IMDRF International Medical Device Regulators Forum

Personalized Medical Devices (PMD) Working Group

IMDRF Stakeholder Open Forum – 13 September 2022

Personalised Medical Devices Working Group (WG) members

Jurisdictions

Argentina
Australia
Brazil
Canada
China
Europe
Japan
Saudi Arabia
Singapore
South Korea
UK
USA

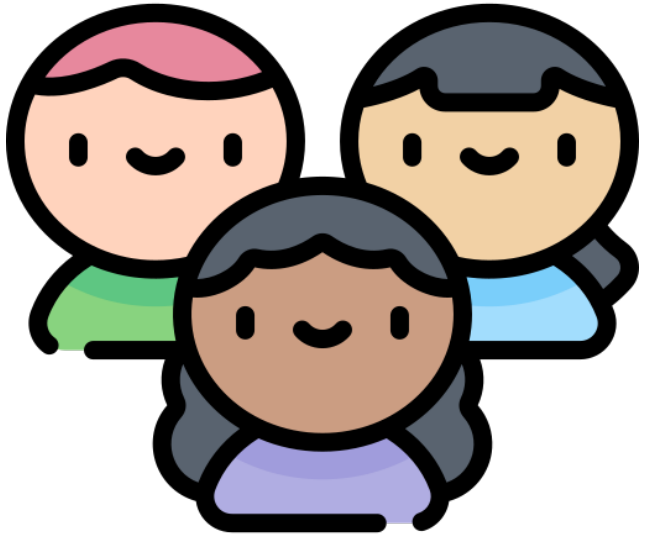
Personalised Medical Devices (PMD) working group publications

1. Definitions for PMD (N49)

   Published in October 2018

2. Regulatory Pathways for PMD (N58)

   Published in March 2020



Tasks given to the Personalised Medical Devices (PMD) working group - IN PROCESS

1. **REVISE**
   Regulatory Pathways for PMD (N58): Revisions presented in position paper to the IMDRF Management Committee (MC) in March 2022 based on feedback from stakeholders

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

Proposed revisions N58 Regulatory Pathways for PMDs

MC meeting April 2022: MC agreed to recommendations made in the position paper to revise the N58 document. MC noted that separate Point-of-Care (POC) manufacturing guidance may be required in the future

MC meeting June 2022: MC noted disruptions to WG activities in March and April 2022; and agreed to a new timeline to submit the two documents to the secretariat in August 2022

Proposed revisions N58 Regulatory Pathways for PMDs

MC agreed to proposal to make the following revisions to N58 document:

1. Revise the definition of **Medical Device Production System (MDPS)** to no longer limit the concept to PMDs;
2. Revise the MDPS framework to better represent real world applications, thereby facilitating the adoption and implementation of MDPSs by stakeholders; and
3. Revise N58 to expand the scope of Appendix 2 to incorporate a broad range of medical devices, not limited to PMDs.

Proposed revisions N58 Regulatory Pathways for PMDs

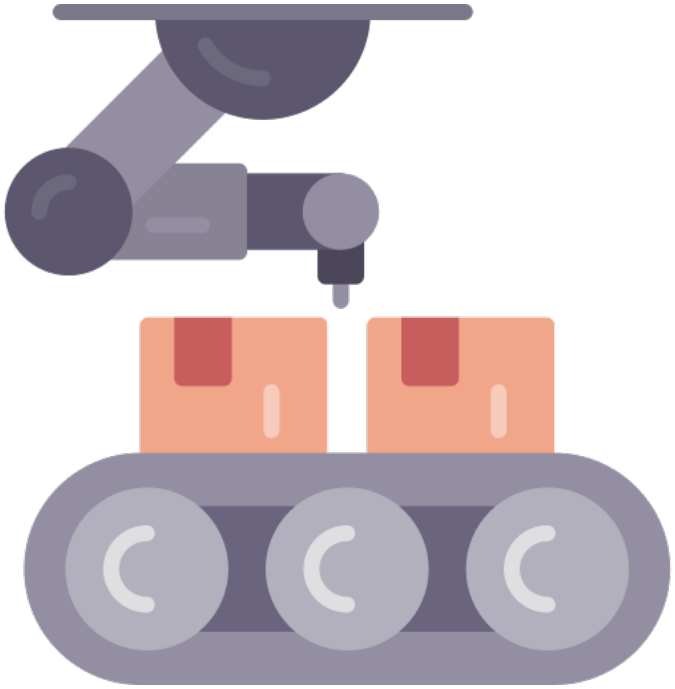
Changes:

