

3rd AHWP TC Advisors Comments

- 1st meeting of AHWP TC Advisory Committee with TC leaders was held in March 2013
 - Both parties were unclear how the process would work
 - However at the end of the meeting all agreed that good progress had been made together
 - The TC Advisors appreciate that AHWP recognizes the role for industry in harmonization

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- As Advisors we believe that our experience in industry, with previous harmonization activities, and on international standards may be helpful as AHWP continues to increase their presence globally on medical device regulations
- We were impressed with the activities and progress of the AHWP work groups
- We also recognize the challenges AHWP faces with many different stake holders

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- One concern was the number of projects that AHWP is trying to manage and it is recognized that prioritization will be critical for success.
- Another discussion was the varying degrees of experience in AHWP member economies and how this will be managed and effect implementation.
- The third discussion was what will the future of AHWP look like as the GHTF organization has been disbanded?

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- Some TC Advisor recommendations on the concerns were as follows:
 - Project Prioritization – This is always a challenge but maybe some of it can be mitigated by not making some of the same mistakes GHTF had made in the past.
 - Varying levels of experience – AHWP economies HAVE actually implemented GHTF guidelines. Could they now create a playbook for those that have not started implementation on what must be considered to succeed?

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- Some TC Advisor recommendations on the concerns (cont):
 - What does the future look like for AHWP with no active GHTF organization?
 - Maybe AHWP can take things further that GHTF was not able to do and address needs at a different level?
 - What would GHTF have done differently and can AHWP do it?
 - What is the role of AHWP in global harmonization and standards development?

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- Summary
 - As TC Advisors, we look forward to helping AHWP not only identify the future work, but work together on cost effective solutions for better patient access to safe medical devices

THANK YOU!