U.S. FOOD & DRUG ADMINISTRATION

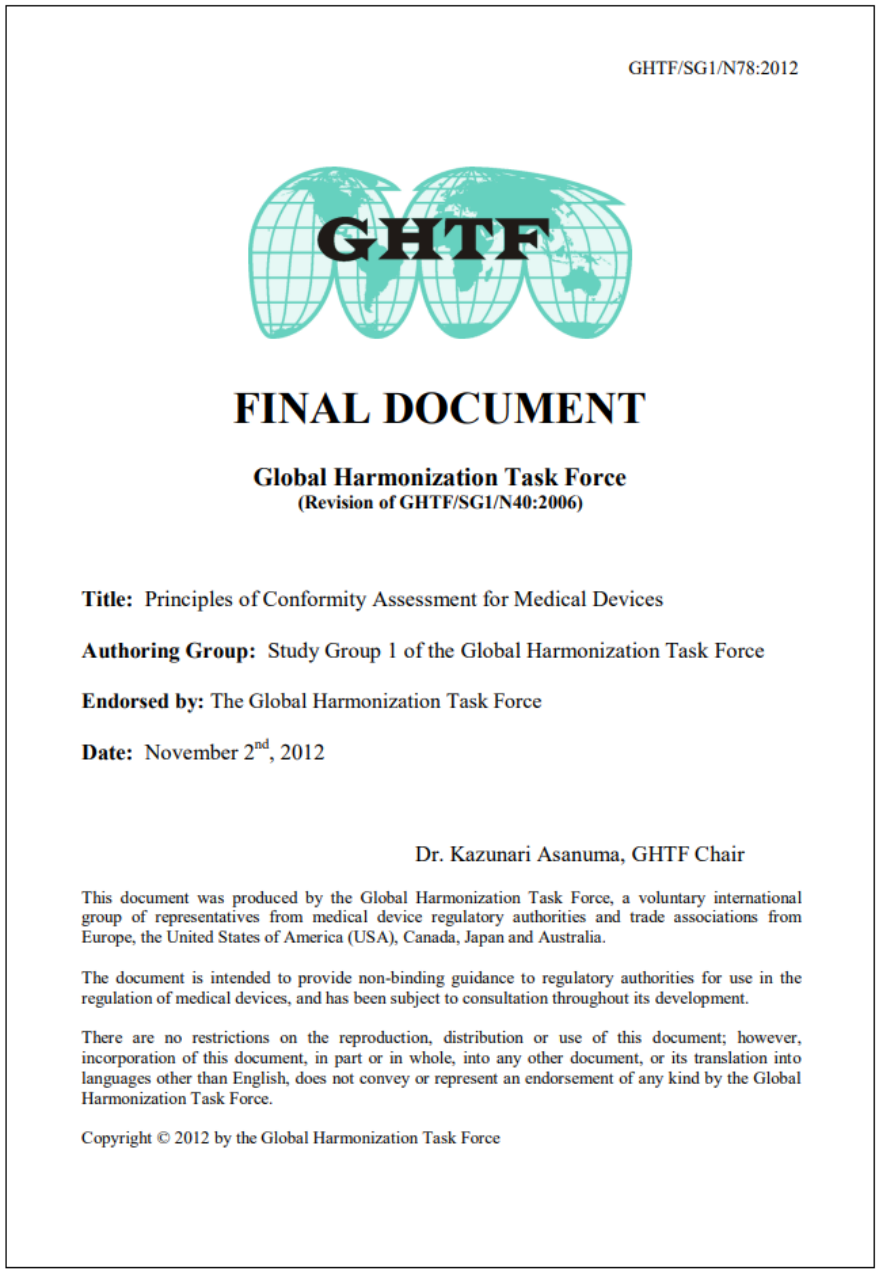
Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012)

During this presentation, we will

- Discuss what **conformity assessment** is, particularly within the context of medical device regulation
- Articulate the **purpose** of GHTF/SG1/N78:2012
- Describe the **5 conformity assessment elements** included in N78
  - Quality management system (QMS)
  - System for post-marketing surveillance
  - Technical documentation
  - Declaration of conformity
  - Registration of manufacturers and their medical devices by the Regulatory Authority

