



ASIAN HARMONIZATION  
WORKING PARTY

# **WG3 (QMS) update**

**AHWP TC Meeting**

**Manila, Philippines 5<sup>th</sup> - 7<sup>th</sup> June 2012**

**By**

**Ali Al Dalaan (WG Chair)**








**Ee Bin Liew (WG Co-chair)**



# WG3 Strategic Objectives

- **Recognize** the similarities and differences of the QMS requirements within the AHWP; strengthen similarities, work on gaps and differences to harmonize towards ISO 13485
- **Review and revise** GHTF QMS guidance documents and current knowledge base to facilitate easier adoption by AHWP member economies; build up AHWP member economy QMS knowledge capability
- **Establish a credible voice** for AHWP on QMS standards and regulations

# WG3 Work Plan 2012 - 2014

Work Items / Time	2012										2013									
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	
Review Guidance documents	Review <a href="#">N19</a> documents and comments on it		Review <a href="#">N15</a> and receive the comments on it						Review <a href="#">N99 1-10</a> document and receive comments on it				Review <a href="#">N17</a> and <a href="#">N18</a> document							
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ISO13485 / TC210			Review and comment on any coming update related to ISO 13485 2003 and TC 210 documents						Continue ISO13485 and TC 210 documents work.					Continue ISO13485 and TC 210 documents work.						
QMS survey for AHWP		Draft analysis complete				present final results and recommendations														
New Initiatives					Receive any initiative and proposed work				Receive any initiative and proposed work					Receive any initiative and proposed work						
New guidance documents											 provide new proposed doc									
Meetings		TC meeting in Philippines	SG3 meeting in Ottawa			10 in Cali forn	AHWP Annual meeting in Taipei													

## 3. Work Plan Progress 2012-2014

Priority	Work Item	Deliverables	Action Plan and Timeline
1	AHWP QMS Survey; QMS Adoption and Implementation in AHWP member economies	<p>Completed all member economies survey forms, full analysis of results</p> <p>Develop a strategy for assisting countries to prioritize QMS activities based on QMS survey results and local activities (manufacturing, distribution)</p>	<p>Collect remaining surveys <b>(REAL challenge!)</b></p> <p>Analyze results question by question <b>(completed)</b></p> <p>Survey complete by July 2012, strategic actions by Oct 2012</p>
2	Joint AHWP -WG3 GHTF SG3 activity	NI9 "Nonconformity Grading System for Regulatory Purposes and Information Exchange"	Last meeting to review public comment and finalized document the on 9-12 July 2012 <b>(Ongoing)</b>
3	Joint AHWP WG3 GHTF SG3, ISO/TC210 /WGI meetings	<p>ISO13485 update (user requirements survey, TC210 collaboration etc.)</p> <p>AHWP join ISO/TC210</p> <p>Continue working and providing input on the revision of ISO 13485 - 2003</p>	<p>WG3 Chair &amp; S. Advisor Participated. March 27-29 ,2012 .Chiswick UK <b>(Completed)</b></p> <p>AHWP Accepted as a Liaison Member with ISO. <b>Completed. WG3 members Ali, Ee Bin, Jack Albert Li are now members</b></p> <p>Oct 9-12 October 2012 meeting in Santa Rosa, CA.</p>

### 3. WG3 Plan Progress 2012-2014

Priority	Work Item	Deliverables	Action Plan and Timeline
4	<p>Review released documents</p> <p>N17 Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers.</p> <p>N18 Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes</p> <p>N15 R8/2005 Implementation of Risk Management Principles and Activities Within a Quality Management System</p> <p>N99-10 (Edition 2) Quality Management Systems - Process Validation Guidance</p>	<p>Revised to be more useful and usable guidance documents for adoption in AHWP member economies</p>	<p>Comment via standard GHTF process, 2013- 2014</p>
5	<p>QMS Training Program</p>	<p>Develop training and information sharing program for QMS in conjunction with ISO</p>	<p>To work with WG6 (Training) <b>(Engage with WG6 in June 2012)</b></p>