- **Medical Device Production System (MDPS)** definition broadened to include devices other than patient-matched devices
- Clarification of the components of an MDPS – drawing a distinction between the system (which is a medical device in its own right) and the “resultant medical device”
- Addition of information about MDPS supply models:
  - Build, Own, Operate
  - Build, Own, Operate, Transfer
  - Build, Own, Transfer
- Removal of references to “off-label” use of MDPSs

Proposed N58 revisions - Medical Device Production System (MDPS)

MDPS definition:

A *medical device production system* (MDPS) is a combination of the resultant medical device and the medical device production process (MDPP) elements. The elements of an MDPP includes the raw materials, software and digital files, main production, and post-processing (if applicable) equipment, and operating instructions intended to be used by specific end users at a healthcare facility (HCF), to produce a specific type of medical device for treating the patients of the HCF.

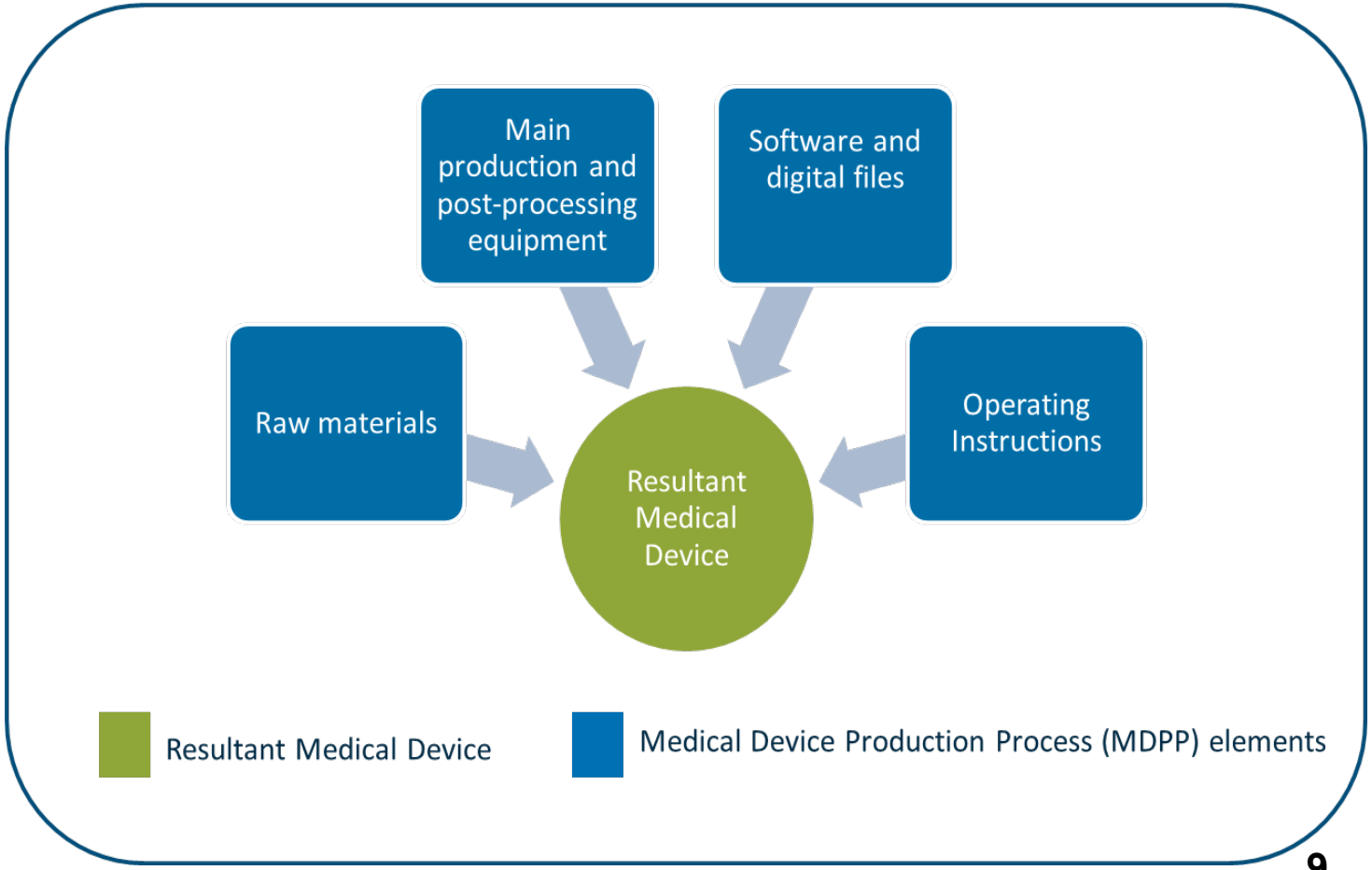


Proposed N58 revisions - MDPS

A MDPS has **two** primary constituents:

