Outcome of IMDRF Standards WG, closed in 2021, and future view

～Value for National competent authority through joining global standard development activities～

Division of Standards for Medical Devices
Pharmaceuticals and Medical Devices Agency (PMDA)
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Background : summarized page3-4 in IMDRF/Standard WG N15

-IMDRF has adopted most GHTF documents. First generation for IMDRF Standard WG, it is summarized the GHTF regulatory model is based on "Medical device essential principles", and international standards should specify (interpret) in detail how medical devices (processes or manufacturers) could come into regulatory compliance (e.g. with the essential principles).

In addition, it quoted followings;
-The GHTF paper "Role of Standards in the Assessment of Medical Devices"
GHTF/SG1/N044:2008 states: International standards, such as basic standards, group standards and product standards, are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices. ...

- Regulatory Authorities should encourage the use of international standards.
- Regulatory Authorities should establish a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating conformity with the Essential Principles. This mechanism should also include a procedure for withdrawal of recognition. ...

It concluded ; Every Region should have established (or should be in the process of establishing) or is using a list of recognized standards.

Quite strong message, and it hits point!

Result of Initial survey 2012 on recognized standards (ISO/IEC) by IMDRF member countries fully/partially adopted

- Conducted in **early 2012**; 12 years ago
- 6 IMDRF MC members joined : US, Japan, EU, Canada, Au, Brazil
- 727 ISO/IEC standards provided for survey

- Result
  - 0 (zero) standard all members recognized
  - 4/5 adopted: 17 standards (ISO 5840/ 10993-3/ 10993-4/ 0993-6/ 10993-7/ 10993-14/ 10993-15/ 10993-17/ 11135-1/ 11137-1/ 11607-1/ 11607-2/ 11737-1/ 14155/ 14937/ 17664/ 17665-1)
  - Range of number of recognized standard by members varied from 18/727 to 222/727 per country among provided 727 standards.

History

1. IMDRF Standards WG (closed in 2018)

2012 – 2018: Chair: Federal Ministry of Health Germany

Accomplishment: "IMDRF/Standards WG/N15: List of recognized standards"

"IMDRF/Standards WG/N51: Optimizing Standards for Regulatory Use"

2. Standards – Improving the quality of international medical device standards for regulatory use WG (closed in 2021)

The **purpose** is to identify and explore possibilities to improve the process of developing international standards used for regulatory purpose and discuss these with stakeholders and SDOs, and describe possible actions. :referenced from "Standards - Improving the quality of international medical device standards for regulatory use".

2019 -2021: Chair: US FDA

Accomplishment: "IMDRF/Standards WG/ N72: IMDRF Standards Liaison Program Framework"

2021 : Closed

＊Ongoing action: IMDRF/MC needs to appoint liaison(s) to ISO/TC210 and IEC/TC62 based on IMDRF/Standard WG/N72

Outcome: Technical Documents authored by Standard WG

Date of issuance	Document #	Title
Nov 21, 2014	IMDRF/Standards WG/N15	List of international standards recognized by IMDRF management committee members
Nov 12, 2018	IMDRF/Standards WG/N51	Optimizing Standards for Regulatory Use
May 13, 2022	IMDRF/Standards WG/ N72(edition 1)	IMDRF Standards Liaison Program Framework

IMDRF/Standard WG/N72: IMDRF Standard Liaison Program Frame work; May 12, 2022

-indicated framework to establish and maintain liaison activities between TCs/SCs in SDOs such as ISO/IEC, etc.

-IMDRF and ISO/TC210 & IEC/TC62 has already reached liaison (category A) agreement.

-This N72 issued as internal document initially, however, published on IMDRF website, for useful information to SDOs.

Value for NCA and future **view**

1. Value

- Effective utilization of resource in national competent authority by followings;

-Domestically, reduction of queries between applicants and officials
-Globally, timely communication with SDOs for development of international standards through liaison activity under IMDRF liaison program

2. Future view

- More effective utilization for review resource in NCA by using globally recognized international standards.
- Proactive participation for supporting global standard developing activities with SDOs to establish criteria for domestic approval/certification by globally recognized standards through outcome from IMDRF **LIAISON** activities and liaison program with SDOs.

➡ IMDRF plans to send liaison(s) to ISO/IEC in near future