:00 - 9:30 am      **Digital Transformation – A Journey Towards a Data Driven Organization**  
Dorian Tisdale, Janssen Pharmaceutical Companies of Johnson & Johnson

9:30 - 10:00 am      **Future in the Cloud**  
Dr. Shakthi Kumar, Amazon Web Services

**10:00 - 10:30 am**      **Break (30 min)**

**10:30 - 11:10 am**      **Table Tutorials (Meeting Room 1-4)**

**Stop Emailing Me, Annotate Me Instead... Using Annotation Feature for Submission Review**

Ginny Smith & Rachele Butt, United Therapeutics Corporation

**Reusing EU Marketing Authorization Application in the US and Vice Versa**

Claudia Bernal-Vallejo, LORENZ Life Sciences Group

**Functions & Permissions: Differences between Groups & Roles**

Sebastian Hagedorn, LORENZ Life Sciences Group

**How LORENZ RIM Supports Registration Tracking & Reporting**

Matthias Spiller, LORENZ Life Sciences Group

**Break (10 min)**

**11:20 - 12:00 pm**      **Table Tutorials (Meeting Room 1-4)**

**Exploring Hidden Gems in LORENZ docuBridge**

Hilary Hafeken, Roivant Sciences Ltd.

**LORENZ MetaSync – Flexible Metadata Synchronization**

Dr. Katharina Schmitz, LORENZ Life Sciences Group

**Simplifying Submission Handling and Sending: Introducing the Submission Repository**

Anna Kispál, LORENZ Life Sciences Group

**What's New in LORENZ docuBridge 23.1**

Jessica Lemley & Parul Patel, LORENZ Life Sciences Group

**12:00 - 1:30 pm**      **Lunch (90 min)**

1:30 - 2:00 pm      **LORENZ docuBridge & Veeva: From a Company's Regulatory Need for Global Products to Health Authority Submissions**  
Dr. Max Nattermann, Bayer AG

2:00 - 2:30 pm      **Enhancing Local Affiliate Engagement for Efficient Global RIM Programs**  
Steve Gens, Gens and Associates

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

**2:45 pm**      **End of Conference**