Preparing for an FDA Inspection 101

Orange County Regulatory Affairs Discussion Group (OCRA)

Wednesday, February 22, 2012

1:00 - 5:00 pm

Location:
Irvine Marriott
1800 Von Karman Avenue, Irvine, CA  92612

Program Managers:
Eri Hirumi, RAC, Regulatory Affairs Manager, Beckman Coulter, Inc.
Craig Tingley, Director, Process Improvement, Loma Linda University Medical Center
Erin Cummings, RAC, Quality Assurance Consultant, CALIFY Consulting

Synopsis:
Nothing beats hands on practice and getting direct inputs from the FDA and seasoned veterans of the FDA inspection process. Come join us for a chance to practice preparing and stepping through an inspection. See what it is like to participate in a inspection with different roles. Come experience the who, what and how's of an inspection.

1. Who should coordinate the inspection?
2. What does the FDA look for?
3. What are the signal they are trained to detect?
4. What kind of documentation are they looking for?
5. How quick is quick enough?

This session will be split in two parts. There will be an one hour preparation meeting 1 week (Feb. 15) via teleconference (before the actual session). At this meeting, the attendees will be assigned/organized into specific groups and given a checklist of documents to prepare from their businesses. These sample documents may be changed or redacted to protect the all. Documents may be sent in to the "Inspectors" to get evaluations and inputs on the quality of the documentation.

On the day of the session, there will be approximately 10 volunteer inspectors. Each inspector will have their industry specialty clearly described (Medical devices, food, drug, combination or biologics) 4-5 attendees will be assigned to each inspector. The attendees will play one of the following roles:
1. Company CEO
2. Company Regulatory Vice President
3. Company Scribe
4. Company Quality Vice President
5. Inspection Facilitator

We will role play for two sessions of 45 minutes each. We will switch roles and inspectors in between the two sessions. (1.5 hours)

Then each inspector will have 15 minutes to make comments/write notes (30 minutes)

Then we will share with the whole group what each inspections learned (15 mins/team - total 30).

Questions and answers with the complete group for 30 minutes.

**Proposed Schedule:**
12:30 PM - 1:00 PM Registration/Check In
1:00 PM - 1:15 PM Introduction and organization
1:15 PM - 2:00 PM Session 1 inspection
2:15 PM - 2:30 PM Inspectors to give immediate input to the small team
2:30 PM - 2:45 PM People break/move
2:45 PM - 3:30 PM Session 2 inspection
3:30 PM - 3:45 PM Inspectors to give immediate input to the small team
3:45 PM - 4:00 PM Break and return to complete group
4:00 PM - 4:30 Q&A and discussion with whole group

Note: Your fee includes snacks and drinks during the meeting, access to electronic presentations after the meeting and parking.
**Register Online**
Be sure to log on or create a new user profile before registering
http://www.ocra-dg.org/

Follow the steps below to register online.
Use the Online system to receive an immediate receipt and immediate confirmation.

**Be sure to log on or create a new user profile before registering**
http://ocra-dg.org/

**MULTIPLE REGISTRATIONS:**
Our system is set up for one registration at a time. To register multiple people from your company, you can simplify the process by faxing us a cover page on your company letterhead listing the names of your attendees along with their title and email address. Supply a credit card number and expiration date or let us know that a check will be mailed (checks should be received prior to the event). If you need a receipt, please let us know to whom it should be emailed.

**SINGLE REGISTRATION:**
Log on to the OCRA Web site with your username and password or create a new user profile:
http://ocra-dg.org/

Once you are logged on, click on “Register for a Meeting” on the right-hand side of the page. Next click on the meeting for which you would like to register, then follow the online instructions. You will receive an immediate confirmation and receipt.

