WG2 – Pre-market: IVDD

AHWP 19th TC Meeting
5 Nov 2015, Bangkok

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Membership Status

- Chair: Dr. Wen-Wei TSAI
- Co-Chair: Ir Albert POON
- Advisor: Ms. Shelley TANG
- No. of WG members: 27
  - 11 regulators
  - 16 industries

Objectives 2015-2017

- To assist AHWP member economies in implementing regulatory framework of IVD medical devices by
  - Developing AHWP documents on premarket regulatory control of IVD medical devices.
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices.
- To support regulatory convergence through
  - Participating in International/Global Organization collaboration and activities. (e.g. ISO/TC 212, etc.)
  - Encouraging interest and participation for AHWP member economies in reviewing the specific needs for IVD regulation controls.

Proposed Work Plan 2015-2017

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No.	Work Item	Deliverables	Action Plan and Timeline
1	Develop AHWP documents	Guidance document	
(1)	Definition of MD/ IVD		Collaborate with WG1 Mar 2015 to Dec 2015
(2)	IVD Common Submission Template		Jun 2015 to Dec 2016
(3)	Conformity Assessment for IVDs		Aug 2015 to Aug 2017
(4)	Classification of IVDs		Aug 2015 to Aug 2017
(5)	IVD Labelling		Jan 2016 to Dec 2016
(6)	Advertising and promotion		Jan 2017 ~
2	Participate in International/Global Organization collaboration and activities (e.g. ISO/TC 212, etc.)	Standard	Attend the activities of ISO/TC 212/WG3 to work on standard regarding technical requirements for IVDs
3	Environmental scanning and survey for IVD premarket regulatory controls	Survey Report	Mar 2015 to Jun 2016

WG Progress Update (I)

since last AHWP Seoul TC Meeting in 2014

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No.	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	Feb 2015 to Dec 2015	27 members in total 11 Regulator Members; 16 Industry Members
2	Development of AHWP Guidance Document	1) Definition of MD/ IVD	Mar 2015 to Dec 2015	• Collaborate with WG1 on MD Definition. • Discussion by telecon on 11 Mar 2015 and 10 Jun 2015. • Internal draft circulating within WG2 and WG1 until end of July 2015. • Have held the 1st FTF meeting in Taipei on 11-13 Aug 2015 to finalize the draft document. • Have called for comments on the PROPOSED document until the end of September 2015. • Incorporated comments and finalize document for endorsement.
		2) IVD Common Submission Template	Jun 2015 to Dec 2016	• Discussion by telecon on 10 Jun 2015. • Start to draft the documents in the WG2 1st FTF meeting in Taipei on 11-13 Aug 2015. • Conducted a 2nd FTF meeting in Bangkok to continue drafting the documents.
		3) Conformity Assessment for IVDs	Aug 2015 to Aug 2017	
		4) Classification of IVDs	Aug 2015 to Aug 2017	

WG Progress Update (II)

since last AHWP Seoul TC Meeting in 2014

No.	Work Item	Deliverables	Timeline	Progress Update
3	Participating in ISO/TC 212	Establish IVD WG representation to ISO/TC 212 regarding technical requirements for IVDs	2015 to 2017	AHWP Secretariat has assisted to confirm addition of WG2 contacts to the ISO/TC 212 distribution list. Two WG2 contacts had been added sucessfully.
4	Survey on IVD regulation status and premarket requirements for AHWP member economies	Survey Report	Mar 2015 to Jun 2016	• Apr to May 2015: Disseminate the questionnaire to all TC regulatory reps and WG2 members. • May to Aug 2015: Collect the response; 13 responses have been received. • Aug to Sep 2015: Have compiled and analyzed the responses.

