IMDRF International Medical Device Regulators Forum

Personalized Medical Devices Working Group Update

Working Group Chair: Dr Elizabeth McGrath

Therapeutic Goods Administration

Department of Health, Australia

NWIE Purpose

- The goal of this project is to develop an IMDRF Technical Document that will provide recommendations to support a harmonized approach to regulating medical devices that are manufactured for individual patients.

Rationale

- Technology has progressed to where it is now possible to ‘mass produce’ individualized medical devices:
  - e.g. 3D printing of devices based on patient CT Scan data.
- Original GHTF documentation does not adequately address these types of devices.

Benefits

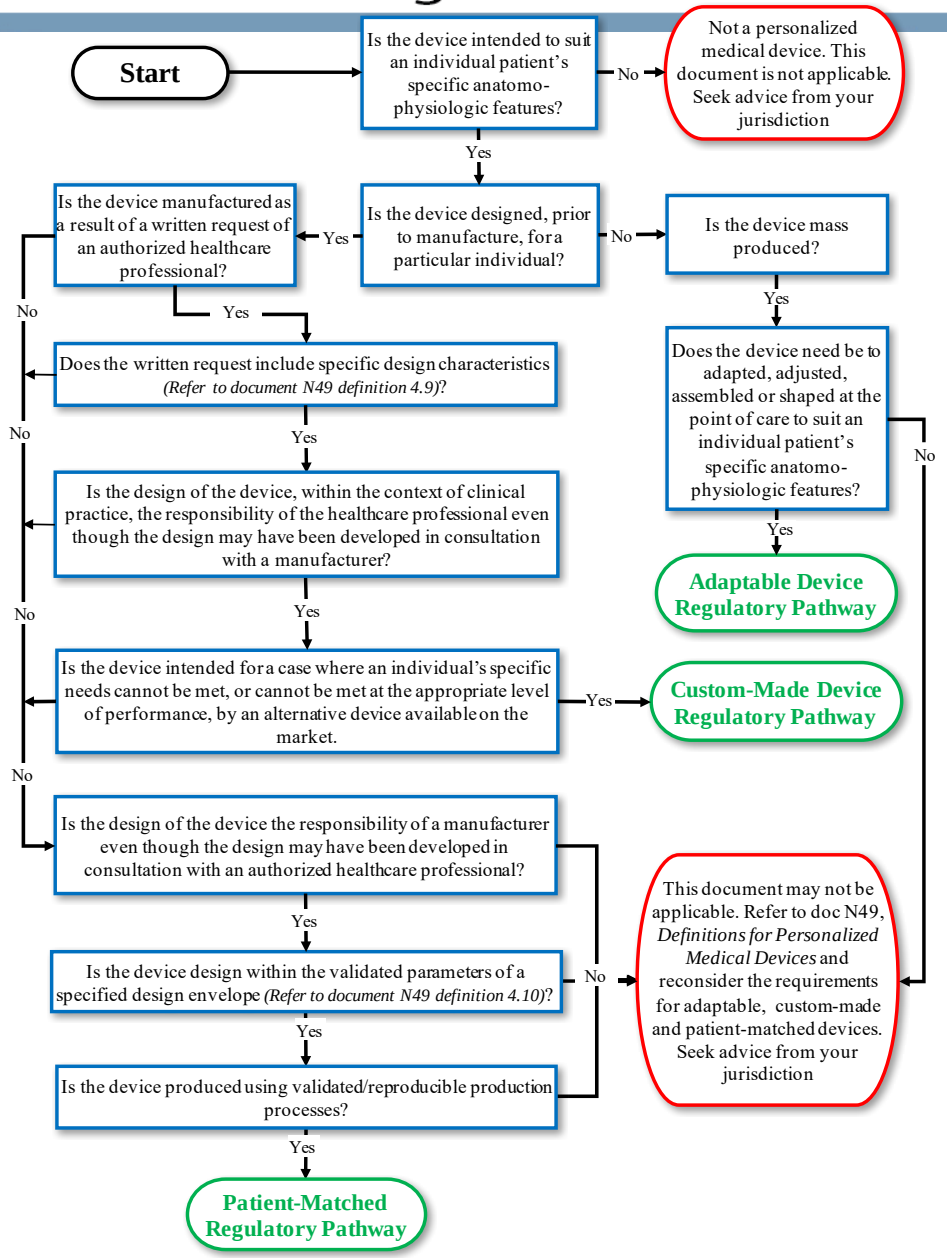
- Addresses an emerging trend towards personalized treatments in the medical devices sector.
- Ensures an appropriate level of regulatory oversight is undertaken
- Leads to harmonization of requirements for safety, performance and manufacturing of these products
- Provides a basis for consistent and transparent requirements across multiple jurisdictions.
- Aligns with IMDRF Strategic Priorities.

