



Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Amendment 9 to the Global Harmonization Working Party (GHWP) & GHWP Technical Committee (GHWPTC) Terms of Reference (TOR)

Authoring Group: GHWP SECRETARIAT

Date: 15th February 2022

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/F001:2021 resolved in 25th AHWP/GHWP Meeting and announced on 1st Dec 2021.
- 2.2. Under the existing TOR, Official Observers must be approved by the unanimous consent of the voting members present in GHWP annual meetings.
- 2.3. This amendment of TOR is mainly to revise the endorsement requirements on the applications for joining GHWP as Official Observers.
- 2.4. The new endorsement requirements for joining GHWP as Official Observers will be aligned with the existing endorsement requirements for joining GHWP as Liaison Members, both do not participate in the decision-making process and have no voting rights in GHWP meetings.
- 2.5. The Amendments will follow the general principle that TOR can override the GHWP House Rules when there is any discrepancy.

3. Proposed Amendments to the GHWP TOR

- 3.1. The following under the current Clause 1.6 on Official Observers:-

The GHWP leadership may designate Official Observers on the basis of expected contribution and value. [Official Observers must be approved by the unanimous consent of the voting members present in GHWP annual meetings.](#) Official Observers do not participate in the decision making process.

Is proposed to be replaced by:-

The GHWP leadership may designate Official Observers on the basis of expected contribution and value. [Official Observers must be approved by GHWP Chair.](#) Official Observers do not participate in the decision making process.

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