WG2 1st FTF Meeting, 11-13 Aug 2015

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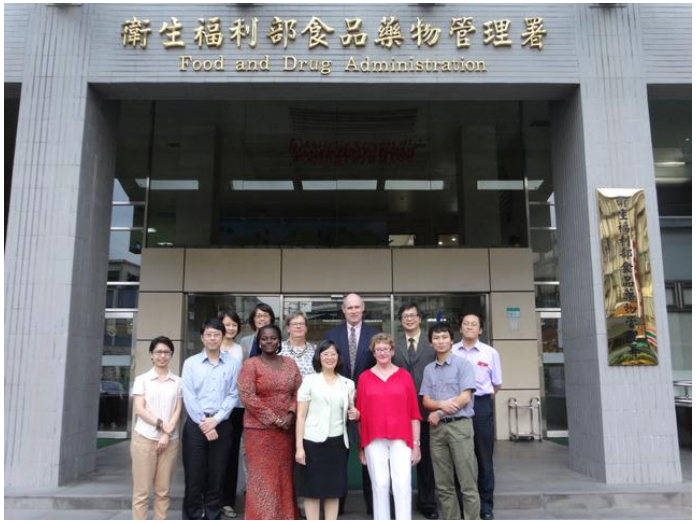
- The meeting was held in Taipei and was attended by 3 AHWP advisors and 11 members
- Achievements:
  - Discussion on AHWP Proposed Documents
    - AHWP/WG2-WG1/P001:2015 – Definition of medical device and IVD medical devices
  - Discussion on the survey of IVD medical device regulatory status
    - The survey was circulated in the WG2 and forwarded to all TC regulatory representatives of 24 member economies, and had 13 respondents
  - Discussion on AHWP WG2 work items
    - Guidance document on common submission template for IVD medical device



AHWP/WG2-WG1/P001:2015 – Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'

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- Scope of paper:
  - This document applies to all products that fall within the definition of medical device and In Vitro Diagnostic (IVD) Medical Device.
- Objective of paper:
  - To provide harmonized definitions of the terms 'medical device' and 'In Vitro Diagnostic (IVD) medical device'.
- Summary:
  - The present guidance serves as guidance for Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry on the definitions for the terms 'medical device', and an 'In Vitro Diagnostic medical device'.
  - The document contains the definition of the terms 'medical Device', 'In Vitro Diagnostic (IVD) medical device' , 'accessory to a medical device' and 'accessory to an IVD medical device'.

Survey on IVD Medical Device Regulations

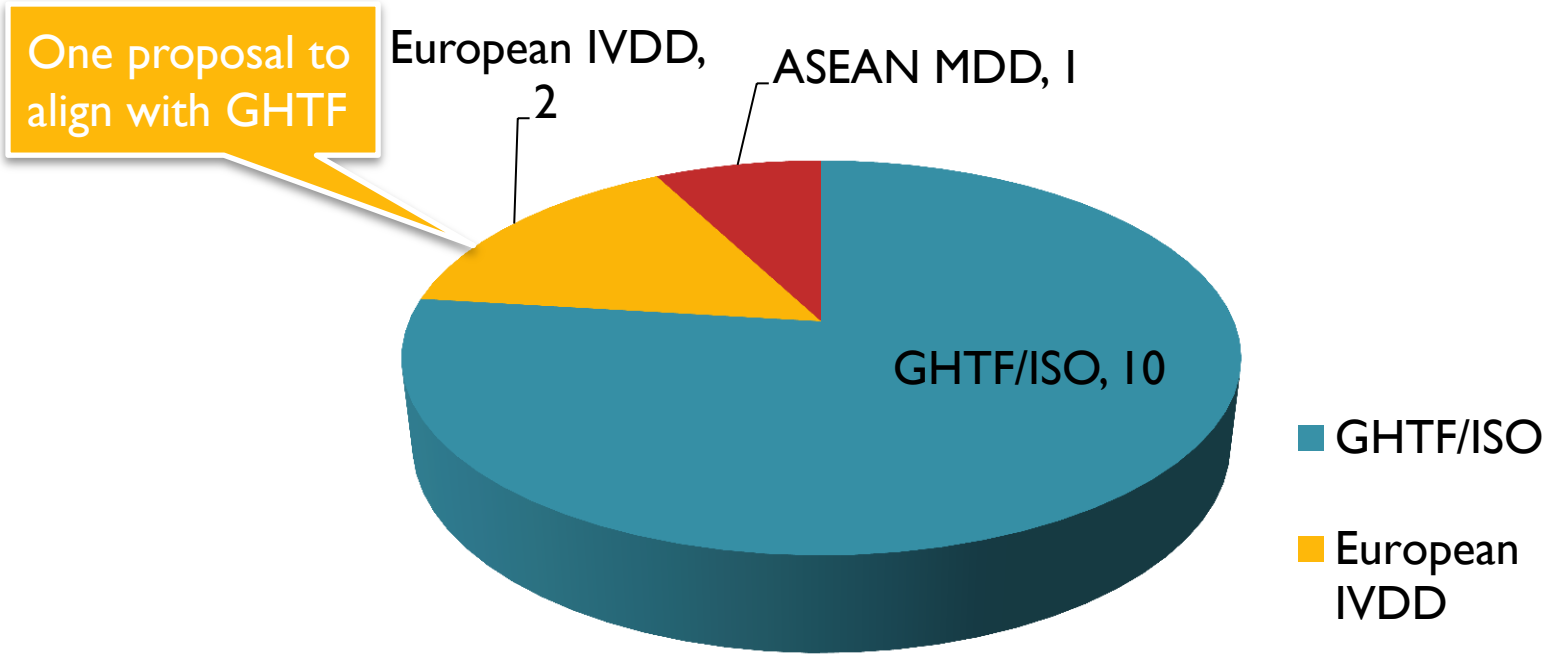
Subsequent report by Co-Chair Albert Poon