Conformity assessment is…

- the **systematic examination** of **evidence** generated and **procedures** undertaken **by the manufacturer**, under r**equirements established by the Regulatory Authority**, to determine that a **medical device** is **safe** and **performs as intended** by the manufacturer
- conducted **before** and **after** medical device is placed on the **market**
- intended to provide the **objective evidence** of **safety**, **performance**, and **benefits** and **risks** to maintain **public confidence**
- **primarily** the **responsibility** of the medical device **manufacturer**, but undertaken in the **context** of the **regulatory requirements** established in the jurisdiction where the **device is sold**



GHTF/SG1/N78:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force
(Revision of GHTF/SG1/N40:2006)

Title: Principles of Conformity Assessment for Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Endorsed by: The Global Harmonization Task Force

Date: November 2nd, 2012

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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The **purpose** of N78 is to provide **guidance** on:

- the **evidence** and **procedures** that may be used by the **manufacturer** to **demonstrate** that a medical **device** is **safe** and **performs as intended** by the manufacturer.
- the **conformity assessment elements** that apply to each class of device such that the **regulatory demands increase with the hazard presented** by a particular medical device;
- the **process** by which a **RA/CAB** may **confirm** that **such elements are properly applied** by the manufacturer; and
- the **manufacturer's written attestation** that it has correctly applied the conformity assessment elements relevant to the classification of the device, i.e. the "Declaration of Conformity."

Medical device **regulations** should specify the **manner** in which the **manufacturer demonstrates** to the **Regulatory Authority and/or Conformity Assessment Body** that its medical devices **comply with the legislation**.

- There are **5 necessary conformity assessment elements**.
  - a quality management system (QMS)
  - a system for post-market surveillance
  - technical documentation
  - a declaration of conformity
  - the registration of manufacturers and their medical devices by the RA

All 5 conformity assessment elements are **required for each device class**, but there is **flexibility** in the **manner of their application.**

- Example: whether or not **technical documentation** is subject to **premarket review** by the RA/CAB
- Manufacturer may need to **notify RA or CAB prior to implementation** of a **substantial change** if the change could **affect** one or more of the **conformity assessment elements**

- Now let's talk about **each element** in a bit more detail.

Quality Management (System)

- The **manufacturer** should **implement**, **document** and **maintain** a **QMS** that ensures the medical devices it **designs**, **manufactures** and **supplies** to the market are **safe, perform as intended** and **comply** with the relevant provisions of the **regulations**.
- **Scope** and **complexity** of the QMS are influenced by:
  - **range** of different medical **devices** that are under QMS control
  - **processes employed**
  - **size** and **structure** of the **organization**
  - specific **regulatory requirements**
- **Conformity assessment** of the **manufacturer's QMS** is influenced by the **class** of the medical device (e.g., need for design and development controls).
- **QMS** described in separate **GHTF SG3 documents**

System for Post-Market Surveillance

- Prior to placing the product on the market, the **manufacturer** will **establish**, as part of its QMS, a process to **assess the continued conformity** of the device to the Essential Principles of Safety and Performance through the post-marketing phase. This includes:
  - complaint handling
  - post-market vigilance reporting
  - any subsequent corrective & preventive actions
- **RA** or **CAB** will **confirm** that such a **process is in place**, usually at the time of the **QMS audit**
- Specific post-marketing study
  - RA may require **manufacturers** to **perform a specific post-marketing study** of a particular **type of device**, and **report the outcome** to the RA
  - RA will **monitor any post-marketing study** and consider whether any **additional regulatory action** is required after analysing the outcome

Technical Documentation

- **Manufacturers of all classes of device** are expected to **demonstrate conformity** of the device to regulatory requirements through the **preparation** and **holding** of **technical documentation** that:
  - shows **how** each medical device was **developed, designed and manufactured**
  - includes **descriptions** and **explanations** necessary to understand the manufacturer's determination of conformity
- Technical documentation is **updated** as necessary to **reflect the current status**, specification and configuration of the device.

