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

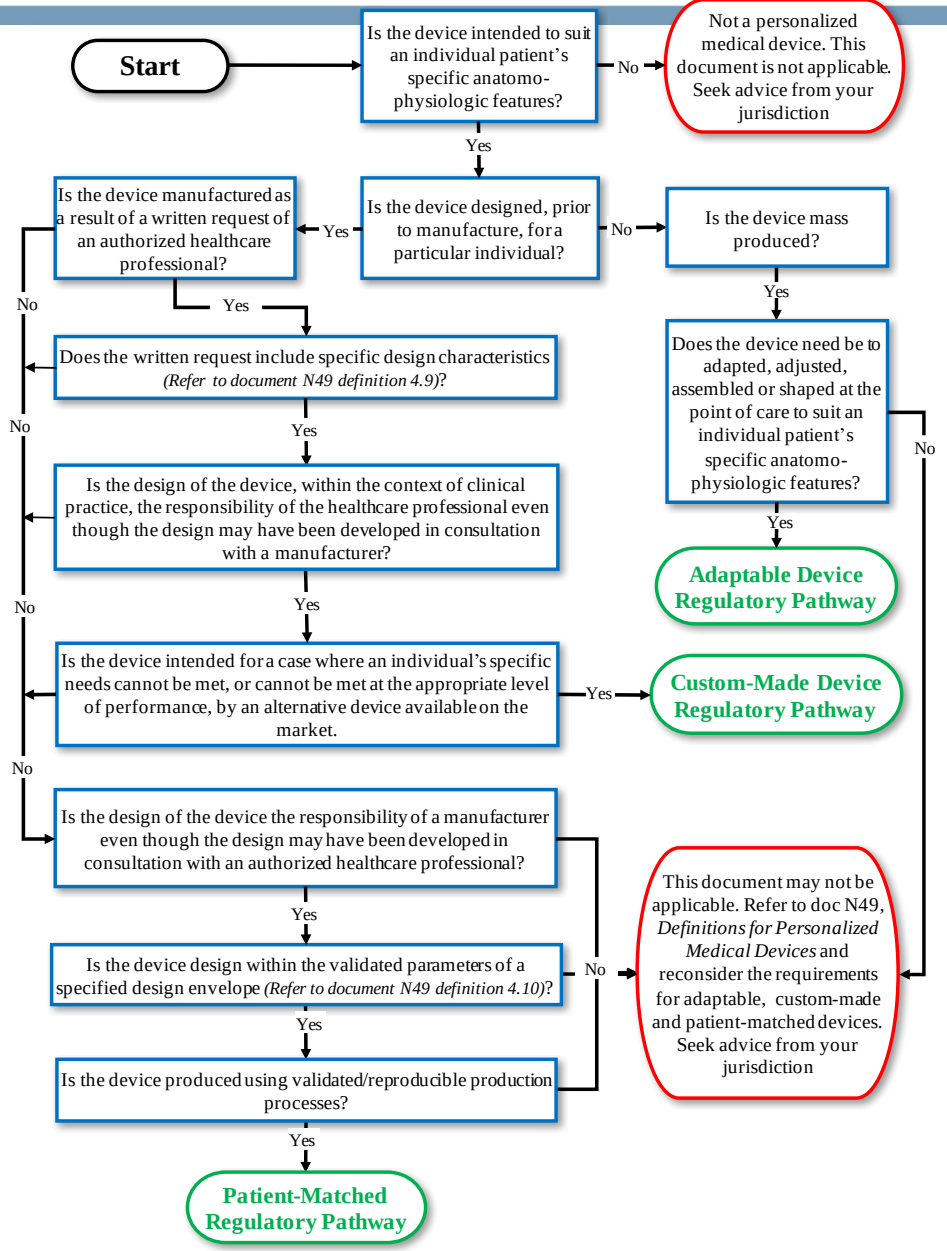
- Addresses an emerging trend towards personalized treatments in the medical devices sector.
- Ensures an appropriate level of regulatory oversight is undertaken
- Leads to harmonization of requirements for safety, performance and manufacturing of these products
- Provides a basis for consistent and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