- Survey conducted during May – June 2015
- Survey areas
  - Set up of Regulatory Authority
  - Definition of IVD medical device
  - Classification
  - Conformity Assessment requirements
  - Post-market surveillance requirements
- Sent to 24 member economies
- 13 respondents

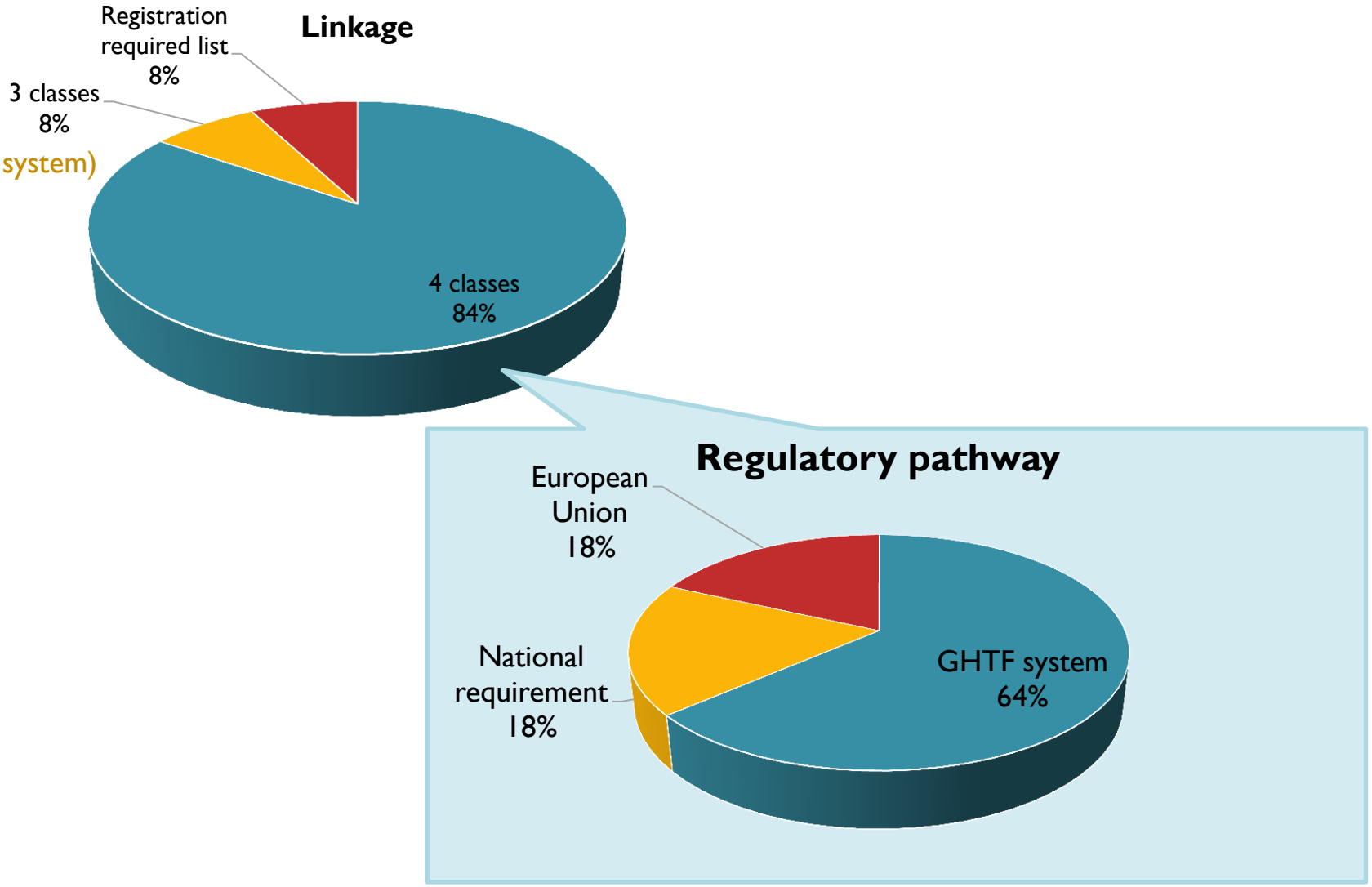
Survey on IVD Medical Device Regulations

