WG I

Pre-Market: General MD

Chair: **Dr. Se-il Park**
Ministry of Food and Drug Safety, Korea

Co-Chair: **Ms. Kate HyeongJoo Kim**
Johnson & Johnson Medical APAC

Advisor: **Dr. Arthur Brandwood**
Brandwood Biomedical Pty Ltd. Australia

Secretary: **Ms. Yon Ju Kang**
Johnson & Johnson Medical Korea

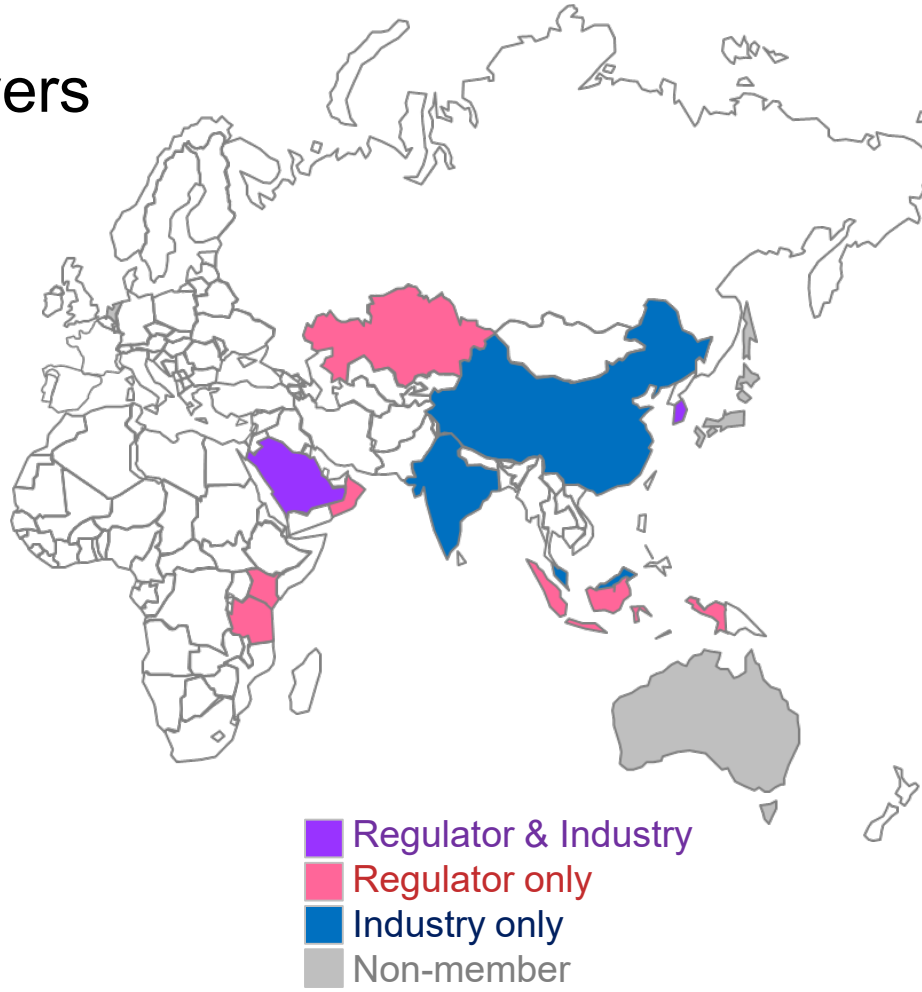
AHWP Annual Meeting
Nov. 11-14, 2019 in Muscat, Oman

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Membership Status

30 members & 2 observers
from 15 countries

- 8 Regulators
  from 7 member countries
- 22 Industry members
  from 16 organizations
  from 7 member countries
- 3 Advisors/observers from
  3 non-member countries



ACTIVITIES

2019 WG1 Activities

- Jan, Feb, Mar, 2019 Chair, Co-chair, Secretary meeting
- Apr. 9-10, 2019 TC meeting in Riyadh, Saudi Arabia
- May 8-10, 2019 WG1 F2F Meeting in Seoul, Korea
- Aug 13-14, 2019 WG1, 2, 3 F2F Meeting in Taipei, Taiwan
- Oct. 29, 2019 - Chair, Co-chair, Secretary meeting
- Nov 11-14, 2019 – Annual Meeting in Muscat, Oman

WG1 F2F Meeting in Seoul, Korea

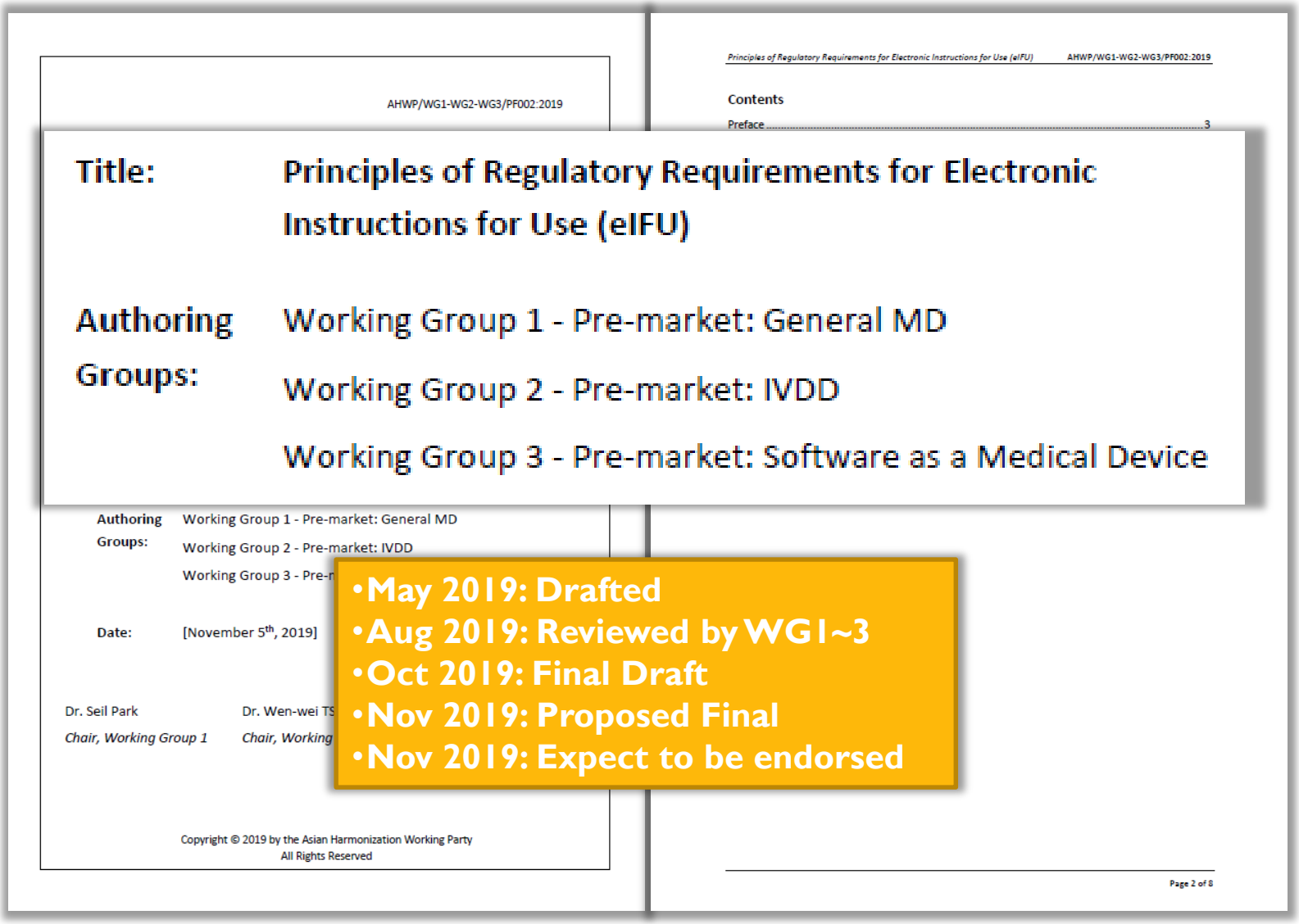
WG1,2,3 Joint Meeting, Aug, Taiwan

WORK ITEMS

Proposed Work Plan (2018-2020)

Work Item	Deliverables	Key Milestones & Progress
1. e-IFU/e-Label as an alternate method for compliance to labeling requirement (co-work with WG2 & WG3)	Guidance document on solutions proposed to overcome potential barriers posed by different stakeholders (regulators, users, or patients) and to ensure compliance to labelling requirements	• End 2018: Draft guidance document  • **End 2019: Guideline adoption by AHWP TC** 
2. Personalized Medical devices	Guidance document on definitions and requirements of Personalized Medical Devices (3D printed medical devices)	• End 2018: Align terms and definitions with IMDRF and other regulatory authorities • **End 2019: Investigate guidelines of personalized medical devices on other regulatory authorities**  • End 2020: Guideline adoption by AHWP TC
3. Guideline for Management of Change Notification for Approved Medical Device (including IVD) (led by WG2)	Guidance document on critical or major changes	• **End of 2019: Guideline adoption by AHWP TC** 

e-IFU – Progress



AHWP/WG1-WG2-WG3/PF002:2019

Title: Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)

Authoring Groups: Working Group 1 - Pre-market: General MD
Working Group 2 - Pre-market: IVDD
Working Group 3 - Pre-market: Software as a Medical Device

Date: [November 5th, 2019]

Dr. Seil Park — *Chair, Working Group 1*

Dr. Wen-wei TS — *Chair, Working*

Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) AHWP/WG1-WG2-WG3/PF002:2019

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- May 2019: Drafted
- Aug 2019: Reviewed by WG1~3
- Oct 2019: Final Draft
- Nov 2019: Proposed Final
- Nov 2019: Expect to be endorsed

e-IFU – Contents

Contents

e-IFU – General

Introduction

Labelling is one of the most important factors for safe use of medical devices. With ever changing types of medical devices and technological advances such as Internet, an electronic format of labelling providing the same information, as provided traditionally by paper, has been introduced gradually.

Jurisdictions such as Australia, Canada, Europe, India, Japan, Singapore, South Korea, and United States of America have adopted and implemented electronic format of instructions for use to enhance user access to important product information as well as to reduce regulatory burden on the medical device industry and to harmonize with these jurisdictions. According to AHWP Working Group (WG) 1 document published in 2017, most of AHWP Members have not introduced electronic instructions for use (eIFU). Working Group 1, 2 and 3 of the AHWP have prepared this guidance document. Comments or questions should be directed to the Chair of AHWP Work Group 1 whose contact details may be found on the AHWP web page (http://www.ahwp.info/).

Purpose

This document is to provide the general principles when the instructions for use (IFU) is provided in an electronic or online format.

Scope

This document applies to applicable medical devices and IVD medical devices intended to be used by professional users.

Regardless of provision of eIFU, applicable regulatory requirements regarding labelling must be followed.

Electronic label is out of scope of this document.

e-IFU – Definition

1 Definitions

1.1 Electronic Instructions for Use (eIFU)

Instructions for Use refers to general and technical information provided by the manufacturer to inform the device user of the medical device or IVD medical device's intended purpose and proper use a
be taken. It is provided by the manu
and appropriate use. (GHTF/SG1/N

Electronic Instructions for Use (eIFU

- by the device ("help" syste
- contained in portable elect
together with the device, o
- online, through the manufa

Note 1: Instructions for use (IFU) ca
for use" and may also include "User

Note 2: The eIFU must be a comple
included in the IFU as specified in t

1.2 Electronic Label

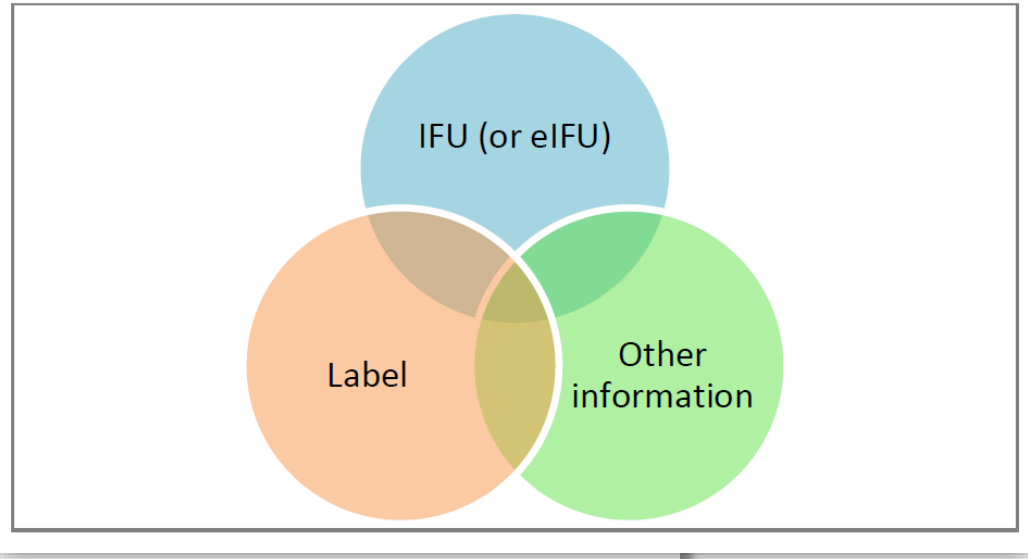
Label is written, printed, or graphic
itself, or on the packaging of each u
(GHTF/SG1/N70:2011)

1.3 Electronic Labelling

Labelling includes the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents (ISO 13485:2016).

Electronic Labelling refers to any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device. (IMDRF/GRRP WG/N52 FINAL:2019).

Figure 1. Labelling (or Electronic Labelling)



e-IFU – Definition (2)

1.4 Lay User

Lay User refers to individual who does not have formal training in a relevant field or discipline.

NOTE 1: Principles for lay person(s) may also apply to self-testing for an IVD medical device.

NOTE 2: For an IVD medical device for self-collection or self-testing, a self-collector or self-tester is considered a lay user.

(IMDRF/GRRP WG/N52 Final: 2019)

1.5 Professional User

Professional User is someone who use a medical device during their professional healthcare activities and holds the required expertise for use through qualifications or training. Professional User may include, but not limited to:

- a medical practitioner, a dentist, or any other kind of health care worker registered or accredited under the law or regulations of the applied jurisdiction, or
- a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer, etc. (TGA # D18-10786654)

e-IFU – Benefits

2 Benefits of eIFU

The information contained within the IFU may be electronically provided as an acceptable alternative to be compliant with regulatory requirements. This not only reduces cost and environmental waste associated with paper-based IFUs, but also brings various advantages such as, but not limited to, the following:

- eIFU is sustainable and free from the risk of physical damage such as loss, wear, tearing, contamination, etc.
- eIFU content can be more timely updated to provide current and time sensitive information and/or important updated information related to product safety and/or performance.
- eIFU content may be accessed anytime and anywhere as it does not need to remain with the physical product, unlike a paper version.
- eIFU content is searchable, unlike paper-based IFUs, allowing the user to immediately find the specific information he or she is looking for in the language of choice.
- Provision of eIFU is the ecological approach by reducing the usage of physical means such as paper IFU or other physical media. eIFU will reduce the waste of providing multi-language IFUs as well as multiple copies of the same printed IFU.
- Professional users who repeatedly use the same medical devices will not need to refer to the same IFU provided with every single product unit.

On the other hand, any jurisdiction who takes eIFU into account may also consider the following:

- Lack of accessibility to Internet at the point of use/care,
- Lack of compatibility of the eIFU with the users' devices, and/or
- Cybersecurity risks.

e-IFU – Points to Consider

3.1 Applicable Medical Devices

Medical devices including IVD medical devices intended to be used by professional users. Such devices include followings, but not limited to:

- Medical devices including IVD medical devices used by a professional user, or
- Medical devices including IVD medical devices only used in a healthcare facility.

Note: Paper or any other physical IFU shall be provided in the following cases.

- Paper or physical IFU shall be provided if the device is used by a lay user.
- Paper or physical IFU shall be provided upon request without undue delay or cost.

3.2 Information on eIFU

The eIFU should include all the information required for Paper IFU and comply with the regulations in the target regulatory jurisdiction. Additionally, eIFU should clearly state the following information.

- Version with effective date

  Note: Version should be controlled by the quality management system. Change history should be documented and provided to the regulatory authority upon request. Obsolete versions of the current eIFU must remain accessible to the users where appropriate.

- Target regulatory jurisdictions where appropriate

3.3 Operating Environment to Display eIFU

eIFU shall be provided in a commonly used format that can be read with freely available software.

Note: It is recommended the distribution format is non-editable and searchable.

eIFU must be verified and validated to function in the operating environment as defined.

Note: eIFU shall be protected against hardware and software intrusion.

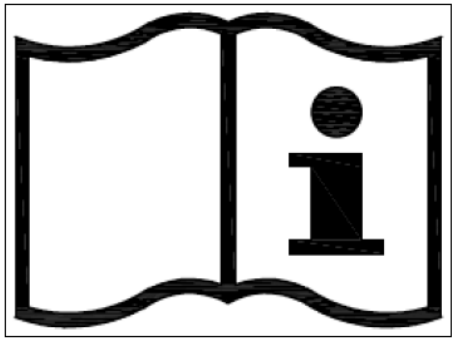
e-IFU – Points to Consider (2)

3.4 Indication of eIFU Provision

When only the eIFU is provided, the label on the device should indicate that the IFU is provided in an electronic form and how to access the eIFU.

Note: ISO 15223-1:2016 Medical devices (Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements) list symbols to be used as the indicator of eIFU provision.

Figure 2. ISO Symbol of eIFU Indicator



3.5 Risk Assessment and Quality Management System

Manufacturers must perform and document an appropriate risk assessment and change control for implementation of eIFU. In addition, procedures to maintain eIFU and revisions should be clearly documented within manufacturers' QMS.

e-IFU – Example

THANK YOU
FOR YOUR ATTENTION.

WG2 – Pre-market: IVDD

Chair: Dr. Wen-Wei TSAI

Co-Chair: Ir Prof. Albert KF POON

Advisor: Ms. Shelley TANG

Secretary: Dr. Christopher CHAN

AHWP Annual Meeting

November 11th-14th, 2019 Muscat

AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Objectives 2018-2020

- To assist AHWP member economies in implementing regulatory framework of IVD medical devices by
  - Developing AHWP documents on premarket regulatory control of IVD medical devices.
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices.
- To support regulatory convergence through
  - Participating in International/Global Organization collaboration and activities. (e.g. ISO/TC 212, WHO, IMDRF etc.)
  - Encouraging interest and participation of the AHWP member economies in establishing and reviewing the specific requirement of IVD premarket regulatory control.

WG2 Project Activities 2019

- 2019 Activities:
  - WG2 1st Teleconference, 20th Feb
  - WG2 1st FTF meeting: 13th ~15th Aug (Taipei) (WG1-WG2-WG3 joint meeting with WG2-WG5 joint Tcon session)
  - WG2 2nd FTF meeting: 15th Nov (Oman) & WG2-WG5 joint meeting
- Guidance development:
  - Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) (collaboration with WG1 & WG3)
  - Categorisation of Changes to a Registered Medical Device (collaboration with WG1 & WG3)
  - Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for In Vitro Diagnostic Medical Devices (Drafting in progress, collaboration with WG5)

WG Progress (I)

	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	to Apr 2019	50 members in total • 17 regulators • 30 industries • 3 Observers
2	Development of AHWP Guidance Document	1) Labelling for In vitro Diagnostic Medical Devices	Jan 2017 to Oct 2018	• Document endorsed in KL Annual meeting, 2018
		2) Categorisation of Changes to a Registered Medical Device (collaboration with WG1 & WG3)	Jul 2018 to Nov 2019	Target to be endorsed in Muscat Annual Meeting, 2019
		3) Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) (collaboration with WG1 & WG3)	2017 to Nov 2019	Target to be endorsed in Muscat Annual Meeting, 2019

WG Progress (II)

	Work Item	Deliverables	Timeline	Progress Update
2	Development of AHWP Guidance Document	4) Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for In Vitro Diagnostic Medical Devices (collaboration with WG5)	2019 to 2020	Drafting in progress, collaboration with WG5, target to be endorsed in 2020
		5) Guideline for Approval of Reagent for Instrument Family	2020 ~	Target to be endorsed in 2020
3	Participation in International/ Global Organization collaboration and activities	1) Contribution to International IVD Standards 2) Contribution to IMDRF in IVD Guidance	2018 to 2020 2019 to 2020	• WG2 has joined ISO/TC 212 as liaison member to participate in standard discussion and contribution from regulators and industry's point of view. • Participation in IMDRF New Work Item "Principals of IVD medical devices Classification"

WG Progress (III)

ASIAN HARMONIZATION WORKING PARTY

	Work Item	Deliverables	Timeline	Progress Update
3	Participation in International/ Global Organization collaboration and activities	3) Contribution to WHO Technical Specification Documents	2018 to 2020	• Continuous contact with WHO IVD PQ team to maintain technical communication • Collect and consolidate comments from WG2 members on the WHO documents, including: ◦ TSS6 Syphilis Rapid diagnostic tests ◦ TSS-7: Rapid diagnostic tests to detect hepatitis C antibody or antigen. ◦ TSS-8: Immunoassays to detect hepatitis C antibody and/or antigen • TSS-10: In vitro diagnostic (IVDs) medical devices used for the qualitative and quantitative detection of Hepatitis C ribonucleic acid • TSS-11: In vitro diagnostic (IVDs) medical devices used for the quantitative detection of HIV-1 nucleic acid • TSS-12: In vitro diagnostic (IVD) medical devices used for the qualitative detection of HIV-1 and HIV-2 nucleic acid

WG Progress (IV)

ASIAN HARMONIZATION WORKING PARTY

	Work Item	Deliverables	Timeline	Progress Update

4	Collaboration with other WGs		2018 to 2020	• WG1 & WG2:
				  • Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) (2019)
				• WG1, WG2 & WG3:
				  • Categorisation of Changes to a Registered Medical Device (2019)
				• WG2 & WG5:
				  • Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for In Vitro Diagnostic Medical Devices

WG Document for Endorsement at the 24th AHWP Annual Meeting 2019, Oman

No.	Title/ Content	Type of Document
1	Categorisation of Changes to a Registered Medical Device (collaboration of WG1, WG2 & WG3)	Guidance Document

- Purpose:
  - This document provides assistance to RAs and manufacturers in categorising and managing changes during the life cycle of medical devices. The document provides guidance on types of changes, principles of change categorisation, and what should be done by the manufacturer in relation to each type of change to its registered medical device. For minor changes, reference should be made into AHWP/WG1/F002:2016 Guidance for Minor Change Reporting, whereby the reportability depends on the jurisdiction.
- Rationale:
  - Consistent worldwide categorisation of changes to medical devices would offer significant benefits to the manufacturer, user, patients and RAs. Eliminating or reducing differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

ASIAN HARMONIZATION WORKING PARTY

Thank you

WG 3: Pre-market: Software as a Medical device

Chair: Dr. Abdullatif Sulaiman Al Watban,
Saudi Arabia FDA, Saudi Arabia

Co-Chair: Mr. Tony Yip
Grifols (HK) Limited, Hong Kong SAR

Advisor: Dr. Ir. Peter W.J. Linders (Philips)

Secretary: Ms. Elly Cho, Philips, Republic of Korea

AHWP Annual Meeting 2019
Nov 13th Muscat, Oman

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Working Group Action Plan 2019 - 2020

Work Item	Deliverables	Status
White paper / Position paper on Pre-market initial Submission format for SaMD • To draw up a white paper or position paper for AHWP TC covering the **pre-market submission format** for SaMD highlighting the need for considering approaches different from those in practice for traditional MDs.	White paper / Position paper	**Proposed Final Document submitted to AHWP, for further AHWP process and endorsement.**
Proposed new item: White paper on Cyber Security for SaMD • *To draw reference from different jurisdiction to provide basic information on further development of AHWP document on Cyber Security measures.* • *To provides recommendations to consider and information to include pre-market submission for effective cybersecurity management(could be a separate work item)*	White Paper	**Final Draft under WG discussion and review**
White paper/Guidance on SaMD Change management – Requirements and Processes • To address life cycle management in terms of regulatory requirements/submissions needed. • This work item becomes the **Joint WG1, WG2 & WG3 project** for **medical device change guidance**.	White paper / Position paper	Started in Q1 2019 **Proposed Final Document submitted for AHWP process and endorsement.**

