



## PROGRAM ANNOUNCEMENT

Saturday, 23 June 2018

### Data Integrity Training Workshop

By  
Sarah B. Tanksley, M.S.  
President & CEO, Tanksley Consulting Group

#### Event Agenda:

Date: Saturday, 23 June 2018

Time:

8:45 – 9:00 AM	Registration
9:00 – 12:00 PM	Training Session – Part 1 & 2
12:00 – 1:00 PM	Lunch
1:00 – 3:00 PM	Training Session – Part 3 & 4

**LOCATION:** BD (former CareFusion) (directions on last page of this flyer)  
3770 Torrey View Court  
San Diego, CA 92130

#### Training Workshop Summary:

Worldwide, regulators continue to express concern over the lack of reliable product data in the pharmaceutical industry. During 2016 alone, over 40 FDA warning letters cited data integrity issues, from blatant falsification to lack of control of electronic records. Sarah Tanksley, President & CEO, Tanksley Consulting Group and a former FDA reviewer and inspector from CBER, will provide training on overview of data integrity, Good Documentation Practices for Paper and Electronic Data, Current Regulatory Expectations for Data Integrity, and Audit Tips and Remediation Strategies. She will also provide tips for implementing a risk-based strategy for data governance and culture of data integrity within a pharmaceutical environment.

This interactive session will be divided into 4 parts:

#### **PART 1: Data Integrity Introduction and Overview**

An introduction to data integrity definitions and concepts. Discussion of Part 11 and how it is related to data integrity. Discussion of potential consequences of poor data integrity practices.

#### **PART 2: Good Documentation Practices for Paper and Electronic Data**

ALCOA definitions, expectations for meeting ALCOA for paper and electronic records are discussed. Examples of paper and electronic record breaches are provided. Recent warning letters on the topic

are discussed.

### **PART 3: Current Regulatory Expectations for Data Integrity**

Highlights from recently published regulatory guidance documents are discussed. Regulatory expectations for data governance plans, data lifecycle mapping, and risk-based approaches to managing data. Discussion of recent warning letters.

### **PART 4: Audit Tips and Remediation Strategies**

Tips for detecting data integrity issues and strategies for remediation are given. Case studies are discussed.

### **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:**

[Register Here](#)

**Please make your reservation early. The online registration due date is Thursday, 21 June 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.**

### **Online registration (through Wednesday, 20 June 2018):**

\$50 SDRAN Member

\$75 Non-Member

### **Onsite Registration:**

\$60 SDRAN Member

\$85 Non-Member

**For Questions Email: [programs@sdran.org](mailto: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