

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, 15min)
4. AdvaMedDx (Ms. Tharini, 15min)
5. Cepheid., Inc. (Ms. Hallie, 10 min)
6. CBDL (Mr. Fabio, 10min)
7. CBDL (Mr. Carlos, 15min)