



Global Harmonization Working Party

Towards Medical Device Harmonization

FINAL DOCUMENT

Title: Amendment 8 to the Global Harmonization Working Party (GHWP) & GHWP Technical Committee (GHWPTC) Terms of Reference (TOR)

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1. Purpose

This document proposes to make amendment to the Global Harmonization Working Party (GHWP) & GHWP Technical Committee (GHWPTC) Terms of Reference (hereafter as "TOR") as detailed in section 3 below under "Proposed Amendment to the GHWP TOR".

2. Background

- 2.1. The current TOR is specified under the Final Document AHWP/SECRETARIAT/F001:2019 resolved in 24th AHWP Meeting and announced on 22 Nov 2019.
- 2.2. This amendment of TOR is mainly to revise "Asian Harmonization Working Party" to "Global Harmonization Working Party", "AHWP" to "GHWP" and "AHWPTC" to "GHWPTC", due to re-branding of AHWP into GHWP.
- 2.3. The Amendments will follow the below general principles: -
 - 2.3.1. TOR can override the GHWP House Rules when there is any discrepancy.
- 2.4. The following roles and responsibilities will remain unchanged after nomenclature revision:
 - 2.4.1. Voting rights.
 - 2.4.2. Responsibilities.
 - 2.4.3. Participation.
 - 2.4.4. Name of member.

3. Proposed Amendments to the GHWP TOR

- 3.1. The name of the Working Party in all TOR Clauses: -

[Asian Harmonization Working Party](#)

Is proposed to be replaced by: -

[Global Harmonization Working Party](#)

- 3.2. The abbreviation of the Working Party in all TOR Clauses: -

[AHWP](#)

Is proposed to be replaced by: -

[GHWP](#)

- 3.3. The abbreviation of the Technical Committee in all TOR Clauses: -

[AHWPTC](#)

Is proposed to be replaced by: -

[GHWPTC](#)

- 3.4. The following under the current Clause 1.1 Vision: -

[To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry in Asia and other continents.](#)

Is proposed to be replaced by: -

To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry.

3.5. The following under the current Clause 1.3 on Goals: -

To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

Is proposed to be replaced by: -

To develop and recommend approaches for the **global** convergence and harmonization of medical device regulations.

3.6. The current Clause 1.4A on Membership: -

AHWP is a non-profit organization which consists of regulatory authorities and industry. Its members come from the Medical Device Regulatory Authorities (“Regulatory Authorities”) and the medical device industry including government agencies which are not Medical Device Regulatory Authorities (“Industry”) of a country or region (Region includes, for example, a Special Administrative Region of one country). Membership is open to those representatives from the Asian and other continents that support the above stated goals. Any regulatory authority and industry of a country and/or regions interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the AHWP Secretariat.

Is proposed to be replaced by: -

GHWP is a non-profit organization which consists of regulatory authorities and industry. Its members come from the Medical Device Regulatory Authorities (“Regulatory Authorities”) and the medical device industry including government agencies which are not Medical Device Regulatory Authorities (“Industry”) of a country or region (Region includes, for example, a Special Administrative Region of one country). Membership is open to **all stakeholders** that support the above stated goals. Any regulatory authority and industry of a country and/or regions interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the **GHWP** Secretariat.

3.7. The following Clause 2.4C is proposed to be added under Working Groups (WGs) and Special Task Groups (STGs) Membership: -

Chairs of Working Groups and Special Task Groups are preferably from different countries / regions, except for the case where there is only one candidate for a vacant of WG Chair or STG Chair, such candidate would also be considered.

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