



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

The 4-Step Procedure for Preparing AHWP Official Documents

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7 June 2012



Content

- ◆ The 4-step Procedure of going through Drafting, Call for Comment, Discussion, Approval and/or Resolutions of AHWP Official Documents at AHWP Meetings
- ◆ The Process for Documenting AHWP Reference Documents

The 4-step Procedure with 4-Type of Doc

AHWP Final Documents (including Guidance Documents)

Step 4

FINAL

- Documents accepted, approved and/or passed resolutions
- Available at AHWP web as AHWP official documents

Step 3

PROPOSED FINAL

- Documents prepared for approvals and/or resolutions
- Post on AHWP website + circulations → Call for Comments

Step 2

PROPOSED

- Documents discussed in AHWP and/or TC Meetings
- Post on AHWP website + circulations → Call for Comments

Step 1

DRAFT

- Initialed by: Chairs of Committees/ WGs / STGs / Secretariat
- Documents discussed within group members

Example:

Endorsing a GHTF Guidance Doc as an AHWP Guidance Doc (4-step Procedure)

AHWP Guidance Documents

Step 4

- a. Label as “(doc name)_FINAL”
- b. Secretariat post on AHWP website under Final Document & Guidance Document
- c. **AHWP Guidance Document (as a kind of Final Doc) will bind to all AHWP members**

Step 3

- a. Necessary revision → Label as “(doc name)_PROPOSED FINAL”
- b. WG Chair/Co-chair present in AHWP Annual Meeting for resolutions, and/or approvals
- c. After the meeting: Post on AHWP website + email circulations → Call for Comments
- d. Further revision

Step 2

- a. Necessary revision → Label as “(doc name)_PROPOSED”
- b. WG Chair/Co-chair present in the TC Meeting
- c. After the meeting: Post on AHWP website + email circulations → Call for Comments

Step 1

- a. Convert to an AHWP document and label as “(doc name)_DRAFT” (please quote the reference)
- b. Discussed within WG members

Procedure for Documenting an AHWP Reference Document

(no need to go through the 4-step Procedure)

1. Initialed by: TC/WGs/STGs
2. Discussed within group members
3. Endorsed by Chair & Co-chair
4. Discussed and Endorsed in TC Meeting
5. Post on AHWP website under Reference Doc

AHWP Reference Documents are NOT binding to all AHWP members

Example:

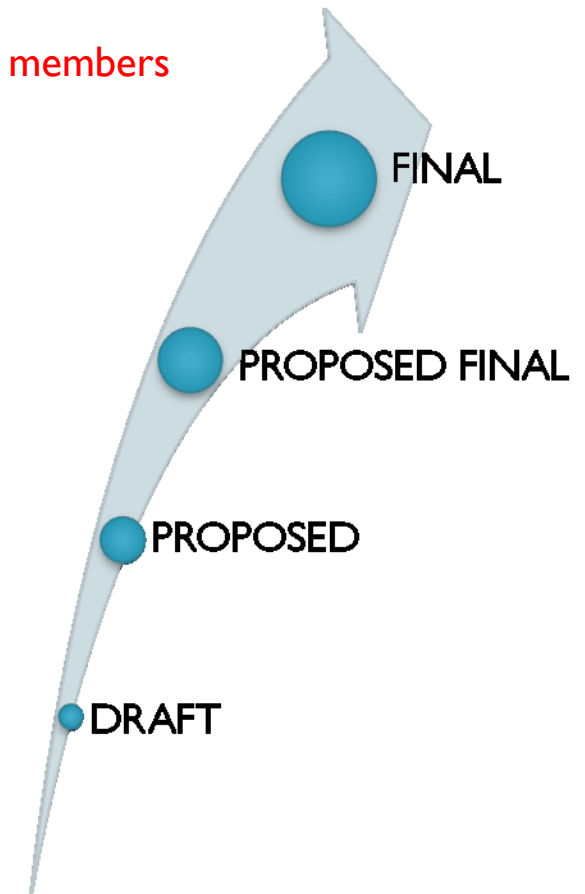
Endorsing an AHWP Reference Document

AHWP
Reference Documents

Mapping table of STEP and CSDT

1. Discussed within WG01 members
2. Endorsed by WG01 Chair & Co-chair
3. Discussed and endorsed at TC Meeting
4. Post on AHWP website under Reference Doc

AHWP
Final & Guidance Documents





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Guidance Documents

Adoption of "The Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers"

Updated: Wed, 02/11/2011 - 16:25

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Final Documents on Safety Alert Dissemination System (SADS) and Survey Post Market Surveillance System

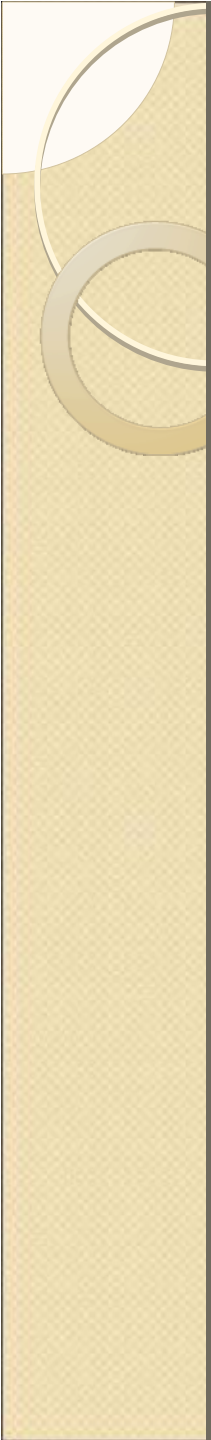
Updated: Sun, 02/11/2008 - 15:40

[Read more](#)

GUIDANCE for Member Economy hosting the Meetings of AHWP or its Technical Committees

Updated: Fri, 24/11/2006 - 16:20

[Read more](#)



Please forward your enquiries, comments and suggestions to Bryan SO / Carol LIU of the AHWP Secretariat
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Thank You!