



AHWP WG6 – Progress Report

AHWP TC Meeting, Indonesia (Nov 2011)

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Asian
Harmonization
Working Party



Objectives

- Training helps develop regulatory talent to meet industry and regulator needs
- Training is an enabler of harmonisation of medical device regulatory controls





Enabling harmonisation through training collaboration with APEC HC

APEC Harmonisation Committee (APEC HC) has expressed an interest with working with AHWP on regulatory training for the medical devices sector.

WG6 is currently exploring this opportunity to collaborate with APEC HC. Further details would be provided in near future.





Enabling harmonisation through training collaboration with APEC HC

Certain areas of harmonisation identified by Regulatory Harmonisation Steering Committee's Vision 2020 (A strategic Framework for Regulatory Convergence for Medical Products by 2020):-

- Common definition of medical devices
- Harmonised risk-based device classification system
- Labelling requirements
- Quality management systems
- Post-market surveillance systems
- Good review practices
- Clinical evidence

Training would be based on GHTF principles and guidances and recognition of international standards relevant to medical device industry.





Developing Medical Device Regulatory Training

- Exploring medical device training platforms. E.g. WMDO
- Collaboration with interested training providers, e.g. AHC
- Topics of interest include: combination products, post-market training programs and clinical evaluation





Other training platforms under exploration/ follow-up items

Continued development of on-line medical device regulatory training course with interested universities (e.g. NEU, HKU).

Collaboration with Regulatory Affairs Professionals Society (RAPS) to be explored.

Further details will be furnished in the near future once these training options are formalised.

NOTE: Training information to be consolidated and published on website.





THANK YOU !



Working Towards
Medical Device
Harmonization
in Asia



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA