



## AGENDA, 18-20 September 2018

Time	18 September 2018
<b>08:00 - 09:00</b>	<b>REGISTRATION &amp; WELCOME COFFEE</b>
09:00 - 10:00	<b>LORENZ Keynote</b> Raoul-A. Lorenz & Christian Kaas, LORENZ Life Sciences Group
<b>10:00 - 10:45</b>	<b>BREAK (45 min)</b>
10:45 - 11:15	<b>CESP Application Dataset Module - Implementation of IDMP using SPOR?</b> Dr. med. Klaus Menges, BfArM - Federal Institute for Drugs and Medical Devices
11:15 - 11:45	<b>ICH Update IDMP &amp; SPOR</b> Dr. Andreas Franken, ICH M8 / BAH - German Federal Association of Pharmaceutical Manufacturers
11:45 - 12:15	<b>Case Study, Get prepared for eCTD v4.0</b> Steven Tan & Dr. Ulrike Vollmer, Bayer
<b>12:15 - 13:45</b>	<b>LUNCH (90 min)</b>
13:45 - 14:15	<b>Achieve business goals with transparent compliance</b> Klavs Esbjerg, Epista Life Sciences
14:15 - 14:45	<b>RIM - a single system or a happy family?</b> David Warner, Generis
14:45 - 15:15	<b>RIM implementation and integration. Tailoring the evaluation for the RIGHT Solution</b> Amara Tonkiss, Accenture
<b>15:15 - 15:45</b>	<b>BREAK (30 min)</b>
15:45 - 16:15	<b>Structured Content Management for CTD</b> Hans van Bruggen, eCTDconsultancy
16:15 - 16:45	<b>Content Validation</b> Dr. Margaret E. Hurley, Hurley Consulting Associates
<b>16:45</b>	<b>END OF CONFERENCE DAY 1</b>

## Time 19 September 2018

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- 08:00 - 08:30 WELCOME COFFEE**
- 08:30 - 10:05 **Table Tutorials** ([see separate Agenda](#))
- 10:05 - 10:40 BREAK (35 min)**
- 10:40 - 12:15 **Table Tutorials** ([see separate Agenda](#))
- 12:15 - 13:45 LUNCH (90 min)**
- 13:45 - 14:15 **BREXIT and UK medicines regulation**  
Prof. Sir Alasdair Breckenridge, Dr. Regenold
- 14:15 - 14:45 **Insight in the EU Telematic strategy, including the impact of SPOR on Regulatory Affairs**  
Remco Munnik, Asphalion
- 14:45 - 15:15 **EU Clinical Trial Portal and Database**  
Harald von Aschen, BfArM - Federal Institute for Drugs and Medical Devices
- 15:15 - 15:45 BREAK (30 min)**
- 15:45 - 16:45 Panel Discussion:  
**CTA - eCTD a requirement? How to prepare for upcoming challenges?**  
Dr. Andreas Franken, ICH M8 / BAH - German Federal Association of Pharmaceutical Manufacturers  
Dr. Barbara Gansewendt, Bayer  
Dr. med. Klaus Menges, BfArM - Federal Institute for Drugs and Medical Devices  
Prof. Dr. Burkhard Sträter, STRÄTER Lawyers
- 16:45 END OF CONFERENCE DAY 2**

## Time 20 September 2018

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- 08:00 - 08:30 WELCOME COFFEE**
- 08:30 - 09:00 **Health Canada Updates**  
Vianney Caron, Health Canada
- 09:00 - 09:30 **EU Policy 0070 submissions today and in the future**  
Helle Ainsworth, Novo Nordisk
- 09:30 - 10:00 **Master Data And How To Manage It**  
Gary Wilson, CorrIT
- 10:00 - 10:45 BREAK (45 min)**
- 10:45 - 11:15 **Pharma Regulation in the next decade, how the GCC is leading the way**  
Mona Al Moussli, Professionals Regulatory Affairs - Middle East
- 11:15 - 11:45 **Submissions in Asia Pacific**  
Dr. Philip Hall, AbbVie
- 11:45 - 12:15 **Submission Migration - A Challenging and Learning Experience**  
Andrea Fischer, Elke Schydlo & Luka Kovacic, Sandoz
- 12:15 - 12:30 **Closing Remarks**  
Raoul-A. Lorenz, LORENZ Life Sciences Group
- 12:30 - 13:45 END OF CONFERENCE & LUNCH**