Asian Harmonization Working Party Technical Committee Leaders Meeting

26st & 27nd Feb 2013

Mrs Joanna Koh
TC Chair
Singapore Health Sciences Authority

ASIAN HARMONIZATION WORKING PARTY

Purpose of TC Leaders Meeting

- Clarify the roles of advisors to AHWP TC
- Work plan and deliverables of each Work Group for next 18 months
- Discussion on the roles of consultants in AHWP

ASIAN HARMONIZATION WORKING PARTY

Agenda: Day 1

26 Feb 2012

Time	Agenda	Responsible Person(s)
0900 – 0915	Opening of Meeting	Mrs Joanna Koh, TC Chair
0915 – 1000	Role of AHWP to provide members with technical support	All participants
1000 – 1015	Tea break	All participants
1015 – 1200	WG update and plans for next 18 months -WG 1 -WG 1a -WG 2	All participants
1200 – 1300	Lunch	All participants
1300 – 1500	WG update and plans for next 18 months -WG 3 -WG 4 -WG 5 -WG 6 -STG (N)	All participants
1500 – 1515	Tea break	All participants
1515 – 1630	Discussion on the role of Consultants in AHWP	All participants
1630 – 1700	AHWP/RAPS Conference update	Ms Tran Quan

AHWP
ASIAN HARMONIZATION WORKING PARTY

Agenda: Day 2

27 Feb 2012

Time	Agenda	Responsible Person(s)
0915 – 1030	Closed Door Meeting for TC Leaders -Role of advisors to AHWP TC Closed Door Meeting for Advisors -Discussion on WG plans presented on Day 1	TC Leaders Advisors
1030 – 1045	Tea break	All participants
1045 – 1215	Discussion on Roles 1.Role of TC and WGs -Where are we, where are we going? and what can we achieve 2. What we would hope Advisors role to encompass	All TC participants
1215 – 1315	Lunch	All participants
1315 – 1500	1. Advisors sharing of GHTF experience 2. What are the concrete steps AHWPTC can take to achieve its goals & objectives 3. What role do Advisors see themselves playing in the AHWP TC a. Support to WGs work plans b. Support to WGs to move towards alignment with Strategic Framework	Advisors
1500 – 1515	Tea break	All participants
1515 – 1700	Advisors sharing of GHTF experience	All participants

Opening Remarks
Dr Saleh AL-Tayyar
AHWP Chair

AHWP Technical Committee Leaders

- TC Chair: Mrs Joanna Koh, Singapore Health Sciences Authority
- TC co-chair (regulator): Eng. Ali M. Al-Dalaan, Saudi Food & Drug Authority
- TC co-chair (non-regulator): Ms Chadaporn TANAKASEMSUB (Miang), Zimmer, Asia Pacific
- TC Secretariat: Prof Jack Wong, Johnson and Johnson Medical Singapore

ASIAN HARMONIZATION WORKING PARTY

AHWP Technical Committee

WG1: Pre-Market Submission and CSDT	WG1a: IVDD	WG2: Post-Market Surveillance and Vigilance	WG3: Quality Management System
• Regulatory Chair • Alfred KWEK	• Li-Ling LIU • Jeffrey CHEN	• Yorkie CHOW • Saini KULWANT	• Ali M AL-DALAAN • Ee Bin LIEW

WG4: Quality System Audit	WG5: Clinical Safety/Performance	WG6: Capacity Building and Regulatory Training	STG: Medical Device Nomenclature
• Abdulah AL RASHEED • Eun Hee CHO	• Regulator Chair • Sumati RANDEO	• Dr Rama SETHURAMAN • Jack WONG	• Yang Lian CHUN • Carol YAN

AHWP
ASIAN HARMONIZATION WORKING PARTY

Goals of AHWP

To study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

Proposed Elements of the AHWP Strategic Framework 2012-2014

1. AHWP Membership Expansion
2. Training and capacity building
3. Harmonization in Key Areas based on GHTF Principles
4. Working Alongside with APEC towards Regional Regulatory Harmonization Goal by 2020
5. Increase AHWP's Global Presence

AHWP Technical Committee

AHWPTC is the executive arm of the Working Party.

