WG4 - <Quality System Audit>

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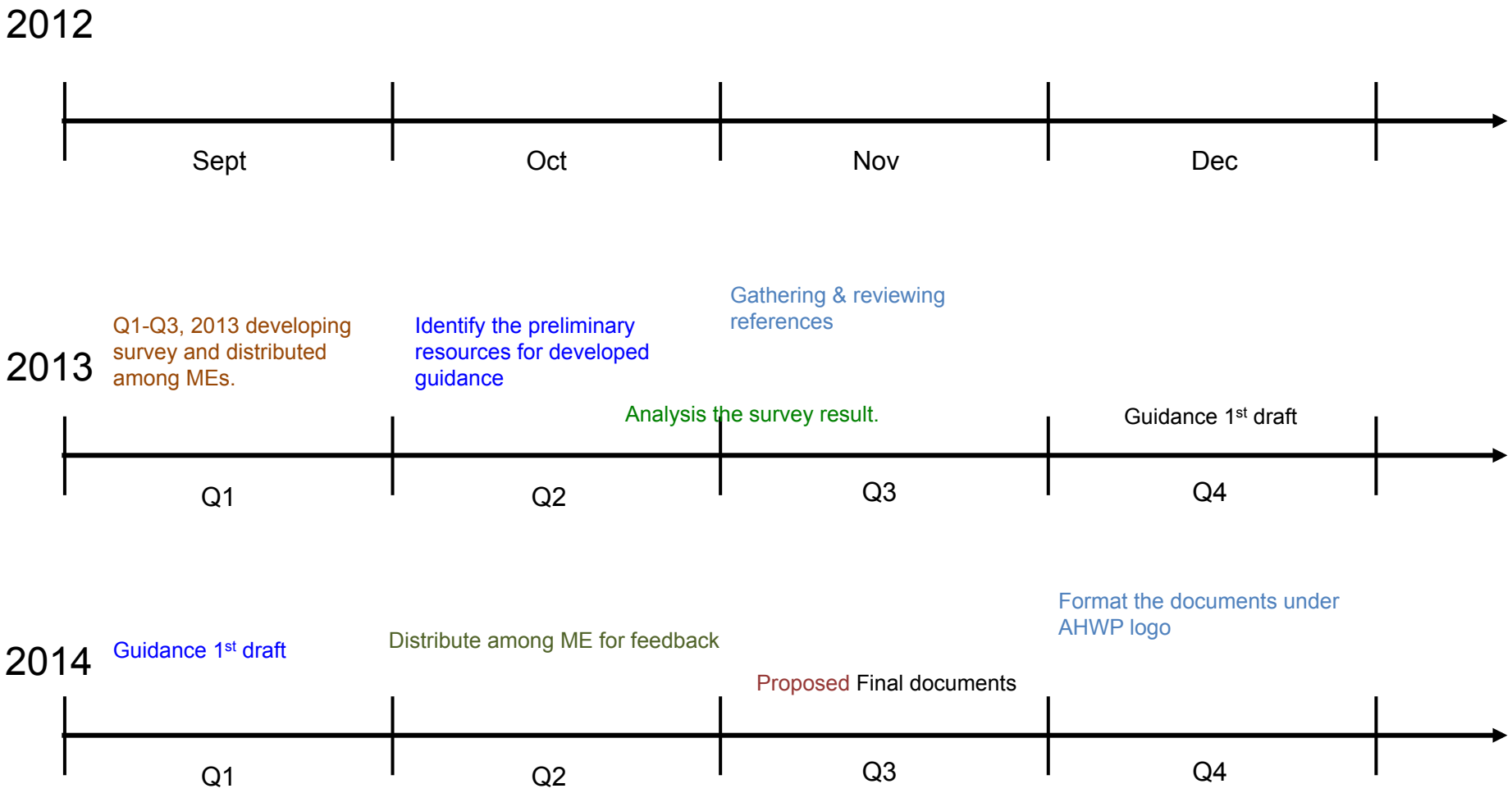
Proposed Work Plan 2012 - 2014

Priority	Work Item	Deliverables	Action Plan and Timeline	Status
1	Finalizing the group documents to be published under the AHWP logo.	Official AHWP Guidance Documents for Auditing.	- Documents will be posted under "Call for Comment" as "Proposed Final document. - Re-formatting under AHWP logo in 2012	Under process
2	Training of AHWP Guidance Documents for member economies.	Training or workshop for member economies to be familiar with guidance.	• 2012-2014.	
3	Development for auditing guidance for importers & distributors	Official AHWP Auditing Guidance for Importers/Distributors.	• Investigation of references in 2012-2013. • Development of guidance for I&D in 2013 -2014. • Finalizing in 2014.	

AHWP WG04 Projects Completion Timeline



Detailed Work Plan

	Tasks	2012	2013	2014	Status
1	Identify the work items.	Q1			Done
2	Develop survey format.		Q1		Done
3	Training at annual official AHWP meeting		Q4		
4	Identify the preliminary resources for developed guidance		Q2		
5	Analysis the survey result.		Q2/Q3		
6	Gathering & reviewing references		Q3		
7	Guidance 1st draft		Q4	Q1	
8	Distribute among ME for feedback			Q2	
9	Proposed Final documents			Q3	
10	Format the documents under AHWP logo			Q4	
11	Training at annual official AHWP meeting.			Q4	

Why developing I&D Audit guidance?

- Is to provide a guidance to regulator and auditing organization conducting audit of QMS based on certain requirements.
- To improve audit process by having a clear guidelines for I&D.
- To promote greater collaboration between regulatory bodies.
- To assure a high degree of services will be delivered.
- Greater consistency in audit reports.
- Most of ME have I&D more than having manufacturers.
- Guidance for countries developing medical device regulatory systems.