- Respondents
  - Australia
  - Chinese Taipei
  - Germany
  - Ghana
  - Hong Kong
  - Indonesia
  - Kenya
  - Korea
  - Malaysia
  - Philippines
  - Singapore
  - Tanzania
  - United Kingdom

Definition of IVD



Classification

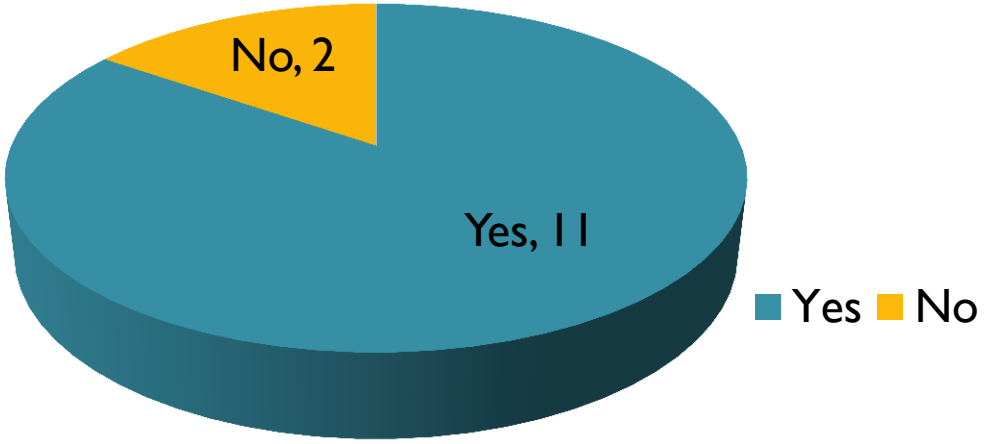


(US FDA system)

Conformity Assessment- Essential Principles

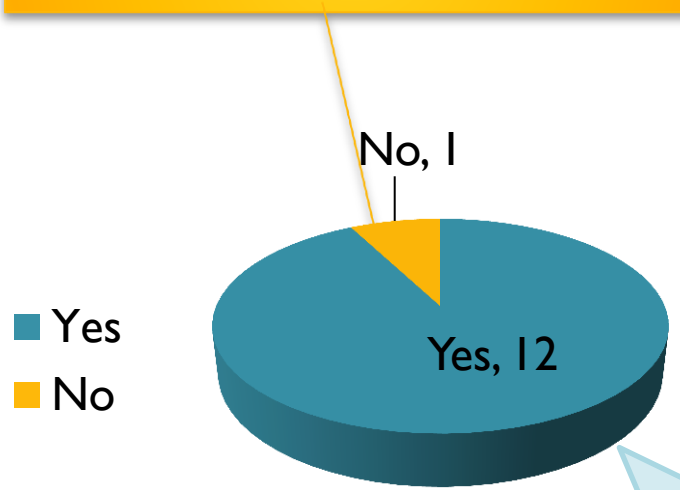
1. most cases that will be based on GHTF EP compliance or similar.