To Register With Company or Personal Check:

Please submit the online registration form. Mail your check made payable to OCRA to the following address:

**Orange County Regulatory Affairs Discussion Group**
5319 University Dr., Suite 641, Irvine, CA 92612
Tel: 949-387-9046
Fax: 949-266-8461 or 949-387-9047
Email: ksyre@cox.net

**OCRA’s non-profit Federal Tax ID# 33-0630455**

NOTE: We will ask for a credit card payment for any checks not received by the meeting date

Cancellation Deadline:
For a refund, please cancel by February 15, 2012

*If you have reserved a space but do not attend, your payment MUST be remitted.*
OCRA REGISTRATION FORM
Preparing for an FDA Inspection 101
Wednesday, February 22, 2012

Use the Online system to receive an immediate receipt and immediate confirmation. Be sure to log on or create a new user profile before registering: http://ocra-dg.org/

This document can also be used as a registration form. Fax this one-page registration form with credit card information to: (949) 266-8461. Name badges and receipts will be provided at the on-site registration desk. If you would like a receipt prior to the event, please use the Online or PayPal payment option. Submit one copy for each person attending.

Please check type of card: _____ VISA   _____ MASTERCARD   _____ AMERICAN EXPRESS

Card #:__________________________________________________________
Expiration Date:_____________________________________________
Name on Card:___________________________________________________
Signature:_______________________________________________________

Registration Rate is:
_____ $ 95 - OCRA Members
_____ $ 145 - Non-members (includes OCRA membership through end of 2012)
_____ $ 65 - Government and students*

*Student Rate is for Full-time students only. The Student Rate does not apply to working professionals taking one or two courses on the side (full-time students only). Student ID and copy of current class schedule required to register. Final eligibility determined by OCRA.

Your Contact Information:
FIRST NAME:__________________________________________________
LAST NAME:__________________________________________________
COMPANY:___________________________________________________
TITLE:_______________________________________________________
ADDRESS:___________________________________________________
CITY:________________________________________________________
STATE:_________________ ZIP:_______________________________
PHONE:_________________ FAX:_______________________________
E-MAIL:____________________________________________________
DRIVING DIRECTIONS:

Irvine Marriott
1800 Von Karman Avenue, Irvine, CA 92612
(949) 553-0100

HOTEL RESERVATIONS, PLEASE CALL - (800) 228-9290

Shuttle Service:
There is shuttle service from the Orange County airport to the hotel. The shuttle runs every 30 minutes outside of Baggage Claim. For faster service it is recommended that you call the Irvine Marriott from the courtesy phone in baggage claim to let them know you are there and waiting.

From OC/John Wayne Airport:
Exit airport on Michelson Drive. Go straight to Von Karman Avenue and turn Left onto Von Karman Avenue. Turn Right onto Quartz and Left at the stop sign. The Marriott Hotel is on the left hand side.

From LAX - Los Angeles International Airport:
Take 405 South (San Diego Freeway). Exit Jamboree and turn Right off ramp. Turn Right onto Michelson Drive and Right onto Von Karman Avenue. Turn Right onto Quartz and Left at the stop sign. The Marriott Hotel is on the left hand side.

From Ontario International Airport:
Take 10 West (San Bernardino Freeway) to the 57 South (Orange Freeway). Take 57 South to the 5 South (Santa Ana Freeway). Take 5 South to the 55 South (Newport Beach Freeway) and then to 405 South (San Diego Freeway). Exit Jamboree, turn Right off ramp. Right onto Michelson Drive and Right onto Von Karman Avenue. Turn Right onto Quartz and Left at the stop sign. The Marriott Hotel is on the left hand side.

From Downtown Los Angeles:
Take 5 South (Santa Ana Freeway) to 55 South (Newport Beach Freeway). Take 55 South to 405 South (San Diego Freeway). Exit Jamboree and turn Right off the ramp. Turn Right onto Michelson Drive and Right onto Von Karman Avenue. Turn Right onto Quartz and Left at the stop sign. The Marriott Hotel is on the left hand side.

From San Diego:
Take 5 North (Santa Ana Freeway) to 405 North (San Diego Freeway). Exit Jamboree and turn Left off the ramp. Turn Right onto Michelson Drive and Right onto Von Karman Avenue. Turn Right onto Quartz and Left at the stop sign. The Marriott Hotel is on the left hand side.