



IMDRF International Medical
Device Regulators Forum

Day 2: IMDRF Stakeholder Forum
Wednesday 15 March 2017 – 9:00 to 18:00

Venue: Crystal Pavilion B&C, Pan Pacific Hotel
300-999 Canada Place

9:00 – 12:15 - AM Session

	TIME	ITEM	Material
1	9:00 – 9:05	Introduction by IMDRF Chair	
2	9:05 – 10:35	Management Committee Member Regulatory Updates (10 min each)	
	9:05 – 9:15	a. Australia	
	9:15 – 9:25	b. Brazil	
	9:25 – 9:35	c. Canada	
	9:35 – 9:45	d. China	
	9:45 – 9:55	e. European Union	
	9:55 – 10:05	f. Japan	
	10:05 – 10:15	g. Russia	
	10:15 – 10:25	h. Singapore	
	10:25 – 10:35	i. United States	
	10:35 – 10:50	Coffee/tea break	
3	10:50 – 12:00	Overview of progress to date on work items (10 min each)	
	10:50 – 11:00	a. National Competent Authority Report (NCAR) (EU)	
	11:00 – 11:10	b. Software as a Medical Device (SaMD) (USA)	
	11:10 – 11:20	c. Regulated Product Submission (RPS) (Canada)	
	11:20 – 11:30	d. Medical Device Patient Registries (USA)	
	11:30 – 11:40	e. Medical Device Adverse Event Terminology (Japan)	
	11:40 – 11:50	f. Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers (USA)	
	11:50 – 12:00	g. Improving the quality of international medical device standards for regulatory use (EU)	
4	12:00 – 12:15	Questions and Answers on Work Items	

12:15 – 13:30 Lunch break sponsored by GMTA

13:30 – 17:40 - PM Session

	TIME	ITEM	Material
5	13:30 – 14:00	GMTA New Work Item Proposal on Harmonized Unique Device Identifier (UDI) Application Guide Jackie Elkin, Medtronic, GMTA	
6	14:00 – 15:45	Cybersecurity Panel – Software and connectivity are increasingly playing a crucial role in medical technology, as is the need to protect medical systems from cybersecurity threats. Experts from academia, industry, and the security research community will explore the challenges, opportunities & complexity of medical device cybersecurity in a panel format.	
	15:45 – 16:00	Coffee/tea break	
7	16:00 – 17:20	Stakeholder Sessions	
	16:00 – 16:20	a. DITTA	
	16:20 – 16:40	b. GMTA	
	16:40 – 16:50	c. APEC	
	16:50 – 17:00	d. WHO	
	17:00 – 17:10	e. AHWP	
	17:10 – 17:20	f. PAHO	
8	17:20 – 17:30	IMDRF General Questions and Answers PM Session	
9	17:30 – 17:40	Concluding remarks by IMDRF Chair	

18:00 Reception Sponsored by DITTA