Working Group Action Plan 2019 - 2020

ASIAN HARMONIZATION WORKING PARTY

Work Item	Deliverables	Action Plan and Timeline
Guidance on eIFU • To address the implementation concerns while implementing the electronic Instruction For Use (eIFU). • This work item becomes the **Joint WG1, WG2 & WG3 project** for **medical device change guidance**.	Guidance	**Proposed Final Document submitted for AHWP endorsement.**
Guidance document on Cyber Security for SaMD • *To provides recommendations to consider and information to include pre-market submission for effective cybersecurity management(could be a separate work item)*	Guidance	**In progress** the **first draft** is ready to be reviewed by the working group.
Guidance for Pre-Market Submission Format for SaMD • To draw up a guidance document for AHWP members covering the **pre-market submission format** for SaMD, highlighting the need for considering approaches different from those in practice for traditional MDs.	Guidance	Q1 2020 (First draft), depends on status of white paper review and endorsement.
Guidance for Review and Approval on Medical Device Software • Follow to the outcome of the white paper published, to cover the **pre-market submission format** for SaMD highlighting the need for considering approaches different from those in practice for traditional MDs.	Guidance	Start in Q4 2020 / Q1 2021

Our Journey for SaMD – since 2014

ASIAN HARMONIZATION WORKING PARTY

WG4 Post Market

Chair: Mr. Yorkie Chow
(Department of Health, HKSAR, China)

Co-Chair: Ms Kitty MAO (GE Healthcare, Singapore)

Advisors: Dr Jorge GARCIA (TGA, Australia)
Ms Joanna KOH (Singapore)

24th AHWP Annual Meeting
Nov 11-14, Muscat Sultanate of Oman

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Updates (1)

- Confirmation of WG membership by TC Chair on 31 Dec 2018

- No. of WG members: 17 (excluding chair and co-chair)
  - 3 from Regulatory Authorities

    Hong Kong Saudi Arabia
  - 14 from Industry

    Chinese Taipei Hong Kong South Korea Malaysia

Updates (2)

- Activities
  - Formulation of WG4 work plan 2018-2020 and identification of work tasks in 2018
  - WG members grouped into 4 teams each working on a work task
  - WG Tele-con held on 21 Mar 2019
  - Progress summary on WG4 matters for WG members

    24 Dec 2018 12 Mar 2019 06 May 2019 08 Oct 2019

Proposed Work Plan 2018 – 2020

Work Item	Description	Deliverables	Timeline
1	Updating the Post-market Resource Centre	• Updates of hyperlinks and information posted in the post-market resource centre • (Updates: Once/Twice a year)	On-going from 2016
2	Performing Gap Analysis on the implementation of AHWP guidance among AHWP members	• Gap analysis report	Q3/Q4 2020
3	Supporting the TC initiative to develop the AHWP Handbook (Actual Implementation of a Regulatory System)	• AHWP Handbook - Post-market	Subject to the progress of development of AHWP Handbook
4	Participating in the development works of the ISO /TC210/WG6: Application of post market surveillance systems to medical devices	• Provision of comments to the draft technical reference document where appropriate • Adoption of published document(s) in the AHWP guidance documents where appropriate	Subject to the progress of the development of the relevant PMS documents (i.e. ISO/AWI TR 20416: Medical devices -- Post-market surveillance for manufacturers)

Progress Update

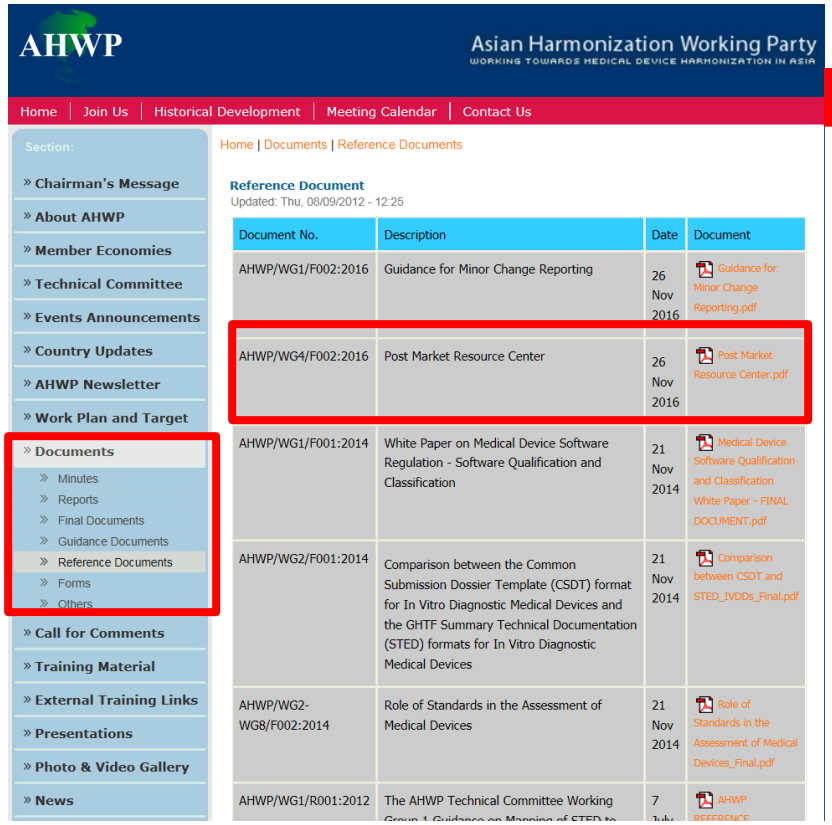
(Since TC Leader Meeting in Apr 2019)

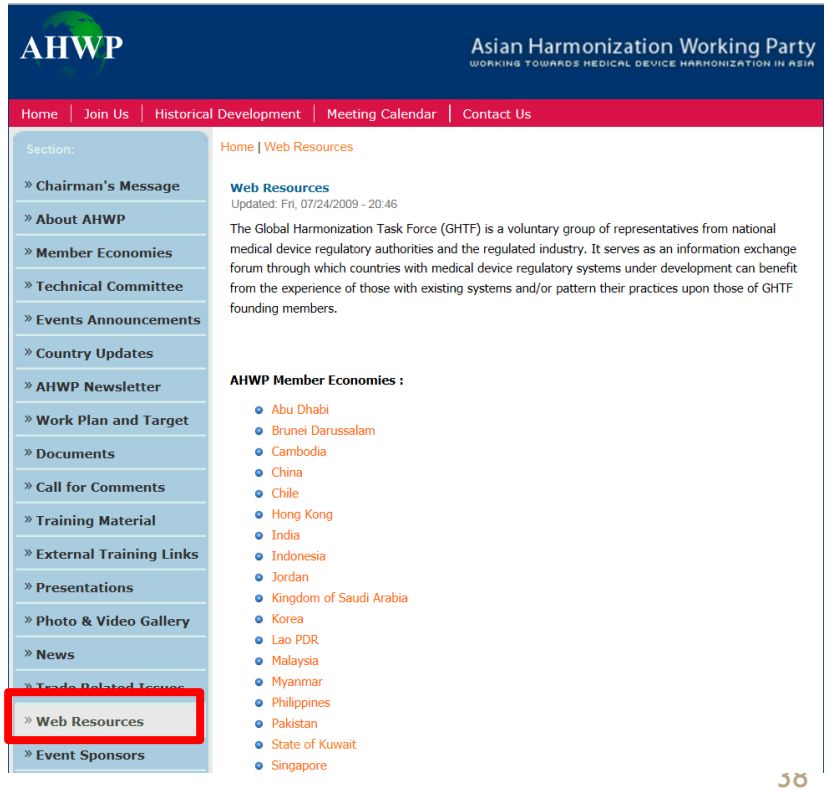
Work Item	Description	Achievements	Status
1	Updating the Post-market Resource Centre	• Hyperlinks and information posted in the post-market resource centre has been updated	On-going from 2016
2	**Performing Gap Analysis on the implementation of AHWP guidance on AE Reporting among AHWP members**	• **Survey questionnaire has been sent out to AHWP RA members**	**In progress**
3	Supporting the TC initiative to develop the AHWP Handbook (Actual Implementation of a Regulatory System)	• A WG4 task group for the AHWP Handbook has been formed	In progress
4	**Participating in the development works of the ISO /TC210/WG6: Application of post market surveillance systems to medical devices**	• **WG4 representative attended ISO/TC210/WG6 meeting in Jun 2019 and presented AWHP WG4 comments on the ISO TR20416 document**	**In progress**

Work Item 1 : Updating Post-market Resources Center (1)

- Post-market Resources Centre (AHWP/WG4/F002:2016)
  - A tool developed by WG4 to provide "one-stop" location for Regulatory Authorities and the Medical Device Industry to access to post-market regulations and reporting information easily across the world
  - Updates to be done once or twice per year
  - First Issue : 26 Nov 2016
  - Updates: Dec 2017, Dec 2018 & Aug 2019
  - Document AHWP/WG4/F002:2016 is now available in AHWP website under Reference Documents, will work with AHWP Secretariat to set up hyperlinks under Web Resources

Work Item 1 : Updating Post-market Resources Center (2)





Work Item 2 : Gap Analysis on Implementation of AHWP Post-market Guidance (1)

- Purpose and Rationale
  - Determine the shortcomings of the AHWP proposed framework and the progress of harmonization
  - Identify improvement areas in the work of AHWP on post-market surveillance
- Scope
  - Compare the existing post-market measures on AE reporting implemented (e.g. ASEAN guidelines) in the AHWP members with the AHWP guidance
  - Identify the gap, develop means to fill the gap and prioritize requirements to bridge the gap

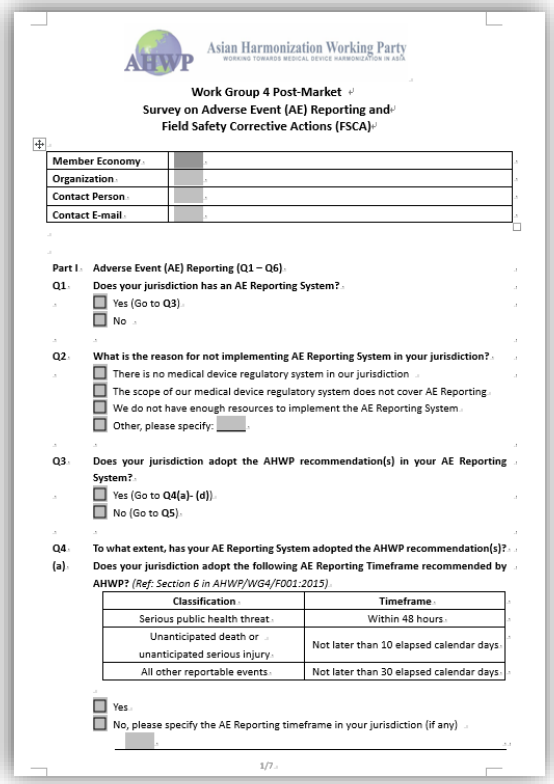
Work Item 2 : Gap Analysis on Implementation of AHWP Post-market Guidance (2)

- General Work Plan and Timelines

Item	Work Plan	Timeline
1	Preparation of the Study	May – Dec 2018
2	Conduction of the Study (Data collection and analysis)	Jan 2019 – Jun 2020
3	Publishing Results	Q3 – Q4 2020

Work Item 2 : Gap Analysis on Implementation of AHWP Post-market Guidance (3)

- Progress
  - Questionnaire has been distributed to AHWP RA members via AWHP Secretariat on 24 September 2019
  - Deadline of survey : 31 Oct 2019
  - As of 01 Nov 2019, only **FOUR** (out of 30) AHWP members (*Chinese Taipei, Hong Kong, Kingdom of Bahrain and Zimbabwe*) returned their reply.
  - Given low response rate (13.3%), the deadline of survey will be extended to **31 December 2019**



Asian Harmonization Working Party

Work Group 4 Post-Market
Survey on Adverse Event (AE) Reporting and
Field Safety Corrective Actions (FSCA)

Member Economy	
Organization	
Contact Person	
Contact E-mail	

Part I Adverse Event (AE) Reporting (Q1 – Q6)

Q1 Does your jurisdiction has an AE Reporting System?
- ☐ Yes (Go to Q3)
- ☐ No

Q2 What is the reason for not implementing AE Reporting System in your jurisdiction?
- ☐ There is no medical device regulatory system in our jurisdiction
- ☐ The scope of our medical device regulatory system does not cover AE Reporting
- ☐ We do not have enough resources to implement the AE Reporting System
- ☐ Other, please specify:

Q3 Does your jurisdiction adopt the AHWP recommendation(s) in your AE Reporting System?
- ☐ Yes (Go to Q4(a)- (d))
- ☐ No (Go to Q5)

Q4 To what extent, has your AE Reporting System adopted the AHWP recommendation(s)?

