International Trend on Medical Device Regulatory Convergence

5th Joint Conference of Taiwan and Japan on Medical Products Regulation

December 1, 2017
Taipei

衛生福利部
食品藥物管理署
FDA Food and Drug Administration
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Content

Overview of major international harmonization activities and outcomes in :

- AHWP
  - Work Group 2 – Pre-market: IVD
- APEC
  - LSIF-RHSC

Asian Harmonization Working Party

- Asian Harmonization Working Party (AHWP) is established as a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards. The Working Party is a group of experts from the medical device regulatory authorities and the medical device industry. Membership is open to those representatives from the Asian and other regions that support the above stated goals.

Source: http://www.ahwp.info/index.php?q=node/7

Membership and Structure of AHWP

Totally, 26 Member Economies
In Asia, Africa, Middle-East, Latin America


Kazakhstan


Mongolia

AHWP Organization Structure

AHWP

Chair (Regulatory Authority)
Vice-chair (Regulatory Authority)
Vice-chair (Industry)

Secretariat Team

AHWP Administration Services Ltd. (ASL)

Technical Committee (TC)

TC Chair (Regulatory Authority)
TC Co-chair (Regulatory Authority)
TC Co-chair (Industry)

Advisory Panel to TC

Working Groups (WGs) and Special Task Groups (STGs)

Work Group 1 (WG1) - Pre-market: General MD
Work Group 2 (WG2) - Pre-market: IVDD
Work Group 3 (WG3) - Pre-market: Software as a Medical Device
Work Group 4 (WG4) - Post-Market
Work Group 5 (WG5) - Clinical Evidence for Performance and Safety
Work Group 6 (WG6) - Quality Management System: Audit & Assessment
Work Group 7 (WG7) - Quality Management System: Operation & Implementation
Work Group 8 (WG8) - Standards
Work Group 9 (WG9) - Training
STG (U&N) - Special Task Group on UDI & Nomenclature

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TFDA involve in AHWP TC WG2

- AHWP TC WG2 – Pre-market: IVDD
- TFDA regulators took the WG2 Chair position in the past two terms(6 yrs from 2012-2017)
- TFDA organized 4~5 face-to-face and teleconference working meetings per year to discuss and conduct WG2 work plan

WG2 Achievements

AHWP guidance/reference documents developed and endorsed by AHWP

- In 2012-2014 :
  - AHWP/WG1a/F001:2013 AHWP Regulatory Framework for IVD Medical Devices
  - AHWP/WG1a/F002:2013 Essential Principles of Safety and Performance of IVD Medical Devices
  - AHWP/WG1a/F004:2013 Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format
  - AHWP/WG2-WG8/F002:2014 Role of Standards in the Assessment of Medical Devices
  - AHWP/WG2/F001:2014 Comparison between CSDT and STED IVDDs
- In 2015-2017 :
  - AHWP/WG2-WG1/F001:2016 Definition of the Terms "Medical Device" and "In Vitro Diagnostic (IVD) Medical Device"
  - AHWP/WG2/F003:2016 Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices
  - AHWP/WG2/F002:2016 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
  - AHWP/WG2/F001:2016 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
  - AHWP/WG2/WD001:2017 Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices (towards endorsement at the 22nd AHWP Annual Meeting, 2017)

Promote Good Registration Management (GRM) in APEC

Roles in RHSC

- **GRM Roadmap co-champion**
- **GRM CoE hosting institution**

Goal of the GRM roadmap and each key element

- Promote the concept of Good Registration Management (GRM)
- Enhance mutual trust for regulatory convergence among the APEC member economies by 2020

Regulatory Harmonization Steering Committee

APEC

Life Sciences Innovation Forum

Good Review Practices (GRevP)	Good Submission Practice (GSubP)
To strengthen the **performance**, **predictability**, and **transparency** of regulatory agencies through the implementation or enhancement of GRevP and quality measures stepwise in each interested APEC economy.	To enhance the **quality** and **efficiency** of the medical product registration process by **improving the quality of submission** as well as its management.

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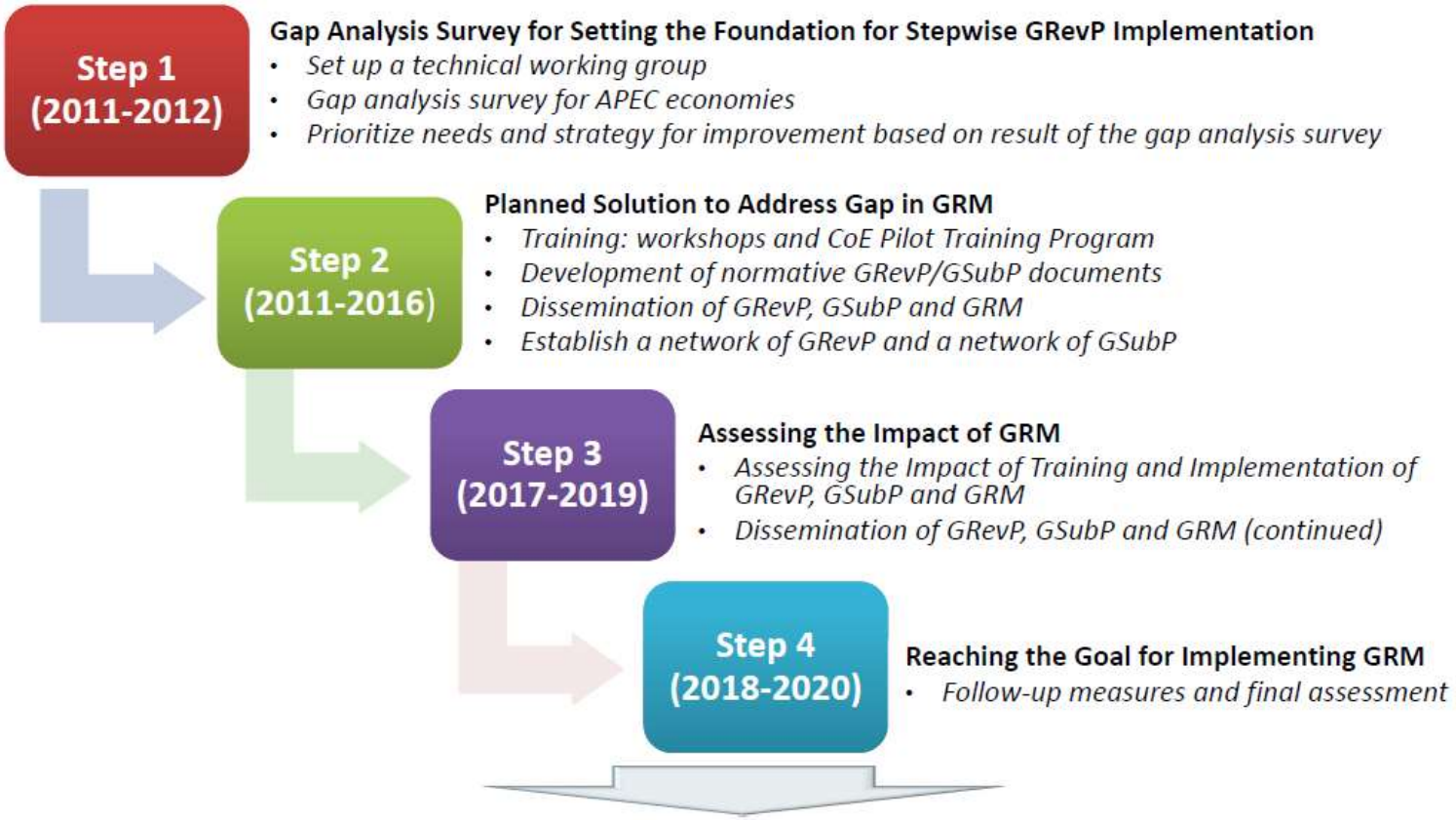
Specific Activities and Timeframe of the GRM Roadmap



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Milestones of the GRM Roadmap

Year	Milestone
2011	Good Review Practice (GRevP) was endorsed as a priority work area (PWA) by APEC LSIF-RHSC. Chinese Taipei was endorsed as the champion.
2013	APEC 2020 Roadmap for GRevP on Medical Products was endorsed.
2014	Good Submission Practice (GSubP) was endorsed as a PWA by RHSC.
2014-2015	**Good review practices: guidelines for national and regional regulatory authorities was adopted and published by WHO.**
2016	**Good Submission Practice Guideline for Applicants was endorsed by RHSC.** **GRevP and GSubP were merged as a PWA entitled Good Registration Management (GRM).** A combined roadmap was endorsed by RHSC. Chinese Taipei and Japan were endorsed as the co-champions. **RAPS Taiwan Chapter was endorsed as a Center of Excellence (CoE) for GRM pilot program by RHSC. A CoE Pilot Workshop was held in Taipei in Nov 2016.** Mexico Cofepris was endorsed as a CoE for GRM pilot program by RHSC.
2017	**TFDA in partnership with RAPS Taiwan Chapter was endorsed as a formal APEC GRM CoE by RHSC. An MOU with LSIF was completed.** CPFEPRIS hosted a GRM CoE Pilot in June. TFDA and RAPS Taiwan Chapter hosted a GRM CoE Workshop in October.

Thank You

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