SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, 17 April 2019

Monthly Program

FDA Cybersecurity Requirements for Design and Post-market

Program Speaker:
Dan P. Olivier,
President,
Certified Compliance Solutions, Inc.

Event Agenda:

Date: **Wednesday, 17 April 2019**

Time*:

5:15 – 6:00 PM	Registration, Snacks, & Speed Networking
6:00 – 6:05 PM	Welcome and Announcements
6:05 – 7:05 PM	Program Presentation
7:05 – 7:30 PM	Q & A

*Times are approximate.

Program Topic:

Medical devices are increasingly connected to the Internet, hospital networks, and other medical devices to provide features that improve health care and increase the ability of health care providers to treat patients. These same features also increase the risk of potential cybersecurity threats.

Medical devices, like other computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. Threats and vulnerabilities cannot be eliminated, therefore, reducing security risks is especially challenging. The heath care environment is complex, and manufacturers, hospitals, and facilities must work together to manage security risks.

The presentation will address the FDA's guidance documents regarding pre- and post-market cybersecurity. Practical approaches to meeting cybersecurity requirements will be addressed as well as what areas are of most interest to the FDA. Cybersecurity risk analysis and threat models will also be discussed.

Speaker Biography:

Dan Olivier is president of Certified Compliance Solutions, Inc. He is an acknowledged expert in the field of medical device and pharmaceutical system validation and safety risk management with over 28 years of experience. He is a frequent speaker at conferences, author of over 20 medical device related articles, and recognized as a leading industry expert in medical device software. His company provides consulting support

for validation, safety risk management, audits, training, software development, and testing services to meet the requirements of FDA regulations and ISO standards.

Location: Hologic Inc.
10210 Genetic Center Drive
San Diego, CA 92121

To register for the meeting, click here to access the SDRAN registration system (123Signup) for this event.

* **Please make your reservation early. The pre-registration due date is *Monday, 15 April 2019*. Advanced registration is appreciated to assist in event planning.**

** ***Space is limited for our monthly programs. Registration is capped at 100 participants. Register today to ensure your seat. Once our limit is reached, registration will close. Events with closed registration will not allow walk-ins.***

Online registration (through Monday 15 April 2019):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@SDRAN.org

Directions to Hologic:

From the North I-5 and I-805

I-5 South toward San Diego
Exit toward I-805 S
Exit toward Mira Mesa Blvd
Turn left onto Sequence Dr
Turn right to the facility

From the South I-805

I-805 North toward Sorrento Valley
Exit toward Mira Mesa Blvd
Turn left onto Sequence Dr
Turn right to the facility