DITTA Workshop on International Standards

Standards are everywhere and rightfully so!

In conjunction with the 10th meeting of IMDRF in Florianópolis, Brazil

Monday 12 September 2016 from 09:00 to 16:45

Location: Costão do Santinho Resort
Estrada Vereador Onildo Lemos, 2505 | Praia do Santinho, Florianópolis, Santa Catarina 88058-700, Brazil

The forthcoming DITTA workshop on international standards will be the 3rd one in the context of IMDRF. The main goal is to provide the latest information on how regulators consider standards in their regulatory framework as well as how standards are used by industry at global level. In addition, information will be shared on standards development at IEC and ISO levels and latest updates on their work programmes will be given. This workshop is a great opportunity for interactive discussions between various key players and networking.

Agenda

Note: Speakers to be confirmed

08:30 – 09:00 Coffee and registration

09:00 – 09:05 Opening remarks Satoshi Kimura, DITTA Chair

09:05 – 09:15 Welcoming words Fabio Quintino, IMDRF Chair

09:15 – 09:35 Status update of IMDRF Work Item on Standards Phase 1: mapping exercise Matthias Neumann, IMDRF Standards WI Lead

09:35 – 10:05 WHO Regulatory Global Model and the use of standards Joséé Hansen, WHO

10:05 – 10:35 Regulators Vision on the use of standards in support of regulatory requirements Scott Colburn, US FDA

10:35 – 11:00 Coffee break

11:00 – 11:30 The use of standards in support of regulatory requirements in Brazil Leandro Pereira, ANVISA

11:30 – 12:00 How do ISO and IEC develop standards today including "standards life cycle" Maurizio Andreano, DITTA
12:00 – 12:30  Panellists discussions incl. Q&As - Address the better direction for the standards  
All speakers

12:30 – 13:30  Lunch break

13:30 – 13:55  DITTA vision on the use of standards in support of regulatory requirements  
Naoki Morooka, JIRA

Linda Lindsay, MEDEC

14:15 – 14:35  IEC/TC 62: Overview & work program  
Norbert Bischof/Nicole Denjoy, COCIR

14:35 – 14:55  ISO/TC 194: Overview & work program  
Greg LeBlanc, GMTA

14:55 – 15:25  Coffee break

15:25 – 15:45  ISO/TC 210: Overview & work program  
Peter Linders, DITTA

15:45 – 16:05  The situation of Brazilian companies regarding the implementation of standards in Brazil  
Marcio Godoy, Abimed

16:05 – 16:35  Panellists discussions incl. Q&As - Address the better direction for the standards  
All speakers

16:35 – 16:45  Closing remarks  
Nicole Denjoy, DITTA Vice Chair