IMDRF International Medical Device Regulators Forum

Personalized Medical Devices (PMD) Working Group March 2021 Update

Tracey Duffy
Therapeutic Goods Administration - Australia

IMDRF International Medical Device Regulators Forum

Working group members

Jurisdiction	Representatives
Argentina	Marcela Rizzo
Australia	Tracey Duffy (Chair) Rebecca Bateson Uphar Chamoli Madeleine Neill
Brazil	Priscilla Consigliero de Rezende Martins Maria Angela da Paz Marcia Cristina de Moraes Reis Ribeiro
Canada	Andrea Katynski
China	Yue Min Shuo Pan
European Commission	Nada Alkhayat
Germany	Matthias Neumann

Jurisdiction	Representatives
Japan	Yoshifumi Nagai Kanako Sasaki Yoshimasa Yokoyama
Portugal	Mariana Isabel Vaz Afonso Pires Madureira
Russia	Konstantin Ivanov
Saudi Arabia	Abdullatif S. Al Watban
Singapore	Shuling Peng
South Korea	Jang-yong Choi Seon-mi Lee Sang-jin Park
USA	Matthew A. Di Prima

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

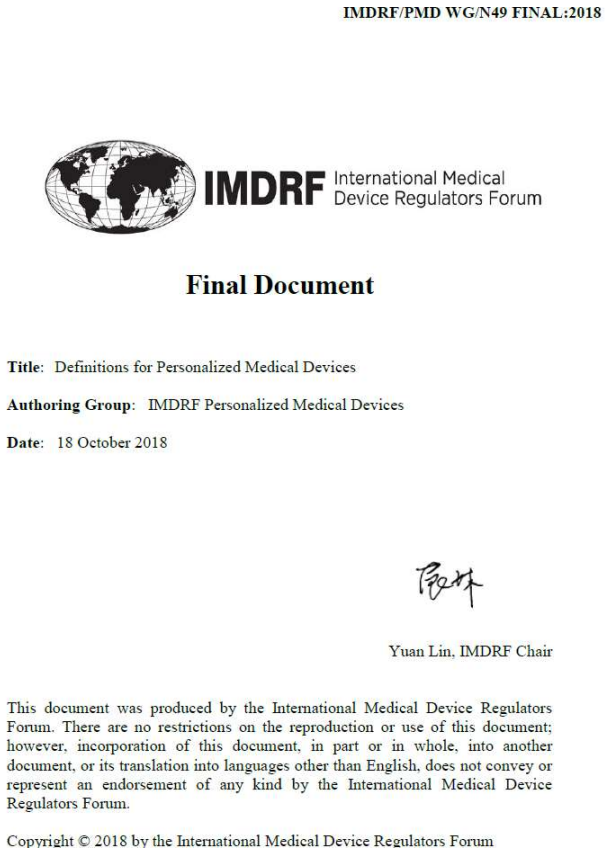
PMD working group publications

Definitions for PMD (N49)

Published in October 2018

- Custom-made medical device
- Patient-matched medical device*
- Adaptable medical device

* Designed and produced within a specified design envelope



IMDRF/PMD WG/N49 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Definitions for Personalized Medical Devices

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 October 2018

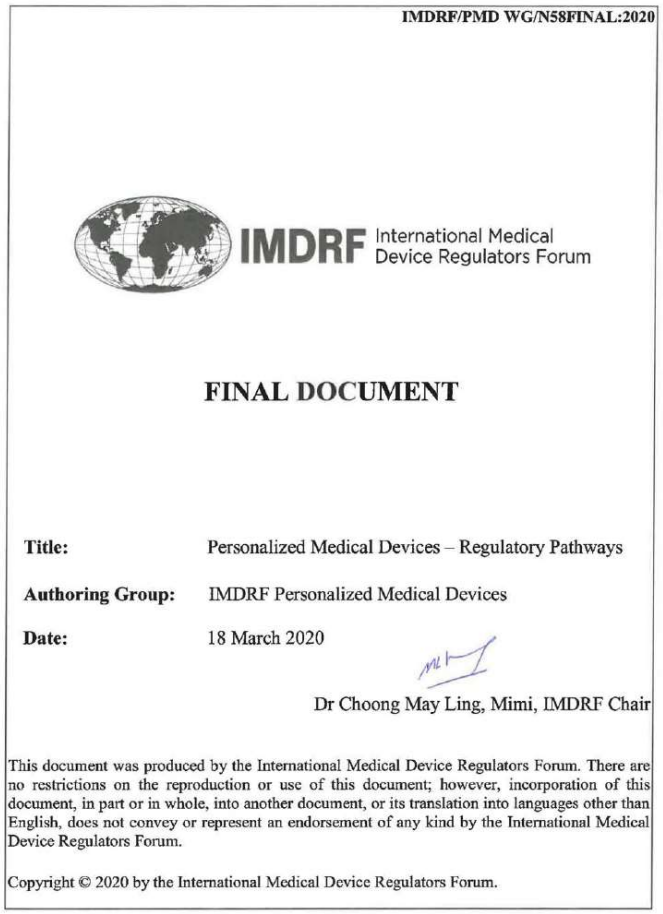
Yuan Lin, IMDRF Chair

PMD working group publications

Regulatory Pathways for PMD (N58)

Published in March 2020

- Regulatory requirements for different categories of PMD
- Medical Device Production System
- Considerations for point-of-care manufacturing of PMD



IMDRF/PMD WG/N58FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Personalized Medical Devices – Regulatory Pathways

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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PMD working group publications

- N49, N58 introduced new definitions and concepts relating to the production of personalized medical devices
- PMD Working Group proposed developing a new technical document building on the previous publications
- Technical document to propose requirements for validation of production processes that are unique to PMD
- MC approved drafting of the new technical document (New Work Item Extension) on 25 September 2020

New Work Item Extension (NWIE)

PMD – Production Validation

Scope of work

Technical considerations for validation aspects of a specified design envelope	Technical considerations for validation aspects of a Medical Device Production System
• Intended use(s) and range of user needs	• Quality management system requirements
• Geometrical, material, performance, operational variants	• Risk management plans
• Worst-case scenario design validation testing	• Usability assessments
• Clinical evaluation, etc.	• Requirements for labelling and instructions for use, etc.

PMD - Production Validation

- First meeting (held 15 December 2020) via teleconference
  - Discussed the scope of work
  - Identified a number of countries already have useful documents that can inform this NWIE
- Members have shared relevant documents to inform the Working Draft
- Working Draft to be discussed at the next Working Group meeting in March 2021

Forward plan

Key dates:

- Working Group currently developing the Working Draft
- Aiming to submit the final Working Draft to the MC in January 2022 for review*
- Three months (March-May 2022) public consultation on the Proposed Document
- Potentially Final Document due to the MC for consideration before September 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

Forward plan

Key dates:

- Targeted circulation of Working Draft among Working Group members (October – November 2021)
- Final Working Draft forwarded to the MC (January 2022)
- Public consultation of the Proposed Document (March – May 2022)
- Submission of Final Document to MC (July – August 2022) for consideration at the September 2022 meeting

	2021			2022								
Event	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**
Targeted circulation of Working Draft												
Final Working Draft to MC												
Public consultation of Proposed Document												
Final document for MC consideration												

Thank you