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

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

   5.2 Study Group 2

   5.3 Study Group 3

   5.4 Study Group 4

   5.5 Study Group 5
   5.5.1 New Work Item Proposal - Post-Market Clinical Follow-Up for Medical Devices

6. **Cooperation with international bodies**
    - **IEC application to become a Liaison Body**
    - **WHO & NCAR**

7. **Steering Committee Initiatives**

    - **Training Ad Hoc – status report**
    - **Software Ad Hoc – status report**
    - **Whether GHTF should ask for changes to ISO 13845 – discussion**
    - **GHTF Workbook and Glossary**
    - **Retrospective Assessment – status report**

8. **GMDN – Business plan report**

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

10. **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**

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

    - **ISO**
    - **AHWP**

12. **Upcoming meetings**

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

13. **Next GHTF SC meeting**
    - **30 September – 2 October 2007**

14. **AOB**

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