IMDRF-4 Stakeholder Forum
Wednesday 13 November 2013 - 9.00 am to 5.00 pm
Venue: Room 3D
Centre de Conférences Albert Borschette (CCAB) rue Froissart 36 – 1040 Brussels

Innovation for Safety: achievements and challenges
(Contribution of the different stakeholders from conception to disposal)

9:00 – 10:00 Opening

1. Introduction by IMDRF Chair Ms D. Spanou

2. Update on regulatory situations in the IMDRF Jurisdictions (3 min each + ±20 min Q/A each)
   1. Australia,
   2. Brazil,
   3. Canada,
   4. China,
   5. European Union,
   6. Japan,
   7. Russian Federation,
   8. United States of America.

10:00 – 10:30 Coffee/tea break

10:30 – 12:15

3. Progress reports on the work items (10 min each PPT + Q/A)
   - Review of the NCAR system,
   - Roadmap for Implementation of UDI system,
   - Medical Device Single Audit Program,
   - Recognized standards,
   - Regulated Product Submission,
   - Standalone Medical Device software.

12:30 – 14:00 Lunch break
14:00 – 17:00

4. Stakeholders experience in the continuous improvement of products safety & performance

   Short introduction by IMDRF Chair

   Stakeholders' presentations (presentations by representatives of patients, healthcare professionals, industry and notified bodies)

5. Discussion
   (Q/A)

6. Concluding remarks by IMDRF Chair Ms D. Spanou from a Regulatory Authority standpoint and possible questions