WG Progress

- Published N49 - Definitions for Personalized Medical Devices November 2018
- Developed draft document proposing regulatory pathways for the different categories of personalized medical devices.
- Submitted draft document to the Management Committee for consideration at the March 2019 meeting
- Incorporated Management Committee comments to the document
- Published draft document for public consultation 24 May 2019

Features of the Draft Document

Personalized Medical Device Decision Tree



Proposed Regulatory Pathways

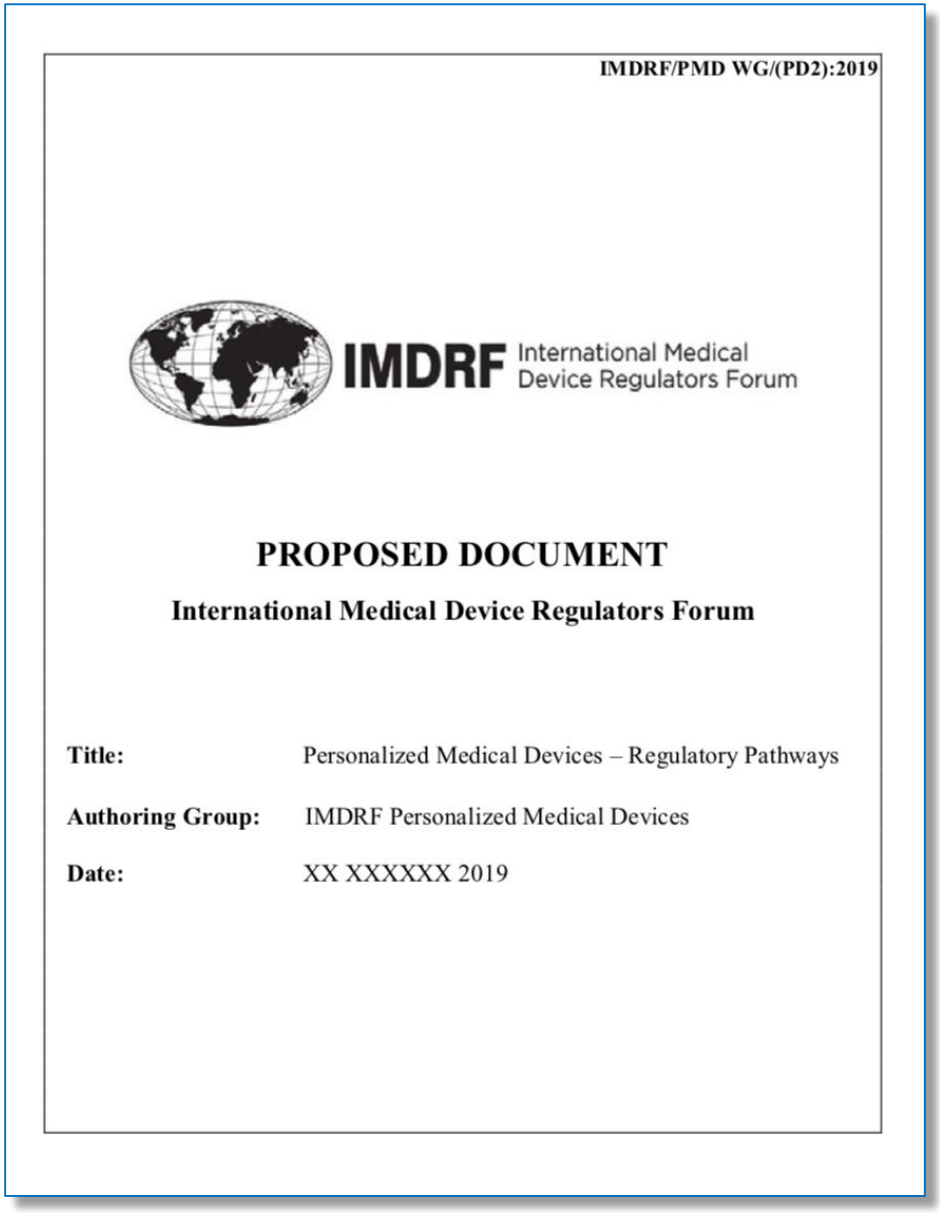
- Custom-made Medical Devices
  - Highest level of detail
  - Recognizes unique pathway for custom-made devices
- Patient-matched Medical Devices
  - Reliance on usual regulatory requirements, according to the device risk classification
  - Focus on validation of design envelope
- Adaptable Medical Devices
  - Reliance on usual regulatory requirements, according to the device risk classification
  - Focus on validated instructions for the adaptable features

Proposed Annexes

- Annex 1 Considerations for Additive Manufacturing
  - Focus on status of raw materials for additive manufacture
- Annex 2 Considerations for Point of Care Manufacture
  - Introduces concept of medical device production system (MDPS) – collection of goods for producing a particular medical device
  - MDPS regulation similar concept to regulation of adaptable medical device
  - Based on the device it is intended to produce
  - Reliance on validated instructions for using the specified system

Consultation

- Two month public consultation held 24 May 2019 through 24 July 2019
- 17 submissions from Australia, Canada, Europe, Singapore, Taiwan, USA
- 150 Individual comments



IMDRF/PMD WG/(PD2):2019

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PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title:	Personalized Medical Devices – Regulatory Pathways
Authoring Group:	IMDRF Personalized Medical Devices
Date:	XX XXXXXX 2019

Next Steps

- 24 July 2019
  Public Consultation Closed
- August-September 2019
  Planning for Face to Face Meeting
  Early analysis of Consultation Submissions
- October 2019
  Face to Face Meeting to Incorporate Public Comments
  Canberra Australia
- December 2019
  Submit Final Document for Management Committee Consideration

Thank You