IMDRF International Medical Device Regulators Forum

Personalized Medical Devices Working Group Update

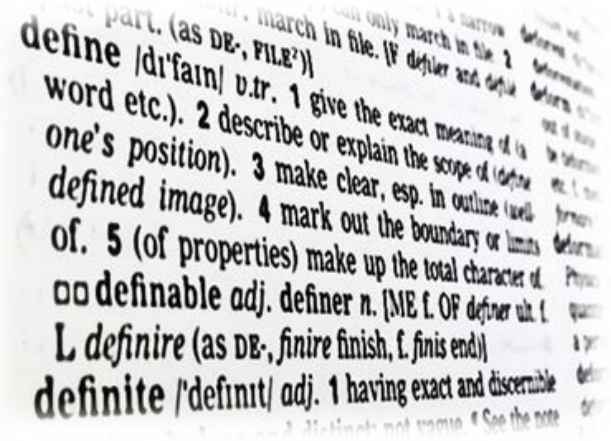
Working Group Chair: Dr Elizabeth McGrath

Therapeutic Goods Administration

Department of Health, Australia

NWIP Purpose

- Develop an IMDRF Technical Document that provides recommendations supporting a harmonized approach to defining medical devices that are manufactured for a particular individual.



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.

Progress

- Conducted public consultation on draft definitions document, Apr-May 2018.
- Held a face to face meeting in Seoul to incorporate comments, Jun 2018 (thank you to Korea MFDS).
- Submitted to MC for consideration at September meeting:
  - Final draft definitions document
  - New work item extension to develop recommendations for regulatory pathways.

Key Feedback Themes from Consultation

Improve the examples

- e.g. - The examples are helpful but would be more useful if additional text were provided to explain why one example meets one definition instead of another, particularly between the custom-made and patient-specific devices.

Confusion over the term ‘industrial manufacturing process’

- e.g. - Is there a chance for IMDRF to provide a common understanding of “industrial manufacturing process” ?

Key changes following consultation

- Explanatory text added to each example to better illustrate relevant concepts for each device category
- Removed the term ‘industrial manufacturing process’ from the note under custom-made
- Removed the term, ‘patient-specific’ from the document in favor of ‘patient-matched;’ as ‘patient-specific’ could be misconstrued as ‘custom-made,’ whereas ‘patient-matched’ is more descriptive of the devices in this category

Key changes following consultation

- Added a section of supporting definitions:
  - batch
  - DICOM files
  - homogenous batch
  - mass-produced medical device
  - specific design characteristics
  - specified design envelope

Proposed Definitions

- **personalized medical device** – a generic term to describe any of the types of medical devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device.

Proposed Definitions

custom-made medical device – a medical device that, at a minimum, meets the following requirements:

- it is intended for the sole use of a particular individual (which could be a patient or healthcare professional); and
- it is specifically made in accordance with a written request of an authorized healthcare professional, which gives, under their responsibility, specific design characteristics; even though the design may be developed in consultation with a manufacturer; and
- it is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended.

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Proposed Definitions

custom-made (continued)

Note 1: Medical devices that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made

Note 2: A custom made device is intended for a case where an individual's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an alternative device available on the market.

Proposed Definitions

patient-matched medical device – a medical device that meets the following requirements:

- it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and
- it is typically produced in a batch through a process that is capable of being validated and reproduced; and
- it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.

Proposed Definitions

patient-matched (continued)

Note 1: A written request from an authorized healthcare professional may be present; but is not mandatory.

Note 2: The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.

Note 3: The design must remain within the validated parameters of the specified design envelope.

Proposed Definitions

adaptable medical device – a medical device that meets the following requirements:

- it is mass-produced; and
- it is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physiologic features prior to use.

Proposed Annex

Examples of each personalized medical device category:

- **custom-made medical devices,**
- **patient-specific medical devices,**
- **adaptable medical devices.**

Next Steps

Sept 2018	Oct-Dec 2018	Jan 2019	Apr 2019	Jun 2019
MC Face to Face Meeting Approve Final Draft Definitions & NWIE for Regulatory Pathway Recommendations	WG Teleconferences Develop Draft	MC Teleconference Approve Draft for Public Consultation	WG Face to Face Meeting Incorporate comments (Location TBD)	MC Teleconference Approve Final Draft Regulatory Pathways


Thank You