

AHWP IVD Group Update

Tran Quan

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AHWP IVD Group

- In the process of recruiting members
(attempts to connect with Abbott & Roche)
- Current members:
 - Tran Quan (Lead - JNJ)
 - Lee Seow Phing (MOH, Malaysia)
 - Al-Gifar Abdulrahman S. (Saudi FDA)
 - Chen Jiing Feng (ITRI)

GHTF IVD Study Group

- Study Group meeting to be held in USA, 7 –8 May
 - As the AHWP IVD group membership is yet to be formalized, AHWP Chair has officially appointed Quan & Seow Phing to represent AHWP to the study group meeting
 - Mechanism for subsequent AHWP representation at GHTF study group meeting is under discussion

GHTF IVD Guidance Documents

- New guidance documents submitted to Steering Committee for endorsement
 - Principles of IVD Medical Device Classifications
 - Principles of conformity Assessment for IVD Medical Device
- In the meeting on 7-8 May, expect to finalize proposal for STED for IVD