Regulatory Inspections: Understand the Process and Manage the Consequences

Wednesday, July 29, 2020
6:00-8:30 pm
Zoom Meeting
Log in from the convenience of your home or office—Zoom link will be provided.

Speaker:
Janet E. Holwell, CCRC, CCRA, TIACR, FACRP
Clinical Research Consultant

Program Description:
Do you understand the expectations following an FDA Inspection? What are the possible outcomes? How can you best respond? We will be covering important information including a review of the documents exchanged during an inspection and the process followed by FDA to determine whether a warning letter will be issued. We will identify and define the possible outcomes of an inspection. This interactive program is designed for clinical research professionals interested in learning about what happens after an inspection is completed. We will employ a hands-on activity utilizing breakout rooms to create corrective and preventive actions (CAPAs), utilizing root cause analysis (RCA) procedures to address FDA citations in warning letters.

Upon completion of this Webcast, attendees should be able to:
1. Describe at least 3 regulatory actions FDA can take following an inspection.
2. Discuss appropriate strategies for responding to inspection findings.
3. Implement realistic and appropriate corrective and preventive actions to successfully resolve inspection findings.

Agenda:
6:00-6:10 Welcome and Chapter Meeting
6:10-8:30 Educational Program and Q&A

Cost: Complimentary for NY Metro Chapter Members/$25 Non NYM Chapter Members.

Registration: Register at Eventbrite. Log in information will be sent one week prior to the event.

Contact hours: 2.5 Contact hours have been applied for through ACRP. Membership is not required for online registration of contact hours.

Contact Hour Cost: Complimentary for NY Metro Chapter Members/$15 ACRP Members/$30 Non-Members

To receive contact hours: Purchase the contact hours on the ACRP NY Metro Chapter website the up to two weeks after the event. Between 1 and 30 days after attending the program, go to https://acrp.digitellinc.com/acrp/login to complete the evaluation. You can also get to it by going to the “My Courses” link and clicking on the button for Chapter Events (the button on the left side). Once you are on the platform, click on Chapter Events on the left, click on the correct event, select the CE Information tab and click on the “Take Evaluation” button. It takes one business day for the information to refresh in your account.