2. some documentary requirements only.



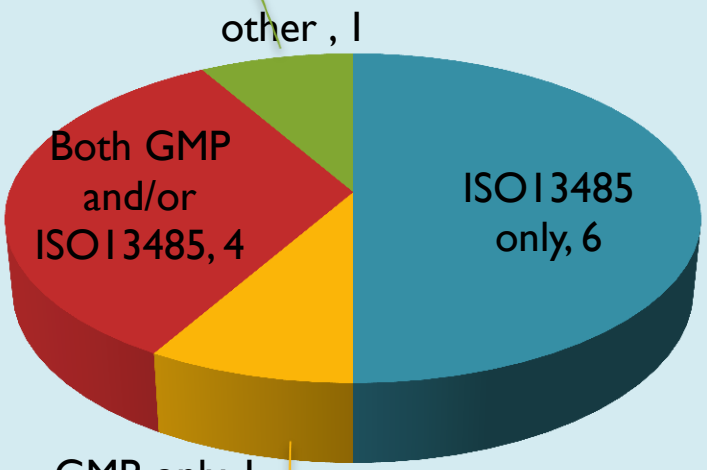
Conformity Assessment- QMS requirement

QMS standard advised but not mandatory



Analysis of the twelve respondents

Mandatory standard similar to ISO13485



