Personalized Medical Devices Working Group

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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

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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

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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


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