Preliminary LORENZ userBridge.11 program - July'11

This year's userBridge will be held on September 20–22 in Turin, Italy. Based on our motto LEARN, DISCUSS, and INTERACT, and our positive experiences from previous userBridge conferences, we will again be offering a combination of educational, informational, and networking opportunities.

LEARN:

Presentations will be held on various themes, focusing primarily on the eSubmission (eCTD, RPS) but also on other key regulatory affairs issues from the perspectives of both the government authorities and the pharmaceutical & biotech industries. Topics we are looking to cover:

General Topics	Confirmed Speaker
Industry Experiences with ASP Systems	Beate Kienzler, Dr. Regenold GmbH
ASMF/DMF	**ASMF/DMF in eCTD Format** Robert Molzahn, EXCELLA GmbH
Practical Solutions in Submission Management	**Coordinating Remote Sites and Relative Submission Documents** Ron de Boer, Astellas Europe B.V.
Regulatory Considerations	**AMNOG – "Nutzendossier" in Electronic Format – Critical Aspects** Dr. Maren von Fritschen, PharmaLex GmbH **New Validation Criteria** Charles Mathis, LORENZ Life Sciences Group **Marketing Medicines in ZA and Southern Africa** H. Vienings, R. Daniel, MRA Regulatory Consultants
Government Authority	**Moving Forward with the eCTD at Health Canada** Vianney Caron, Health Canada
Registration Data Tracking	**Management of Clinical Trial Information** Gabriela Billig, LORENZ Life Sciences Group
FDA's New Validation Guidelines	**Facilitation of FDA Meetings via eCTD** Helen Ribbans, B&H Consulting Services, Inc.
Documentation Practices in Regulatory Procedures	**Best Practices in Regulatory Document Management to Ensure Compliant eSubmissions** Kathleen Clark, NextDocs Corporation
Case Studies	**Implementation of LORENZ docuBridge in Certification of Substances Division at EDQM** Fiona McLeod, EDQM
	With more to come…

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

INTERACT:

This year's table tutorials will offer you help and support for each step of the regulatory process. There will also be a chance to learn more about improving your system and processes while learning more about configuration possibilities and transitioning from LORENZ docuBridge 3.6 to version 5.0.

Table	Tutorial Title - Leader	Session 1 13.45 14.35	Session 2 14.40 15.30	Session 3 16.00 16.50
1	Challenges of Submitting for Registration in ZA and Southern Africa H. Vienings, R. Daniel, MRA Regulatory Consultants	x		
1	LORENZ docuBridge 5.0 A. Zapf, LORENZ Life Sciences Group		x	x
2	Effective Outsourcing of e-Submissions B. Cory, L. Steinhoff, Regxia Inc.	x	x	
2	Marketing Application Authorization in Spain and Portugal Marta Estruch, InvoFarma			x
3	LORENZ authorBridge A. Care, LORENZ Life Sciences Group			x
3	Using LORENZ drugTrack to Manage Marketing Authorizations G. Billig, LORENZ Life Sciences Group	x	x	
4	Agency Round Table J. Johnson, LORENZ Life Sciences Group	x	x	
4	New Validation Criteria C. Mathis, LORENZ Life Sciences Group			x
5	Populating Regional Module 1 per EU Specification J. Draguhn, LORENZ Life Sciences Group	x	x	x
6	10 most Common Validation Issues C. Hapke, LORENZ Life Sciences Group	x	x	
6	What You Should Know about RMTrack C. Hapke, LORENZ Life Sciences Group			x
7	Configuration Possibilities J. Berning, LORENZ Life Sciences Group	x	x	
7	Working with an External DMS NextDocs Corporation			x

DISCUSS:

The "e-Regulatory Forum" will give you the opportunity to learn from and discuss with the experts. Use this opportunity to take advantage of the experiences of others as well as the networking opportunities that will present themselves at userBridge.11.

At userBridge.11 we would like to present the key topic of the e-Regulatory Forum:
The Foreign Review. A Foreign Review is when evaluations of marketing authorization documents are written by the Health Authority of another country. Such evaluations of data submitted can be used by registered users to support case for granting the medicinal marketing authorization of a pharmaceutical product in another country.

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In this context, the approaches will be discussed:

- What is a Foreign Review, and where is it accepted?
- What are the benefits and potential pitfalls?
- How can it be implemented?

Panel leader and moderator:
Dr. Christine Mayer-Nicolai (Head Regulatory Coordination Europe & Global Regulatory Intelligence, Merck Serono**)**

e-Regulatory Forum guests:

- **Dr. Susanne Keitel** (European Directorate for the Quality of Medicines & HealthCare, EDQM)
- **Dr. Supriya Sharma** (Director General, Therapeutic Products Directorate, Health Canada)
- **Dr. Christa Wirthumer-Hoche** (Federal Ministry of Health and Women, Austria)

Program Timelines

From	To	September 20th	September 21st	September 22nd	September 23rd
8:00 a.m.	8:30 a.m.	Registration			
8:30 a.m.	12:15 p.m.	Presentations	Presentations	Presentations e-Regulatory Forum	Conference for Agencies only IADUG Meeting
12:15 p.m.	2:45 p.m.	**Lunch**	**Lunch**	**Lunch** End	
2:45 p.m.	5:00 p.m.	Presentations	Table Tutorials		
5:00 p.m.		End	End		

Dear Regulatory Affairs Professional,

It will be a pleasure to welcome you to userBridge.11 conference in Turin, Italy. Annually userBridge brings together LORENZ's most valuable people: our customers, our employees, and our partners.

Learn – Discuss – Interact. Over two-and a half days you will benefit from being together with docuBridge and regulatory affairs experts from around the globe.

Ms. Alba Lenertz is available to address any questions you might have at the following telephone number: +49-69-78991-150 or via email at alenertz@lorenz.cc.

I will be glad to welcome each of you at userBridge.11 in Turin and wish you a memorable conference.

Wolfgang Witzel
President

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