GMP harmonized with ISO13485

Conformity Assessment- Recognized Standard

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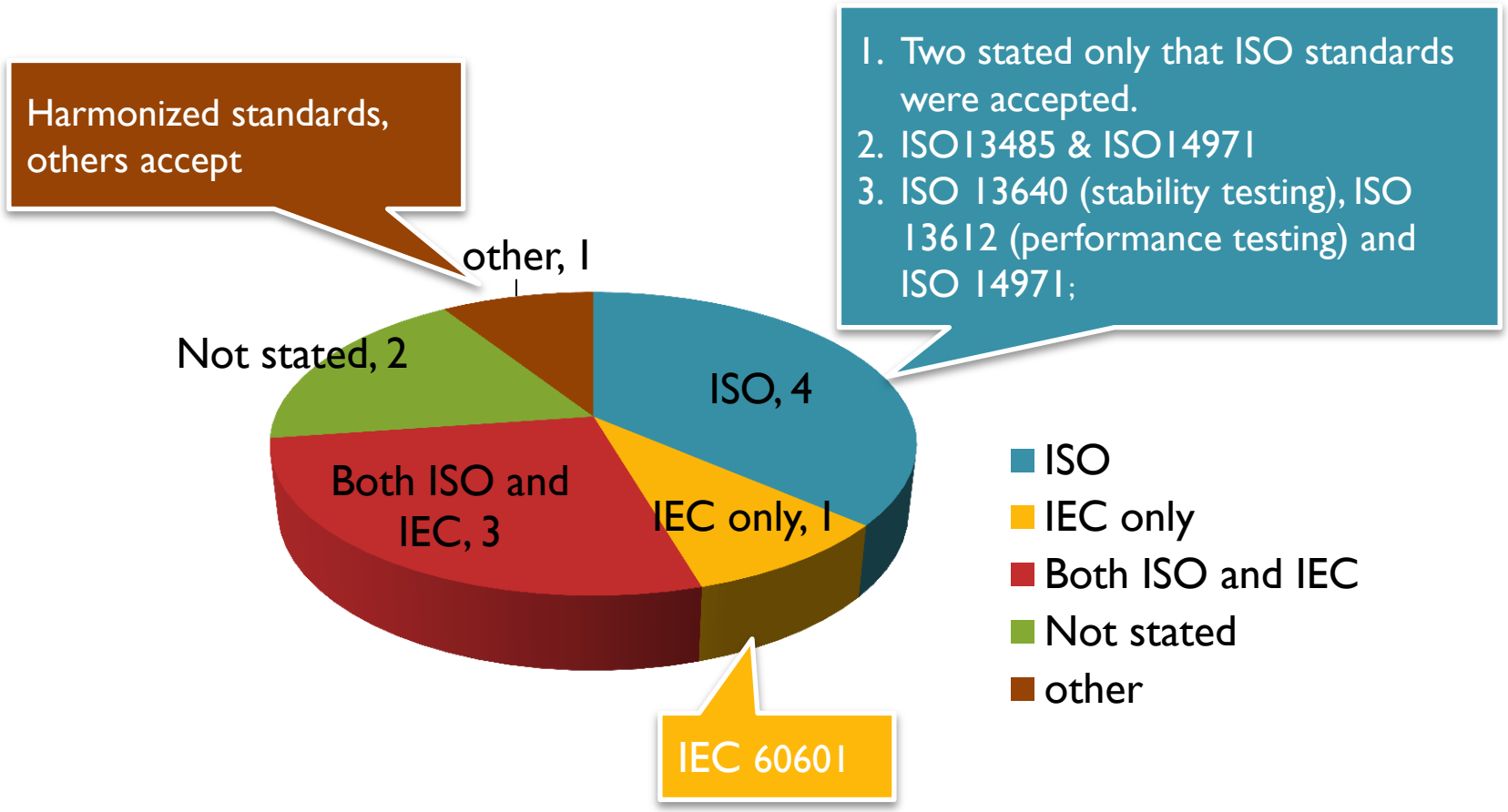
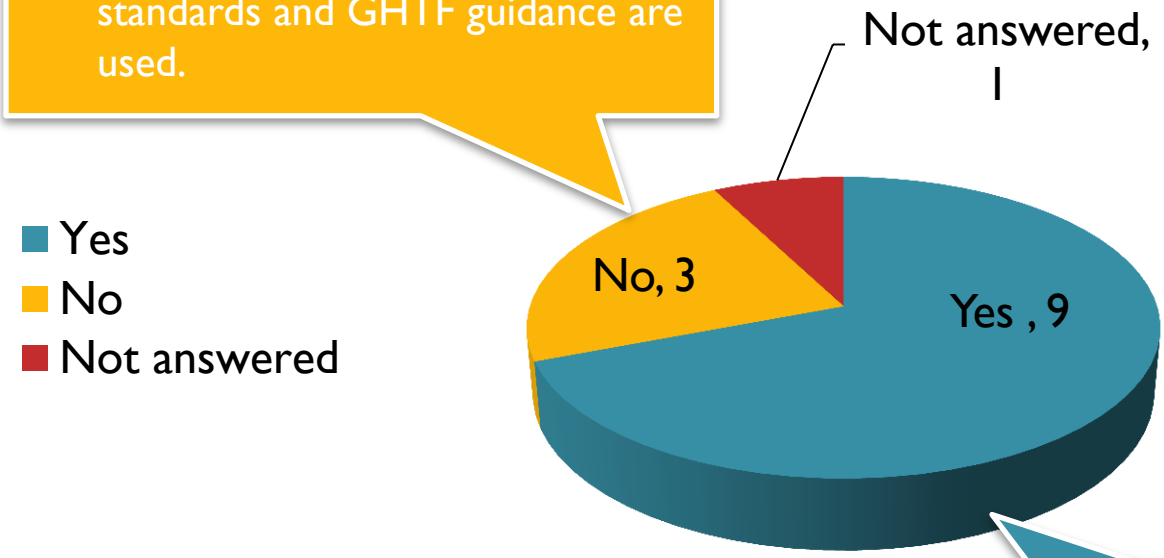


