IMDRF International Medical Device Regulators Forum

Beijing, China

Tuesday 18 to Thursday 20 September 2018

IMDRF-14 AGENDA (update)

Day 1: IMDRF Stakeholder Forum

Tuesday 18 September 2018 – 9:00am to 18:00pm

Venue: Rose Mallow Function Room, 1st Floor, New Otani Chang Fu Gong Hotel
No.26, Jianguomenwai Avenue, Beijing

AM Session, *9:00am – 12:35pm*

	TIME	ITEM	Material
1	**9:00 – 9:10**	**Welcome speech by China-NMPA[1] Deputy Commissioner Dr. XU Jinghe**	
2	**9:10– 10:50**	**Management Committee Member Regulatory Updates (10 min each)**	
	9:10 – 9:20	a. Australia (Speaker: Elizabeth McGrath)	PPT
	9:20 – 9:30	b. Brazil (Speaker: Leandro Rodrigues)	PPT
	9:30 – 9:40	c. Canada (Speaker: David Boudreau)	PPT
	9:40 – 9:50	d. China (Speaker: ZHANG Qi)	PPT
	9:50 – 10:00	e. European Union (Speaker: Erik Hansson)	PPT
	10:00 – 10:10	f. Japan (Speaker: Yumiko Aoyagi)	PPT
	10:10 – 10:20	g. Russia (Speaker: Elena Astapenko)	PPT
	10:20 – 10:30	h. Singapore (Speaker: Wong Woei Jiuang)	PPT
	10:30 – 10:40	i. South Korea (Speaker: Hyeonjoo Oh)	PPT
	10:40 – 10:50	j. United States (Speaker: Jeff Shuren)	PPT
3	**10:50–11:00**	**Questions and Answers**	
11:00 – 11:10		***Coffee/tea break***	

[1] According to the year 2018 Reform Plan issued by the State Council, the newly established National Medical Products Administration (NMPA) is now the medical devices regulator of China, to replace the former China Food and Drug Administration (CFDA).

4	**11:10 – 12:35**	**Overview of progress to date on the work items (10-15 min each)**	
	11:10 – 11:20	a. Regulated Product Submission (RPS) (Canada, Speaker: Nancy Shadeed)	PPT
	11:20 – 11:30	b. Medical Device Adverse Event Terminology (Japan, Speaker: Madoka Murakami)	PPT
	11:30 – 11:40	c. Good Regulatory Review Practice (USA, Speaker: Melissa Torres)	PPT
	11:40 – 11:55 (15 minutes)	d. Standards (USA, Speaker: Melissa Torres)	PPT
	11:55– 12:05	e. Personalized Medical Devices (Australia, Speaker: Elizabeth McGrath)	PPT
	12:05 – 12:15	f. Unique Device Identification (EU, Speaker: Salvatore Scalzo)	PPT
	12:15 – 12:25	g. Medical device clinical evaluation (China, Speaker: Ju Shan)	PPT
5	**12:25– 12:35**	**Questions and Answers**	

12:35 – 13:30, Lunch Time

PM Session, 13:30pm – 17:30pm

	TIME	ITEM	Material
6	**13:30 – 15:00**	**A Special Forum Discussion Session on Robotic Medical Device**	PPTs
15:00 – 15:15		***Coffee/tea break***	
7	**15:15 – 17:45**	**Stakeholder Sessions**	
	15:15 – 15:30	a. China Association for Medical Devices Industry (Speaker: Yang Xiaofang)	PPT
	15:30 – 15:45	b. DITTA (Industry) (Speaker: Patrick Hope)	PPT
	15:45 – 16:00	c. GMTA (Industry) (Speaker: Lindsay Tao)	PPT
	16:00 – 16:15	d. WHO (Official Observer) (Speaker: Irena Prat)	PPT
	16:15 – 16:30	e. APEC (Regional Harmonization Initiatives) (Speaker: Mario Alanís Garza)	PPT
	16:30 – 16:45	f. AHWP (Regional Harmonization Initiatives) (Speaker: Zamane Abdul Rahman)	PPT
	16:45 – 17:00	g. PAHO (Regional Harmonization Initiatives) (Speaker: Marcela Rizzo, ANMAT)	PPT
	17:00 – 17:15	h. Hong Kong SAR (Invited Observer) (Speaker: CHEUNG Yung-yan, Terence)	PPT
	17:15 – 17:30	i. Mexico COFEPRIS(Invited Observer) (Speaker: Mario Alanís Garza)	PPT
8	**17:30 – 17:45**	**Questions and Answers**	
9	**17:45 – 18:00**	**Concluding remarks**	