OCRA
ORANGE COUNTY
REGULATORY AFFAIRS
DISCUSSION GROUP

Orange County Regulatory Affairs Discussion Group (OCRA)

CAPA and Root Cause Analysis

Wednesday, March 5, 2014
8:00 am - 5:00 pm

Location:
DoubleTree, Irvine Spectrum
90 Pacifica, Irvine, CA 92618

Program Managers/Moderators:
Paul Kramsky, President, Rockin' Regulatory, Inc.
Janet Rubin-Halpert, RAC, Sr. Regulatory Affairs Specialist, Aerotek

Speakers:
Larry Bartkus, Distinguished Engineer, Quality Systems, Edwards Lifesciences
Blake Bevill, Director of Compliance Branch, U.S. Food and Drug Administration (FDA)
James (Rusty) Lusk, Principal, Quality Systems International

Synopsis:
Corrective and preventive action (CAPA) is a vital quality management systems process, critical to a company's ability to identify, address and prevent recurrence of product or process problems. CAPA consistently remains one of the most frequently cited areas of noncompliance in FDA inspections and warning letters.

This program will provide the nut-and-bolts for implementing and managing an effective CAPA program and will feature experts from both industry and FDA who will share their experience and perspectives on what constitutes a well-oiled CAPA program -- including failure investigation and root cause analysis -- and the pitfalls that manufacturers should avoid to avert an FDA 483 citation or warning letter.

This program will also include a case study which will provide attendees the opportunity to participate in the evaluation and resolution of a CAPA problem, and will conclude with a panel discussion.

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Schedule

8:00 - 8:25 am **Registration and Continental Breakfast**

8:25 - 8:30 am **Introductions**

8:30 - 9:30 am
CAPA is not a Noun: Understanding the Key Elements of CAPA; CAPA Definitions and Triggers; Implementing and Managing an Effective CAPA Program; Preventive Action Overview; Overview of CAPA Effectiveness Monitoring
James (Rusty) Lusk, Principal, Quality Systems International

9:30 - 9:35 am **Stretch Break**

9:35 - 11:15 am
Conducting Effective Failure Investigations and Root Cause Analysis; Problem Identification and Definition, Tools to Implement Optimal Corrective Action among Possible Corrective Actions; Corrective Action Documentation
Larry Bartkus, Distinguished Engineer, Quality Systems, Edwards Lifesciences

11:15 am - 11:30 am **Break**

11:30 am - 12:15 pm
Typical Problems FDA Observes: Manufacturer Pitfalls with CAPA and How to Address Them
Blake Bevill, Director of Compliance Branch, U.S. Food and Drug Administration (FDA)

12:15 pm - 1:15 pm **Lunch**

1:15 - 2:00 pm
CAPA Optimization and Effectiveness Monitoring: Details / Nuts and Bolts (Scope, Duration, Sampling); Appropriate Types of Data for Effectiveness and Effectiveness Determination
Larry Bartkus, Distinguished Engineer, Quality Systems, Edwards Lifesciences

2:00 - 2:40 pm
Presentation of CAPA Case Study

2:40 - 3:45 pm
Attendee breakouts to work on case study

3:45 - 3:55 pm **Break**

3:55 - 4:20 pm
Presentation of case study results

4:20 - 4:40 pm
Preventive Action -- Details
James (Rusty) Lusk, Principal, Quality Systems International

4:40 - 5:00 pm **Panel Discussion with all Speakers**

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About the Speakers

Larry Bartkus is a Distinguished Engineer for Quality Systems at Edwards Lifesciences. He is responsible for the development and implementation of corporate quality systems. He is a Certified Quality Engineer and Six Sigma Master Black Belt with over thirty five years experience in the Quality profession. He has held previous positions at ev3, Biosense Webster, Johnson & Johnson and Calmar.

He holds a degree in Chemistry from Montclair State University in New Jersey. Larry has been guest speaker at The Society of Plastics Engineers, Society of Manufacturing Engineers, APICS, OCRA, and ASQ. He is a past Chairman of ASQ Section 702 and has served on the Executive Board for over twenty years. He was an instructor for several CQE Refresher Courses and has conducted seminars in Process Control, Statistical Sampling, and Design of Experiments. He was named ASQ Biomedical SCDG Speaker of the Year 2007-2008 for his informative, interactive, and always humorous presentations.

Blake Bevill is the Director of the Los Angeles District's Domestic Compliance Branch. Protection of public health is accomplished by recommending and managing regulatory and enforcement actions such as warning letters, seizures, injunctions, administrative detentions and civil money penalties.

