SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Thursday, 28 February 2019

Open House

Come to this low-cost event and learn what SDRAN can do for you in 2019!
SDRAN serves all levels of Regulatory, Clinical, and Quality professionals

Monthly Program
Ready or Not, Here it Comes: New EU Regulatory Landscape

Program Speaker:
John Beasley, RAC
Senior Consultant
MedTech Review, LLC
Henderson, NV

Event Agenda:

Date: **Thursday, 28 February 2019**

Time*:	5:15 – 6:00 PM	Registration & Snacks
	6:00 – 6:05 PM	Welcome and Announcements
	6:05 – 6:30 PM	Committee Introductions • Education • Programs • Member Relations • Website & Communications • Mentoring
	6:30 – 7:15 PM	Program Presentation
	7:15 – 7:45 PM	Q & A

*Times are approximate.

Program Topic:
What can we expect as the EU Regulatory landscape continues to change in 2019? This program will focus on major changes and key themes in the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). We will explore what has changed compared the previous Medical Device Directive (MDD) and In Vitro Diagnostic Directive (IVDD) and will unpack the impact these changes have/will have on a medical device manufacturer's quality system documentation. The program will also discuss device classification, best practices on transitioning from the MDD to MDR or IVDD to IVDR, and how the impending Brexit decision factors into the regulatory landscape.

Speaker Biography:
John Beasley, RAC (US), founded MedTech Review, LLC in 2003 and services as a Senior Consultant to the medical device industry, where he provides broad-spectrum international quality and regulatory support. He built MedTech Review based on his 32-plus-year career that focused on establishing, evaluating, and remediating quality management systems to meet international regulatory requirements.

During these years, John lived and worked one-third of the time in Asia, where he coordinated the closure of FDA Warning Letters, set up the medical device certification business for one of the leading EU Notified Bodies, and served as a liaison to regional regulators making up the Asian Harmonization Working Party (AHWP).

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

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

** **Please make your reservation early. The pre-registration due date is *Tuesday, 26 February 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.***

On-line Registration:
$10 for SDRAN Non-Members and NO FEE for SDRAN members

On-site Registration:
$10 for SDRAN Non-Members and NO FEE for SDRAN members

For Questions Email: **membership@SDRAN.org** or **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