Draft Agenda

I. Plenary - 10:00 to 13:00 (Authorities and stakeholders)

1. Welcome
2. Debrief on the IMDRF Management Committee (MC) meetings in Kyoto and MC teleconference held on 14.01.2016
3. Presentation of the Draft Agenda of IMDRF-9
4. IMDRF Work Items – Presentation of the state of play and discussion
   a. Review of the NCAR system
   b. Medical Device Single Audit Program
   c. Regulated Products Submission
   d. Software as a Medical Device
   e. Medical Patient Registries
   f. Medical Device Adverse Event Terminology
   g. Good Regulatory Review Practice – Competence and Training Requirements for Pre-market Reviewers and Product Specialists
5. New Work Item Proposals and collaboration between IMDRF and ISO/IEC
6. Update on the Single Audit Pilot Project