He has a Bachelor's Degree in Biology from Harding University and a Master's of Science Degree in Biology from Arkansas State University. He has over 24 years of FDA experience.

As an FDA Investigator stationed in Houston, TX, Jackson, MS, Tallahassee, FL and Little Rock, AR Resident Posts he conducted inspections and investigations in all program areas (Drugs, Devices, Foods, Biologics, Veterinary Medicine, etc.) including foreign drug inspections. As the Resident in Charge of the Tallahassee, FL and Little Rock, AR Resident Posts he was also the primary state liaison responsible for over ten state contracts, partnerships and MOUs.

As a Supervisory Investigator stationed in Atlanta, GA he was responsible for the Import and Veterinary Medicine Programs. As Atlanta District's initial Incident Command System leading responder, he directed the FDA's follow-up on the ground in New Orleans following hurricanes Katrina and Rita.

As the Operations Director he reported directly to the Associate Commissioner of Regulatory Affairs stationed in Rockville, MD and played a leading role in two organizational strategic planning initiatives. He has played a leading role in several organizational, budget, business process development and implementation initiatives. He worked directly with several ORA leading management officials that held positions as Office Director, Division Director, Regional Director, District Director, Compliance Branch Director, and Investigations Branch Director.

James (Rusty) Lusk has over 35 years of experience in regulated and non-regulated industries ranging from early-stage development to Fortune 100 companies. He has held senior management positions in disciplines such as Regulatory, Quality, Clinical Programs, and New Business Development. He is currently a Principal with Quality Systems International; a multidiscipline consulting company serving ISO/EN and FDA regulated industries. He is also co-founder of LifePulse, LLC, an early-stage medical device company and co-inventor of a non-invasive device intended to delay or reverse cardiovascular disease and improve quality of life.
He is a Past President of OCRA. He has a MBA from Pepperdine University and BS in Biological Sciences from UC Irvine. He holds numerous domestic and international certifications including RABQSA, US and EU RAC from RAPS and CMQ/OE, CQE, CQA, CQA_{HACC} from ASQ.

OCRA Online Registration Instructions

Registration fee includes continental breakfast, lunch, parking and access to electronic presentations (if approved by speakers for distribution).

Step 1:
Click on this link:
http://www.ocra-new.com/ocra/index.php/en/component/dtregister/

Step 2:
Immediately log in with your username and password OR Create a new account by selecting "Register" on the top right hand side. If you are not an OCRA Member, it will ask you to join. Please keep in mind that to attend any OCRA meeting, we require you to become a Member.

Step 3:
Once you have logged on (and paid for membership) select the meeting you would like to attend and complete the registration process by filling in the appropriate fields.

NON MEMBERS
If you are not an OCRA Member, we require you to join OCRA before registering for this meeting.

To join OCRA go to this link: http://www.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
Email: ksyre@cox.net
OCRA's non-profit Federal Tax ID# 33-0630455

Cancellation Deadline:
For a refund, please email your cancellation request to Rob Fleming (rob.fleming@yahoo.com) by February 26, 2014.
NOTE: We will ask for a credit card payment for any checks not received by the meeting date.
If you have reserved a space but do not attend, your payment MUST be remitted.

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OCRA REGISTRATION FORM

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This document can be used as a registration form. Fax this one-page registration form with credit card information to: (949) 266-8461. Please check type of card:

_____VISA _____ MASTERCARD _____ AMERICAN EXPRESS

Card #:_____Expiration Date:_____

Name on Card:_____

Signature:_____

Name badges 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.

Registration Rate:

_____$ 200 – OCRA Members

_____$ 250 - Non-members (includes OCRA membership for one year)

_____$ 100 - Government and students*
***Student Rate is for full time students only. Student ID and copy of current class schedule required to register.**

Your Contact Information:

FIRST & LAST NAME: _____

COMPANY: _____

TITLE: _____

ADDRESS: _____

MAIL CODE: _____

CITY: _____

STATE: _____ ZIP: _____

PHONE: _____

FAX: _____

E-MAIL: _____

DRIVING DIRECTIONS:

DoubleTree, Irvine Spectrum
90 Pacifica, Irvine, CA 92618
(949) 471-8888

From LAX:
Take 405 Freeway South. to 133 Freeway North.
Exit at Barranca Parkway.
Turn Left onto Pacifica.
The DoubleTree will be on the Left Side.

From San Diego:
Take 5 Freeway North.
Exit at Alton Parkway.
Turn Left onto Alton Parkway.
Turn Right onto Pacifica.
The DoubleTree will be on the Left Side.

It is recommended that you look up driving directions from your own starting point.