(a) Does your jurisdiction adopt the following AE Reporting Timeframe recommended by AHWP? *(Ref: Section 6 in AHWP/WG4/F001:2015)*

Classification	Timeframe
Serious public health threat	Within 48 hours
Unanticipated death or unanticipated serious injury	Not later than 10 elapsed calendar days
All other reportable events	Not later than 30 elapsed calendar days

- ☐ Yes
- ☐ No, please specify the AE Reporting timeframe in your jurisdiction (if any)

1/7

Work Item 4 : Participation in the Development Work of the ISO TC 210/WG6 (1)

- Purpose and Rationale
  - ISO TC210/WG6 being responsible for the development of the technical reference document: *ISO TR20416 Medical devices -- Post-market surveillance for manufacturers*, we should work together with them to promote harmonization
- Scope
  - Monitor the latest development of ISO TC 210/WG6 and participate in their work
  - Adopt the published document(s) in the AHWP guidance documents where appropriate

Work Item 4: Participation in the Development Work of the ISO TC 210/WG6 (2)

- Progress

Dec 2018	*Comments on ISO TR20416 working draft from WG4 was sought*
24-26 Jun 2019	*WG4 representative attended the ISO/TC210/WG6 meeting in Arlington, VA, US and presented WG4 comments on the working draft. All comments submitted were reviewed and resolved*
7-9 Oct 2019	*ISO/TC210/WG6 face-to-face meeting was held in London to discuss the results of approval voting and collected comments*
In progress	*Final editorial review for publication*

End of Report from WG4

WG5 – "Clinical Evidence for Performance and Safety"

Chair: Fikriansyah Bin Irman

Co-Chair: Sumati Randeo

Secretary: Mie Ohama

AHWP TC Meeting
November 13th, 2019
Oman

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ASIAN HARMONIZATION WORKING PARTY

WG5 Membership & Meeting Updates

- Total number of WG members: 14
  - Regulators: 7, Industry: 7
- Advisors: 2
  - Shelly Tang , Martin Devitt
- Steering Committee Members: 5
  - Fikriansyah Bin Irman, Sumati Randeo, Greg LeBlanc, Asma Zuberi, Mie Ohama

Note: Members of the WG who would like to actively engage in drafting and finalizing the guidance documents can apply for the membership of the steering committee to the Chair and Co-Chair, with their respective areas of interest.

WORK PLAN 2019

ASIAN HARMONIZATION WORKING PARTY

WG 5 Work Plan & Activities 2019:

Work Item 1 (Framework)	**Target Output**	**Status Update**
Annual review SWOT Analysis of WG 5 Framework ***Annual exercise & analysis***	Report analysis to TC by NOV 2019	Completed and shared in final meeting
Work Item 2 (Regulatory Updates)	**Target Output**	**Status Update**
Regular review of Global clinical regulatory updates	To share and update the WG 5 members of constantly changing regulatory landscape with respect to Clinical Investigation regulations and guidance.	Completed
Comparison of terminology related to clinical investigation among different countries	This action was initiated as suggested by TC leaders during the TC leaders meeting in April 2019.	Completed
Work Item 3 (Collaboration & Liaison with TC & Global Forums)	**Target Output**	**Status Update**
IMDRF	Monitor IMDRF activities and share the updates from the meeting	Updates were shared with the WG periodically during WG conference calls / meeting
ISO 14155	Monitor the progress of updated standard and share the updates	
IVDs -- ISO 20916: In vitro diagnostic medical devices	Monitor the progress of draft standard and share the updates	

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WG 5 Work Plan & Activities 2019:

Work Item 4 (Develop & Draft Guidance Documents)	Output	Target & Status Update
1. General Principles of Clinical Investigation Audit & Inspection	Finalize guidance document Continue to monitor a working draft of ISO 14155 and	On hold since we are waiting for ISO 14155 to be published.
2. Identify areas of focus for AHWP WG 5 guidance document for 2019		Completed
3. Conduct a gap analysis between IMDRF/GHTF and AHWP guidance documents	Share the analysis within WG members	Transfer to the year 2020
Work Item 5 (Standards & Best Practices)	**Output**	**Target & Status Update**
Collaboration with ISO 14155 TC on the development of documents	Mutual input into documents	Completed
Work Item 6 (Training)		
Due to changes on guidances as well as standards, trainings for WG 5 and AHWP members are planned during AHWP annual meeting in 2020.		

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Work item 1:

Annual review SWOT Analysis of WG 5 Framework

Strength	Weakness
WG5 members are actively engaged and participate in various standards and global regulatory framework working groups / forums which brings value to the group in sharing different perspectives	As there is limited participation of member economies in the WG 5 with constantly evolving Clinical evaluation and evidence regulations it is pertinent that more and more member economies actively join WG 5
Opportunity	**Threat**
AHWP WG 5 collaboration and networking with other various global forums to foster convergence of AHWP WG 5 endorsed documents	Regulations, standards and guidelines are constantly evolving hence it becomes difficult for AHWP WG5 to keep pace with these continuing changes and finalize guidance documents for endorsement on time.

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Work item 2:

Regular review of Global clinical regulatory updates

I. New and changing clinical regulations in 2019:

Countries	Title
Canada	CMDRs Revisions and New Guidance Document, Public Release of Clinical Information

Summary

- Health Canada updated the Canadian Medical Device Regulations with the addition of section 43.11: Disclosure of Information in Respect of Clinical Studies or Investigational Testing.
- Health Canada has issued a Guidance Document entitled: Public Release of Clinical Information. The guidance document applies to amendments to Food and Drug Regulations and the Medical Device Regulations, which came into force on February 28, 2019.
- These regulatory amendments specify the clinical information in drug submissions and medical device applications that cease to be confidential business information following a final regulatory decision and authorize Health Canada to publicly release this information. This guidance document describes the scope of clinical information eligible for public release and the procedures to remove information that remain CBI and to protect personal information prior to public release.

Work item 2:

Regular review of Global clinical regulatory updates

I. New and changing clinical regulations in 2019:

Countries	Title
Europe	Medical Device Regulation (MDR)

Summary

- Additional updates to Informed Consent documents and other documents awaiting EudaMed database are planned for December 2019 Batch release.

Countries	Title
Japan	Registration of clinical trial status related to machinery and equipment

Summary

- This notification describes the detailed guidance for the registration of clinical study status, which is mentioned in Section 4 of the document "Handling related to notification of clinical trial plan etc. for medical devices etc. (Yakusyokukihatsu 0329No.10, http://www.pmda.go.jp/files/000159013.pdf (Japanese only))" dated March 29, 2013.
  The scope of clinical study, the type of information and the timing to register and update etc. in a public registry in Japan (e.g., Japan Registry of Clinical Trials, etc.) are explained.
  URL for related information: http://www.pmda.go.jp/review-services/trials/0003.html (Japanese only)

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Work item 2:

Comparison of terminology related to clinical investigation among different countries

I. Background:

The AHWP Technical Committee (TC) meeting took place in April 2019. A request was raised to develop a gap analysis document on terminologies related to clinical investigation. This request came up since different terminologies are utilised among IMDRF, GTHF and ISO standards.

II. Action taken:

A gap analysis was completed. The following GCPs were used for gap analysis:

- ISO 14155 FDIS, ICH GCP, EU MDR, US FDA, Japan GCP, China GCP, Malaysia GCP, India MDR/GCP, Indonesia GCP

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Work item 2:

Comparison of terminology related to clinical investigation among different countries

AHWP WG5

Comparison of GCP terminologies among different countries

	ISO FDIS dated 5 April 2018		ICH GCP Rev.2	Indonesia GCP	India MDR	China GCP	Japan GCP	Malaysia Revision	US FDA	EU MDR
	Section/ Terminologies	Definition								
1	3.1 Adverse Device Effect (ADE)	adverse event related to the use of an investigational medical device	Not applicable **Note**: ICH GCP is applicable for pharmaceutical products.	Terminology is used but no definition available.	Terminology is used but no definition available.	Terminology is not used and no definition available.	Terminology is not used and no definition available.	Not applicable **Note**: MY GCP is set up based on ICH GCP.	Terminology is used but no definition available.	Terminology is not used and no definition available.
2	3.2 Adverse Event (AE)	untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated.	Yes, Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.	Terminology is used but no definition available	Terminology is used but no definition available	Yes, Adverse events, refer to the medical events with disadvantages occurred during the clinical trials, no matter whether they are related to investigational medical devices or not.	Yes, The term "adverse event" as used in this Ministerial Ordinance means any disease or injury, or its clinical signs occurring in a subject who has been treated with an investigational device or post-marketing study device.	Yes, Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any undesirable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.	Yes, Adverse event is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects.	Yes, Adverse event means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;
3	3.3 Audit	systematic examination of activities and documents related to clinical investigation performed by (an) independent person(s), to determine whether these activities were conducted, and the data recorded, analyzed and accurately reported, according to the CIP, standard operating procedures, this document and applicable regulatory requirements	Yes, A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).	Yes, Audit of a clinical study may be conducted by the applicant or third party appointed by the applicant to evaluate compliance with the CIP, written procedures, this manual and prevailing regulatory requirement. This audit may cover all the relevant parties, system, facilities and is independent of and separate from routine monitoring or the quality control function.	Terminology is not used and no definition available.	Yes, Audit may be part of routine work of quality management of clinical trials of sponsor or may be adopted to evaluate the effectiveness of monitoring activities, or may be carried out aiming at serious or repeated clinical trial protocol deviation and suspected fabrication.	Yes, The term "audit" as used in this Ministerial Ordinance means an examination of trial-related activities to determine whether the clinical trial or post-marketing study has been conducted in compliance with this Ministerial Ordinance and the protocol or the post-marketing protocol, in order to assure the reliability of data collected in the clinical trial or post-marketing study. Such examination is performed by a sponsor or a post-marketing study sponsor, or by an individual appointed by a sponsor-investigator	Yes, A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).	Terminology is used but no definition available.	Yes, audit the manufacturer's quality management system, in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions of this Regulation which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of this Regulation are met.
4	3.4 Audit Trail	documentation that allows reconstruction of the course of events	Yes, Documentation that allows reconstruction of the course of events.	Terminology is not used and no definition available.	Terminology is not used and no definition available.	Terminology is not used and no definition available.	Terminology is not used and no definition available.	Yes, Documentation that allows reconstruction of the course of events.	Yes, Audit trail means a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record.	Terminology is used but no definition available.

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Work item 2:

Comparison of terminology related to clinical investigation among different countries

III. Result of the gap analysis:

- Since the current version of ISO 14155 was released in 2011, many new and changing requirements (e.g. EU MDR, ICH GCP, US FDA guidance, China GCP) have been introduced in the global clinical regulatory environment. To align with those requirements, the new and changing definitions are introduced in the revised ISO 14155.
- For some countries, while terminologies are used in the GCPs, clear definitions are not available.
- For some countries, GCPs are developed per ICH GCP. Thus, pharma terminologies are used.

IV. Conclusion:

It is recommended to use the definitions from the revised ISO 14155 for development of AHWP WG5 guidance documents.

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3. Work item 3:
Collaboration & Liaison with TC & Global Forums

I. Collaboration with AHWP WG2:

Collaboration is on-going with WG2 on development of Clinical Performance Studies for IVD Medical Devices.

II. IMDRF:

WG5 provided feedback on the following IMDRF draft guidance documents.

- Clinical evaluation,
- Clinical Evidence – Key Definitions and Concepts
- Clinical Investigation

III. ISO TC194/WG4 (ISO14155):

The current status was shared with WG5. Input on draft ISO 14155 DIS were submitted.

IV. ISO TC210 (ISO 20916):

For collaborative activities with WG2 on development of Clinical Performance Studies for IVD Medical Devices, ISO 20916 was used.