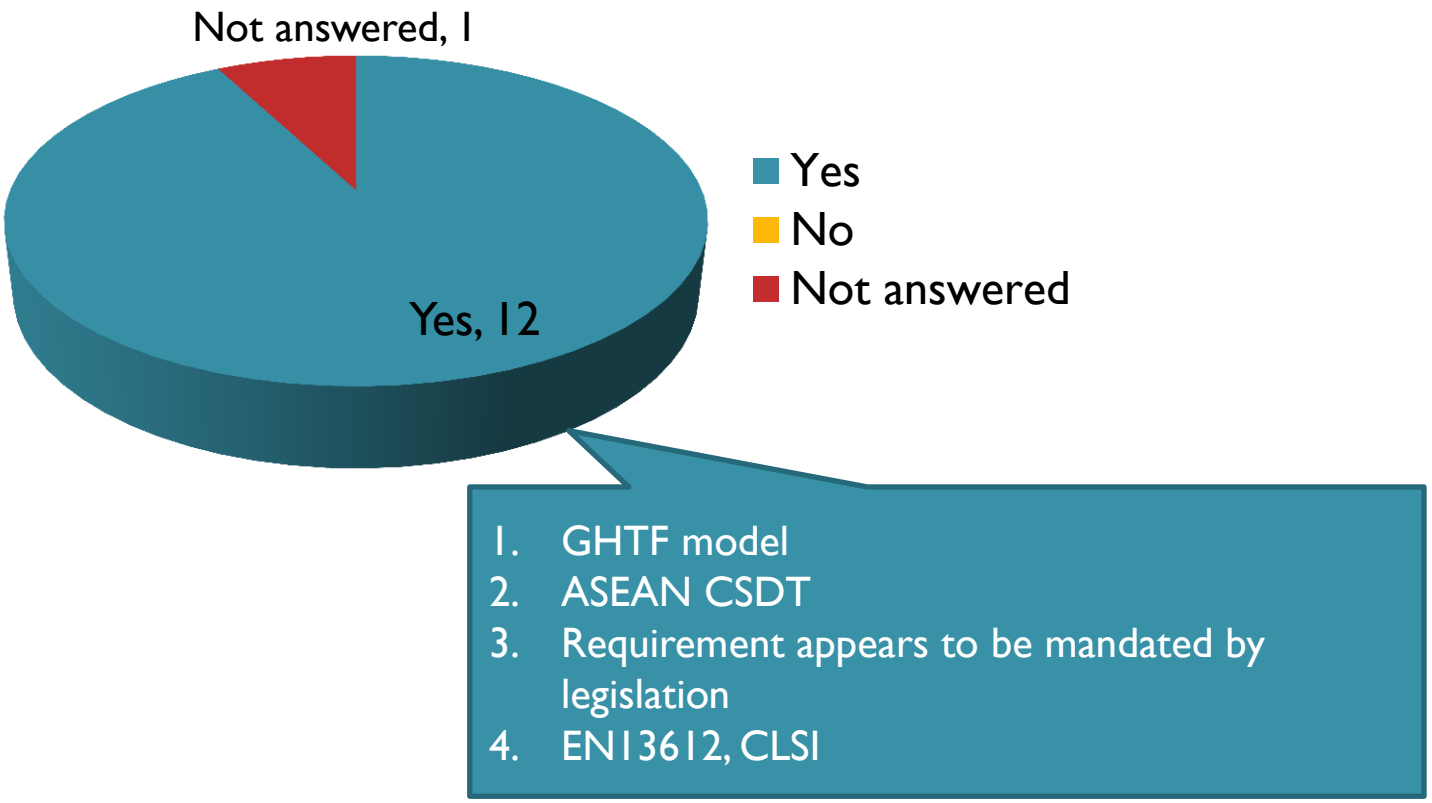
Conformity Assessment- Recognized professional standards

1. Not applicable
2. Currently no processes in place
3. The list of European harmonized standards and GHTF guidance are used.