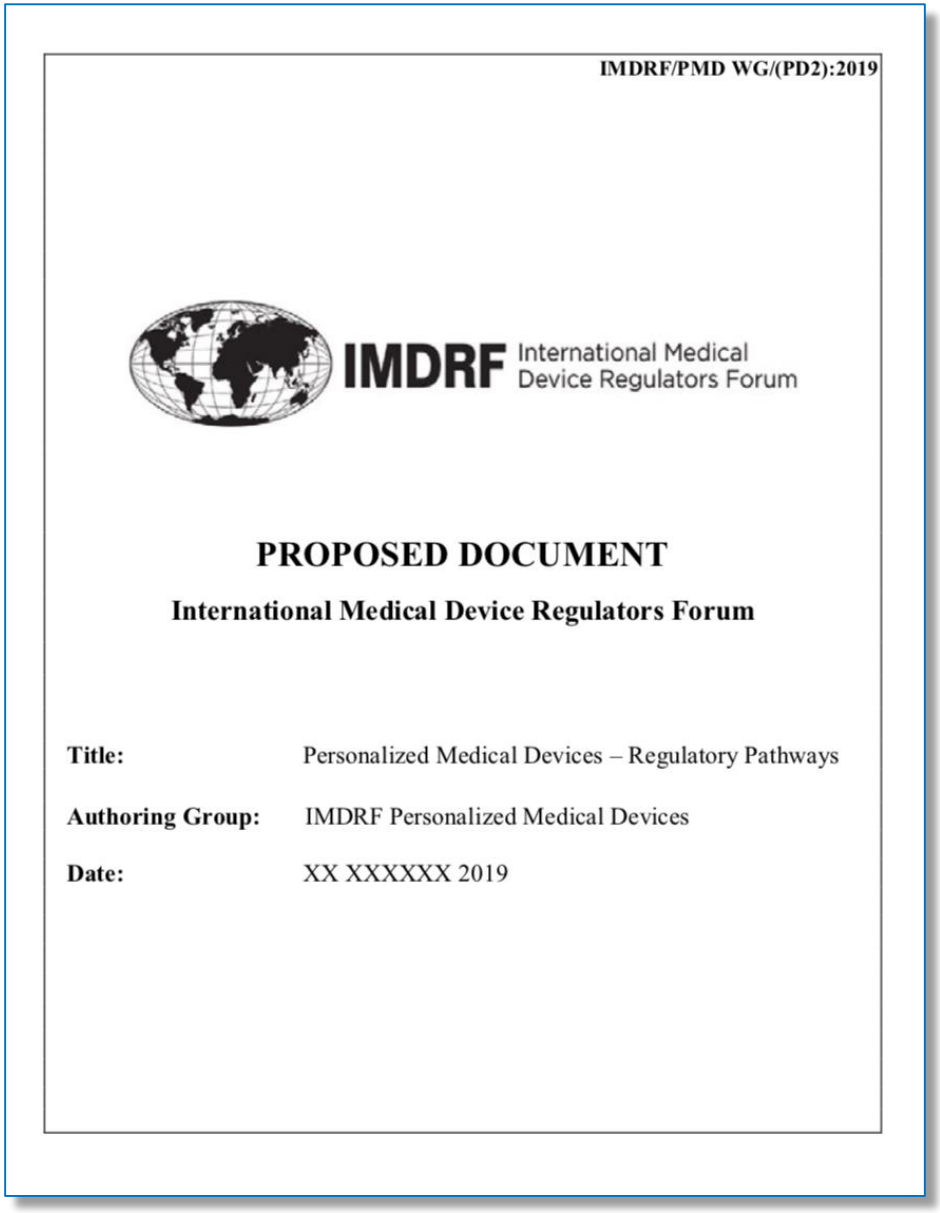
Proposed Annexes

- 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