PROGRAM ANNOUNCEMENT

Wednesday, 23 October 2019

Monthly Program

Audits and Inspections: Setting Yourself Up for Success

Program Speaker:

Bill Bressler
Director of GXP Compliance and Quality Systems
Navigate BioPharma Services

Event Agenda:

Date: **Wednesday, 23 October 2019**

Time*:
5:15 – 6:00 PM Registration, Snacks, & Networking
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:05 PM Program Presentation
7:05 – 7:30 PM Q & A

*Times are approximate

Program Topic:

Regulatory authorities, including the Federal Food and Drug Administration (FDA) and European Medicines Agency (EMA) regularly inspect a company's manufacturing and distributing of regulated products to verify compliance with relevant regulations. These inspections ensure the reliability and integrity of the data that support the quality, safety, and effectiveness of drugs and medical devices once they are marketed. Several types of inspections can be performed, including pre-approval inspections once a company submits an application to market a new product, a routine inspection of a regulated facility, or a "for-cause" inspection to investigate a specific problem that has come to FDA's attention. This presentation will identify best practices for manufacturers during regulatory inspections and will focus on the three primary areas of inspection/audit management:

1) Preparation of staff and documents for the inspection
2) Preparing your site for the tour
3) Setting up the inspection room to your advantage

Speaker Biography:

William (Bill) Bressler is a regulated industry professional with 32 years of Engineering and Quality experience. He is a contributing author for 9 regulatory applications for drug or device approval, providing direct support for 8 pre-approval inspections and the approval of 5 drug/device products. Bill has experience in both pharma and medical device areas. He has supported drug product programs that range from aseptic injectables to non-sterile liquids for oral administration. His experience with device products range from combination products and companion diagnostics to simple mechanical fixtures. Bill has been responsible for the architecture, improvement and maintenance of Quality Systems, System Lifecycles, and Product Lifecycles in compliance with 21 CFR Parts 11, 49, 58, 211, 803, and 820, and select ICH regulations. He is currently the Director of GMP Compliance and Quality Engineering at Navigate BioPharma Services.

Location: Pfizer Inc.
10770 Science Center Drive (visitors center)
Conference Room #1110
San Diego, CA 92121

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

* **Please make your reservation early. The pre-registration due date is *Monday, 14 October 2019*. Advanced registration is appreciated to assist in event planning.**

** ***Space is limited for our monthly programs. Registration is capped at 85 participants. Register today to ensure your seat. Once our limit is reached, registration will close. Events with closed registration will not allow walk-ins.***

*** ***A photo ID is required to sign in at the venue.***

Online registration (through Monday, 14 October 2019):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@SDRAN.org

Directions to Pfizer:

From the North

I-5 South toward San Diego
Take Exit 29, turn left into Genesee Ave
Turn right onto Science Center Dr
CB2 Visitors Center is located at the end of the cul-de-sac

From the South

I-5 North toward Downtown
Take Exit 29, turn right into Genesee Ave
Turn right onto Science Center Dr
CB2 Visitors Center is located at the end of the cul-de-sac