



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Amendment 5 to the Asian Harmonization Working Party
House Rules

Authoring Group: AHWP SECRETARIAT

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1. Purpose

This document proposes to make amendment to the Asian Harmonization Working Party (AHWP) & House Rules (hereafter as "AHWP House Rules") as detailed in section 3 below under "Proposed Amendments to the AHWP House Rules".

2. Background

- 2.1. The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F003:2016 resolved in the 21st AHWP Meeting and announced on 26 November 2016.
- 2.2. To clarify the roles and responsibilities of AHWPTC members, and AHWPTC WGs and STG membership.
- 2.3. The amendments to AHWP House Rules in section 3 of this document are prepared to facilitate the aforementioned purposes.
- 2.4. AHWP & AHWPTC Terms of Reference can override AHWP House Rules when there is any discrepancy.

3. Proposed Amendments to the AHWP House Rules

- 3.1. The below new clause 18 Roles and Responsibilities of Technical Committee is proposed to be added in AHWP House Rules after the current clause 17 Advisor to AHWPTC:-

Clause 18 Roles and Responsibilities of Technical Committee

A. Role and Responsibility of AHWPTC Chair

- i. The AHWPTC Chair shall conduct the decision-making on the overall WG work plan.*
- ii. The AHWPTC Chair shall designate a TC secretary who can dedicate his/her time and effort for AHWPTC, especially for WI and Guidance document management.*
- iii. The AHWPTC Chair shall conduct the final approval on WG members, WG advisors, Capacity Building trainers/leaders.*
- iv. The AHWPTC Chair shall designate TC advisors.*
- v. The AHWPTC Chair shall assign tasks to TC advisors.*
- vi. The AHWPTC Chair shall make the overall confirmation of TC workshop program and In-country training.*
- vii. The AHWPTC Chair shall sign communication letter with international partners, e.g. IMDRF, ISO, etc., for technical related subjects.*
- viii. The AHWPTC Chair shall conduct the overall approval on AHWPTC and WG member's nomination for representing AHWP in international organization, e.g. ISO, IMDRF, etc.*
- ix. The AHWPTC Chair shall make the overall confirmation of speaker on behalf of AHWP or AHWPTC.*

B. Role and Responsibility of AHWPTC Co-chair (Regulatory Authority)

- i. The AHWPTC Co-chair shall conduct the overall coordination of program of AHWPTC workshop.*
- ii. The AHWPTC Co-chair shall be the contact person for important international organizations, e.g. IMDRF, WHO, APEC, PAHO, etc.*
- iii. The AHWPTC Co-chair shall take over AHWPTC Chair's responsibilities in case of absence.*
- iv. The AHWPTC Co-chair shall recommend AHWPTC WG member's nomination for representing AHWP in international organizations.*
- v. The AHWPTC Co-chair shall recommend speaker on behalf of AHWP or AHWPTC.*

C. Role and Responsibility of AHWPTC Co-chair (Industry)

- i. The AHWPTC Co-chair shall be the contact person for Industry Liaison Members, i.e. APACMed, DITTA and GSI.*
- ii. The AHWPTC Co-chair shall conduct the overall coordination of Joint-workshop program of AHWPTC workshop with Liaison Members.*
- iii. The AHWPTC Co-chair shall recommend AHWPTC WG member nomination for representing AHWP in international organizations.*
- iv. The AHWPTC Co-chair shall recommend speaker on behalf of AHWP or AHWPTC.*

D. Role and Responsibility of WG Chairs and Co-chairs

- i. The WG Chairs and Co-chairs shall conduct the management of WG members and updates.*
- ii. The WG Chairs and Co-chairs shall designate member with the confirmation by AHWPTC Chair.*
- iii. The WG Chairs and Co-chairs shall make progress report to AHWPTC Chair every 3 months.*
- iv. The WG Chairs and Co-chairs shall set up prior or post side-meeting to AHWP Meeting to avoid any influences on AHWP main meetings.*

E. Additional Role and Responsibility of AHWPTC Advisors

- i. The AHWPTC Advisors shall designate a leader of AHWPTC Advisors*
- ii. The AHWPTC Advisors shall report assignment to AHWPTC Chair.*

- 3.2. The below new clause 19 AHWPTC WGs and STG Membership is proposed to be added in AHWP House Rules after the proposed clause 18 Roles and Responsibilities of Technical Committee:-

Clause 19 AHWPTC WGs and STG Membership

- A. Only members of AHWP member economies can be accepted as WGs or STG members.*
- B. In case of absence of WG chair, AHWPTC Chair can assign one of the WGs or STG regulatory members with the most expertise along with AHWPTC Co-chairs agreement.*
- C. Members of non-AHWP member economies can participate in WGs or STG as an observer or can become a WG advisor on a case-by-case basis with an approval of TC Chair.*
- D. All WGs and STG members need to be confirmed by TC Chair.*

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