IMDRF International Medical Device Regulators Forum

Personalized Medical Devices Working Group Update

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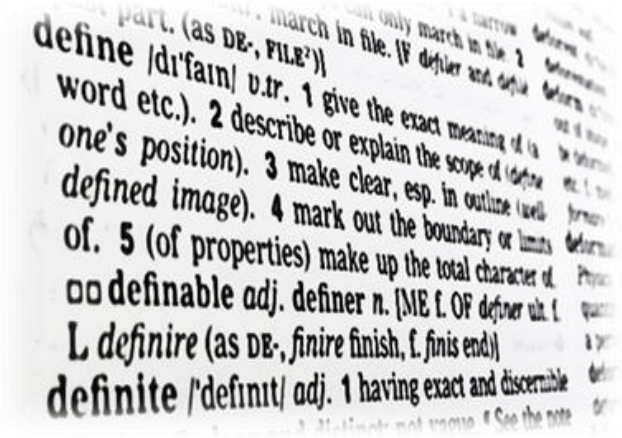
NWIP Purpose

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


define /dɪ'faɪn/ v.tr. 1 give the exact meaning of (a word etc.). 2 describe or explain the scope of (define one's position). 3 make clear, esp. in outline (well-defined image). 4 mark out the boundary or limits of. 5 (of properties) make up the total character of. □□ definable adj. definer n. [ME f. OF definer ult. f. L definire (as DE-, finire finish, f. finis end)]
definite /'definɪt/ adj. 1 having exact and discernible

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

- Address an emerging trend towards personalized treatments in the medical devices sector.
- A common understanding of definitions for these types of medical devices will:
  - lead to harmonisation of requirements for safety, performance and manufacturing of these products; and
  - ensure an appropriate level of regulatory oversight is undertaken.
- Industry stakeholders will benefit from consistent and transparent requirements across multiple jurisdictions.
- Aligns with IMDRF Strategic Priorities.

Progress

- Established Working Group membership – all member jurisdictions represented, also one Affiliate Organization member.
- Reviewed GHTF foundation documents for references to custom-made devices.
- Conducted Working Group member survey for definitions in own country regulations or guidance that address personalized medical devices.
- Developed draft document proposing relevant definitions.

Asian Harmonization Working Party

AHWP
ASIAN HARMONIZATION WORKING PARTY

- **AHWP (**Handbook for Approval of Patient-matched Medical Devices Using 3D Printers**)** ~~*patient-matched medical device":*~~ refers to a device that is built specifically for the patient based on patient's anatomical features.

- **SFDA (**MDS – G15**)** *Custom-Made Medical Device*: means any medical device specifically made in accordance with a healthcare professional's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. Custom-made medical devices exclude those devices which are generally available from a dispenser such as orthotics or glasses.

Australia TGA

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
TGA Health Safety Regulation

From the Therapeutic Goods (Medical Devices) Regulations 2002:

custom-made medical device means a medical device that:

(a) is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and

(b) is intended:

(i) to be used only in relation to a particular individual; or

(ii) to be used by the health professional to meet special needs arising in the course of his or her practice.

There are no other definitions or guidance related to personalized devices.

Brazil Anvisa

Brazil does not currently have relevant definitions published in the legislation.

From ANVISA internal procedure:

- **Custom made device** - a device that has specific design characteristics and is intended for use of a specific patient, manufactured in accordance with a healthcare professional‘s prescription.

Custom made devices are not subject to registration, but require ANVISA´s permission to manufacture (evaluated on a case by case basis).

Health Canada

Health Canada

From Canadian Regulations:

> ***custom-made device*** means a medical device, other than a mass-produced medical device, that
>
> **(a)** is manufactured in accordance with a health care professional's written direction giving its design characteristics;
>
> **(b)** differs from medical devices generally available for sale or from a dispenser; and
>
> **(c)** is
>
> > **(i)** for the sole use of a particular patient of that professional, or
> >
> > **(ii)** for use by that professional to meet special needs arising in the course of his or her practice. (*instrument fait sur mesure*)

Health Canada does not currently define customized medical device, mass-produced medical device, patient-specific, patient-matched medical device, or personalized medical device in regulations or in any guidance documents.

China FDA

- There is no general definition or regulation for personalized medical device, custom device or patient-specific device.

- For some specific products there are definitions and guidance, such as customized denture. Customized denture could be divided into customized fixed denture and customized removable denture, and now there are two draft guidance documents for these two kinds of products.

- There is a draft guidance document on personalized additive manufactured medical devices, which is now under consultation.

European Union

The European Medical Device Regulation defines "custom-made medical devices" as follows (article 2(3)):

- ***'custom-made device'*** *means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.*

- *However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;*

Japan MHLW

MHLW JAPAN

- Currently, Japan does not have definitions for either custom-made, customized, patient-specific, personalized, nor mass-produced medical devices.