IMDRF/RPS WG/N9(Edition 3) FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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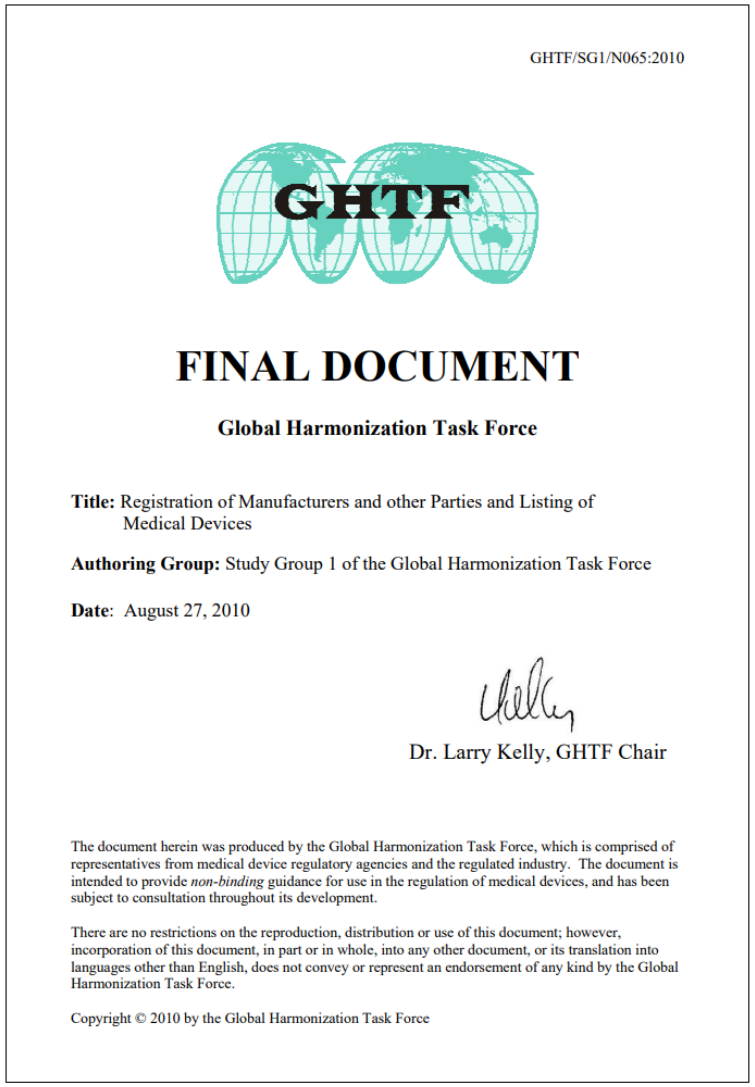
Technical Documentation

- N78 references the Summary of Technical Documentation (**STED**) as **mechanism** for **manufacturers** to provide **evidence to the RA/CAB** that the subject medical device is in conformity with regulatory requirements.
  - Recommend the Table of Contents document instead of STED now
  - The TOC:
    - reflects the status of the medical device at a **particular moment in time** (e.g. at the moment of premarket submission or when requested by a RA for post-marketing purposes
    - is **prepared in order to meet regulatory requirements** (i.e., compilation and summary of already existing documentation)
    - Includes **attestation** that the contents is **truthful and accurate**
  - The **extent of evidence** in TOC is likely to **increase with the class** of the medical device, its **complexity**, and the extent to which it incorporates **new technology**.
- The **RA or CAB** determines the **adequacy** of the **documented evidence** in support of the **manufacturer's attestation of conformity** to regulatory requirements through a review of the TOC.
  - The **depth** and **timing** of the **review** is likely to be **influenced by the class** of the medical device, its **complexity**, and the extent to which it incorporates **new technology**.

Declaration of Conformity

- **Manufacturer attests** that its medical device **complies fully with all regulatory requirements** and draws up a **written "Declaration of Conformity"** containing specific information (see section 5.4)
- The **RA or CAB** may **review and confirm** the adequacy of the Declaration of Conformity and, if required, examine the supporting documents or other evidence



GHTF/SG1/N065:2010

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Registration of Manufacturers and other Parties and Listing of Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: August 27, 2010

Dr. Larry Kelly, GHTF Chair

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Registration of Manufacturers and their Medical Devices by the Regulatory Authority.

- **Prior** to placing a medical device on the **market**, the **manufacturer**, or **distributor**, or **importer**, or **authorised representative** should **provide the RA** with the information it needs in respect of **registration** and medical device **listing** requirements.
- Guidance on the **information** to be provided may be found in the document entitled **Registration of Manufacturers and other Parties and Listing of Medical Devices** (GHTF/SG1/N065:2010)
- The **RA** will **implement** and **maintain** the **register**

I am thrilled to be a part of the discussion today and look forward to learning from all of you how we each are implementing the principles of conformity assessment for medical devices as described in N78.

Thank you!