i. **Medical Device Production Process (MDPP)** elements: which may include raw materials, main production and post-processing equipment, software and digital files, and the operating instructions supplied by the MDPS manufacturer to produce a specific medical device; and

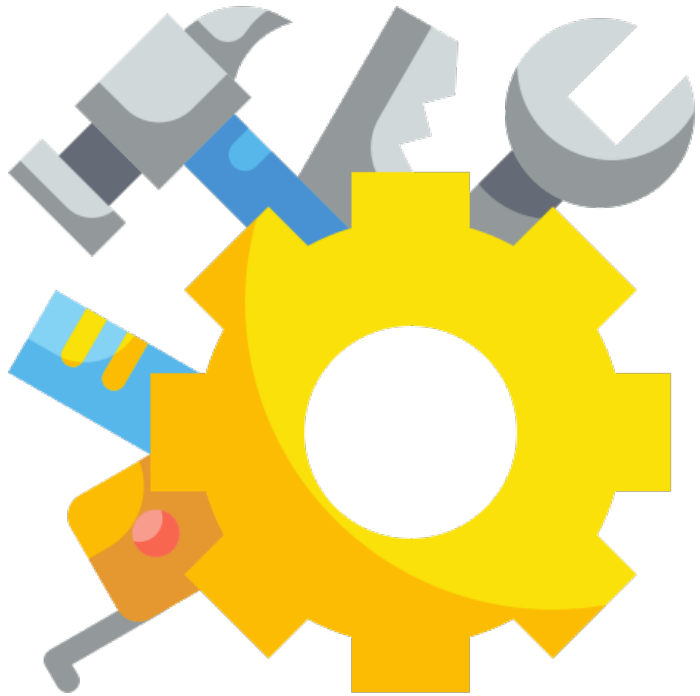
ii. **Resultant Medical Device**: the specific medical device that the MDPP produces using the operating instructions supplied by the MDPS manufacturer.



NWIE – PMD Production Validation

Part I: Verification and validation aspects of Specified Design Envelope

- Device description
- Range of user needs & Intended uses
- Design envelope schema
- Implantable versus non-implantable medical device
- Use of imaging data for patient-matching
- Design verification and validation activities
- Clinical evidence requirements
- Labelling requirements



NWIE – PMD Production Validation

Part II: Verification and validation aspects of MDPS

- MDPS description
- Key Considerations in MDPS Design Development
  - *Resultant medical device design development*
  - *Medical Device Production Process (MDPP) design development*
  - *Medical Device Production System (MDPS) verification*
  - *Medical Device Production System (MDPS) validation*
- Risk management plan for MDPS
  - *Medical Device Production Process (MDPP)*
  - *Resultant medical device*
- User facility requirements, competence, training, and human factors validation
- Clinical evidence requirements
- Labelling requirements
  - *Medical Device Production Process (MDPP)*
  - *Resultant medical device*

WG progress on N58 and NWIE PMD Production Validation

- WG has met virtually ten times since December 2020, most recently on 10 August 2022
- WG held four ‘deep dive’ sessions from 5-10 August 2022, to discuss and finalize the working drafts
- The working draft has undergone multiple rounds of feedback and refinement
- The two documents were submitted to the IMDRF secretariat on 11 August 2022 for consideration by MC at this meeting

New timelines for the N58 and NWIE PMD Production Validation documents

August 2022: Final Working Draft submitted to the MC for consideration at the September 2022 meeting

October-December 2022: Following MC's approval, three months public consultation on the Proposed Document

January 2023: Submission of the Final Document to MC for consideration at the next meeting

Forward Plan

- Pending consideration by MC at this meeting, publish the following documents for public consultation:
  - Revisions to IMDRF/N58 PMD Regulatory Pathways (60 days)
  - New Work Item Extension (NWIE) – PMD Production Verification and Validation (90 days)
- Revise documents based on feedback received during public consultation
- Submit final documents for MC consideration at the January 2023 meeting

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Thank you/Questions

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