New Work Item Proposal

Definitions for Patient-Specific, Customized and Custom-made Medical Devices

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Purpose

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

Rationale

• Technology has progressed to where it’s 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 this type of device.

• Given individual jurisdictions are developing their own approaches to this, there is a risk of international divergence.
Proposed scope

• Address the differences between custom-made, customized, and patient specific medical devices
  – Provide definitions for each.

• Address medical devices that are manufactured in a repeatable manner (apart from patient dimensions), especially those produced via additive manufacturing.

• Consider devices that are intended by the original manufacturer to be modified to suit an individual after the device is supplied.

• Recognize that some medical devices are produced in a unique manner, and should continue to be eligible for existing custom-made exemptions.
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.
Previous work / sources of expertise

• Some jurisdictions have already developed relevant guidance and/or changes in regulatory requirements:

• Sources of necessary expertise:
  – Experts in premarket regulatory review process

• Proposed Working Group Chair:
  – Dr Elizabeth McGrath, TGA, Australia
Proposed work plan

- Review GHTF foundation documents for references to custom-made devices.

- Review relevant guidance from member jurisdictions that address custom-made and/or patient specific devices.

- Develop draft document proposing relevant definitions – January 2018

- Public consultation on draft, comments incorporated (where appropriate).

- Final draft presented to Management Committee for consideration and approval – September 2018

- If approved, draft becomes new IMDRF document.
Thank You