Draft agenda

GHTF STEERING COMMITTEE Meeting May 6-8, 2007 (*)

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(*) **May 6 -** Industry and regulators will be meeting separately.
Meeting rooms have been booked for that purpose.

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1. **Welcome**

2. **Approval of the agenda**

3. **Update GHTF Steering Committee Membership List and Contact Details**

4. **Summary Records from the 11th Steering Committee Meeting**

5. **Cooperation with international bodies**
   - **IEC application to become a Liaison Body**
   - **WHO & NCAR [hold for discussion at end of 8 May]**
   - **Standards Report – Carl Wallroth**
   - **Cooperation with CASCO**

6. **Steering Committee Initiatives**

   - **Training Ad Hoc – status report**
   - **Software Ad Hoc – status report [hold for morning of 8 May]**
   - **Whether GHTF should ask for changes to ISO 13845 – discussion**
   - **GHTF Workbook and Glossary**
   - **Retrospective Assessment – status report [hold for morning 8 May]**

- **Ad Hoc Groups**

7. **GMDN – Business plan report**

8. **Planning of the GHTF Conference 2007 – Washington, DC**

9. **Update of Main Developments in Founding Members Regulatory Systems**
   (Members are invited to inform about ongoing developments)
   - **Implementation Barriers – status report**
   - **Combination Products – status report**

10. **Update of Main Developments for Liaison Bodies**

    - **AHWP**

11. **Upcoming meetings**

    - **GHTF Conference 2007**
    - **GHTF participation in APEC meetings**

12. **Next GHTF SC meeting**
    - **30 September – 2 October 2007, Washington, DC**
    - **Regional Meeting 2008**

13. **Steering Committee Initiatives**

    - **Software Ad Hoc – status report**

    - **Retrospective Assessment – status report**

14. **Study Group's work - Progress reports and documents**
    (This section will begin after the lunch break on 8 May 2007)

    14.1. Study Group 1
    14.1.1 – *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (SG1(PD)/N045R12)R3)*
    14.1.2 *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices (SG1(PD)/N46)*

    14.2 Study Group 3

    14.3 Study Group 4

14.4 Study Group 5

14.4.1 *Clinical Evidence – Key Definitions and Concepts (SG5/N1R8)*

14.4.2 *Clinical Evaluation (SG5/N2R8)*

14.4.3 Working Draft – *Clinical Investigation (N3R2)*

14.4.4 New Work Item Proposal - Post-Market Clinical Follow-Up for Medical Devices

14.5 Study Group 2

14.5.1 Cooperation with international bodies - NCAR and WHO

15. AOB

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