It performs the following roles and responsibilities to support the Working Party:

- Execute the Working Party's decisions and resolutions;
- Make recommendations to the AHWP Chair for decisions;
- Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;
- Provide expert opinions and advice;
- Develop technical documents and policy papers;
- Plan and organize meetings, training, seminars, workshops and experience sharing sessions;
- Work with related organizations and participate in their activities; and
- Report on the progress of its activities to the AHWP Meetings.

From: AHWP Terms of Reference

Goals of AHWP Technical Committee

To support the goals of AHWP:

1. AHWP Membership Expansion

   → All WGs: understand the needs of each member economy.

   → WG6: capacity building

2. Training and capacity building

   → WG6 (in coordination with all WGs)

ASIAN HARMONIZATION WORKING PARTY

Goals of AHWP Technical Committee

To support the goals of AHWP:

3. Harmonization in Key Areas based on GHTF Principles:

a) Harmonized definition of the term "medical device" (WG1)
b) Registration of manufacturers, distributors, and importers and listing of medical devices marketed (WG1)
c) Risk-based classification of medical devices (WG1)
d) Single adverse event reporting and post-marketing surveillance system (WG2)
e) Single medical device nomenclature system (STG [Nomenclature])
f) Single quality management system requirements and harmonised quality management system audit report by authorized competent authorities (WG3)
g) Acceptance of clinical evidence gathered, and evaluations conducted by, other AHWP/GHTF members (WG5)

Other areas for regulatory convergence eventually (by 2020)
a) Recognition and use of international standards
b) Clinical evaluation and evidence
c) Single submission format for premarket evaluation

ASIAN HARMONIZATION WORKING PARTY

Goals of AHWP Technical Committee

To support the goals of AHWP:

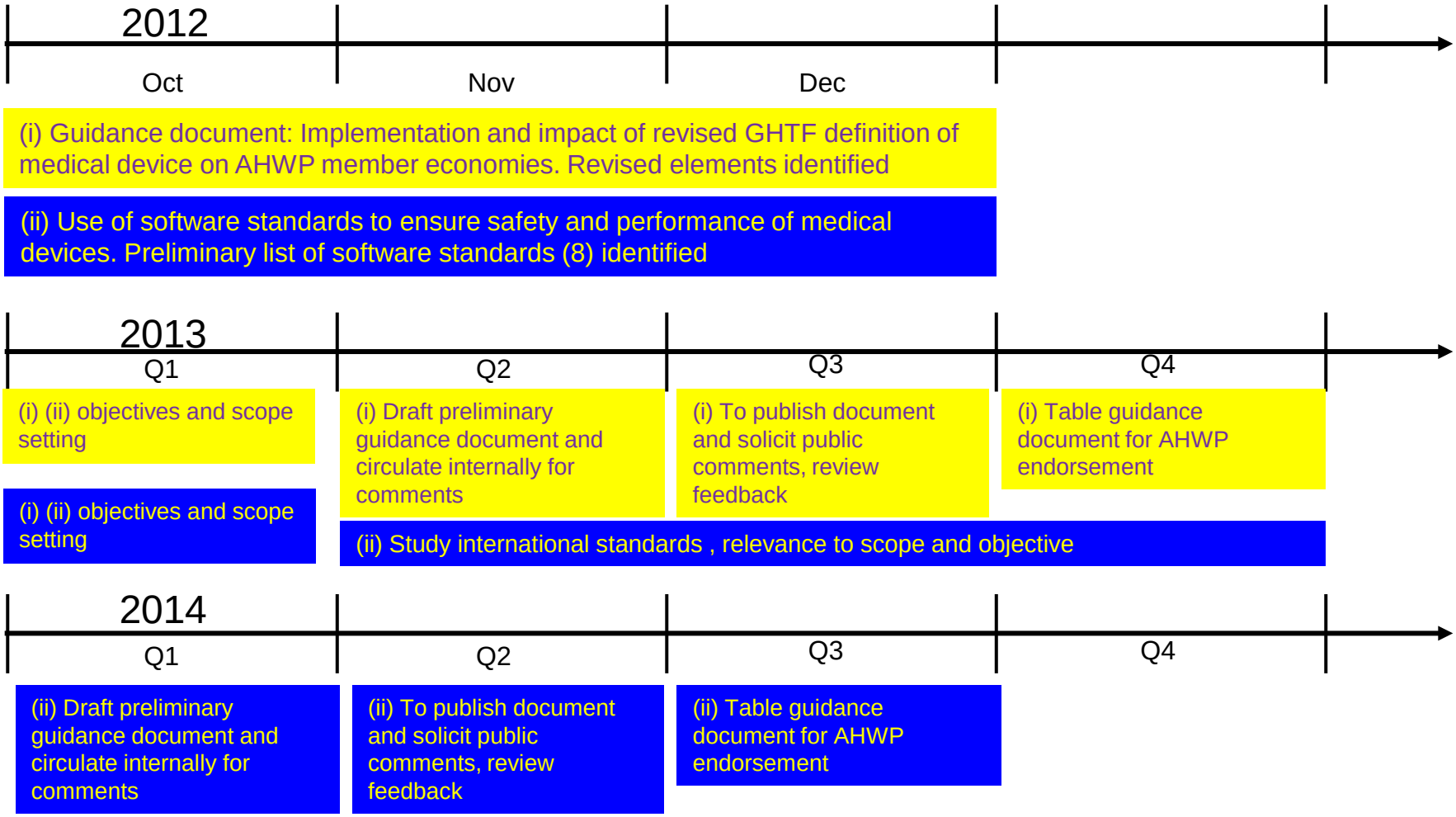
4. Working Alongside with APEC towards Regional Regulatory Harmonization Goal by 2020
5. Increase AHWP's Global Presence

