IMDRF /DITTA joint workshop on

Optimizing Standards for Regulatory Use

Monday 18 March 2019

Venue: *President Hotel, Bolshaya Yakimanka Street 24, Yakimanka, 119134* Moscow
(Большая Якиманка 24, Якиманка, 119134 Москва

Abstract: Standards help ensure that devices are safe and perform as intended and, as such, can be used for regulatory compliance. Internationally recognized standards facilitate regulatory convergence at the global level.

IMDRF recently adopted the guidance document on Optimizing Standards for Regulatory Use[1]. This workshop will explore how regulators and standards developers will use the recommendations of the guidance at a practical level. In addition, the next steps for the IMDRF and its activities on standardization are discussed. Information will also be shared on specific standardization activities in IEC and ISO.

Opportunity will be given to audience to ask for questions after each speech.

No	Topic	Speaker	Scheduled Time
Section 1: Opening Remarks			
1	Improving the quality of international medical device standards for regulatory use– five years of achievements & findings remaining challenges	Keynote speech by Vladimir Antonov, SWG, Roszdravnadzor	9:30 – 9:45
2	DITTA Opening Remarks	Nicole Denjoy, DITTA Chair	9:45 – 10:00
Section 2: Outcome of IMDRF Standards WG			
3	How the guidance supports the goal of regulatory harmonization	Melissa Torres, IMDRF MC, US FDA	10:00 – 10:15
4	Guidance structure and key proposal - overview	Madoka Murakami, SWG, PMDA	10:15 – 10:40
	Coffee break		*10:40 – 11:05*
5	How standards are used for regulatory purposes among IMDRF members	Tatiana Pika, SWG, Roszdravnadzor	11:05 – 11:30
Section 3: Role of Standards for Regulatory Purposes			
6	Optimized standards to support Essential Principles of Safety and Performance of medical devices	Erik Hansson, EC	11:30 – 11:50
7	Best practices of regulatory use of standards	Anton Shalaev, Deputy Head of Federal Agency on technical regulating and metrology	11:50 – 12:05
8	Test methods in standards: requirement and proposals	Jia Zheng, SWG, NIFDC, China (prerecorded)	12:05 – 12:30

[1] IMDRF/Standards WG/N51 FINAL:2018, Optimizing Standards for Regulatory Use

	Lunch		*12:30 – 13:30*
Section 4: Expected improvement by IMDRF Standards Guidance Documents			
9	How new work items come to be "good standards development practice"	Peter Linders, SWG, ISO TC210 Chair	13:30 – 13:45
10	How standards are improved by following the guidance?	Scott Colburn, SWG Chair, US FDA	13:45 – 14:10
11 12	Use of improved standards from Russian industry perspective Why standards that follow the guidance are good for business?	Sergey Vanin, IMEDA/DITTA/GMTA Morooka-san, SWG, DITTA	14:10 – 14:25 14:25 - 14:40
	Coffee break		*14:40 – 15:05*
Section 5: Informative Section of the standards for regulatory purposes			
13	How IEC can contribute to IMDRF to support regulatory convergence	Katharine Fraga, IEC Head of Governance and Global Strategy	15:05 – 15:25
14	Future of ISO 13485 (quality management systems) and update on revision of ISO 14971 on medical device risk management	Peter Linders, SWG, ISO TC210 Chair	15:25 – 15:40
15	The future of IEC 60601-1	Maurizio Andreano, DITTA Standardization WG vice-chair	15:40 – 15:55
Section 6: Key note and Panel Discussion			
16	**Key note followed by Panel discussion:** - How can Regulatory Authorities and SDOs collaborate more to support each other? - How IMDRF thinks to best become structurally involved in standards development - How can IMDRF benefit from its category A liaisons with key technical committees of ISO and IEC? - Suggestion to support the IMDRF liaison to TC of SDOs. *Conclusions from Panel Lead*	Keynote speech by Matthias Neumann, SWG, EU (lead of panel discussion)	*Keynote:* 15:55 – 16:10 *Panel discussion:* 16:10 – 16:55
Section 7: Closing Remarks			
17	Conclusions from workshop chair	Vladimir Antonov, SWG, Roszdravnadzor	16:55 – 17:00