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Work Item 4: Identify areas of focus for WG5 activities

GHTF Technical Documents (http://www.imdrf.org/documents/doc-ghtf-sg5.asp)		Is there an equivalent document under AHWP WG5? (http://www.ahwp.info/index.php?q=node/151)	
Document number	Title	yes/no	If yes, add a reference of AHWP WG5 document
GHTF/SG5/N6:2012	GTHF SG5 Clinical Evidence for IVD Medical Devices – November 2012	Yes	AHWP/WG5/F002:2015 Clinical Evidence for IVD Medical Device – Key Definitions and Concepts
GTHF/SG5/N7:2012	GHTF SG5 Scientific Validity Determination and Performance Evaluation – November 2012	Yes	AHWP WG5/F003: 2015 Clinical Evidence for IVD – Scientific Validity Determination and Performance evaluation
GHTF/SG5/N8:2012	GHTF Clinical Performance Studies for IVD Medical Devices – November 2012	No	
GHTF/SG5/N5:2012	Reportable Events During Premarket Clinical Investigations	No	
GHTF/SG5/N4: 2010	GTHF SG5 - Post Market Clinical Follow-Up Studies – November 2009	Yes	AHWP/WG5/F002:2017 Post Market Clinical Follow-Up Studies
GHTF/SG5/N3: 2010	GTHF SG5 – Clinical Investigation – February 2010	Yes	AHWP/WG5/F001:2017 Clinical Investigation
GHTF/SG5/N2R8:2007	GHTF SG5 – Clinical Evaluation – May 2007	Yes	AHWP/WG5/F001:2015 Clinical Evaluation
GHTF/SG5/N1R8	GHTF SG5 – Clinical Evidence – Key Definitions and Concepts – May 2007	Yes	AHWP/WG5/F002:2015 Clinical Evidence for Medical Device – Key Definitions and Concepts

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Recommendation:

Document 1	GHTF/SG5/N8:2012	GHTF Clinical Performance Studies for IVD Medical Devices

- Although the GHTF document GHTF Clinical Performance Studies for IVD Medical Devices was published by GHTF SG5, it was written by the GHTF IVD sub-group.
- WG2 of AHWP has this document noted in its future workplan, as a collaboration item with WG5.
- The document does not appear to require much updating, but should perhaps be reviewed once ISO 20916, In vitro diagnostic medical devices -- Clinical performance studies using specimens from human subjects -- Good study practice, is published. It is currently released as FDIS, for comment by mid-April 2019.
- It is recommended to have a call with Mr. Wen-Wei Tsai, the Chair of WG2 to discuss the timelines for this work item with a view to review perhaps later this year.

Document 2	GHTF/SG5/N5:2012	Reportable Events During Premarket Clinical Investigations

Per the current FIDS of ISO 14155, some changes will be implemented on safety definitions. For example, a note was added in the definition of Adverse Device Effect to clarify that the ADE definition is applicable to a comparator. A new definition on Serious Health Threat has been added. Therefore, it is recommended to develop an AHWP guidance document on this topic after the revised ISO 14155 is released.

Note: Once the revised ISO 14155 and ISO 20916 are available, it is necessary to assess if any updates are required for other AHWP WG5 guidance documents.

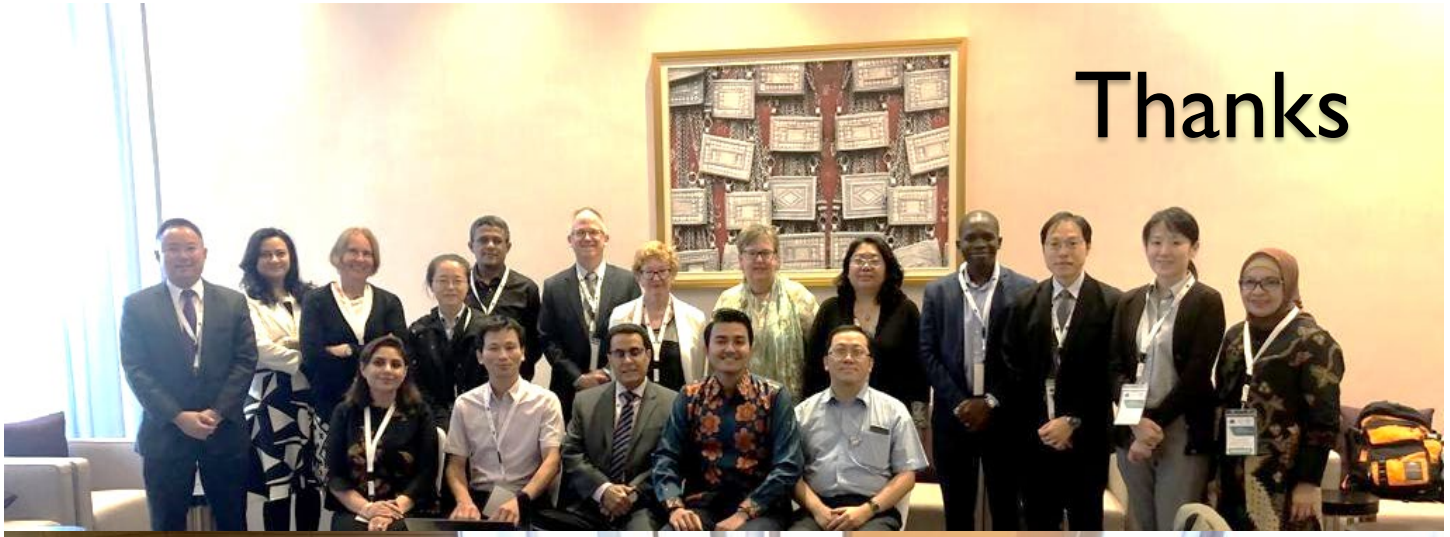
WG 5 Achievements 2019

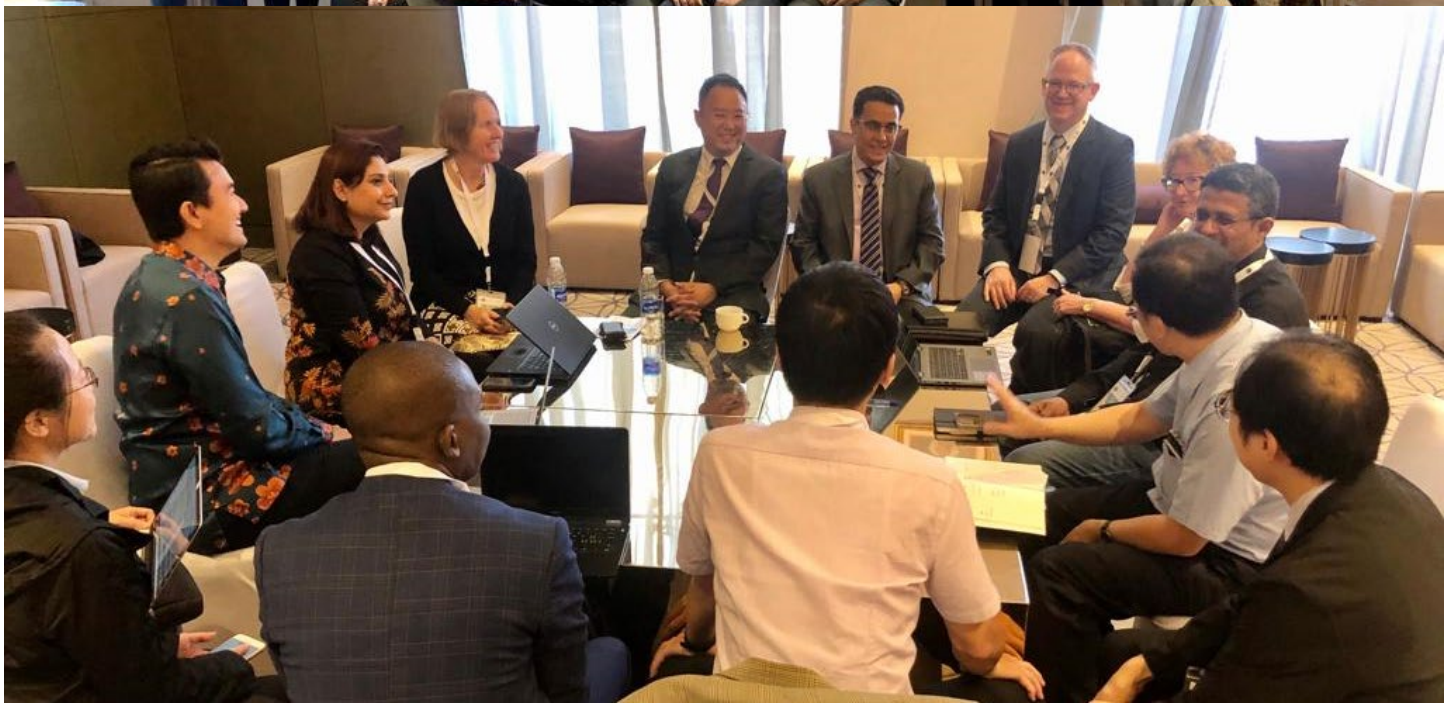
- Cohesive collaboration with AHWP WG2 & other international forums
- On time completion of review and submission of AHWP WG5 comments on IMDRF Guidance Documents (3 Docs) to IMDRF working group chair.
- Constantly reviewing and providing inputs on global clinical performance and safety regulatory updates.

WG 5 Plan 2020

- Collaborate with AHWP WG 2 for IVD Clinical Evidence Guidance document finalization and endorsement in 2020
- Collaborate with AHWP WG4 on AE Terminology
- Review of IMDRF Latest Documents
- Training on new guidance documents and standards.

Thanks





WG6 – Quality System Audit & Assessment

Chair: Abdullah Al Rasheed

Co-Chair: Dr. Vincent LAM

AHWP Annual Meeting
Muscat 2019

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Al Rasheed Abdullah	Saudi Arabia	Regulatory Authority
Dr. Chee Choong, Vincent Lam	Malaysia	Industry
Mr. Tony Low	Malaysia	Industry
Mr. Kumar Asok	India	Industry
Mr. Shankar Vidya	India	Industry
Ms. Sumati Randeo	India	Industry
Ms. Fong An Lee	Chinese Taipei	Industry
Mr. Alber T. W. Li	Chinese Taipei	Industry
Miss Jennifer Han	China	Industry
Ms. Rachel Hyekyung Chung	Korea	Industry
Ms. Hwee Ee Tan	Singapore	Industry
Ms. Jessie Li	China	Industry
Mr. Alhajji Aden Amad	Kuwait	Regulatory Authority
Mr. Kelvin Fan Hong Teng	Singapore	Industry
Ms. Murthy Indira B Narayan	India	Industry
Mr. Nishith Desai	Singapore	Industry
Miss Hailey Chu Hui-ju	Chinese Taipei	Industry
Mr. Peter Kyongho	Korea	Industry
Mr. Kenneth Cheing Teng Wan	Singapore	Industry

Group Action Plan

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Work Item	Deliverables	Status
2018 & 2019		
A guide to understanding best practices in audit life cycle management	GD	On progress Endorsement expected during the annual meeting 2020
A guide to understanding presently available audit duration determination systems.	GD	On progress Endorsement expected during the annual meeting 2020
Conduct training session	workshop	Done
A guidance on how assessment for critical suppliers shall be performed by AOs.	GD	On progress Endorsement expected during the annual meeting 2019

A guide to understanding best practices in audit life cycle management

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- Different MDSAP documents with different topics on the audit life cycle from different angles.
  - AOs req. for RA recognition. (N3)
  - AOs training & competence req. and the RA assessor competence & training requirements.(N4&N6)
  - RA methods for recognition & monitoring by defining assessment program based on N3&N4 requirements. (N5)
  - How to qualify assessor who will assess the AOs. (N8)
  - Grading of NCs. (N11)
  - Audit Report format. (N24)

Rational

- Delegation of duties such as auditing of the quality management systems is an option for Regulatory agencies tasked to ensure the safety and effectiveness of medical devices throughout their lifecycle.
- AHWP economies who plan to appoint conformity assessment bodies are required to address challenges such as defining the general requirements of Auditing Organizations, their competence and how they shall be audited by the regulatory agencies.

Scope

An overview document which will allow the Regulatory authority to view the relevant or applicable IMDRF documents which serve to complete the audit life cycle.

This guidance document serves to summarize the current best practices on audit life cycle management using IMDRF guidance documents.

The right approach for RAs to define general req. of AOs along with their competence

An overview document which will allow the Regulatory authority to view the relevant or applicable IMDRF documents which serve to complete the audit life cycle.

A guide to understanding presently available audit duration determination systems

- MDSAP approach is to mitigate the risk of inconsistent audit time being calculated by different AOs performing similar audit activities with single audit program.
  - Off site Audit time determination (preparation, report writing, etc…) which determined by AOs policies & procedures.
  - Onsite audit duration calculation:
    - audit (initial, surveillance, re-certification)
    - & activities carried out during the audit and must ed. e.g. non-sterile product, products don't require after sales services) shall be considered in audit ation. Conversely, if more than one design or more ufacturing process is selected for audit, which icate the task and must be considered when g audit duration

Calculation of the audit duration is primarily based on the number of tasks associated with audit type

A guide to understanding presently available audit duration determination systems

- IAF approach does not stipulate minimum/maximum times but provides a framework that shall be utilized within a CAB's documented procedures to determine appropriate audit duration, taking into account the specifics of the client to be audited.
  - Audit day = 8h
  - # of personnel depends on the scope of the audit
  - It shows the percentage of the on-site audit and the off-site audit, with considering not to reduce the on-site audit less than 80% of the total audit duration
  - Additional time required for planning and report writing will not be a justification for reducing the on-site audit duration.

A guide to understanding presently available audit duration determination systems

- Issues caused increase in audit duration
  - Complicated logistics (more building, multisite).
  - Staff with different language.
  - The size of the site
  - The complexity of the processes
  - High degree of regulation in terms of security, safety & maturity.

