

**Webinar on Conformity Assessment for Medical Devices**  
**Personalized Medical Devices**  
**Day 1**

**Date: 6 February 2023**

**Time: 7:00 – 9:30PM (7:00AM – 9:30AM EST)**

**Hybrid event – Zoom + in person**

**Objectives.** Provide an overview and open discussion on the implementation of Conformity Assessment and Personalized Medical Devices.

TIME	AGENDA
<b>7:00 – 7:05</b>	<b>Welcome Message</b> Mugant Mehanathan, MDRC (5 min)
<b>7:05 – 7:30</b>	<b>Conformity Assessment – Ensuring Compliance with International Obligations: Checklist</b> - <b>Marina Carvalho</b> , MDRC (15 min) Q&A (10 min)
<b>7:30 – 7:45</b>	<b>Conformity Assessment for Medical Devices – International References</b> <b>Principles of Conformity Assessment for Medical Devices (<a href="#">GHTF/SG1/N78:2012</a>)</b> - <b>Erin Cutts</b> , US FDA (15 min)
<b>7:45 – 8:30</b>	<b>Conformity Assessment – The How to: Regulator and CABs</b> <b>Conformity Assessment in Action</b> <b>Overview of Conformity Assessment and Government utilization of CA</b> - <b>Gordon Gillerman</b> , NIST (15 min) <b>The Accreditation Scheme for Conformity Assessment (ASCA) Program: Putting Standards to Work in Conformity Assessment</b> - <b>Scott Colburn</b> , US FDA (15 min) <b>Conformity Assessment Private Sector Perspective</b> - <b>Aparna Dhawan</b> , TIC Council (15 min)
<b>8:30 – 9:25</b>	<b>Open Discussion</b> (55 min) <b>Moderator:</b> Sandra Ligia González, MDRC
<b>9:25 – 9:30</b>	<b>Closing Remarks</b> Mugant Mehanathan, MDRC (5 min)

**Webinar on Conformity Assessment for Medical Devices**  
**Personalized Medical Devices**  
**Day 2**

**Date: 7 February 2023**

**Time: 9:00 – 11:30 AM (9:00 – 11:30 PM EST)**

**Hybrid event – Zoom + in person**

**Objective.** Provide an overview and open discussion on the implementation of Conformity Assessment and Personalized Medical Devices.

TIME	AGENDA
9:00 – 9:05	<b>Welcome Message</b> Mugant Mehanathan, MDRC (5 min)
9:05 – 9:50	<b>Personalized Medical Devices – International References and Regulators’ Experience</b> <b>Definitions for Personalized Medical Devices</b> ( <a href="#">IMDRF/PMD WG/N49FINAL:2018</a> ) <ul style="list-style-type: none"><li>- <b>Uphar Chamoli</b>, TGA Australia (15 min)</li></ul> <b>Personalized Medical Devices - Regulatory Pathways</b> ( <a href="#">IMDRF/PMD WG/N58</a> ) <ul style="list-style-type: none"><li>- <b>Shuling Ping</b>, HAS Singapore (15 min)</li></ul>
9:50 – 11:25	<b>Open Discussion</b> (95 min) <b>Moderator:</b> Sandra Ligia González, MDRC
11:25 – 11:30	<b>Closing Remarks</b> Mugant Mehanathan, MDRC (5 min)

