GDA Meeting 2015 in Tokyo
May 28-29

Attendees

Dr. Jurgen Schulze (EDMA)
Mr. Jesus Rueda Rodriguez (EDMA)
Mr. Ingmar de Gooijer (EDMA)
Ms. Tharini Sathiamoorthy (AdvaMedDx)
Ms. Hallie Lewis (AdvaMedDx/Cepheid Inc.)
Mr. Fabio Arcuri de Carvalho (CBDL)
Mr. Carlos Eduardo Gouvea (CBDL)
JACRI (Japan) : host association
JAIMA (Japan) : host association

Schedule

1. May 28, 2015 (Thu)
   9:30 – 10:30 Visiting MHLW
      Attendee: GDA (Oversea), JACRI (2-3)
   11:00–12:00 Visiting PMDA
      Attendee: GDA (Oversea), JACRI (2-3),
   13:30- 16:40 GDA Forum at German Cultural Hall in Akasaka
      Theme: Regulatory landscape for expanding molecular diagnostics
      Chairperson Yoshiaki Tazawa (Roche Diagnostics KK)

Opening Remarks and Greeting
13:30 – 13:35 President of JACRI,

Session 1: Current situation and issues of quality control and accuracy control of molecular testing in Japan. (tentative)
13:35 – 14:05 Speaker Honorary Prof. Tsutomu Nobori, Mie Univ.

Session 2: Regulatory issues and landscape on Companion Diagnostics in Japan. (tentative)
14:10 – 14:40 Speaker Dr. Sumimasa Nagai, The Institute of Medical Science, The Univ. of Tokyo

Session 3: FDA’s regulatory role for molecular testing
15:05 – 15:35 Speaker Ms. Tharini Sathiamoorthy (AdvaMedDx)

Session 4: IVD regulatory amendments in EU and its influence to molecular test market
15:40 – 16:10 Speaker Mr. Jesus Rueda Rodriguez (EDMA)

Session 5: Title not fixed.
16:15 – 16:45 Speaker Mr. Carlos Eduardo Gouvea (CBDL)

Presentation of New GDA Website
16:50 – 17:05 Speaker Mr. Ingmar de Gooijer (EDMA)

Closing remarks
17:05 – 17:10

2. May 29, 2015 (Fri)
9:00 – 12:00 GDA Meeting: at JAIMA office
   Agenda: GDA Website and Future Plan of GDA activities etc.
15:30 – 15:45 Presentation of New GDA Website
   (EDMA Mr. Ingmar)
16:00 – 16:45 Special Lecture
   At Kasumigaseki Bldg. 35F, Tokai Univ. Club Hall
   Title (not fixed)
   The Task and Vision of Japan Agency for Medical Research and Development
   Lecturer Dr. Makoto Suematsu, MD, PhD, President of Japan Agency for
   Medical Research and Development
16:50 – 18:20 Social Meeting & IVD Inter-Association Conference
   Speech or Presentation
   1. JACRI (Mr. Teramoto, 5 min)
   2. EDMA (Dr. Schulze, 10 min)
   3. EDMA (Mr. Rueda, 15 min)
   4. AdvaMedDx (Ms. Tharini, 15 min)
   5. Cepheid., Inc. (Ms. Hallie, 10 min)
   6. CBDL (Mr. Fabio, 10 min)
   7. CBDL (Mr. Carlos, 15 min)