



## DITTA Workshop on International Standards

### ***Standards are everywhere and rightfully so!***

*In conjunction with the 10<sup>th</sup> 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 3<sup>rd</sup> 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, <i>DITTA Chair</i>
09:05 – 09:15	Welcoming words	Fabio Quintino, <i>IMDRF Chair</i>
09:15 – 09:35	Status update of IMDRF Work Item on Standards Phase 1: mapping exercise	Matthias Neumann, <i>IMDRF Standards WI Lead</i>
09:35 – 10:05	WHO Regulatory Global Model and the use of standards	Josée Hansen, <i>WHO</i>
10:05 – 10:35	Regulators Vision on the use of standards in support of regulatory requirements	Scott Colburn, <i>US FDA</i>
<i>10:35 – 11:00 Coffee break</i>		
11:00 – 11:30	The use of standards in support of regulatory requirements in Brazil	Leandro Pereira, <i>ANVISA</i>
11:30 – 12:00	How do ISO and IEC develop standards today including “standards life cycle”	Maurizio Andreano, <i>DITTA</i>



12:00 – 12:30	Panellists discussions incl. Q&As - Address the better direction for the standards	All speakers
<i>12:30 – 13:30</i>	<i>Lunch break</i>	
13:30 – 13:55	DITTA vision on the use of standards in support of regulatory requirements	Naoki Morooka, <i>JIRA</i>
13:55 – 14:15	DITTA Good Refurbishment Process standard: the making of and its use	Linda Lindsay, <i>MEDEC</i>
14:15 – 14:35	IEC/TC 62: Overview & work program	Norbert Bischof/Nicole Denjoy, <i>COCIR</i>
14:35 – 14:55	ISO/TC 194: Overview & work program	Greg LeBlanc, <i>GMTA</i>
<i>14:55 – 15:25</i>	<i>Coffee break</i>	
15:25 – 15:45	ISO/TC 210: Overview & work program	Peter Linders, <i>DITTA</i>
15:45 – 16:05	The situation of Brazilian companies regarding the implementation of standards in Brazil	Marcio Godoy, <i>Abimed</i>
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, <i>DITTA Vice Chair</i>