Rational

- A comparative study of available best practices by regulators will serve to provide a cross sectional analysis to understand their nature and bases and lead consequently to developing effective guidelines on the planning of audits on economic operators such as medical device manufacturers, distributors, and authorized representatives.

Scope

- serves to summarize the current best practices on audit duration determination with the aim of eventually developing an audit duration guidance for regulators for the purpose of auditing medical device premises.

Guidance Document on the current best practices in the determination of regulatory audit duration.

Guidance on auditing of critical suppliers

The manufacturer should establish and maintain documented procedures and records to ensure that products or services purchased from their suppliers meet the relevant regulatory requirements.

Purchasing controls will be first assessed by the Notified Body at the premises of the manufacturer

- A guidance on how assessment for critical suppliers shall be performed by Aos to assure that the quality of the purchasing system of the manufacturer are in compliance with the specified requirements.
- Criteria for audit of supplier's premises
- reporting

The purpose of auditing the purchasing control subsystem is to verify that the manufacturer's processes ensure that products, components, materials and services provided by suppliers, (including contractors and consultants) are in conformity

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WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

References

- ISO 13485: 2003 Medical devices — Quality management systems — Requirements for regulatory purposes
- IAF MD5 & MD9
- IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2)Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
- IMDRF/MDSAP WG/N4FINAL:2013 Competence and Training Requirements for Auditing Organizations
- IMDRF/MDSAP WG/N5FINAL:2013 Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations
- IMDRF/MDSAP WG/N6FINAL:2013 Regulatory Authority Assessor Competence and Training Requirements
- IMDRF/MDSAP WG/N8 FINAL: 2015 Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations
- IMDRF/MDSAP WG/N11FINAL:2014 MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

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ASIAN HARMONIZATION WORKING PARTY

Asian Harmonization Working Party (AHWP)

Technical Committee Working Group 7

Quality Management System -Operation and Implementation

Chair: Ms. Wang Aijun

Co-Chair: Mr. Ee Bin Liew

Secretary: Ms. Annie Yin

Advisor : Mr. Hideki Asai

24th AHWP Annual Meeting
Sultanate of Oman
Nov 13, 2019

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

ASIAN HARMONIZATION WORKING PARTY

Current WG7 Membership

Breakdown by Country

China (6)
Japan (1)
India (2)
Republic of Kazakhstan (1)
Saudi Arabia (2)

- Refreshed membership
- Actively engaging with recruiting regulators
- Better country distribution
- Committed members

ASIAN HARMONIZATION WORKING PARTY

WG7 Workplan 2018-2020

Item	Work Item	Deliverables	Action Plan and Timeline
1	Comparison study of new ISO13485 vs. QMS requirements in each country	Matrix of AHWP country QMS requirement status Compare the country specific QMS requirement vs. the new ISO13485 standards. Present the study report at AHWP TC and release to AHWP members	• Q4 2018: Call for volunteers for drafting committee • Q3 2019: Survey of QMS requirements in each country • Q4 2019: Comparison study of new ISO13485 vs. QMS requirements in each country • Q2 2020: Study Report of Asian Country QMS Requirement Comparing to ISO13485 • Q4 2020: Present the study report at AHWP TC and release to AHWP members
2	QMS Consideration for manufacturers and importers for localisation	Create guidance document and introduce to AHWP member economies	• Q3 2018: Call for volunteers for drafting committee (same group of people for Work Item 1) • Q4 2019: Proposal for Guidance Document • Q4 2020: Complete Guidance Document. and release to AHWP members

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WG7 Workplan 2018-2020

- Item 1: ISO 13485 / TC 210 WG1

2018			2019				2020		
Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Call for volunteers for WG1 drafting committee work		Comparison study of new ISO13485 vs. AP country/region quality system requirement			Draft Asian quality system handbook			Present at AHWP TC and release to AHWP members	

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Summary of AHWP QMS Survey

Currently, 16 member economies have responded, others pending.

	Non-regulated	Unknown	GMP or GSP(GDP)	Other Local Regulation	Not Applicable
QMS Requirements	3 Brunei Darussalam, Cambodia, Laos PDR	1 Myanmar	9 China, Indonesia, Philippines, Singapore, Malaysia, Taiwan, Pakistan, Thailand, Republic of Korea,	2 India, Vietnam	1 Hongkong SAR, China

	Mandatory, Full	Optional, Full	Optional, Partial	Non-regulated	Unknown	Not Applicable
ISO:13485 Adoption	6 Singapore, Philippines, Malaysia, Republic of Korea, Taiwan, Vietnam (from 2020 Jan.)	2 China, India, Vietnam (before 2020 Jan.)	2 Indonesia, Thailand	3 Brunei Darussalam, Cambodia, Laos PDR	1 Myanmar	2 Hongkong SAR China, Pakistan

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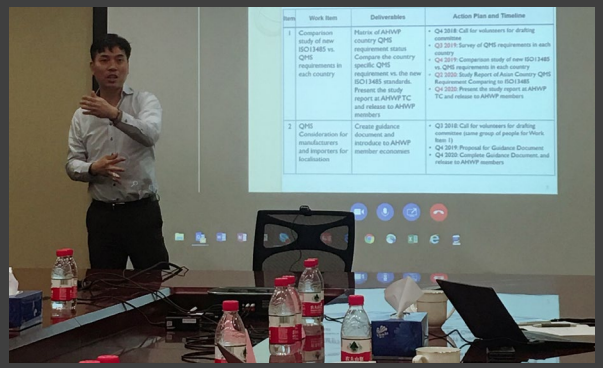
WG7 Workplan 2018-2020

Collaboration and Liaison

Liaison	Collaboration
ISO TC210 WG1	AHG for High level structure **– continued engagement** Note: the **systematic review for ISO13485 was completed** - no revision in the coming years.
ISO TC210 JWG1	ISO14971/ISO TR24971 **completed,** pending release
ISO TC210 WG6	ISO TR 20416 – **completed**, pending release
International Accreditation Forum (IAF)	1. User Advisory Committee 2. Participate in future IAF Industry Day



AHWP TC WG7 f2f Meeting

- Beijing, Sept 2019, CFDI office
- **12 members** attended for one day for workplan discussion and wok items update

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Guidance Document for Medical Device Organisations - Product Localisation for Manufacturing and Importation

- This guidance document provides general methodologies on various aspects of localisation for quality management system of manufacturers
- Quality systems considerations for manufacturers to **comply with the manufacturing requirements in the local regulated country**
- Quality systems considerations for manufacturers to **comply with the importation requirements of medical device**. For example,
  - Labelling and identification
  - Graphic user interface
  - Language
  - Power supply

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Guidance Document for Medical Device Organisations - Product Localisation for Manufacturing and Importation

Benefit to AWHP countries

- More efficient compliance to setting up the local factory in the member economies
- More efficient compliance in importation to various regulated countries.

Expected Audience:

- Manufacturers looking to manufacture in local regulated country
- Manufacturers looking to import to local regulated country

Proposed Structure of Guidance Document

- Forward – background of the creation of the document
- Introduction – purpose, linkages to global harmonisation / regulatory convergence
- Purpose, Scope, Definitions
- How to utilise the document
- Deliverables for localisation (both situations)

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Proposed Structure of Guidance Document

- For both in-country localised factory, and localisation for imported devices
  - Describe in the design and development process - Indicate which areas steps may have localisation considerations
  - Describe in the strategic marketing planning process - Indicate which areas steps may have localisation considerations
  - What are the likely elements of localisation
  - Specific methods for each element of localisation
- What are the quality system considerations?
  - Documentation, design input, output, verification, production controls, design transfer, storage/distribution

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

DRAFT DOCUMENT

Title: **Guidance Document for Medical Device Organisations - Product Localisation for Manufacturing and Importation**

Authoring Group: Working Group 7 – QMS- Operation and Implementation

Date: [November 11st, 2019]

Dir. Wang Aijin
Chair, Working Group 1

Mr. Liew Ee Bin
Co Chair, Working Group 2

Preface

The document herein was produced by the Asian Harmonization Working Party (AHWP), a voluntary group of medical device regulators and industry from AHWP members in Asia and beyond. The document has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the AHWP.

Introduction

Many medical device companies, large and small, constantly face challenges when navigating various regulatory requirements in order to achieve market entry. For ISO13485:2016, many clauses mention "applicable regulatory requirements" to emphasize the importance of regulatory compliance as the ISO13485 standard in its intent, was established for regulatory purposes. Regardless of shifting regulatory requirements as well as the increasing regulatory oversight by countries previously unregulated, implementation of product localisation for both importation and manufacturing, has the same fundamental aspects to consider in the organisation's quality management system. AHWP Technical Committee Working Group 7 – Quality Management System – Operation and Implementation (2018-2020), as part of the Working Group Workplan, aims to provide specific guidance on product localisation

Purpose

This document is to provide the general principles of quality management system considerations with regards to the tasks and deliverables necessary to achieve regulatory compliance in various countries and markets, with respect to product localisation for imported medical devices, and manufacturing sites that have transferred to another country with a regulatory framework

Scope

This document applies to applicable medical devices and IVD medical devices intended to be marketed in to regulated countries, or manufactured in regulated countries.

Guidance Document for Manufacturers with regards to Product Localisation for Manufacturing and Importation
AHWP TCWG7

1 Definitions

1.1 Authorized Representative

Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation
[SOURCE: GHTF/SG1/N055:2009, 5.2]

1.2 Distributor

Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user

Note 1 to entry: More than one distributor may be involved in the supply chain.

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.
[SOURCE: GHTF/SG1/N055:2009, 5.3]

1.3 Importer

natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed
[SOURCE: GHTF/SG1/N055:2009, 5.4]

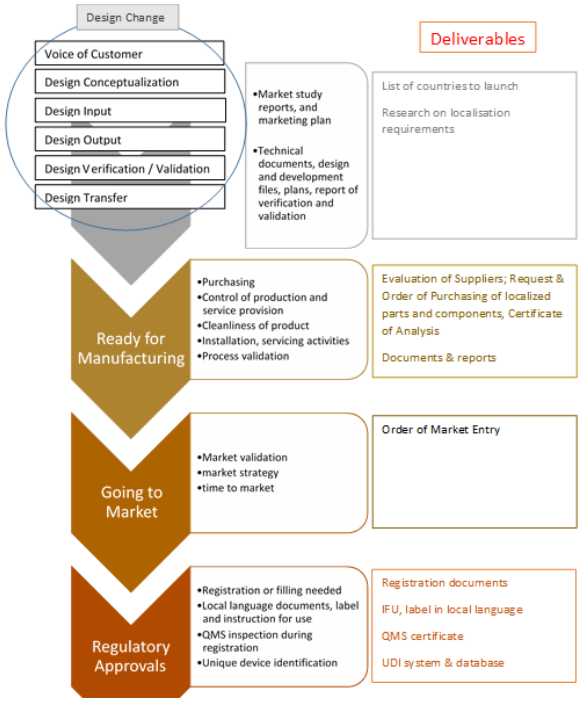
1.4 Instructions for use (IFU)

Instructions for Use refers to general and technical information provided by the manufacturer to inform the device user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use.
(GHTF/SG1/N70:2011)

Note: Electronic Instructions for Use (eIFU) refers to instructions displayed in electronic form:

- by the device ("help" system, or graphical user interface (GUI)-based dialogues),
- contained in portable electronic storage media supplied by the manufacturer together with the device, or
- online, through the manufacturer's website. (TGA # D18-10786654)

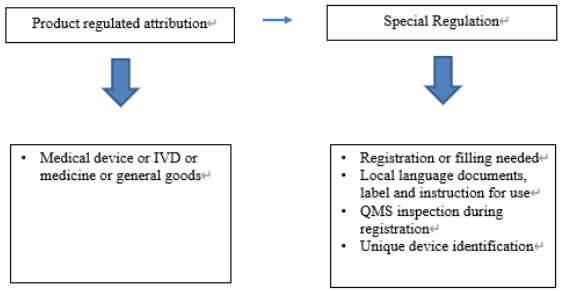
2. Process Steps



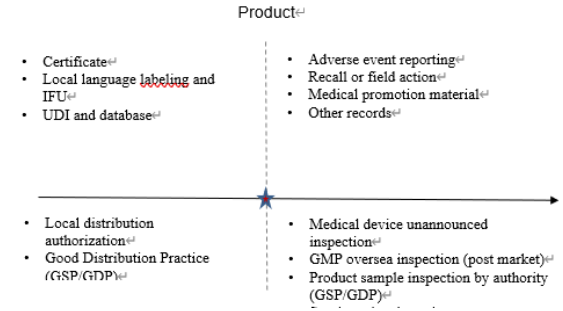
Guidance Document for Manufacturers with regards to Product Localisation for Manufacturing and Importation
AHWP TCWG7

Considerations for manufacturers about product localization for importation

Pre Market:



Post Market



3. Clause by Clause Analysis

The manufacturer should consider below elements besides ISO 13485 requirements when they plan to import their medical device to specific region.

