



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Amendment 3 to the Asian Harmonization Working Party House Rules

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Date: November 21, 2014

1. **Purpose**

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

2. **Background**

- 2.1 The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F002:2013 resolved in the 18th AHWP Meeting and announced on 6 December 2013.
- 2.2 To clarify the roles of AHWP Technical Committee (TC) Advisors as the responsibilities of AHWP TC Leaders and TC Advisors should be distinguished.
- 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 Amendment to the AHWP House Rules**

- 3.1 The below new clause 17.B Advisor to AHWPTC is proposed to be added in AHWP House Rules between the current clause 17.A and 17.B, with numbering of clauses under Clause 17. Advisor to AHWPTC to be updated accordingly:-

Clause 17 Advisor to AHWPTC

B. The role of TC Advisors is to bring their knowledge and experience to support the activities of the AHWP. This is accomplished via such activities as providing objective advice, gauging future trends for new strategic positioning, advocating for the AHWP's harmonization work with the increase in its visibility globally, as well as providing input on the scope of work through comments and recommendations, providing support to TC's and WG's activities covering guidelines development, for the decision making by AHWP TC and WG leaders on WG work items. TC Advisors operate and provide input under the direction of the TC Chair.

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