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Roadmap to Promote Regulatory Convergence for Medical Device Regulatory Systems

Lead Economies: U.S., Republic of Korea, Japan

I. Introduction

Regulatory harmonization and regulatory convergence promote innovation, accelerates patient access to safe and effective products, and reduces regulatory burdens and cost.

Although some specific regulatory issues related medical devices have been included as part of other APEC RHSC work items, to-date there has not been a Priority Work Area (PWA) dedicated to addressing the unique regulatory issues related to medical devices. Regulation of medical devices is quite different than regulation of pharmaceuticals and should be addressed separately.

The proposed work item: "Roadmap to Promote Regulatory Convergence for Medical Device Regulatory Systems," aims to promote international harmonization initiatives (i.e., International Medical Device Regulators Forum (IMDRF) and former Global Harmonization Task Force (GHTF) Guidance Documents), build regulatory capacity and knowledge, and support harmonized implementation efforts among APEC economies.

The work will focus on training and education efforts related to topics across the total product life cycle of the device (i.e., pre-market, post-market, etc.). Through this work, we hope to gain greater understanding of international best practices, achieve harmonized approaches, and facilitate regulatory convergence for medical devices in APEC economies.

II. PWA Structure

The **Co-Champions** provide strategic direction and guidance on all activities of the PWA and oversee the work of identified Sub-Champions and Centers of Excellence (CoEs) to maintain efficient operation and progress, with consultation and endorsement from the RHSC. The Co-Champions also manage and update the core curriculum for the medical device PWA (See Annex – Core Curriculum) based on harmonized guidance documents. The core curriculum encompasses the total product lifecycle of medical devices (i.e., pre-market, post-market, etc.).

The **Sub-Champions** oversee topics under the medical device total product life cycle and are responsible for identifying and recommending Pilot CoE candidates on selected topics for Co-Champion approval. Where needed, the Sub-Champions are responsible for conducting gap analysis on harmonized guidance documents. The Sub-Champions also develop roadmap(s) on selected work areas from the core curriculum, key performance indicators and targets of convergence in collaboration with identified Pilot CoE candidates. The Sub-Champions submit recommendations to PWA Co-Champions for endorsement.

Organizations can apply to become a **Center of Excellence** based on any subject work area(s) under the total product lifecycle of medical devices, which may include premarket, postmarket, and QMS (Quality Management System). The CoEs work closely with the respective Sub-Champion on development of the training materials and workshops. Endorsement from the respective Sub-Champion and Co-Champion is needed.

III. Target of Convergence

The project will focus on the total product life cycle of medical devices, which includes such topics as premarket, Quality Management System (QMS), and postmarket. Although the overarching roadmap describes these topic areas in general below, the Sub-Champions,and CoEs are not limited to these specific areas in developing training programs and workshops because certain work areas may include a mixture of premarket, postmarket and QMS activities.

a. Premarket

To promote harmonization and convergence in the APEC region, it is necessary to establish a conformity assessment system, which is based on IMDRF and GHTF Guidance Documents and international consensus standards. Key considerations include:

- To promote consistency and predictability in the regulatory review of medical device product submissions, the health authority reviewer's competence, conduct, and training requirements are important, particularly in third-party certification systems.
- Harmonizing the process for reviewing medical device product submissions is necessary. This effort is critical because of the nature and diversity of medical device products, and variation of regulation depending on classification and risk.
- To this end, it is necessary to establish a conformity assessment system that verifies and validates conformity to the essential principles.
- Appropriate use of the international consensus standards will promote efficiencies and innovation while facilitating objective assessment of device safety and performance. For medical devices and IVD medical devices, use of conformity assessment of the essential principles is recommended, and the international consensus standards should be used in order to demonstrate the conformity with the essential principle. Where possible, third-party certification bodies are recommended for implementation.
- It is also recommended that a reasonable reviewing period be standardized.

  (For example, Class II and III already marketed category; Three months)

b. QMS

To promote harmonization and advancement of an assessment system for QMS within the APEC region based on IMDRF and GHTF Guidance Documents and international consensus standards.

- It is redundant to conduct individual audits by each country.
- ISO 13485:2016 is recommended as the QMS standard used.
- For reciprocal acceptance of audit reports, consider using reports from the Medical Device Single Audit Program (MDSAP).

c. Postmarket

To promote harmonization and advancement of a vigilance system within the APEC region.

The vigilance system should be based on IMDRF and GHTF Guidance Documents.

- The PWA of Medical Device Vigilance has already been implemented by APEC RHSC and is recommended as a subproject.

IV. Timeline

This project will be conducted from February, 2018 to December, 2020.

(i.) 2018: Co-Champions obtain intersessional endorsement of the Medical Device PWA Core Curriculum. The Core Curriculum is reviewed and updated on a biannual basis.

(ii.) 2018: Solicit interested Sub-Champions. Sub-Champions identify and recommend Pilot CoE candidates on selected topics for Co-Champion approval. Where needed, the Sub-Champions conduct gap analysis on harmonized guidance documents. The Sub-Champions also develop roadmap(s) on selected work areas from the core curriculum, key performance indicators and targets of convergence in collaboration with identified Pilot CoE candidates

(iii.) 2018–2019: Training/Workshops

- Design training programs and workshop proposals to educate APEC economies on IMDRF and GHTF Guidance Documents and international standards.
- Conduct workshops and annual training programs as identified in the work plan.
- The training and workshop shall include contents/topics, for example as follows:
    - Highlighting differences in the regulatory systems in approaches across APEC economies, and in comparison to IMDRF and GHTF Guidance and documents international consensus standards.
    - Investigation of conformity assessment on premarket, QMS and vigilance systems.
    - Standard or model for conformity assessment on premarket, QMS and vigilance system
    - Product improvement conformity assessment on premarket, QMS and vigilance system; provide examples as case studies for individual product item.
    - Best practices of medical device premarket conformity assessment, QMS and vigilance system training program.
    - Methods to exchange conformity assessments outcomes on premarket, QMS and vigilance system within the APEC region.

(iv) 2020: Assessment of Training/Workshop

- Expand reach of trainings to provide more opportunities for regulators.
- Secure programs and a pool of lecturers and experts to disseminate vigilance standards.
- Determine how to capture outcomes and success towards converged regulatory systems in APEC region.
- Consider and propose direction for assessment of regulatory harmonization initiatives, including research and documentation of the regulatory systems for medical devices.

V. Performance Indicators

To be addressed in each topic work area by Sub-Champions. If there is more than one Sub-Champion on the same topic work area, the key performance indicator(s) should be in alignment. The key performance indicator is prepared by Sub-Champions and is endorsed by Co-Champions.

VI. Relevant Guidelines

To be addressed each topic work area by Sub-Champions. They shall be endorsed by Co-Champions.

VII. Similar Activities by Other Organizations (if any)

To be addressed each topic work area by Sub-Champion. They shall be endorsed by Co-Champions.