→ All WGs: Interact and cooperate with international organizations, global leaders and experts regarding the priority work topics identified by AHWP and improve the process of getting input and providing feedback.

→ Support the organisation of AHWP Conference

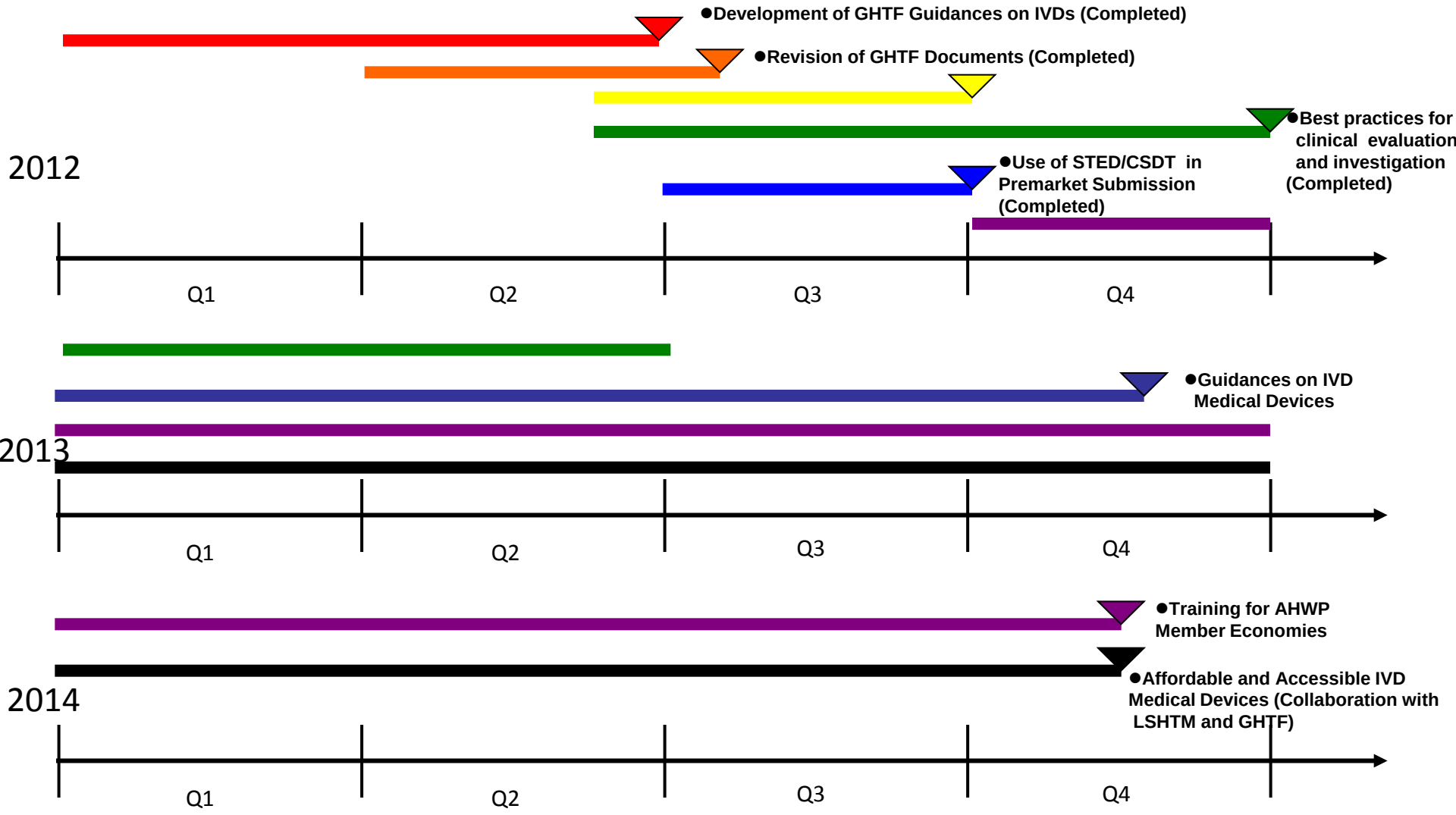
AHWP
ASIAN HARMONIZATION WORKING PARTY

WG01 Projects Completion Timeline



ASIAN HARMONIZATION WORKING PARTY

WG01a Projects Completion Timeline



Key drivers for each working group

AHWP
ASIAN HARMONIZATION WORKING PARTY

WG03 Projects Completion Timeline

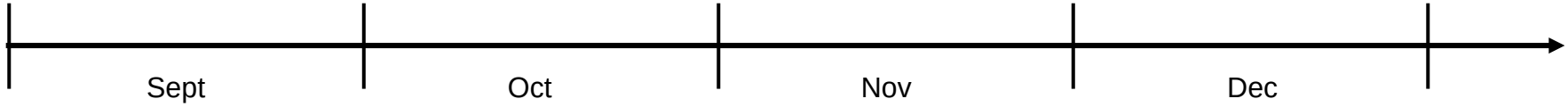
Work Items / Time	2012								2013										
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Review Guidance documents	Review N19 documents and comments on it		Review N15 and