IMDRF International Medical Device Regulators Forum

Personalized Medical Devices Working Group

Chair: Tracey Duffy, TGA Australia

15-19 September 2025, Sapporo Japan

About US

Members: Argentina, Australia, Brazil, Canada, China, El Salvador, Europe, Japan, Paraguay, Saudi Arabia, Singapore, South Korea, UK, USA, GHWP

Strategic Plan: Priority 1 – Premarket: develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices.

Task: A tailored regulatory approach that takes into consideration the unique characteristics and risk of each of these types of devices, which is different from mass-produced medical devices

Publications

Definitions for Personalized Medical Devices (N49)
Published November 2018

Personalized Medical Devices – Regulatory Pathways (N58)
First published April 2020
Revised version published September 2023

Personalized Medical Devices – Production Verification & Validation (N74)
Published April 2023

Current Status

MC agreed at its meeting in Tokyo (March 2025) that the Working Group will close as the work items are complete.

Note: For consistent interpretation of the recommendations in the documents, some members are exploring how the documents could be delivered through a webinar and/or training materials. A challenge is that IMDRF members are at varying stages of implementing the guidance and balancing priorities and resources.

Current Status

To support the adoption and consistent interpretation of the PMD documents, the TGA has progressed the development of a prototype e-learning module based on the *IMDRF N49 Definitions for Personalized Medical Devices*.

Updates will be provided to the IMDRF MC on any activities.

Thank you