

# WG 8 – Standards

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AHWP 21<sup>st</sup> TC Meeting  
7th Dec 2017, India



Asian Harmonization Working Party  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# Proposed Work Plan 2015 - 2018

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Create List of Recognised Standards used in AHWP member economies – <b>Phase 1</b>	Identify & list AHWP individual member economies Recognised Standards used for medical device regulatory purposes.	Apr 2015 – Oct 2015 <b>DRAFT - complete</b>
2	Create List of Recognised Standards used in AHWP member economies – <b>Phase 2.1 &amp; 2.2</b>	Identify & list AHWP individual member economies <u>not covered under Phase 1</u> Recognised Standards used for medical device regulatory purposes.	2.1 Jan 2016 – Dec 2016 <b>DRAFT - complete</b> 2.2 Jan 2016 – Oct 2017
3	Recruitment of core members	To gain active representation from Regulatory Authorities of member economies and industry member whom will be responsible to review, populate (& <i>eventual maintenance of completed</i> ) List of Standards assigned	2015 – 2018 (ongoing )
4	Update of contemporary List of Recognised Standards	<ul style="list-style-type: none"> <li>Roll out of final list for AHWP member (+ new) economies with Recognised Standards in place</li> <li>Endorsement of Paper by 21<sup>st</sup> AHWP TC Meeting (2017)</li> </ul>	Ph.1 List Dec 2015 – Dec 2016 Ph.2 List Dec 2017

# Proposed Work Plan 2015 - 2018

Priority	Work Item	Deliverables	Action Plan and Timeline
5	Progressive	Identification of new work item upon completion of List of Recognised Standards and endorsement of [proposed] AHWP Recognized Standards ( <i>including "commonly accepted" Standards</i> ).	2017
6	(pursue) Working Relationship	ISO TC 210, etc	henceforth
7	New Work Items	Code of Practices for Building, Equipment, People and Process Validation	To be proposed at 21 <sup>st</sup> Meeting in India

## WG Progress Update

# List of Recognised Standards used in AHWP member economies – Phase I

**Status:** List (1<sup>st</sup> Draft) being revised and updated prior to circulation to member economies for:

1. Confirmation and enhancement.
2. Appointment of representative (from Regulatory Authority (*preferred*) or Industry) for above task.

ASEAN	Middle East & Africa	Asia (non ASEAN) & South America
<ul style="list-style-type: none"> <li>• Indonesia</li> <li>• Thailand</li> <li>• Malaysia</li> <li>• Philippines</li> <li>• Singapore</li> </ul>	<ul style="list-style-type: none"> <li>• Abu Dhabi (UAE)</li> <li>• Jordan</li> <li>• South Africa</li> <li>• Kuwait</li> <li>• Tanzania</li> </ul>	<ul style="list-style-type: none"> <li>• Chinese Taipei</li> <li>• Hong Kong SAR</li> <li>• India</li> <li>• China*</li> <li>• South Korea</li> </ul>

## WG Progress Update

# List of Recognised Standards used in AHWP member economies – Phase 2

**Status:** List collation to commence as of 21<sup>st</sup> TC meeting:

1. Confirmation on availability of such Recognised Standards by the economy. Collation if available.
2. Appointment of representative (from Regulatory Authority (*preferred*) or Industry) for completion of 1<sup>st</sup> draft – contingent of item #1 above.

ASEAN	Middle East & Africa	Asia (non ASEAN) & South America
<ul style="list-style-type: none"> <li>• Laos</li> <li>• Myanmar</li> <li>• Cambodia</li> <li>• Vietnam</li> <li>• Brunei</li> </ul>	<ul style="list-style-type: none"> <li>• Saudi Arabia</li> <li>• Yemen</li> <li>• Oman</li> <li>• Bahrain</li> <li>• Zimbabwe</li> </ul>	<ul style="list-style-type: none"> <li>• Pakistan</li> <li>• Chile</li> <li>• Kazakhstan</li> <li>• Mongolia</li> </ul>

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Tack ju faleminderit  
Asante 谢谢 Tak mulțumesc  
kiitos Gracías  
Salamat! Terima kasih Aliquam  
Merci Dankie Obrigado  
ありがとう köszönöm grazie  
Aliquam Go raibh maith agat  
děkuii Thank you