receive the comments on it						1-Continuo N15 work 2-Review N99 1-10 document and receive comments 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		

ASIAN HARMONIZATION WORKING PARTY

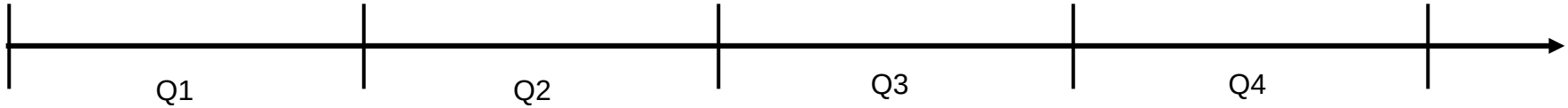
WG04 Projects Completion Timeline

2012



Documents re formatted under AHWP logo and published on AHWP website

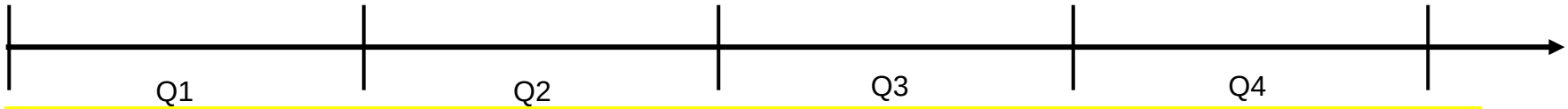
2013



Developing survey and distribute among MEs

drafting, finalizing and publishing of the I&D auditing guidance document

2014



drafting, finalizing and publishing of the I&D auditing guidance document

Key drivers for each working group

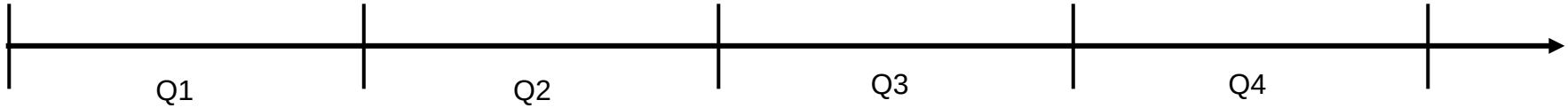
WG06 Projects Completion Timeline

2012

To collate training needs of different workgroups and prioritization.

Explore available online training platforms e.g. RAPS, WMDO, university

2013



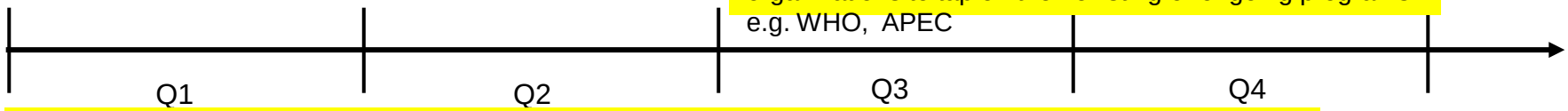
Working towards setting up a post-training feedback system

To analyse and share above feedback with AHWP TC members and propose next steps

To work to create materials for those AHWP TC WG specific topic

2014

Mapping our training requirements with other organizations to tap on their existing or ongoing programs e.g. WHO, APEC



Establish and Implement basic on-line system and program for each WGs

Key drivers for each working group

ASIAN HARMONIZATION WORKING PARTY

WG06 Update Report

WG6: Capacity Building and Regulatory Training

Chair: Rama SETHURAMAN, Regulator, HSA, Singapore
Co-chair: Jack WONG, Industry, Singapore

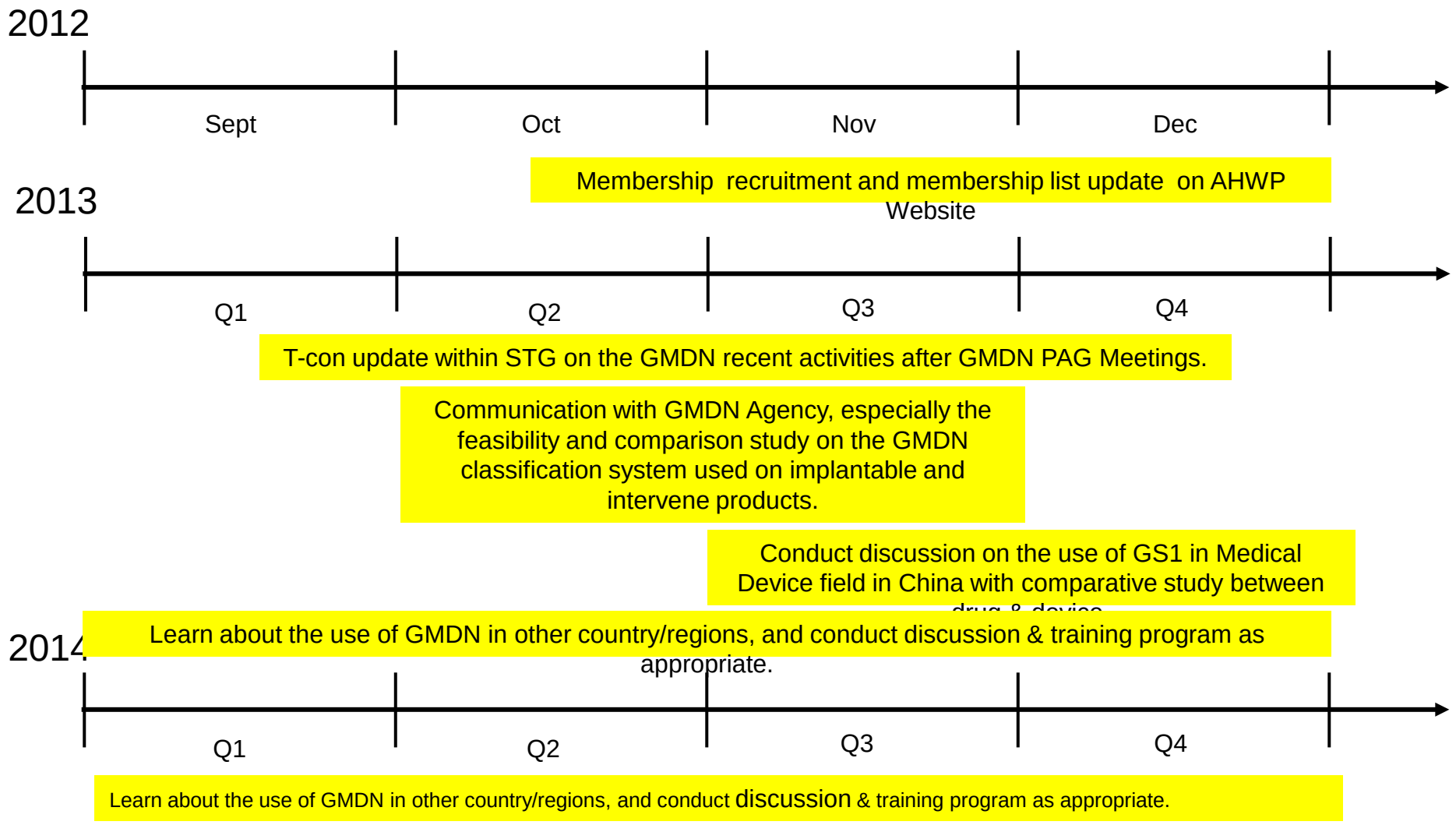
Key Achievements:

1. Training needs of TC workgroups collated, prioritized and some topics covered in current AHWP meeting.
2. Links to external training platforms for members' review on AHWP website.

Next Steps:

1. Setting up of a post-training feedback system
2. Explore other training platforms and collaboration partners (e.g. WMDO, RAPS)

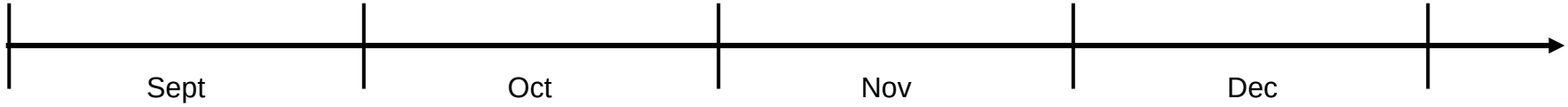
STG(N) Projects Completion Timeline - Nomenclature



Key drivers for each working group

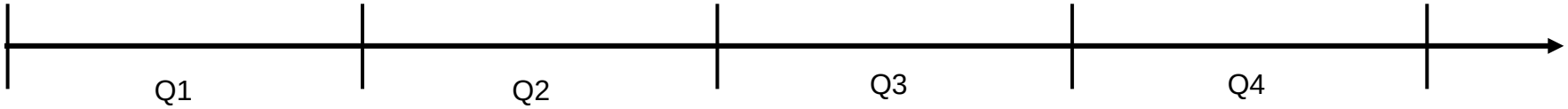
STG(N) Projects Completion Timeline - UDI

2012



Membership recruitment and membership list update on AHWP Website

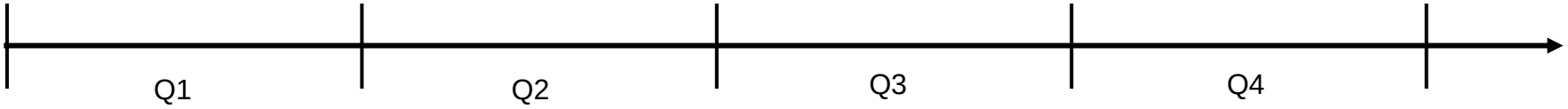
2013



Learn about the FDA UDI final rules and its implementation, invite US experts conduct related training.

T-con update within STG on UDI recent activities and developing trends after IMDRF UDI Ad Hoc WG Meetings.

2014



T-con update within STG on UDI recent activities and developing trends after IMDRF UDI Ad Hoc WG Meetings.

Key drivers for each working group

ASIAN HARMONIZATION WORKING PARTY

STG(N) Update Report

STG: Nomenclature and UDI

Chair: Lianchun YANG, Regulator, SFDA, China
Co-chair: Carol YAN, Industry, China

Key Achievements:

1. Member recruitment and membership list update.
2. Connection with GMDN by face-to-face training and discussion of using GMDN with specific classification rules on Implantable/Intervene Devices in China.
3. Face-to-face training of the implementation of UDI in major regulatory societies; boost member communications on their UDI implementation efforts and conducted investigational discussion on the feasibility of using UDI with various stakeholders in China .

Next Steps:

1.Conduct training and comparison study on Nomenclature via GMDN PAG platform.
2. Conduct training and investigational study on implementation of UDI via IMDRF platform.

THANK YOU