MDSAP: Current Status and Future Plans

Seminar hosted by DITTA in conjunction with the 11th meeting of the IMDRF Management Committee

Venue: Pan-Pacific Hotel, Vancouver, BC Canada – Crystal Pavilion BC (capacity 150)

Monday, March 13 2017 8:30 – 1:00

Thanks to the support of the IMDRF Chair, DITTA is pleased to provide an opportunity to learn more about the Medical Device single Audit Program (MDSAP). Medical device regulators, Assessing Organizations, and regulated industry participating in the initiative and pilot program will share their experiences and lessons learned. We will also explore the findings of DITTA's survey to industry, discussing the identified challenges openly, and collaborating on efforts to strengthen, streamline, and expand implementation of MDSAP.

The seminar will bring together experts from a variety of backgrounds to share their perspectives on MDSAP:

- Regulatory Authorities
- Regulated Industry
- Assessing Organizations

DITTA invites you to register for ***MDSAP: Current Status and Future Plans*** by clicking here.

8:30 Opening Session

Welcome and introductory remarks: Host Organizations

- Kimby Barton –Interim Director of the Medical Devices Bureau, Health Canada
- Patrick Hope – Executive Director, MITA; Chair, DITTA

8:45 Session 1 – Regulator perspectives

MDSAP Program: Overview of the program and its mechanics

- Marc-Henri Winter, USFDA – USA Program Lead for MDSAP

MDSAP: Current status, Timelines, and Plans for MDSAP consortium members

- Fabio Quintino Pereira, ANIVSA – Chair of MDSAP RAC

Q&A

9:30 Session 2 – Assessing Organization perspectives

AOs participating in MDSAP share their experiences: achievements, challenges, suggestions

- Gary Minks - Vice President, Quality & Regulatory Affairs – TÜV SÜD America Inc.
- Patricia Murphy – Global Head, MDSAP Program – BSI Healthcare

Q&A

10:15 – BREAK 30 min

10:45 Session 3 – Regulated Industry perspectives

DITTA Survey on Industry Participation in MDSAP: Findings and Conclusions

- Patrick Hope – Executive Director, MITA; Chair, DITTA

Industry participating in MDSAP share experiences: achievements, challenges, suggestions

- Philip Steinborn – Vice President of Quality and Regulatory for the Americas – Medtronic
- Emmett Deveraux – Director, Government and Regulatory Affairs, EMEA – Cook Medical
- Naoki Morooka – Senior Manager, Quality Assurance – Shimadzu Medical Systems
- Vijay Madikonda – Johnson & Johnson Medical Devices

Q&A

12:00 Closing session – Multi-stakeholder perspective panel discussion

Panel discussion and Q&A: speakers from industry, regulators, AOs (no presentations)

- Moderator: Brian Lewis, MEDEC
- Marc-Henri Winter - USFDA
- Jun Kitahara – PMDA Japan
- Nancy Shadeed – Health Canada
- Cheryl McCrae – TGA Australia
- Fabio Quintino Pereira – ANVISA Brazil
- Gary Minks – TÜV SÜD America Inc.
- Patricia Murphy – BSI Healthcare

Closing remarks from DITTA host organization

- Brian Lewis – MEDEC