

Agenda

a.m.

	Day 1	Day 2	Day 3
8.30		<b>RPS – The new eCTD Format</b> (C. Mathis, LORENZ Life Sciences Group)	<b>Table Tutorials</b> (for more details, please see pages 16 & 17)
9.00	<b>Introduction</b> (R.-A. Lorenz, LORENZ Life Sciences Group)	<b>Update on European Telematic Implementation Group e-Submission &amp; Development of RPS/eCTD NMV</b> (K. Menges, BfArM – German Health Authority)	
9.30	<b>LORENZ Services &amp; Support Insight</b> (K. Briggs, LORENZ Life Sciences Group)	<b>Managing eCTDs &amp; Electronic Submissions at AGES – Progress Report</b> (F. Schuller, AGES – Austrian Health Agency)	
10.00	Break		
10.45	<b>LORENZ Product Insight</b> (LORENZ Life Sciences Group)	<b>e-Submissions JAZMP point of view</b> (D. Obranic, JAZMP (Slovenian Health Authority))	<b>Table Tutorials</b>
11.15		<b>Parallel eCTD Submission to EU, US, CA</b> (S. Teuchmann, Exalon GmbH)	
11.45		<b>eCTD and EDMS Process Improvement Opportunities with docuBridge</b> (S. Harsen, e-DRA)	
12.15	Lunch		

p.m.

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Day 1	Day 2	Day 3	
<b>eCTD Lifecycle Management in an Mutual Recognition Procedure</b> (C. Dinter, Bayer Healthcare AG)	<b>The New EU Variation Guideline and the eCTD: Starting to Think Horizontally</b> (D. Boecker, Bayer HealthCare AG)	END	13.30
<b>The Taming of the eCTD – How Industry Copes with the Challenges of e-Submissions</b> (K.-H. Loebel, Pharmalex GmbH)	<b>I'll be back! – since 2007</b> (H. Emoto, Digital Media System Co., Ltd.)		14.00
<b>Optimising Global Submission Management – from first draft to final submission</b> (I. Neubauer & E. Klein, NDA Regulatory Service GmbH)	<b>Real-world Submission Publishing Optimizing your PDF Output</b> (S. Mackey, Adlib Software)		14.30
	Break		15.00
<b>Implementation of eCTD in POLPHARMA</b> (M. Piwowarski, Polpharma SA)	<b>Structured Authoring - Applying DITA Technology in the Pharmaceutical Industry</b> (S. Frederiksen, Content Technologies ApS)		15.45
<b>System Migration Challenges</b> (T. Banerji, Bayer Corporation USA)	<b>Status of eCTD in Poland</b> (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of Poland, Invited)		16.15
END	END		16.45