Personalized Medical Devices Working Group

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IMDRF International Medical Device Regulators Forum
Personalized Medical Devices Working Group

• Established December 2020; 26 members from 12 jurisdictions

• Objectives:
  − To develop technical guidance documents and harmonized recommendations for regulating PMDs across various jurisdictions
  − To engage with stakeholders in the development, adoption, and implementation of the recommendations

• Eighteen virtual meetings since December 2020

• Objectives align with IMDRF Strategic Plan 2021-2025
  − Priority 1 Pre-market
  − Priority 3 Relationships with Stakeholders
Public Consultations were undertaken to develop the following publications:

1. **Definitions for Personalized Medical Devices** *(IMDRF/ PMD WG/ N49)*
   - Published November 2018

2. **Personalized Medical Devices - Regulatory Pathways** *(IMDRF/ PMD WG/ N58)*
   - First published April 2020; Revised version published in September 2023

3. **Personalized Medical Devices - Production V&V** *(IMDRF/ PMD WG/ N74)*
   - Published April 2023
Training Materials for PMD Stakeholders (NWIE)

- A Proposal will be discussed with the IMDRF MC in March 2024 to develop training materials for PMD stakeholders.
- PMD documents present new definitions and concepts for regulation of PMDs and point-of-care manufacturing of medical devices.
- If agreed by the IMDRF MC, the WG intends to:
  - promote the three IMDRF PMD documents and educate stakeholders.
  - develop in collaboration with relevant stakeholders, artefacts to assist in training for regulators and industry (eg: PPT, video, Q&As).
  - monitor implementation and collect feedback.
United States of America

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