



IMDRF

International Medical
Device Regulators Forum

Personalized Medical Devices (PMD) Working Group September 2021 Update

**Tracey Duffy (Chair, PMD Working Group)
Therapeutic Goods Administration - Australia**



Working group members

Jurisdiction	Representatives	Jurisdiction	Representatives
Argentina	Marcela Rizzo Adriana David	Japan	Yoko Tateno Yoshimasa Yokoyama
Australia	Tracey Duffy (Chair) Rebecca Bateson Uphar Chamoli Madeleine Neill	Russia	Konstantin Ivanov
Brazil	Priscilla Consiglierio de Rezende Martins Maria Angela da Paz Marcia Cristina de Moraes Reis Ribeiro	Saudi Arabia	Abdullatif S. Al Watban
Canada	Andrea Katynski	Singapore	Shuling Peng
China	Yue Min Shuo Pan	South Korea	Jang-yong Choi Seon-mi Lee Sang-jin Park Yunju Lee
Europe	European Commission Nada Alkhatat Germany Matthias Neumann Portugal Mariana Isabel Vaz Afonso Pires Madureira	UK *	Camilla Fleetcroft Ashley Stratton-Powell
		USA	Erin Keith Matthew A. Di Prima

* UK MHRA joined the working group in June 2021



Benefits of additional guidance for PMD

- Addresses an emerging trend for increased use of personalized treatments in healthcare
- Enhances sharing and use of relevant information and scientific expertise among stakeholders
- Supports harmonization for safety, performance and manufacturing of these products
- Provides a basis for consistent and transparent requirements across multiple jurisdictions
- Aligns with IMDRF strategic priorities



PMD working group publications

1. Definitions for PMD (N49)

[Published in October 2018](#)

2. Regulatory Pathways for PMD (N58)

[Published in March 2020](#)

MC approved drafting of a new technical document (New Work Item Extension - NWIE) on 25 Sept 2020, to provide recommendations for PMD production validation



NWIE – PMD Production Validation

Part I: Validation aspects of a specified design envelope*

- i. Device description
- ii. Range of user needs and intended uses
- iii. Design envelope schema
- iv. Implantable versus non-implantable medical device
- v. Use of imaging data for patient-matching
- vi. Design verification and validation activities
- vii. Clinical evidence requirements
- viii. Labelling requirements

* Specified design envelope is a characteristic feature of patient-matched medical devices as defined in the [IMDRF PMD document N49](#)



NWIE – PMD Production Validation

Part II: Validation aspects of an MDPS*

- i. MDPS description
- ii. An integrated approach to MDPS validation
- iii. Risk management plan for MDPS
- iv. User competence, training, and human factors validation
- v. Clinical evidence requirements
- vi. Labelling requirements



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Progress on Working Draft

- Working Group has met four times since December 2020 via teleconference
- Discussed Version 4.0 of the Working Draft at the last meeting on 17 August 2021
- Agreement on the topics and subtopics to be included
- Overwhelming feedback received from members – currently developing the next version of the Working Draft



Challenges

- Degree of alignment and/or adoption with IMDRF guidance on PMD varies significantly between jurisdictions
- Developing recommendations for MDPS validation (relatively new concept that only Australia has introduced so far)
- Developing recommendations for clinical evidence requirements for PMDs (heterogeneous in design)
- Using consistent and standard IMDRF terminologies



Forward plan

- Working Group to meet again in Oct'21 to discuss Version 5.0 of the Working Draft
- Aiming to submit the final Working Draft to the MC in Jan'22 for review*
- Three months (Mar-May'22) public consultation on the Proposed Document
- Potentially Final Document due to the MC for consideration before Sept' 2022 meeting#

* Following MC approval, the Working Draft will advance to the Proposed Document stage

Following resolution of comments received during the public consultation, the Proposed Document will advance to become the Final Document



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Thank you