SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, 20 June 2018

Monthly Program
Current Hot Topics within FDA and Inspection Preparation

Program Speaker:
Sarah B. Tanksley, M.S.
President & CEO, Tanksley Consulting Group

Event Agenda:

Date:	Wednesday, 20 June 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:	Sarah B. Tanksley, M.S.	

Program Topic:

The Food and Drug Administration (FDA) conducts careful inspections of regulated facilities to determine a firm's compliance with regulations and the Food, Drug and Cosmetic Act. Inspections are one of the many ways FDA protects the public health. The prospect of inspections can be intimidating but being prepared and having your site ready can help reduce anxiety before FDA arrives.

Program Summary:

This talk will provide the most recent updates on some of the challenges within the FDA today, including the following:

- Enforcement actions and warning letter trends
- Mutual recognition program for inspections
- Cellular and gene therapy regulatory strategies
- Regulation of laboratory developed tests
- Status of the Quality Metrics reporting program
- New serialization requirements

Also, Ms. Tanksley will discuss how to prepare for an FDA inspection in today's regulatory environment. Topics will include:

- Preparing your facility to face an FDA inspection
- Training subject matter experts on how they should conduct themselves during questioning
- Handling challenging topics and contentious conversations
- Understanding specific behaviors that FDA investigators are trained to recognize and record

Speaker Biography:

Sarah Tanksley has been consulting in the area of pharmaceutical quality and compliance since 2011. She has led several remediation projects involving breaches in data integrity and has led audits which have detected both gaps and falsified data. She regularly lectures on the topic of data integrity to audiences worldwide. Prior to consulting, she was a Consumer Safety Officer in the Office of Compliance, Center for Biologic Evaluation and Research (CBER) at the Food and Drug Administration, where she reviewed new applications for approval and conducted prior approval inspections as well as routine GMP inspections. Sarah joined the FDA after several years as biologist in the laboratory at the National Institutes of Allergy and Infectious Disease, National Institutes of Health.

Sarah has a MS in Biochemistry and Molecular Biology from Georgetown University, a MS in Regulatory Science from Johns Hopkins University, and a BS in Biology from the College of William and Mary.

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

Please make your reservation early. The online registration due date is Monday, 18 June 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday 18 June 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

From the South 5:

Court Facility is on the right-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