Preliminary Agenda – Speakers

(June 2010) – for 21st and 22nd September 2010

Title:	Introducing eCTD in a middle-size Pharma Company
Speaker:	Dr. Ursula Schickel
Company:	Merz Pharmaceuticals GmbH

Title:	Switching from paper/NeeS to eCTD: The important role of baseline submissions
Speaker:	Dr. Michael Braun
Company:	Exalon GmbH

Title:	CH M1 v1.0.x – Experiences from Industry Perspective
Speaker:	Mr. Ron de Boer
Company:	Astellas Europe R&D

Title:	Efficiency Compilation & Management of Quality Documents
Speaker:	Mr. Navaneetha Selvan
Company:	Shasun Chemicals and Drug Limited

Title:	eCTD in Canada
Speaker:	Ms. Betty Cory
Company:	Regxia Inc.

Title:	PIM Project
Speaker:	Mr. Andreas Franken
Company:	BAH (Bundesfachverband der Arzneimittel-Hersteller e.V.)

Title:	How do Agencies review eCTD's? What do they want to see more of, and less of?
Speaker:	Mr. Klaus Menges
Company:	BfArM (German Health Authority)

Title:	RPS - Update & Status on new Regulated Product Submission
Speaker:	Mr. Martin Moxham
Company:	i-Regulatory Ltd.

Title:	Efficient eCTD compilation with DB 3.6: Reuse of outline components
Speaker:	Dr. Christian Dinter
Company:	Bayer Schering Pharma AG

Title:	Consequences of the New Regulations for Variations
Speaker:	Dr. Michaela Peruci
Company:	Gebro Pharma GmbH

… and more!

Table tutorial information to follow.

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