



**IMDRF** International Medical  
Device Regulators Forum

Moscow, Russia

**Tuesday 19 to Thursday 21 March 2019**

**IMDRF-15 AGENDA\* (draft)**

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

**Day 1: IMDRF Stakeholder Forum**

**Tuesday 19 March 2019 – 9:00am to 17:40pm**

**Venue: President-Hotel**

**No. 24, Bolshaya Yakimanka Street, Yakimanka, Moscow**

**Concert Hall, 2<sup>nd</sup> Floor**

<b>AM Session, 9:00am – 13:30pm</b>		
<b>8:00 – 9:00</b>		<b><i>Welcome Coffee/tea break and registration</i></b>
<b>1</b>	<b>9:00 – 9:10</b>	<b>Welcome speech by Roszdravnadzor</b>
<b>2</b>	<b>9:10 – 11:40</b>	<b>Management Committee Member Regulatory Updates (10 min each + 5 min Q&amp;A)</b>
	9:10 – 9:25	a. Australia
	9:25 – 9:40	b. Brazil
	9:40 – 9:55	c. Canada
	9:55 – 10:10	d. China
	10:10 – 10:25	e. European Union
	10:25 – 10:40	f. Japan
	10:40 – 10:55	g. Russia
	10:55 – 11:10	h. Singapore
	11:10 – 11:25	i. South Korea
	11:25 – 11:40	j. United States
	<b>11:40 – 12:00</b>	<b><i>Coffee/tea break</i></b>
<b>3</b>	<b>12:00 – 13:30</b>	<b>Overview of progress to date on the work items (10 min each)</b>
	12:00 – 12:10	a. Regulated Product Submission (RPS)
	12:10 – 12:20	b. Medical Device Adverse Event Terminology

	12:20 – 12:30	c. Good Regulatory Review Practice
	12:30 – 12:40	d. Standards
	12:40 – 12:50	e. Personalized Medical Devices
	12:50 – 13:00	f. Unique Device Identification
	13:00 – 13:10	g. Medical device clinical evaluation
	13:10 – 13:20	h. Medical device cybersecurity Guide
	<b>13:20 – 13:30</b>	<b>Q&amp;A&amp;D Session</b>
	<b>13:30 – 14:30</b>	<b>Lunch break</b>
<b>PM Session, 14:30pm – 17:45pm</b>		
<b>4</b>	<b>14:30 – 15:30</b>	<b>Stakeholder Sessions</b>
	14:30 – 14:40	a. Eurasian Economic Commission
	14:40 – 14:50	b. WHO (Official Observer)
	14:50 – 15:00	c. APEC (Regional Harmonization Initiative)
	15:00 – 15:10	d. AHWP (Regional Harmonization Initiative)
	15:10 – 15:20	e. PAHO (Regional Harmonization Initiative)
	15:20 – 15:30	f. DITTA (Industry)
	15:30 – 15:40	g. GMTA (Industry)
	15:40 – 15:50	h. Union of designers, manufactures and users of medical equipment
	15:50 – 16:00	i. IMEDA (Industry)
	16:10 – 16:20	<b>Q&amp;A&amp;D Session</b>
	<b>16:20 – 16:40</b>	<b>Coffee/tea break</b>
<b>5</b>	<b>16:40 – 17:40</b>	<b>A Special Forum Discussion Session on The regulatory approach for next generation sequencing (NGS) testing</b>
<b>6</b>	<b>17:40 – 17:45</b>	<b>Concluding remarks by IMDRF Chair</b>