



PROGRAM ANNOUNCEMENT

Wednesday, June 14, 2017

Monthly Program:

Current Regulatory Expectations for Data Integrity

Program Speaker:

Sarah Tanksley, MS

Senior Quality Compliance Consultant

Quality Compliance Partners, Inc.

Event Agenda:

Date: Wednesday, June 14, 2017

Time: 5:15 – 6:00 PM Registration & Snacks
5:20 – 5:50 PM *Speed Networking*
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:35 PM Program Presentation
7:35 – 7:50 PM Q & A

NEW LOCATION: BD (former CareFusion) (directions on last page of this flyer)
6055 Lusk Blvd
San Diego, CA 92121

Program Speaker: Sarah Tanksley, MS

Program Topic:

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, a former FDA reviewer and inspector from CBER, will discuss key elements of a strong data integrity program. She will also provide tips for implementing a risk-based strategy for data governance and culture of data integrity within a pharmaceutical environment.

Program Summary:

It isn't enough to simply review lab notebooks or validate computer systems and rely on staff to be honest when capturing and reporting electronic raw data. Increasingly, regulators are citing companies for failing to have proper systems in place to review data and relevant metadata, and for not having systems in place to detect a fraudulent record.

The purpose of this session is to provide an overview of the current worldwide regulatory expectations for data integrity, including expectations for both paper and electronic records as outlined in the 2016 FDA Data Integrity and Compliance with GMP Guidance. Also, the concepts of data governance and data lifecycle mapping, used by the MHRA and other worldwide regulators, will be discussed.

Specifically, we will discuss the following

- How to ensure your electronic records are “bulletproof”
- Common data integrity pitfalls
- Key “buckets” for data integrity citations in warning letters
- Considerations for implementing a data governance plan
- Remediation strategies for data integrity breaches

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.

She 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:

<https://www.123signup.com/register?id=hgytx>

The above registration link can also be accessed on the SDRAN website Events page at:

http://www.sdran.org/#!_events-and-seminars

Please make your reservation early. The online registration due date is Monday June 12, 2017. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday June 12, 2017):

\$15 SDRAN Member

\$25 Non-Member

Onsite Registration:

\$25 SDRAN Member

\$35 Non-Member

For Questions Email: jodyuro@hotmail.com

Directions to BD (former CareFusion):

❖ NOTE – NEW LOCATION UNTIL FURTHER NOTICE

From the North 5:

- I-5 South toward San Diego
- Keep left and continue on I-805 South
- Take exit 27 toward Mira Mesa Blvd
- Take Mira Mesa Blvd to Lusk Blvd
- Turn left on to Sorrento Valley Road
- Stay on the road until it turns into Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left (notice Holiday Inn Express & Chili's)
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead

From the South 5

- I-5 North
- From the right hand lane, take Exit 27A for Mira Mesa Blvd
- From the right hand lanes, turn right on to Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left you will notice:
 - Holiday Inn Express / Chili's
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead