

Experience Working as AHWP TC Advisors: The Last Two Years



Seoul, S. Korea

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Our Experience as AHWP TC Advisors

- We have learned and observed much with the AHWP TC as they work towards harmonization of medical device and IVD medical device regulations
- We all know regulatory harmonization remains challenging
- We hope that AHWP can avoid duplicative and redundant controls in member economies; thereby reducing the burden on regulators and industry while allowing everyone to focus on the critical issues
- AHWP will play an important global role in reducing healthcare costs and assuring patient access to innovative and needed devices in its member economies and globally



Our Experience as AHWP TC Advisors

- We commend AHWP on the work they have done in the last two years
- We appreciate that AHWP continues to support the different needs for IVD medical devices
- It has been nice to see that the implementation of the AHWP Strategic framework is under way.
- We believe our contributions have helped to contribute to the process.



Accomplishments

- As TC Advisors, it has been exciting to see the TC and Working Groups efforts come into reality through various work items
 - Asian Harmonization Working Party Strategic Framework Towards 2020 - “The Foreseeable Harmonization Horizon
 - Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Ex-change
 - Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative
 - Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format
 - Essential Principles of Safety and Performance of IVD Medical Devices
 - AHWP Regulatory Framework for IVD Medical Devices
 - Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions
 - Medical Device Adverse Event (AE) Report Form



Contributions of the TC Advisors Role

- We hope that our experience has helped to provide content, guidance and technical expertise on such AHWP documents
- We strive to make sure AHWP can learn from our experiences gained in working with different geographies
- As TC Advisors we are proud to be AHWP “Ambassadors” in other venues (IMDRF, APEC, WHO, etc...) to help market the global efforts of AHWP towards medical device harmonization



Recommendations from the TC Advisors

- Continue to develop AHWP documents based on the foundation laid by GHTF
- Further develop this work using AHWP documents that take into account the specific regulatory needs of the member economies; therefore lead to appropriate harmonization within AHWP member economies
- Rigorously set priorities and focus on key work items to drive progress and continual improvement
- Partner where appropriate with other organizations as an important stakeholder, but reduce redundant efforts between organizations (WHO, APEC, ISO, IMDRF etc...)



Future

- As we look to the future, the TC Advisors are excited and ready to provide support to new work items and initiatives
- We continue to believe that open dialogue and collaboration from countries and among stakeholders is critical to support the AHWP strategic framework
- We believe that the future work in the following areas could have significant value to AHWP member states and are excited to help where possible
 - AHWP Playbook
 - ISO TC 210 collaboration on ISO 13485 revision
 - IVD, Software, and Standards working group work items
 - Training programs



Moving Forward

- It is important for the TC, AHWP, and the Advisors to have clear, common, and actionable objectives in order to assure progress is made. This is critical to the success of all stakeholders
- We look forward to continuing support where it makes sense and working together with the TC to further define our roles as TC Advisors
- As TC Advisors we are happy to offer support to the member economies in order to implement AHWP regulatory work products
- We have enjoyed our time with the current leadership and look forward to working with the new leadership



Experience working as Advisors

- As TC advisors we believe the role is important and thank AHWP for their foresight in creating such a position
- We believe our role as TC Advisors is important to maintain as AHWP develops and matures to the global voice in harmonization

**THANK YOU AHWP for the
Opportunity !**

