IMDRF International Medical Device Regulators Forum

IMDRF Stakeholder Forum
Wednesday 20 September 2017 – 9:00 to 17:10
Venue: Pearson Room, Lord Elgin Hotel
100 Elgin Street

9:00 – 12:15 - AM Session

	TIME	ITEM	Material
1	**9:00 – 9:05**	**Introduction by Assistant Deputy Minister, Health Products and Food Branch, Health Canada**	
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 DITTA

13:30 – 17:10 - PM Session

	TIME	ITEM	Material
5	**13:30 – 13:45**	**New Work Item Proposal on Patient Specific Devices** Therapeutic Goods Administration, Australia	
6	**13:45 – 15:15**	**Real World Evidence Panel –** Real World Evidence is a term increasingly being discussed in the context of medical devices. Leveraging Real World Evidence has the potential to provide powerful insights into the benefits and risks of medical devices. Panel members will explore the opportunities, challenges & complexity of using real world evidence to drive device pre- and post-market regulatory decisions.	
15:15 – 15:30		***Coffee/tea break***	
7	**15:30 – 16:50**	**Stakeholder Sessions**	
	15:30 – 15:50	a. DITTA	
	15:50 – 16:10	b. GMTA	
	16:10 – 16:20	c. APEC	
	16:20 – 16:30	d. WHO	
	16:30 – 16:40	e. AHWP	
	16:40 – 16:50	f. PAHO	
8	**16:50 – 17:00**	**IMDRF General Questions and Answers PM Session**	
9	**17:00 – 17:10**	**Concluding remarks by IMDRF Chair**	

17:30 Reception Sponsored by GMTA