Asia-Pacific
Economic Cooperation

Promoting Regulatory Convergence for MDV

Champion APEC Economies of the RHSC:

Korea – MFDS

Japan-MHLW/PMDA

US FDA

Overview of Roadmap for Regulatory Convergence

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1. Gap analysis for MDV
2. Development of training curriculum for international harmonization
3. Training for regulators based on IMDRF/GHTF and AHWP guidelines
4. Proposal for ways to share safety information
5. Proposal for expansion of regional training and workshops to promote MDV

OBJECTIVE

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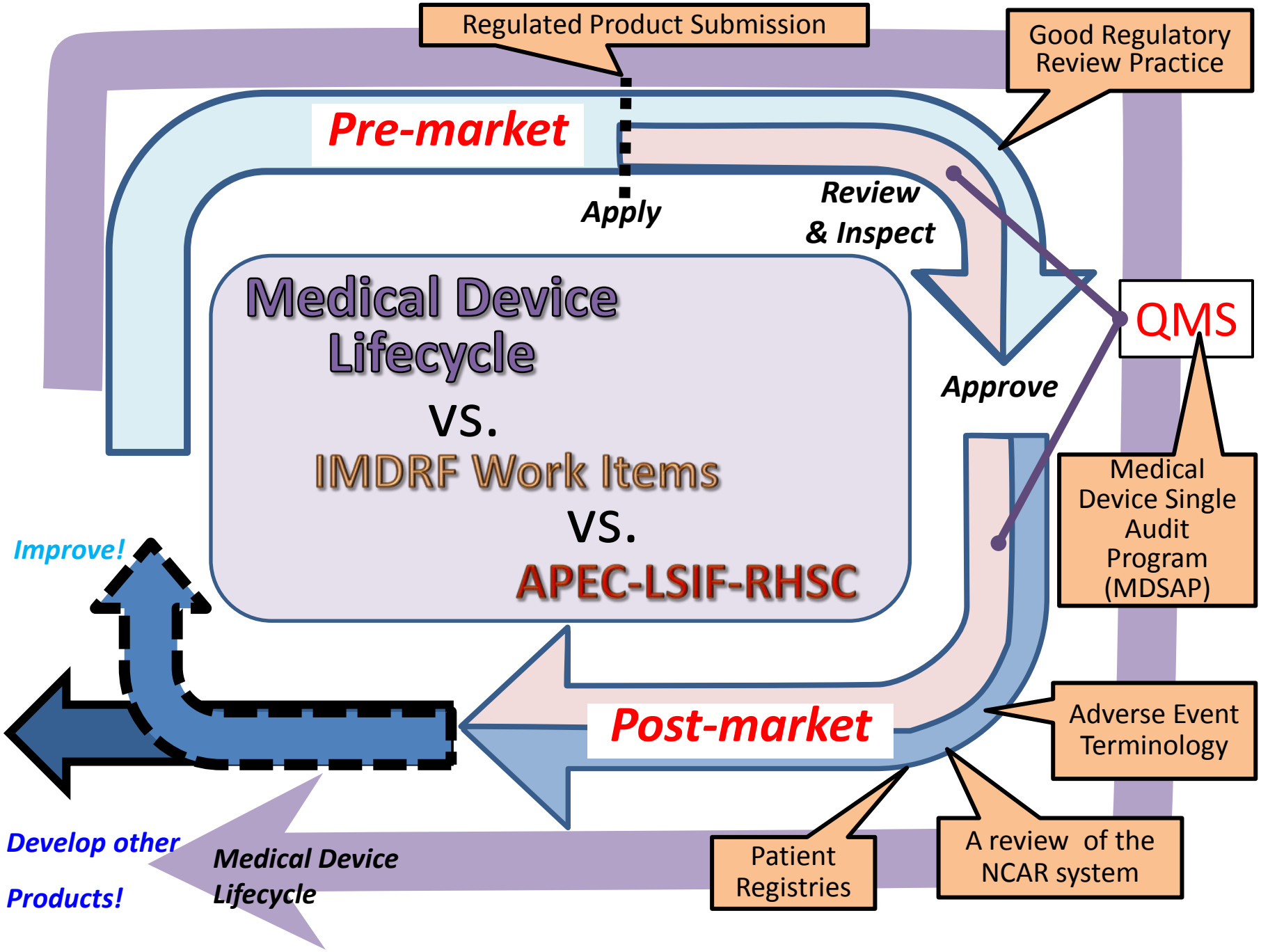
Develop training and education related to topics across the product life cycle of the device (i.e., premarket, postmarket, etc.) and gain greater understanding of international best practices, achieve harmonized approaches, and facilitate regulatory convergence for medical devices in APEC economies


Regulated Product Submission
Good Regulatory Review Practice
Pre-market
Apply
Review & Inspect
Approve
QMS
Medical Device Lifecycle
vs.
IMDRF Work Items
vs.
APEC-LSIF-RHSC
Medical Device Single Audit Program (MDSAP)
Improve!
Post-market
Adverse Event Terminology
Develop other Products!
Medical Device Lifecycle
Patient Registries
A review of the NCAR system

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TARGETS OF CONVERGENCE

PREMARKET

- To promote consistency and predictability in the regulatory review submissions
- Harmonizing the process for reviewing submissions
- establish a conformity assessment system that verifies and validates conformity to the essential principles
- Standarized format of medical device submissions using guidance such as the IMDRF Table of Contents (ToC)

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TARGETS OF CONVERGENCE

QMS

- To promote harmonization and advancement of QMS within APEC based on IMDRF and GHTF Guidance.
- Avoid to conduct individual audits by each country.
- ISO 13485:2016 is recommended as the QMS standard used.
- Reciprocal acceptance of audit reports, consider using reports from the Medical Device Single Audit Program (MDSAP

POSTMARKET

- promote harmonization and advancement of a vigilance system within the APEC region.
- The vigilance system should be based on IMDRF and GHTF