Joint Meeting

PROGRAM ANNOUNCEMENT

Wednesday, April 12, 2017

Medical Device Single Audit Program – one audit multiple market access

Program Speaker

Royth von Hahn, Ph.D.
Vice President, Medical & Health Services, TÜV SÜD America, Inc.

Program Moderator
Frank Pokrop
Director of Regulatory Affairs, Becton Dickinson

Event Agenda:

Date: Wednesday, April 12, 2017

Time:
5:15 – 6:00 PM Registration & Snacks
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:00 PM Program Presentation
7:00 – 7:20 PM Q & A

NEW LOCATION: BD (former CareFusion) (directions on last page of this flyer)
6055 Lusk Blvd
San Diego, CA 92121

Program Speaker: Royth von Hahn, Ph.D.
Program Moderator: Frank Pokrop

Program Topic:

The program will give an introduction of the Medical Device Single Audit Program (MDSAP) and also draws a bigger picture on how MDSAP fits into the various regulatory changes in the medical device and IVD market. MDSAP has gained international traction in the market especially in light of the announcement of Health Canada to make MDSAP certification mandatory from Jan 1st 2019 for the Canadian market.

Program Summary:

The presentations will give different perspectives on the questions of objectives and requirements as well as preparation for MDSAP transition from the point of view of the manufacturer as well as from

the auditing organization. Especially the differences in audit planning, execution and follow up will be highlighted along the lines of real examples.

The following topics will be covered in particular:

- Introduction of MDSAP in the context of other regulatory changes
- Objectives of the program
- Pilot phase completed
- Acceptance by regulators
- Auditing organizations
- Resources (FDA website)
- Implementation
- The Audit Process
- Audit On-Site time calculation
- Nonconformity handling
- Obstacles for manufacturers to implement MDSAP
- Experience from the auditor's perspective

Speaker Biography:

Royth v. Hahn leads the TÜV SÜD Business Unit "Medical and Health Services" in the NAFTA region and manages the technical topics of functional safety and software for medical devices globally. He also leads the "investor's program" with services of technical and regulatory due diligence. He started his career at the University of Bonn and a MedTech spin off/start up in the field of medical ultrasound. He was head of a test laboratory and interim professor at a university of applied sciences in Germany for the topics of signal processing, medical imaging and ultrasound technology. Prior to taking on management positions within TÜV SÜD, Royth worked as Senior Product Specialist for ultrasound devices and lead auditor for active medical devices and software. He is member of several national and international standardization committees.

Royth holds a master's degree for physics from the university of Bonn (Germany), and industrial engineering & management in Koblenz (Germany). He also holds a PhD in electrical engineering from the University Duisburg in Germany.

Moderator Biography:

Frank Pokrop is a Director of Regulatory Affairs at Becton Dickinson in San Diego. His manufacturing experience includes injectable drugs and medical devices. Additional experience includes global submissions, recall management, compliance and investigations, worldwide audit program management, training, standards management and regulatory intelligence. In his current role he is primary contact for UDI issues for BD worldwide.

Frank received his B.S. in double major of biology and political science from the University of Wisconsin-La Crosse. He is a member of ASQ, ISACA and RAPS and holds these certifications: RAC, CSQE, CISA and CPGP. Frank is also the president of the San Diego Regulatory Affairs Network (SDRAN) for 2017.

To register for the meeting, click on the link below to access the SDRAN registration system (123Signup) for this event:

https://www.123signup.com/register?id=nrtzc

The above registration link can also be accessed on the SDRAN website, Events and Seminars page at: http://www.sdran.org/eventsandseminars

Please make your reservation early. The pre-registration due date is Monday April 10, 2017. Credit Cards are accepted on-line only. Cash and Check are accepted at the door.

On-line Pre-registration (through Monday April 10, 2017):

$20 SDRAN Member $35 Non-Member

Late Online Registration (Tuesday April 11, 2017):

$30 SDRAN Member $45 Non-Member

On-site Registration:

$35 SDRAN Member $50 Non-Member

For Questions Email: jodysuro@hotmail.com

Directions to BD (former CareFusion):

❖ NOTE – NEW LOCATION UNTIL FURTHER NOTICE

From the North 5:

- I-5 South toward San Diego
- Keep left and continue on I-805 South
- Take exit 27 toward Mira Mesa Blvd
- Take Mira Mesa Blvd to Lusk Blvd
- Turn left on to Sorrento Valley Road
- Stay on the road until it turns into Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left (notice Holiday Inn Express & Chili's)
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead

From the South 5:

- I-5 North
- From the right hand lane, take Exit 27A for Mira Mesa Blvd
- From the right hand lanes, turn right on to Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left you will notice:
  - Holiday Inn Express / Chili's
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead