Report Highlights - by AHWP TC

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AHC-AHWP JOINT WORKSHOP,
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Content

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- Playbook – Introduction & Launch
- Reflections from TC Advisors
- Work items
  - summary of accomplished work item goals
  - Proposed work items for the future

New Streamlined TC Structure

Aim of new TC structure:

- Increase alignment of AHWP TC work to current global trends in device regulations
- facilitate coordination with related international organizations (IMDRF, APEC, WHO)
- Position AHWP TC to effectively **respond** and **adapt** to trends in medical device technology and regulatory strategies
- Improve **efficiency** and **clarity** in proposal and assignment of work items

New Streamlined TC Structure

Working Group	Positions
WG1: Pre-market - General MD	Chair & co-chair (existing positions of WG1 Chair/co-chair)
WG2: Pre-market - IVDD	Chair & co-chair (existing positions of WG1A Chair/co-chair)
WG3: Pre-market - Software as a Medical Device	Chair & co-chair (**NEW positions**)
WG4: Post-market Scope includes post-market aspect of WG 1-3 device categories	Chair &co-chair (existing positions of WG2 Chair/co-chair)
WG5: Clinical performance & safety	Chair &co-chair (existing positions of WG5 Chair/co-chair)
WG6: Quality Management Systems: Audit & assessment	Chair &co-chair (existing positions of WG4 Chair/co-chair)
WG7: Quality Management Systems: Operation & implementation	Chair &co-chair (existing positions of WG3 Chair/co-chair)
WG8: Standards	Chair &co-chair (existing positions of WG7 Chair/co-chair)
WG9: Training	Chair &co-chair (existing positions of WG6 Chair/co-chair)

The structure and management of ad-hoc group(s) will remain unchanged.

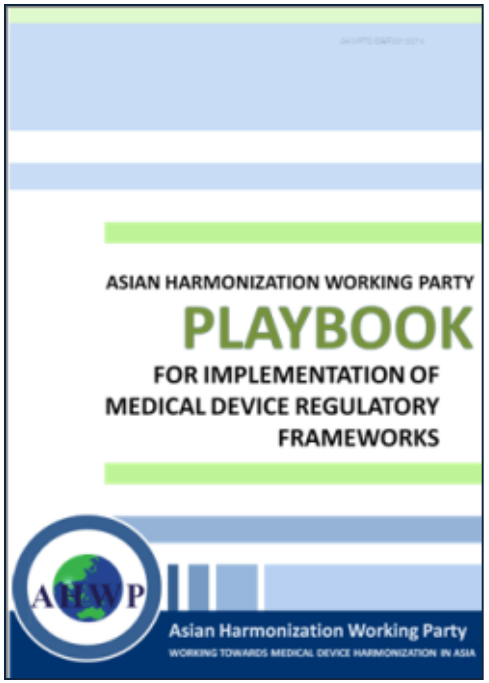
Special Task Group on UDI & Nomenclature	Chair &co-chair (existing positions)

Playbook – Introduction & Launch

The need for:

- **Guidance** to member economies in developing and implementing their medical device regulatory framework

- **Encouragement** to adopt best practices from existing harmonized regulatory frameworks (GHTF model framework)



Consideration for:

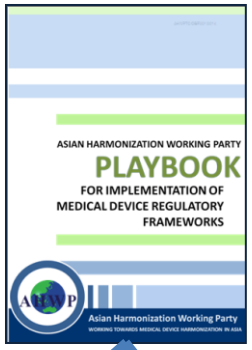
- Practicality of guidelines – hence drawing from experiences of countries that have implemented regulations

Next steps – Guidance to Playbook Application

- Feedback from member economies
- Addition and refinement of topics

Guidance documents development

- Communication
- Resource-pooling



Technical guidance documents

International collaboration & cooperation

Training & Capacity Building

- Program development
- Publicity

AHWP
ASIAN HARMONIZATION WORKING PARTY

2014 AHWP

Reflections & Recommendations from TC Advisors

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TC Advisor's Roles

- AHWP can learn from advisors' experiences gained in working with different geographies
- AHWP "Ambassadors" in other venues (IMDRF, APEC, WHO, etc…) to help market the global efforts of AHWP towards medical device harmonization

Reflections & Recommendations Moving Forward

- Continue to develop AHWP documents based on the foundation laid by GHTF / IMDRF
- Further develop this work using AHWP documents specific to the regulatory needs of the MEs; therefore lead to appropriate harmonization
- Rigorously set priorities and focus on key work items to drive progress and continual improvement
- Partner where appropriate with other organizations, but reduce redundant efforts (WHO, APEC, ISO, IMDRF etc…)
- Avoid duplicative and redundant controls in member economies; thereby reducing the burden on regulators and industry while allowing everyone to focus on the critical issues
- Have clear, common, and actionable objectives in order to assure progress is made. This is critical to the success of all stakeholders

TC WG Work Items

- Accomplished work item goals
- Proposed work items for the future

12 Technical Documents Developed

Pre-market (WG1, WG2, WG3)

- 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
- **Essential Principles** of Safety and Performance of IVD Medical Devices
- AHWP Regulatory Framework for **IVD Medical Devices**
- White Paper on **Medical Device Software Regulation -** Software Qualification and Classification

Post-market (WG4)

- Adverse Event Reporting **Guidance** for the Medical Device Manufacturer or its Authorized Representative
- Adverse Event Reporting **Timelines** Guidance for Medical Device Manufacturer and its Authorized Representative
- Medical Device Adverse Event (AE) **Report Form**
- **Definition and Classification** of **Field Corrective Actions**, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions

12 Technical Documents Developed

Quality management system (WG6, WG7)

- Guidance on the Quality Management System for Medical Device **Distributor**
- Guidelines for **Regulatory Auditing** of Quality Management Systems of Medical Device Manufacturers (Part 1 - 5)
- Quality management system – Medical devices - Nonconformity **Grading System** for Regulatory Purposes and Information Exchange

Playbook (Special Project, TC Chair)

- Playbook for Implementation of a Medical Device Regulatory Framework

Summary of Future Work Items Pre-market - General MD

No.	WG1 Pre-market - General MD
1	Finalize Combination products (Medical Device) guidelines
2	Develop Medical Device Grouping guidelines based on best practices
No.	**WG2 Pre-market - IVDD**
1	Develop/adopt working IVD definitions (Collaborate with WG1)
2	IVD standards (Collaborate with ISO/ TC 212 and WG8)
3	Clinical evidence guidelines for IVD (collaborate with WG5)
4	Conformity Assessment (product evaluation) of IVDs
5	IVD Labelling guidelines
No.	**WG3 Medical Software Guidelines**
1	Medical software guidelines for pre-market registration
	…And Consideration for New Technology Developments for Consideration
1	Software
2	3D Printing
3	Genetic test kits

Summary of Future Work Items

No.	WG4 Post-Market
1	Reviewing quality of reports received through SADS, evaluation of SADS online platform
2	Consideration in extending scope of post-market beyond activities of adverse event reporting and FSCA
No.	**WG5 Clinical performance & safety**
1	Require Training for common understanding and further decision making on adoption of GCP standards and Establishing appropriate AHWP guidelines
No.	**WG6 Quality Management Systems: Audit & Assessment**
1	Implement guidance documents in AHWP member economies
2	Continue to participate actively in TC210 WG1
3	Review IMDRF- MDSAP Documents to develop pilot program among AHWP member economies
No.	**WG7 Quality Management Systems: Operation & Implementation**
1	Finalize Draft of AHWP auditing guidance for importers & distributors
2	Develop auditing of SME(small to medium size enterprise) aligned with WG7.
3	Auditing training programs to enhance capacity of auditors & auditees of AHWP MEs
4	Collaborate with IMDRF to explore their updates and the collaboration if required
No.	**WG8 Standards**
1	Pilot launch on application of standards , including Selection of Standards For Pilot (e.g. ISO (DIS) 13485:2014/2015; ISO 14971; ISO 14155; IEC 60601, etc.)
No.	**WG9 Training**
1	Draft strategy in formal format and build action plan and budget accordingly

Summary of Future Work Items

No.	STG: UDI & Nomenclature
1	**Nomenclature work:** Continued look into the use of GMDN term/code and implementation experience in medical device information exchange.
2	**UDI work: S**hare the China experience learned from pilot study and investigations,US, EU and IMDRF to STG member economies to guide a harmonized approach of UDI in the region.

- Global developments in UDI
- Interest for more participation by other member economies

Thank You