The guidance text is based on Clause 4 to Clause 8 of the ISO13485 Standard.

"Additional Considerations for Requirements" – refer to guidance text for manufacturer if they plan to launch medical device in one specific region.

ISO 13485: 2016 (Clause / Sub-Clause)	Additional Considerations
4 Quality management system	
4.1 General requirements	
4.1.1 4.1.2 4.1.3 4.1.4 4.1.5 4.1.6	Local regulations and standards should be identified, evaluated, documented and implemented in quality system, including both regulations and standards for pre market and post market. - All related regulations, their appendix and guideline documents should be considered according to product and the organization's role . - Any gap for regulation and standard should be addressed and documented the rational Organization define the role in target region, legal manufacturer, importer, distributor or authorized representative. Organization should ensure if there is any special requirements for software used in the quality system, such as language localization, server location, information security.
4.2 Documentation requirements	

Guidance Document for Manufacturers with regards to Product Localisation for Manufacturing and Importation
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	GMP,MDSAP or product inspection * Product distribution related regulation, GSP/GDP
4.2.2 Quality manual	NA
4.2.3 Medical device file	NA
4.2.4 control of documents	Some region has special procedure requirements, local language requirement. Organization should develop these procedures.
4.2.5 control of records	Organization should know if any special record retention requirements in target region, such as warehouse temperature record frequency, code chain record.
5 Management responsibility	
5.1 Management commitment	NA
5.2 Customer focus	NA
5.3 Quality policy	NA
5.4 Planning	NA
5.4.1 Quality objective	NA
5.4.2 Quality management system planning	NA
5.5 Responsibility, authority and communication	

	should be included in quality agreement to clarify the role and responsibility.
8.2.2 Complaint handling	Complaint handling covers all commercial distribution region. If distributor take this responsibility, this should be included in quality agreement to clarify the role and responsibility.
8.2.3 Reporting to regulatory authorities	Organization should know adverse event reporting criteria and timeline in target region, and report adverse event according to regulation requirements Organization should consider if follow up reporting is necessary to authority in target region. Organization should have resource to report adverse event to authority system, if have. If distributor take this responsibility, this should be included in quality agreement to clarify the role and responsibility.
8.2.4 Internal audit	NA
8.2.5 Monitoring and measurement of processes	NA
8.2.6 Monitoring and measurement of product	If final product test report, verification report or certificate of conformance is required. Organization shall consider local standard when they develop product measurement or test criteria. If product sample retention is required. Organization shall document the product retention procedure, ensure resource and infrastructure and keep record according to regulation.

Guidance Document for Manufacturers with regards to Product Localisation for Manufacturing and Importation
AHWP TCWG7

8.4 Analysis of data	Data shall include data from all market. If any region has significant different data trend, special analysis should be performed
8.5 Improvement	
8.5.1 General	Some authorities have mandatory and special AE or PMS regulation, such as timeline, template, language, submission method. Organization need to understand the requirement and adopt these into their PMS plan and report.
8.5.2 Corrective action	NA
8.5.3 Preventive action	NA

- **5. Deliverables Lists**

- **6. Conclusion**

END OF DOCUMENT

Thank you and Contact Us!

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- Co-Chair: Mr. Ee Bin Liew eebin.liew@access2hc.com
- Secretary: Ms. Annie Yin qyin6@ITS.JNJ.com
- Advisor : Mr. Hideki Asai hideki.asai.cw@hitachi-hightech.com

WG 8 – Standards

Chair: **Salbiah Yaakop**
Medical Device Authority, Malaysia

Co-Chair: **Tony Low**
Industry – Malaysia

Secretary: **Hazman** (Regulatory Authority)
Grace Wong (Industry)

Advisor: **Dr Gret W. Bos**

AHWP Annual Meeting
11-14 Nov 2019
Muscat, Oman

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

WG 8 MEETINGS

MEETING's HELD

1. Meeting 1/2018: 22 Oct 2018, Malaysia
2. Meeting 1/2019: 15 Mar 2019, Malaysia
3. Meeting 2/2019: 6 Sept 2019, Malaysia

MEETING's PLANNED

- Meeting 1/2020: Jan 2020, *Venue TBD*

Work Plan Update 2018 - 2020

AHWP ASIAN HARMONIZATION WORKING PARTY

Item	Work Item	Deliverables	Action Plan and Timeline
1	**Recruitment of core members**	To gain active representation from Regulatory Authorities of member economies and industry member whom will be responsible to review, populate (& eventual maintenance of completed) List of Standards assigned	*(ongoing)* New member(s): 1. Mr. Raghavan Nair Asok Kumar
2	**Working Relationships**	[pursue] Working Relationship with ISO TC 210, *etc. henceforth*	*(ongoing)* (WG 8 is **represented in ISO TC 210** and **ISO TC 210 / IEC TC 62** exploratory group on life cycle processes on medical device). WG 8 Chair attended the ISO TC 210 meeting on 7-11 Oct 2019 in London and **tabled the intent for New Proposal** on **COP Good Maintenance Management of Active Medical Devices.**

Work Plan Update 2018 - 2020

AHWP ASIAN HARMONIZATION WORKING PARTY

Item	Work Item	Deliverables	Action Plan and Timeline
4	**Adoption of ISO 16142-1:2016**, *Medical devices - Recognized **E**ssential **P**rinciples of **S**afety and **P**erformance of medical devices - **Part 1**: General essential principles and additional specific essential principles for all **non - IVD** medical devices and guidance on the selection of standards*	Recommendation to AHWP member economies on adoption for harmonization a standard for conformity assessment / demonstrating compliance with the EPSP's for ***non - IVD*** *medical devices*	**2018-2019** Voting paper was sent to TC secretariat on 5 March 2019 for circulation to all AHWP member economies for obtaining agreement of Full adoption of ISO 16142-1 and ISO 16142-2 Standards. It was presented to AHWP-TC meeting in Riyadh, Saudi Arabia on 9-10 April 2019 where **adoption was endorsed for both the ISO 16142-1 and ISO 16142-2 Standards.** These 2 work items are considered completed.
3	**Adoption of ISO 16142-2:2017**, *Medical devices - Recognized **E**ssential **P**rinciples of **S**afety and **P**erformance of medical devices - **Part 2**: General essential principles and additional specific essential principles for all **IVD** medical devices and guidance on the selection of standards.*	Recommendation to AHWP member economies on adoption for harmonization a standard for conformity assessment / demonstrating compliance with the EPSP's for ***IVD*** *medical devices*	

Work Plan Update 2018 - 2020

AHWP ASIAN HARMONIZATION WORKING PARTY

Item	Work Item	Deliverables	Action Plan and Timeline
5	New work item: **Code of Practice for Good Engineering Maintenance Management of Medical Devices**	For proposal as an ISO standard: • applies to all active medical equipment placed for use in any healthcare facility or any other facility which requires maintenance. • Covers matters pertaining to responsibilities, scheduled maintenance, unscheduled maintenance, acceptance testing, mechanisms to avoid failure or breakdown during use, uptime, quality assurance program (QAP), maintenance management information system (MMIS), management of warranties, decommissioned equipment, disposal of equipment, processes for handling hazardous/contaminated equipment, incidents and hazards, user training, stock of genuine spares, on-site library, workshop setup, advisory service, procurement of equipment	**2019-2020** Draft and comment template was sent on 19 Feb 2019 to WG 8 members, TC chair & Secretariat for distribution and comment. Comments received and deliberated in WG 8 meeting held on 15 Mar 2019 and 6 Sep 2019. At the meeting it was agreed to further open the draft for comments for another 2 weeks. Document title was agreed as: *Active Medical Device – Requirements for Good Engineering Maintenance Management* **The WG plans to release the document for comment leading to document finalization in its 1/2020 meeting.** **The the preliminary draft and NP was presented in ISO/TC 210 in London, UK on 7-11 Oct19.**

Work Plan Update 2018 - 2020

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ASIAN HARMONIZATION WORKING PARTY

Item	Work Item	Deliverables	Action Plan and Timeline
6	Collation and onward maintenance of the **listing of standards** used for medical devices regulatory purposes that are **recognized by AHWP member countries**	1. Circulation list of 1102 valid international standards on Medical Devices (ISO/IEC) 2. Indication of the level of recognition of these standards (Y- fully recognized, N-not recognized, P-partially recognized or mandatory) 3. Firstly work on WG 8 member countries: Malaysia, Korea, India, Indonesia, Singapore, China, Taiwan 4. Then other AHWP member countries.	1. Work Item approval: 2018 Q3~Q4. 2. Generate list of standard for AHWP member economies with a clear indication of fully or partially recognized/mandatory standards 2019 Q3 3. Generate standard list for other AHWP member countries Communication sent to TC Chair & Secretariat on 20 Feb 2019 to **request the industry representatives of AHWP member countries to maintain their respective List of Standards** which has been generated **As of to date, WG 8 has not received any nominations from member countries on the representatives for maintaining this list.** Recommendation was made that access to these lists are made available through AHWP website.

Other matters

1. **Suggestions / Comments on Netherland Position on the Revision of Medical Device Software Life-Cycle (IEC 62304)**

Dr. Ir. Peter W.J. Linders **requested feedback** from WG 8 members on Netherlands position paper on **revision of Medical Device Software Life-Cycle (IEC 62304)**. This position paper has since been circulated to WG members accordingly.

2. Development of WG8 Term of Reference (TOR)

The meeting agreed to develop the official TOR for WG 8. It is to provide a clarity as to the scope and function of the WG.

Other matters

3. Proposal / suggestion on New Work Items

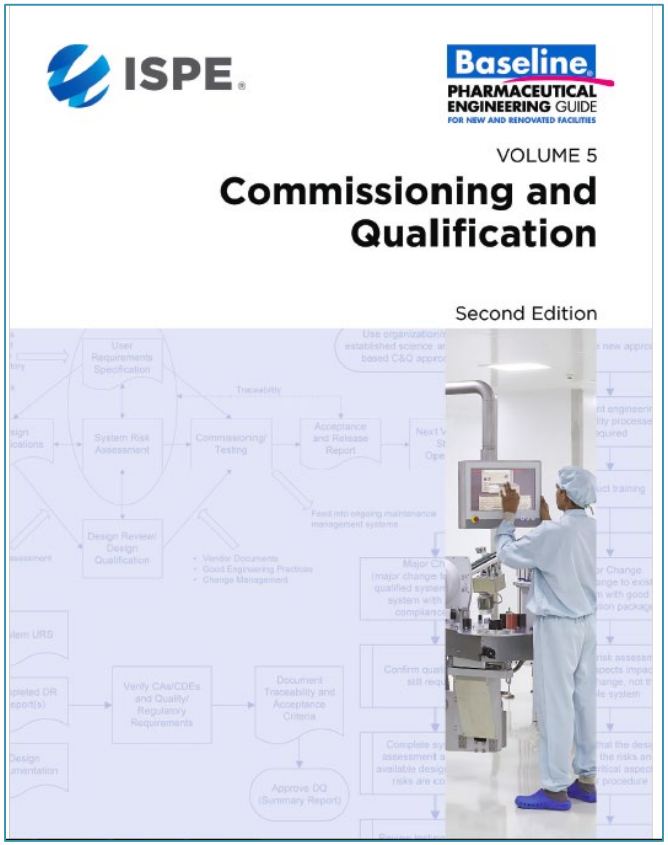
The WG members are encouraged to propose new work items for 2019 - 2020. Two work plans were suggested during the meeting [NP's to follow]:

a) Development of Guidance on regulatory control of **Medical Gas Systems** and any available related standards to adopt e.g. EU guidelines/ national Standards, etc.)

