



**IMDRF** International Medical  
Device Regulators Forum

**Yekaterinburg, Russia**

**Tuesday 17 to Thursday 19 September 2019**

**IMDRF-16 AGENDA\* (draft)**

\*IMDRF Secretariat reserves the right to make amendments to this Agenda

**Day 1: IMDRF Stakeholder Forum**

**Tuesday 17 September 2019 – 9:00am to 17:35pm**

**Venue: Hyatt Regency Yekaterinburg**

**8 Boris Yeltsin Street, Yekaterinburg, Russia**

**Ballroom, 2<sup>nd</sup> Floor**

**AM Session, 9:00am – 14:00pm**

<b>TIME</b>	<b>ITEM</b>
<b>8:00 – 9:00</b>	<b><i>Welcome Coffee/tea break and registration</i></b>
<b>1 9:00 – 9:15</b>	<b>Welcome speech</b>
<b>2 9:15– 11:45</b>	<b>Management Committee Member Regulatory Updates (10 min each + 5 min Q&amp;A)</b>
9:15 – 9:30	a. Australia
9:30 – 9:45	b. Brazil
9:45 – 10:00	c. Canada
10:00 – 10:15	d. China
10:15 – 10:30	e. European Union
10:30 – 10:45	f. Japan
10:45 – 11:00	g. Russia
11:00 – 11:15	h. Singapore
11:15 – 11:30	i. South Korea
11:30 – 11:45	j. United States
<b>11:45 – 12:00</b>	<b><i>Coffee/tea break</i></b>



<b>3</b>	<b>12:00 – 14:00</b>	<b>Overview of progress to date on the work items (10 min each + 5 min Q&amp;A)</b>
	12:00 – 12:15	a. Regulated Product Submission (RPS)
	12:15 – 12:30	b. Medical Device Adverse Event Terminology
	12:30 – 12:45	c. Good Regulatory Review Practice
	12:45 – 13:00	d. Standards
	13:00 – 13:15	e. Personalized Medical Devices
	13:15 – 13:30	f. Medical device clinical evaluation
	13:30 – 13:45	g. Medical device cybersecurity
	13:45 – 14:00	h. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
<b>14:00 – 15:00</b>		<b>Lunch break</b>
<b>PM Session, 15:00pm – 17:50pm</b>		
<b>4</b>	<b>15:00 – 17:25</b>	<b>Stakeholder Sessions (10 min each + 5 min Q&amp;A)</b>
	15:00 – 15:15	a. Russian Ministry of industry and trade
	15:15 – 15:30	b. WHO (Official Observer)
	15:30 – 15:45	c. APEC (Regional Harmonization Initiative)
	15:45 – 16:00	d. AHWP (Regional Harmonization Initiative)
	16:00 – 16:15	e. PAHO (Regional Harmonization Initiative)
	16:15 – 16:30	f. DITTA (Industry)
	16:30– 16:45	g. GMTA (Industry)
	16:45 – 17:30	h. Industry (representative from Russia, to be confirmed)
<b>5</b>	<b>17:30 – 17:35</b>	<b>Concluding remarks by IMDRF Chair</b>
<b>17:35– 17:50</b>		<b>Coffee/tea break</b>

**18:30 Sverdlovsk Philharmonic Performance Hosted by Russia**