



Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Amendment 8 to the Global Harmonization Working Party House Rules

Authoring Group: GHWP SECRETARIAT

Date: 18th March 2022

1. Purpose

This document proposes to make amendment to the Global Harmonization Working Party (GHWP) House Rules (hereafter as “GHWP House Rules”) as detailed in section 3 below under “Proposed Amendments to the GHWP House Rules”.

2. Background

2.1. The current GHWP House Rules is specified under the Final Document GHWP/SECRETARIAT/F002:2021 resolved in 25th AHWP Meeting and announced on 1st Dec 2021.

2.2. This amendment of House Rules mainly to formalize the application of the “New Document Request / New Work Item Proposed Form” for the endorsement by GHWP leadership and GHWPTC leadership on new work items and new initiatives before the preparation of DRAFT documents and other documents in the endorsement procedures.

2.3. The amendments will follow the below general principles: -

2.3.1. GHWP & GHWPTC Terms of Reference can override the GHWP House Rules when there is any discrepancy.

3. Proposed Amendments to the GHWP House Rules

3.1. The following under Clause 14A of the GHWP House Rules: -

Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions /endorsements.

Is proposed to be replaced by: -

Chairs of committees, working groups, special task groups and the Secretariat could [propose new work items](#) and initiate the preparation of documents for discussions, approvals and resolutions/endorsements, [by submitting the “New Document Request / New Work Item Proposal Form” for the endorsement by the GHWP Leadership and GHWPTC Leadership.](#)

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