Proposed 2012-2014 AHWP WG1a Work Plan

Work Item	Description of Tasks	Target for Completion
Revision of GHTF Documents	● SG1(PD)/N068R05 Essential Principles of Safety and Performance of Medical Devices ● SG1(PD)/N071R04 Definition of the Term "Medical Device ● SG5(PD)/N6R3 Clinical Evidence for IVD Medical Devices - Key Definitions and Concepts ● SG5(PD)/N7R4 Clinical Evidence for IVD Medical Devices - Scientific Validity Determination and Performance Evaluation ● SG5(PD)/N8R3 Clinical Performance Studies for In Vitro Diagnostic Medical Devices	● Mar 21, 2012 ● Mar 21, 2012 ● Mar 21, 2012 ● Mar 21, 2012 ● Jun 2, 2012
GHTF SG1 IVD Subgroup Meetings	●1st Meeting ●2nd Meeting ➢ Propose future collaboration initiatives on emerging technologies, e.g., lab-in-situ, LDTs, molecular diagnostics, POCT, etc.	● May 21-25, 2012 (Ireland) ● Jul 9-13, 2012 (Singapore) ➢ To be addressed in both meetings

Proposed 2012-2014 AHWP WG1a Work Plan (Continued)

Work Item	Description of Task	Target for Completion
Implementation Guidelines for AHWP Member Economies	● Safety and performance evaluation with related standards (**Note 1**) ● Best practices for clinical evaluation and investigation **(Note 2**) ● Strategies for implementing regulatory framework and affordable access to IVD medical devices	● Jun 30, 2013 ● Jun 30, 2013 ● Nov 30, 2014
Training for AHWP Member Economies	● Regulatory model revisited, challenges and possible solutions proposed ● Use of standards (case studies) (**Note 3**) ● Sufficiency of clinical evidence for IVD medical devices ● Strategies for implementing regulatory framework and affordable access to IVD medical devices	● Oct 23, 2012 ● Oct 23, 2013 ● Nov 30, 2013 ● Nov 30, 2014

- Note 1: These may include mainly CLSI standards on performance characteristics as the following,

Performance Characteristics	Recognized Standards
Accuracy (trueness and precision)	CLSI EP5-A, CLSI EP12-A, CLSI EP15-A
Analytical sensitivity	CLSI EP12-A
Analytical specificity	CLSI EP7-A2
Linearity and measuring range	CLSI EP-6A
Limit of detection, limit of quantification of the method	CLSI EP-17A
Assay cut-off	CLSI GP10-A
Laboratory error, total analytical error	CLSI EP18-A, CLSI EP21-A
Stability	EN13640:2002
Interference	CLSI EP7-A2

as well as related standards on information supplied by the Manufacturers, e.g., EN ISO18113-1~3:2009; EN 980:2008, etc., or other applicable standards.

- Note 2: This may include practical guidelines or examples in conducting the following:
  - Scientific validity determination
  - Appraisal and analysis of analytical and clinical performance data
  - Clinical performance studies
  - Compilation of clinical evidence

- Note 3: Case studies will focus on safety and performance evaluation on different intended use, intended users, clinical scenario, etc.,