



# Discussion on Terms of Reference for Bearers of AHWPTC

**Al Faisaliah Hotel, Riyadh  
Kingdom of Saudi Arabia  
27 November 2010**



ASIAN HARMONIZATION  
WORKING PARTY

# Agenda

- **Proposal on the refinement of TOR**
- **Resolution to form a consistent structure of Office Bearers in both AHWP & AHWPTC**
- **Others**

# Draft for AHWP TC WG Membership Criteria



## AHWP TC WG Membership Criteria

### Introduction

AHWP Technical Committee currently has the following Work Group and Special Task Groups:

Work Group 01: Pre-market Requirements  
 Work Group 02: Post- market Requirements  
 Work Group 03: Quality System Requirements.  
 Work Group 04: Auditing  
 Wouk Group 05: Clinical Evaluations  
 Work Group 06: Training  
 STG: Legal Entity  
 STG: Nomenclature

This document is intended to facilitate the management of AHWP TC Working Group activities by adequately describing the roles and responsibilities of all those involved in each WG work. The roles and responsibilities outlined in this document are designed to be flexible, so that should the need arise, the AHWP TC can respond to challenges with respect to its objectives in a timely manner.

### 1.0 Membership and WG meetings

Each WG is a voluntary group of representatives from the medical device regulatory authorities (Regulator) or medical device industry including government agencies whom are not medical device regulatory authorities (Industry / Non-Regulator). Membership is primarily open to representatives from AHWP member economies. Representatives from non AHWP member economies may also be part of the Working Group depending on the agreement of the Chair and Co-chair of each WG. The full list of members will be kept by the AHWP Secretariat.

Each WG shall have one Chair from the Regulator, one Co-chair from the Industry and certain members comprising of representatives from both Regulator and Industry. It is recommended that members include one or more representatives from each AHWP member economies and with an appropriate balance between the

number of industry and regulatory technical experts representing different device types or regulatory classes.

In exceptional cases, the WG Chair/Co-chair may authorize an individual, with appropriate knowledge and expertise, to participate in a WG meeting.

Each WG will meet as often as necessary to conduct WG work effectively, but generally no less than once prior to an AHWP TC meeting. Meetings are at the call of the Chair/Co-chair and may be conducted by teleconference or video-conference if necessary.

### 1.1 Membership Criteria

The following qualities are reviewed by WG Chair/Co-chair when assessing applicants applying for membership:

- Expertise in the subject matter,
- Ability to participate in most WG meetings,
- Ability to represent effectively the interests of the geographic area and its regulators or industry,
- Ability to report effectively on WG meetings, and
- Ability to call for and consolidate comments and positions of the respective geographic area on the WG document

The minimum participation required for each WG member is as follows:

- 1 AHWP TC meeting attendance and 1 t-con within a calendar year; OR
- 2 teleconference attendance within a calendar year;

If the above criteria are not met, the WG Chair/Co-chair can make the decision on the continued membership based on the members' contribution in other aspects.

### 1.2 Application Procedures

- 1) The Applicant will apply for a WG membership through an APPLICATION FORM No:.....
- 2) WG Chair/Co-chair will determine the suitability of the applicant and a decision on the membership acceptance will be made
- 3) Upon acceptance by WG Chair/Co-chair, the application is forwarded to AHWP Secretariat to check for multiple WG membership. Applicant's participation as a full WG member is restricted to 2 WGs

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- 4.Upon acceptance, the application is submitted to AHWP TC Chair for endorsement.
- 5.Applicant becomes a full member of WG upon successful endorsement
- 6.The continued membership of the member will be reviewed annually and is subject to the fulfillment of the membership criteria conditions. The final decision is made by the WG Chair and Co-chairs.

## 2.0 Observers


WG members may nominate observers to the WG meetings.

Such nominations must be made for specific meetings and must be addressed to the WG Chair/Co-chair for participation in the WG meetings.

Participation depends on the agreement of WG Chair/Co-chair.



# Registration Form for AHWP TC WG



**AHWP TC Working Group Registration Form**

New application       Update of Contact Details

Name: \_\_\_\_\_

Industry:  No of years of direct experience:

Regulator:

Others:  Please specify: \_\_\_\_\_

Company: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Phone: Office: \_\_\_\_\_ Home: \_\_\_\_\_ Mobile: \_\_\_\_\_

FAX: \_\_\_\_\_

Email: \_\_\_\_\_  
 \_\_\_\_\_

Working experience in regulatory affairs:  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

I wish to apply to be a member of:- WG\*\* No: [ ] (Name of WG\*\*: \_\_\_\_\_) as a Member\* / Observer \*(delete as required)

Are you a member of other WGs? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please name the WG and status of membership:- WG No: [ ] (Name of WG: \_\_\_\_\_)

[\*\* WG – AHWP TC Work Group]

What are the main reasons why you would like to be part of this AHWP WG?  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Please complete the form and submit to :

The Chair & Co-Chairs  
 WG No [ ] AHWP TC  
 c/o AHWP TC Secretariat ( Attn : Mr Jack WONG; Jack.Wong@siggroup.com)

To update the changes in your contact details please submit this completed form to the above email addresses.



# For Endorsement

**Al Faisaliah Hotel, Riyadh  
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27 November 2010**