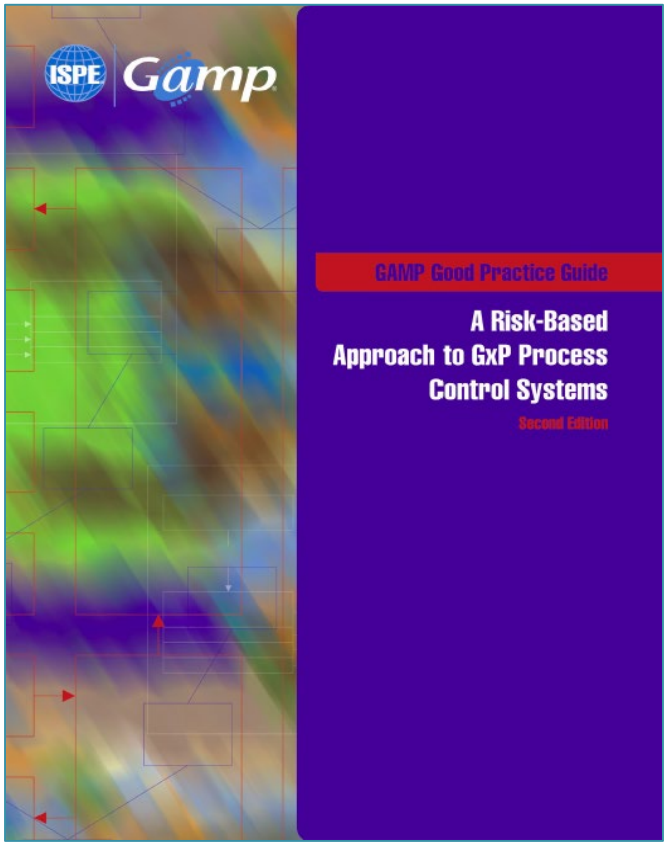
Other matters

b) Review the suitability to adopt the ISPE guidelines:

i. **Process Validation & Building / Facility Qualification** – Risk Based Approach per ISPE Vol.5 Ed.2



ii. **Computerized Systems** – Risk Based Approach per GAMP Ed.2



for your support

New proposal for development of ISO Standard

Title: **Active Medical Device – Good Engineering Maintenance Management .**

Scope: **This standard specifies requirements on good maintenance management of active medical devices.**

This standard applies to active medical devices placed for use in any healthcare facility or any other facility which requires maintenance.

This standard is not applicable to any medical device placed and used in any facility not intended to be used on human.

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Purpose and justification of the proposal

ASIAN HARMONIZATION WORKING PARTY

This standard is strongly recommended as a reference to address the requirements of medical devices during their life-cycle upon being placed for use to ensure:

- their functioning in the intended manner;
- continued safety for the patient and the user; and
- Interruptions of use are minimized.

MS 2058 has been used towards certification of establishments with GDPMD (Good distribution practice of medical devices), where establishments deal with active medical devices (where applicable, based on the device specification, and the manufacturer instructions). In Malaysia, GDPMD certification is mandatory for all establishments other than a manufacturer, to apply for license. For manufacturers, ISO 13485 certification is required and requirements of the MS 2058 needs to be reflected in their procedures if they are dealing with active medical devices which requires maintenance.

Benefits/impact

This standard is good reference to ensure devices already placed in the healthcare institutions are well managed and there is healthy collaboration between the industry players and the users of medical devices. Other than medical device manufacturers, the biomedical service providers will also be directly impacted by the use of this standard.

This standard could be used for regulators of medical devices to ensure continuous safety and proper management of medical devices throughout its lifespan. Users of medical devices will refer to this standard during purchasing, installation up to disposal of the medical devices. This standard will ensure that competent personnel will be involved in the maintenance, installation, testing, commissioning and acceptance of medical devices. It could be used as reference on competency requirements of biomedical technical personnel, service providers.

Member countries are requested to liaise with National Standards Bodies of their respective countries to vote approval on this New Work Item Proposal from ISO/TC 210

for your support

WG9 (U&N)

Chair: Jun LI

Co-Chair: Victoria QU

Secretary: Li YI

AHWP Annual Meeting
November 13, Muscat

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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The Goal and Objective of WG 9

WG 9

UDI & Nomenclature

- Establishment of **a communication platform** between the regulatory agencies and industry
- Promote coordinative and **harmonized approach of UDI and nomenclature** during the development and implementation of related regulations and policies;
- Urge **global convergence of medical device UDI and nomenclature regulations** on behalf of the AHWP members and to actively participate in the coordination of international harmonization initiatives.

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2018-2020 UDI Road Map

Review of 2019 Activities - UDI

Follow up the global UDI activities

Education

Whitepaper

GLOBAL STATUS OF UDI

Medical Device Industry:

- Many countries are or will be implementing UDI
- UDI regulations are in the final phases of adoption in some major markets
- Strict compliance deadlines
- All medical and in vitro devices will need to have an UDI, at every level of packaging (unless exempted)
- Developing and driving harmonized processes across the device ecosystem provides reliable traceability of products
- Companies selling devices in foreign countries, need to be aware of and familiar with the regional regulations

IMDRF Update – UDI Application Guide

The UDI Application Guide is to be used as a supplement to the IMDRF UDI Guidance Document adopted in 2013 which was developed as a high-level conceptual framework containing the basic core concepts of a UDI system

Progress Report

- 3 UDI application guidance documents have been released as final guidance.
- The WI has officially closed.
- GMTA capacity building did not approved by AHWP

A main UDI Application Guide

- **Endorsed** at the IMDRF-15 as the main UDI Application Guide, to be used as a supplement to the IMDRF UDI Guidance (IMDRF/WG/N7Final:2013)

An information document mapping the use/specifications of UDI data elements in different jurisdictions

Endorsed at IMDRF -15. An information document mapping the use/specifications of UDI data elements in different jurisdictions (or UDI data elements dictionary)

An information document related to the use of UDI in electronic health sources

- Endorsed at IMDRF-15. An information document on test cases related to the use of UDI in electronic healthcare systems.

AHWP remains to be the only international organization that continuously monitor the development of global UDI which also keep developing implementation guidance.

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Recent Development on UDI Implementation Among WG9 Members

China

- Actively participate IMDRF UDI Application WI
- UDI Rule published in Aug. 2019.
- 1st wave UDI pilot identified.
- UDI database under development.

Saudi Arabia

- Saudi UDI Rule issued in end 2018.
- Created Saudi UDI Database.
- Enforce UDI to all medical Devices on several phases based on risk.

S. Korea

- Published UDI rule

•Propose upload MD-related information with the IMDIS
•Established MDIIC
•More implementation details to be released soon.
•Compliance time line for UDI compliance and UDI database compliance proposed.

Chinese Taipei

- Voluntary UDI guidance issued and implemented in Oct. 2015.
- Establish traceability e-submission platform by Q1 2020.
- Trainings to all stakeholders ongoing.

China UDI Update

UDI Rule

- Published Aug. 27th, 2019
- Implementati

UDI Standard

- Basic Standard
- Informatic

UDI Database (CUDID)

- API
- Bulk Upload

UDI Implementation Pilot

- Phased-in

End-to-end life-cycle management, partner with NHC

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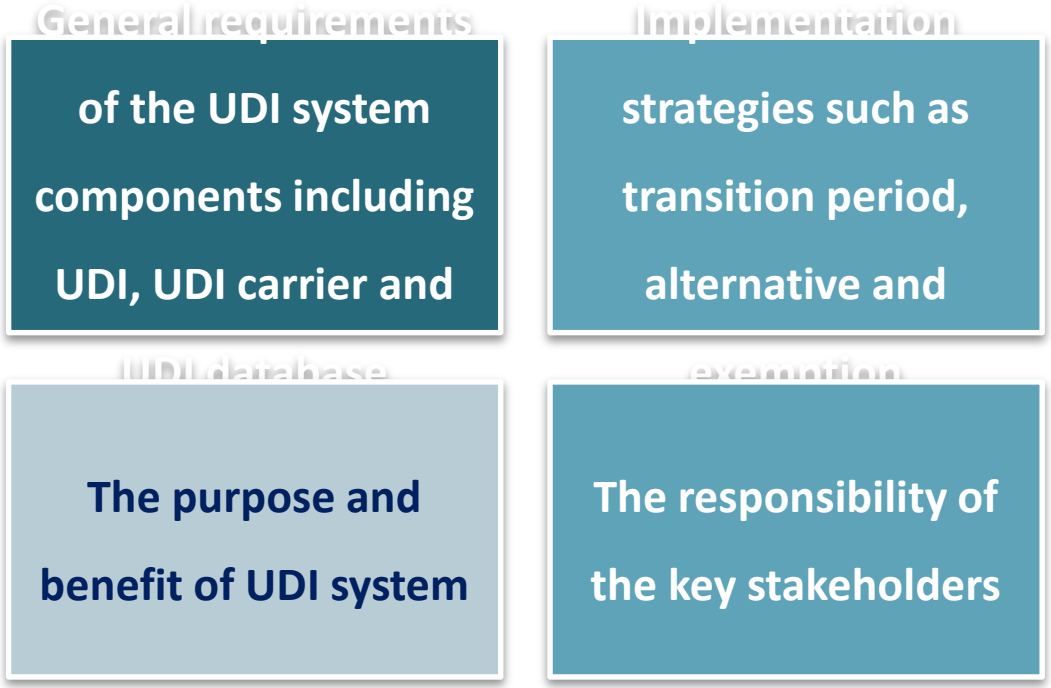
Harmonization Activities in UDI Training & Sharing

UDI Survey & Analysis

- The content of AHWP UDI survey - 25 questions including single choice, multiple choice and open questions distributed among WG9 members.



UDI White Paper-Background

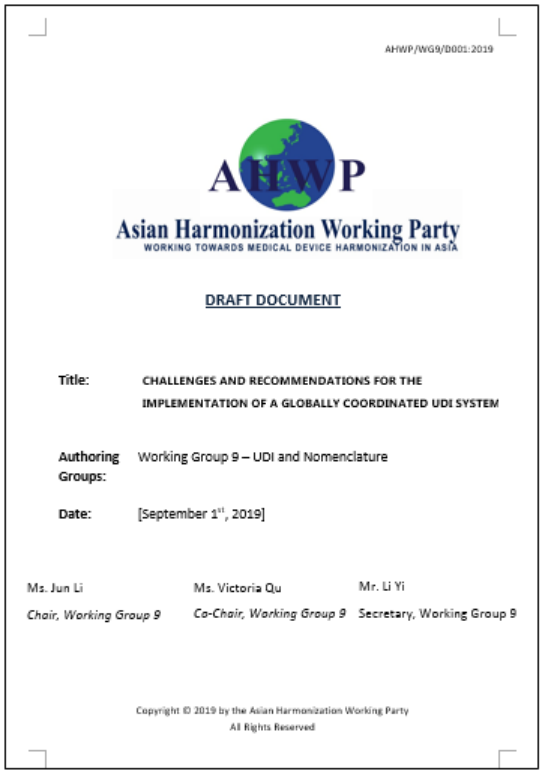
- The understanding of UDI system varies
  - Countries and regions: developing and developed, implemented and still watching, industry status, supervision mode…
  - Type of company: size, product made, marketing area…
- To develop a document more suitable for the AHWP member

UDI White Paper-Background

- IMDRF UDI Guidance (N7) & Application Guide (N48)
  - Framework of a global harmonized UDI system
  - Approach to the application of a UDI system to support IMDRF UDI Guidance

- AHWP UDI White Paper
  - Key points to understand the IMDRF UDI document
  - Major challenges of UDI implantation & the strategies to overcome

UDI White Paper-Content



AHWP/WG9/D001:2019

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DRAFT DOCUMENT

Title: CHALLENGES AND RECOMMENDATIONS FOR THE IMPLEMENTATION OF A GLOBALLY COORDINATED UDI SYSTEM

Authoring Groups: Working Group 9 – UDI and Nomenclature

Date: [September 1st, 2019]

Ms. Jun Li, *Chair, Working Group 9*
Ms. Victoria Qu, *Co-Chair, Working Group 9*
Mr. Li Yi, Secretary, Working Group 9

CHALLENGES AND RECOMMENDATIONS FOR THE IMPLEMENTATION OF A GLOBALLY COORDINATED UDI SYSTEM

1. International progress of UDI system for medical devices

2. Introduction

3. Unique identification of medical devices

4. UDI data carrier

5. UDI database of medical devices

6. Responsibilities of the parties

7. Challenges in the implementation of UDI and suggested ways to cope with them

8. Best practices for global coordination of UDI

NOMENCLATURE UPDATES

Monitor - EU

- The European Medical Device Coordination Group (MDCG) plans to use Italy's CND codes as the basis for the Eudamed device database nomenclature.
- CND codes will be mapped by MDCG to Global Medical Device Nomenclature (GMDN) for ease of use. This will allow all operators registering their device to find CND nomenclature equivalent to a GMDN code.
- Using CND nomenclature provides public access to medical device codes within Eudamed free of charge.
- The Italian coding system has been in use since 2007 to support that country's device database; the CND system is up-to-date and used on a daily basis.

Lead - China

- Developed Nomenclature Guidance

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COMMUNICATE, DEVELOP, SHARE, CONVERGENCE

Thank you