

Asian Harmonization Working Party

RKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA Official Website: www.ahwp.info

To: AHWP Secretariat (secretariat@ahwp.info)

Nomination Form C

(For WG/STG Chair and Co-chair)

As according to the Terms of Reference (TOR) and House Rules of AHWP, each Work Group (WG) or STG (Special Task Group) shall have one Chair from the Regulatory Authority and one Co-chair from the Industry. Since there was no mentioning of detail mechanism for the nomination of WG/STG Chair and Co-chair in the TOR and House Rules, this form is designed based on the decision by the AHWPTC on 20 Oct 2011 regarding nomination requirements for WG/STG Chair and Co-chair.

PART 1 – Type of Nomination The below filled nomination is for the election of Chair (Regulatory Authority) / Co-chair (Industry) (please delete as appropriate) of the following selected WG/STG of AHWPTC in the coming AHWP Annual Meeting in Seoul, 2014:- (Please select by ticking either ONE of the following boxes) Work Group 1 (WG1): Pre-market – General MD Work Group 2 (WG2): Pre-market - IVDD Work Group 3 (WG3): Pre-market – Software as a Medical Device **Work Group 4 (WG4): Post-market** Work Group 5 (WG5): Clinical Performance & Safety Work Group 6 (WG6): Quality Management System - Audit & Assessment Work Group 7 (WG7): Quality Management System - Operation & Implementation Work Group 8 (WG8): Standards Work Group 9 (WG9): Training Special Task Group (STG): Special Task Group on UDI & Nomenclature PART 2 – Nominee's Information and Signatory Name of Nominee Job Title of Nominee Organization Member Economy Email Contact This is to confirm that I am eligible to be nominated and agreed to be nominated for the above position as stated in Part 1 of this nomination form. (# Eligible as according to the Remarks in Section 4 of this Nomination Form C, as well as the guidance note regarding WG and STG terms of reference available on AHWP website) (Signatory of the Nominee)



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PART 3 – Supporters' Information

Supporter ONE		
Name :	 	
Title :		
Organization :	 	
Member Economy :		
Email Contact :		
Supporter TWO		
Name :	 	
Title :		
Organization :	 	
Member Economy :		
Email Contact :		

PART 4 – Remarks

- a) A nominee of WG/STG Chair or Co-chair must be a member of AHWP, and from one of the AHWP member economies.
- b) The nominee may not need to attend the WG/STG Chair or Co-chair Election.
- c) The two supporters in Part 3 of this Nomination Form C must either be an AHWP Primary Representative (Regulatory Authority) or AHWP Primary Representative (Industry) from any AHWP member economies.
- d) Each supporter in Part 3 of this Nomination Form C can only support **ONE** nominee for each of the position as stated in Part 1 of this nomination form.
- e) Only the submission of nomination with i) <u>completely filled Nomination Form C ii) a brief CV (maximum 2 pages in A4 size paper) of the nominee</u> will be processed. The submission should reach the AHWP Secretariat at secretariat@ahwp.info <u>on or before 11:59 p.m. (GMT+8), 7 November 2014</u>. Any late submission will not be considered.
- f) The AHWPTC Chair has the full authority to review the voting rights and validity of the nominee, and to reject any applications that cannot fulfill the requirements as stated in this Nomination Form C.
- g) Should there be any queries, please contact the AHWP Secretariat at "secretariat@ahwp.info".