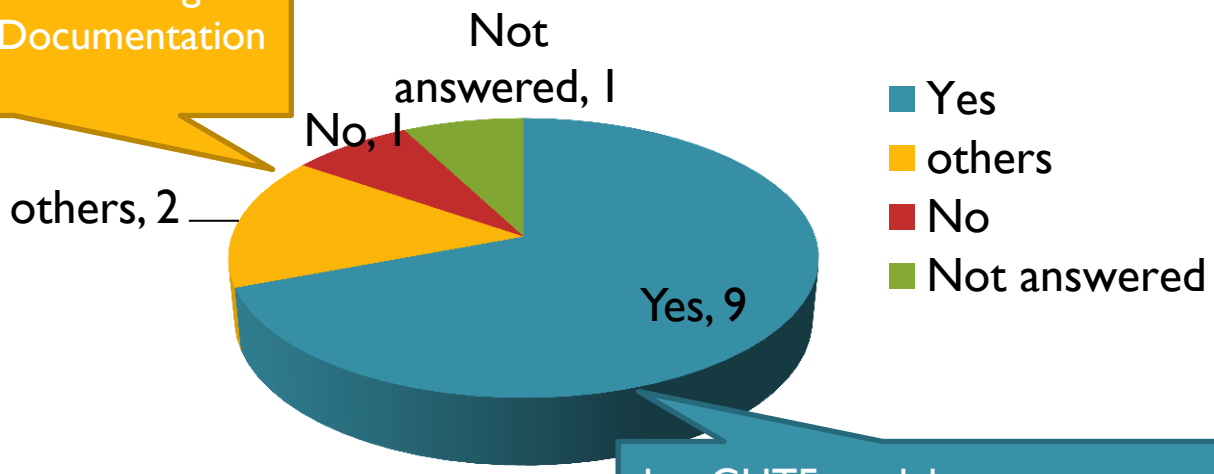
AAMI, CLSI. ASLM. Compliance with an EP and case by case

Conformity Assessment- Analytical performance studies



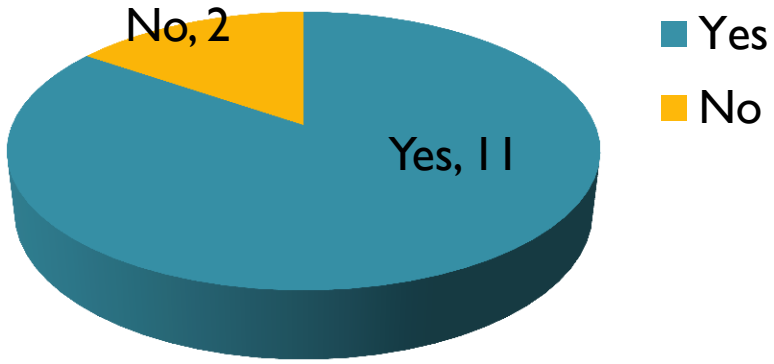
Conformity Assessment- Clinical performance studies

1. Not required if substantial equivalence to IVD registered
2. May be exempted according to the Criteria for Documentation

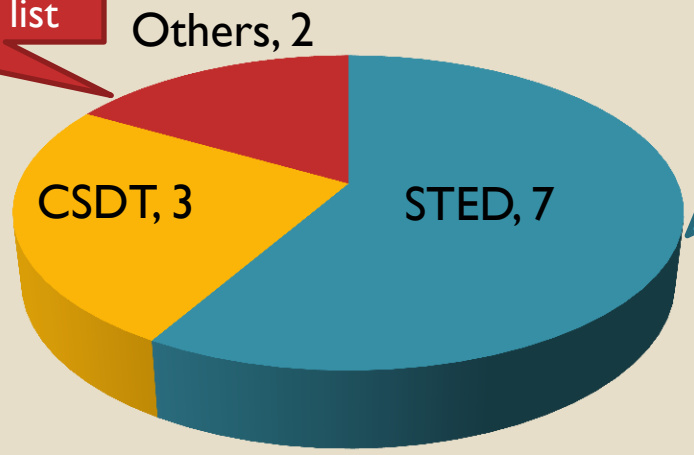


1. GHTF model
2. Requirement appears to be mandated by legislation, e.g. Health products Act
3. EN13612, CLSI

Conformity Assessment-Specific document format for pre-market submission



1. Other official format
2. Regional specific check list



one of the EU respondents stated that this is a recommendation for the future, while the other indicated current use.

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Thank you

WG2 - Premarket : IVDD
Dr. Tsoi Wen-Wei
Ir Albert Poon