

Agenda

LORENZ Connect North America 2021 May 11-12, 2021

Time	May 11, 2021		
08:30 - 09:00 am PDT 11:30 - 12:00 pm EDT	LORENZ Keynote Raoul-A. Lorenz, LORENZ Life Sciences Group		
09:10 - 09:40 am PDT 12:10 - 12:40 pm EDT	Global Regulatory Updates Akira Yamaguchi, LORENZ Life Sciences Group	Word Emergency Kit - Five Things to Check When Your Document Breaks Down Kelly Crossett, Whitsell Innovations, Inc.	What's New in LORENZ docuBridge? Kristina Roberson, LORENZ Life Sciences Group
09:45 - 10:15 am PDT 12:45 - 01:15 pm EDT	Strategies to Adopting Structured Data Submissions - Data Quality, Connectivity, and Governance Steve Gens and Kelly Hnat, Gens and Associates, Inc.		
10:20 - 10:50 am PDT 01:20 - 01:50 pm EDT	Technical Rejection Criteria for Study Data: Are You Ready? Shannon Heacock, WAYS Pharmaceutical Services LLC	They Asked for What? Bridging the Gap Between Reviewer Requests and eCTD Specifications Ginny Smith, United Therapeutics Corporation	FDA and LORENZ docuBridge - Project Journey Prasanna Sadashivaiah, LORENZ Life Sciences Group
10:55 - 11:25 am PDT 01:55 - 02:25 pm EDT	Health Canada Updates Irena Pastorekova, Health Canada		
11:25 am PDT 02:25 pm EDT	End of Conference Day 1		

Time	May 12, 2021		
08:00 - 08:30 am PDT 11:00 - 11:30 am EDT	RA Efficiency Through Process Optimization: A Bayer Case Study Dr. René Klünsch, Jerianne Minervini, Anna Sahl, Dr. Ulrike Vollmer, Bayer AG		
08:35 - 09:05 am PDT 11:35 - 12:05 pm EDT	The Rise of the Chief Data Officer and Data Stewards: Fostering Reliable Data Hans van Bruggen, Qdossier B.V.		
09:10 - 09:40 am PDT 12:10 - 12:40 pm EDT	Automation for Submissions Dr. Katharina Schmitz, LORENZ Life Sciences Group	LORENZ Validation Services: How They Can Add Value For Our Customers Massud Fazelly & Leonhard Keller, LORENZ Life Sciences Group	LORENZ docuBridge for Advertising and Promotional Materials via eCTD Melissa Andaya & Jessica Romero, Gilead Sciences, Inc.
09:45 - 10:15 am PDT 12:45 - 01:15 pm EDT	LORENZ Roadmap & eCTD 4.0 LORENZ Life Sciences Group		
10:20 - 10:50 am PDT 01:20 - 01:50 pm EDT	Utilizing LORENZ docuBridge and iSubmit for Document/Report Level Publishing Michelle Farmer, LORENZ Life Sciences Group	Continuing to Adapt: The Continued Evolution of Publisher into Supporting Other Areas and Beyond Jillian Carinci, Biogen Corporation	What's New in LORENZ docuBridge? Kristina Roberson, LORENZ Life Sciences Group
10:55 - 11:25 am PDT 01:55 - 02:25 pm EDT	Cloudy With a Chance of COVID - Regeneron's Journey to Implement LORENZ During a Global Pandemic Jim Czubachowski, Joseph Moy, Robert Pers, Vladlen Rotshteyn, Regeneron Pharmaceuticals, Inc.		
11:25 am PDT 02:25 pm EDT	End of Conference Day 2		

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