



DITTA Workshop on RPS and SaMD

During The 7th edition of IMDRF in Tokyo, Japan

Monday 23 March 2015 from 10:00 to 14:30

Location: Nadao Hall

*Shin-Kasumigaseki Building LB floor,
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo*

A workshop to discuss “RPS” and “SaMD” that are opened work items under IMDRF is organized by DITTA. This workshop will include achievements and the current status from regulators, insight from industry and the future of these topics.

Interpretation: Simultaneous Japanese/English will be provided.

9:30 – 10:00 Registration

10:00-10:05: **Opening Remarks** *Mr. Kimura DITTA Chair*

RPS Workshop chaired by Ms. Nancy Shadeed, IMDRF RPS Work Item Chair, Health Canada

10:05-10:10: **Introduction** *Ms. Nicole Denjoy DITTA Vice-Chair*

10:10-10:55: **Introduction to RPS and overview on progress made with status as of today** *Ms. Nancy Shadeed, IMDRF RPS Work Item Chair, Health Canada*

10:55-11:15: **Industry involvement and state of play** *Mr. Hans Beinke, DITTA Board of Director Member and DITTA RPS Working Group Vice-Chair, Siemens*

11:15-11:35: **Questions and Answers** *moderated by Ms. Nicole Denjoy DITTA Vice-Chair*

11:35-12:30 Lunch: Sandwich and Coffee

SaMD Workshop chaired by Mr. Bakul Patel, IMDRF SaMD Work Item Chair, US FDA

12:30-12:35 **Introduction** *Ms. Nicole Denjoy DITTA Vice-Chair*

12:35-13:45 **Introduction to SaMD and overview on progress made with status as of today** *Mr. Bakul Patel, IMDRF SaMD Work Item Chair, US FDA*

13:45-14:00 **Industry involvement and state of play** *Dr. Peter Linders, DITTA Board of Director Member and DITTA SaMD Working Group Member, Philips*

14:00-14:20 **Questions and Answers** *moderated by Ms. Nicole Denjoy DITTA Vice-Chair*

14:20-14:30 **Closing Remarks** *Mr. Kimura DITTA Chair*

