SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, 18 July 2018

Monthly Program

Device Regulatory Update

Program Speaker:
Janet Trunzo, MS
Sr. Advisor to President and Sr. Executive VP,
Technology & Regulatory Affairs, Advamed

Event Agenda:

Date:	Wednesday, 18 July 2018
Time:	5:15 – 6:00 PM Registration & Snacks 6:00 – 6:05 PM Welcome and Announcements 6:05 – 7:05 PM Program Presentation 7:05 – 7:30 PM Q & A
LOCATION:	BD (former CareFusion) (directions on last page of this flyer) 3770 Torrey View Court San Diego, CA 92130
Program Speaker:	Janet Trunzo, MS

Program Topic:

Since the passage of the 21st Century Cures Act in December 2016, and the reauthorization of Medical Device User Fee Amendments (MDUFA) and the device-related provision in the FDA Reauthorization Act (FDARA) in August 2017, there are numerous key device regulatory reforms underway at the Agency.

Program Summary:

The talk will provide updates on FDA's implementation of device regulatory reforms including:

- Breakthrough pathway
- Exemption from 510(k) submissions for low-risk device types
- Application of least burdensome principles
- Process improvements in MDUFA IV
- New MDUFA IV performance goals
- Inspections process improvements

- Streamlined classification for device accessories

The talk will also include an overview of the planned restructuring of CDRH based on a total product life cycle approach.

Speaker Biography:

Janet E. Trunzo is Senior Advisor to the President and Senior Executive Vice President, Technology and Regulatory Affairs, for the Advanced Medical Technology Association (AdvaMed) where she leads a team of regulatory experts. During her tenure at AdvaMed, she has focused on the passage of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), its reauthorization in 2007 and in 2012, and the subsequent negotiation for MDUFA IV. She also concentrates on global regulatory harmonization and represented the U.S. device industry on the Global Harmonization Task Force. Currently, Ms. Trunzo chairs the international Board of Trustees for the Global Medical Device Nomenclature Agency and chairs the Regulatory Committee for the Global Medical Technology Alliance. Prior to joining AdvaMed, Ms. Trunzo held positions at Hybritech, Inc., a medical device and diagnostics manufacturer, and Scripps Clinic and Research Foundation, a hospital, diagnostic clinic and research institute.

Ms. Trunzo received her M.S. in health physics from Rutgers University and her B.S. in Chemistry from California University of Pennsylvania.

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

Please make your reservation early. The online registration due date is Monday, 16 July 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday 16 July 2018):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@sdran.org

Directions to BD (former CareFusion):

From the North 5:

I-5 South toward San Diego
Exit toward Carmel Mountain Rd Left onto Carmel Mountain Rd
Left onto Torrey View Court Facility is on the right

From the South 5:

I-5 North toward Del Mar
Merge onto I-5 local Bypass
Take Carmel Mountain Rd exit (32)
Turn right onto Carmel Mountain Rd
Turn left onto Torrey View Court
Facility is on the right