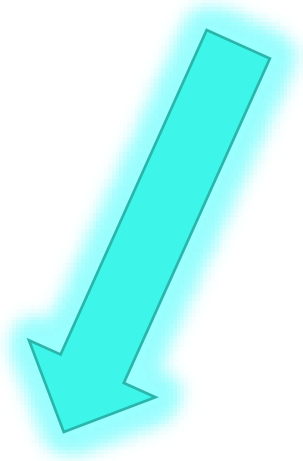
IMDRF International Medical Device Regulators Forum

Personalized Medical Devices(PMD) Working Group

WG Chair: Tracey Duffy, Therapeutic Goods Administration (Australia)



Provide your feedback on this Working Group!

IMDRF 24th Session (26 September 2023) – Stakeholder Forum - Berlin, Germany

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PMD Working Group

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*

- Current Working Group established in December 2020
- Eighteen virtual meetings since December 2020; most recently on 10 August 2023
- Objectives align with IMDRF Strategic Plan 2021-2025 (Priority area: Pre-market)

PMD Working Group members

Jurisdiction	Representative
Argentina	Marcela Rizzo Adriana David
Australia	Tracey Duffy (WG Chair) Rebecca Bateson Uphar Chamoli
Brazil	Adriano Soares da Silva Joao Henrique Campos de Souza Maria Angela da Paz
Canada	Andrea Katynski
China	Yue Min Shuo Pan
Europe	Nada Alkhayat (European Commission) Matthias Neumann (Germany) Mariana Madureira (Portugal) Stefan De Vos (Belgium)

Jurisdiction	Representative
Japan	Mariko Ando Ryosuke Morita Takashi Ooba Yudai Nakazuru
Saudi Arabia	Abdullatif S. Al Watban
Singapore	Shuling Peng
South Korea	Si Hyung Yoo Yunju Lee
UK	Penny Wilson
USA	Matthew A. Di Prima Erin Keith

Publications

- Definitions for Personalized Medical Devices (IMDRF/PMD WG/ N49)

  Published November 2018

- Personalized Medical Devices – Regulatory Pathways (IMDRF/PMD WG/ N58)

  First published April 2020; Revised version being prepared for publication

- Personalized Medical Devices – Production V&V (IMDRF/PMD WG/ N74)

  Published April 2023

PMD Production Verification & Validation (N74)

- Document published 11 April 2023

- Builds on the definitions and concepts in N49 *Definitions of Personalized Medical Devices* and N58 *Personalized Medical Devices – Regulatory Pathways*

- Technical guidance on verification and validation aspects of
  - specified design envelope (patient-matched medical devices)
  - medical device production systems

PMD Regulatory Pathways (N58) - Revisions

- Scope of N58 revisions include:
  - revising the MDPS definition and framework to better represent real world applications, and facilitate its adoption
  - expanding the scope of Appendix 2 to incorporate a broad range of devices, not limited to PMDs

- Feedback from public consultation (Sept – Nov 2022) considered in developing the revised N58

- Revisions approved for publication by the MC, pending minor changes and WG consensus

Opportunities and Challenges

- Sharing and use of relevant information and scientific expertise amongst stakeholders
- Recommendations provide a basis for consistent and transparent requirements across jurisdictions
- Definitions for different categories of PMDs (IMDRF N49) adopted in most member jurisdictions
- WG's current focus on finalizing minor changes to the N58 (revised) document and its publication

Opportunities and Challenges

- Developing timely and fit-for-purpose recommendations to address risks introduced by new and emerging technologies in PMDs
- Consistent interpretation and understanding of the recommendations by all stakeholders
- WG intends to:
  - promote IMDRF PMD documents and educate stakeholders
  - develop training/guidance materials for stakeholders in line with N76 recommendations
  - monitor implementation and collect feedback
- Inviting stakeholders to provide suggestions on developing effective training and guidance materials to ensure consistent interpretation of the documents

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Thank you / Questions

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