- There is no guidance for such personalized medical devices, but a license is required to manufacture —custom-made" medical devices for dental care (such as tooth filling, denture, and mouthpiece etc).

Korea MFDS

Ministry of Food and Drug Safety

- Korea does not yet have definitions for custom-made, customized, patient-specific, or personalized medical devices in the regulations.

- Korea does have a guideline on how to review and approve the patient-matched devices that are manufactured by 3D printers, but the guideline does not specifically define the different types of "customized", "custom-made", or "personalized" devices. The guideline does have a definition for patient-matched devices.

- The AHWP handbook document for patient-matched medical devices using 3D printers was derived from Korea MFDS's guideline and it defines the patient-matched medical devices in the introduction.

Russia Roszdravnadzor

- Russia currently does not have definitions in the legislation for custom-made, customized, mass-produced, patient-specific, or personalized medical device.

- Federal Law states that custom-made medical devices are not subject to registration.

Singapore HSA

Regulations state:

"~~c~~**ustom-made medical device**" means a medical device that —

(a) is made at the request of a qualified practitioner and in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device;

(b) is intended to be used only in relation to a particular individual; and

(c) is not adapted from a mass-produced medical device;

There is no guidance which defines customized medical device, mass-produced medical device, patient-specific / patient-matched medical device, or personalized medical device.

United States FDA

FD&C Act - Section 520(b)

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

United States FDA

FD&C Act - Section 520(b)

(b) CUSTOM DEVICES (continued)

(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

United States FDA

PATIENT-SPECIFIC (Custom Device Exemption Guidance):

- "Patient-specific devices are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically."
- "While some in industry have sometimes colloquially referred to these devices as —customized," they are not custom devices meeting the FD&C Act custom device exemption requirements unless they comply with all of the criteria of section 520(b)."

WG Member Survey - Summary

Jurisdiction	Regulatory definition for custom-made	Regulatory definition for other personalized devices	Any guidance material related to personalized devices
AHWP	N/A	N/A	✔
Australia	✔		
Brazil			
Canada	✔		
China			✔
Europe	✔		
Japan			
Korea			✔
Russia			
Singapore	✔		
United States	✔		✔

WG Member Survey - Summary

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Australia	✔		
Brazil			
Canada	✔		
China			✔
Europe	✔		
Japan			
Korea			✔
Russia			
Singapore	✔		
United States	✔		✔

OPPORTUNITY FOR HARMONISATION

Proposed Definitions in Draft Document

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

Proposed Definitions in Draft Document

- **mass-produced medical devices –** identical medical devices that are produced in continuous production runs or homogenous batches**.**

Note: A batch is considered homogeneous when equivalent parts or materials are manufactured and/or tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person, or with the same machine/equipment set-up and fulfill the same specifications [Ref *MEDDEV* 2.5/6 Rev. 1 http://ec.europa.eu/DocsRoom/documents/10287/attachments/1/translations].

Proposed Definitions in Draft Document

- **adaptable medical device** – a mass-produced medical device that must be adapted or assembled 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 Definitions in Draft Document

- **patient-specific or patient-matched medical device** – a medical device produced by a manufacturer based on a standard device template model, or specified design envelope (e.g., minimum and maximum dimensions, mechanical performance limits, and other clinically relevant factors), that is matched to a patient‘s anatomy using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging, and which is produced through a process that is capable of being validated.

Proposed Definitions in Draft Document

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; and
- it is specifically made in accordance with a written request of an authorized healthcare professional, which gives, under their responsibility, specific design characteristics; and
- it is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended.

Proposed Definitions in Draft Document

custom-made (continued)

Note 1: **patient-specific medical devices, adaptable medical devices and mass-produced** medical devices made by means of industrial manufacturing processes in accordance with the written request of an authorized healthcare provider, shall not be considered to be custom-made.

Note 2: ‗Specific design characteristics' means unique design specifications that are based on an individual's specific anatomo-physiological features or pathological condition, and that cannot be proposed by a manufacturer without the involvement of a healthcare professional during the conception phase. (For example, transmitting only dimensions/geometric parameters (such as DICOM files from CT scans) to a manufacturer prior to the production of a medical device is not sufficient to be considered as giving specific design characteristics.)

Proposed Annex in Draft Document

Examples of each personalized medical device category:

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

Next Steps


April/May 2018 - Public Consultation
Jun 2018 – Face to Face Mtg to Incorporate Public Comments (Location TBD)
Jul/Aug 2018 - Teleconferences
Sept 2018 – Final Draft for MC Consideration & NWIP for Phase 2 – Regulatory Pathway Recommendations
Nov 2018 – Face to Face Mtg to Kickoff Phase 2 (Location TBD)


Thank
You