Personalized Medical Devices
Working Group Update

Working Group Chair: Dr Elizabeth McGrath
Therapeutic Goods Administration
Department of Health, Australia
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.
• 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
Next Steps

24 July 2019
Public Consultation Closed

24 July 2019
Planning for Face to Face Meeting
Early analysis of Consultation Submissions

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