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
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Brazil	Priscilla Consigliero de Rezende Martins Maria Angela da Paz Marcia Cristina de Moraes Reis Ribeiro
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China	Yue Min Shuo Pan
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Jurisdiction	Representatives
Japan	Yoko Tateno Yoshimasa Yokoyama
Russia	Konstantin Ivanov
Saudi Arabia	Abdullatif S. Al Watban
Singapore	Shuling Peng
South Korea	Jang-yong Choi Seon-mi Lee Sang-jin Park Yunju Lee
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

* MDPS or Medical Device Production System as defined in the IMDRF PMD document N58

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

Thank you