ASIAN HARMONIZATION WORKING PARTY

WG3 (QMS) update

AHWP TC Meeting

Bangkok, Thailand 26th - 27th Feb 2013

By

Ali Al Dalaan (WG Chair)

WG Plan, May 2012 – November 2013

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 N19 documents and comments on it		Review N15 and receive the comments on it						1-Continuo N15 work 2-Review N99 1-10 document and receive comments on it					Review N17 and N18 documents					
						Waiting N19 Doc approval from GHTF SC		Post N19 on AHWP website for public comments			Start to write the modification of this doc. If any					request for approval.			
ISO13485 / TC210			Review and comment on any coming update related to ISO 13485 2003 and TC 210 documents					Continue ISO 13485 and TC 210 documents work. Japan March 11-15 2013						Continue ISO13485 and TC 210 documents work.					
QMS survey for AHWP		Draft analysis complete					Present final results and recommendations	*New guidance documents(QMS Guidance documents for local industry ,Distributer and importer)											
(IMDRF)MDSAP						Participate and comment on WG3 (PD1)N3R3 doc. Brazil 28 Jan 31 Jan 2013		Continue MDSAP Doc . Work											

Work Items / Time	2014											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1-*New guidance documents 2- Continue ISO13485 and TC 210 documents work .	Complete QMS Guidance documents for local industry ,Distributer and importer				1- Review and Modify N17, N18,19 if require 2-Complete ISO13485 and TC 210 documents work .							Provide new proposed doc
Meetings		TC meeting in Philippines	SG3 meeting in Ottawa			AHWP Annual meeting in Taipei		IMDRF Meeting in Brazil	ISO/TC210 Meeting in Chiba ken			

Work in Progress

- Adapt GHTF Quality Management System – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange N19.
- Development of the ISO 13485 Guidance document for small manufacturers/ importers/ distributors
- Review of Quality management System-Process Validation Guidance