The FDA-OCRA Educational Conference is a unique co-sponsored event by the FDA and OCRA, that affords you maximum interaction with both LA District and Washington-based FDA personnel. We are proud to bring the FDA and Industry together for this one-of-a-kind local conference.

**Who Should Attend**
- Regulatory Affairs/Compliance
- Quality Affairs/Quality Control
- Consultants & Analysts
- Clinical Affairs/Auditors
- Marketing & Advertising
- Operations & Management
- Legal Staff
- Product Development

**June 3 is Plenary Sessions in AM and Three Breakouts in the PM:**
1. Clinical Trials Breakout Sessions - Back by Popular Demand
2. International Breakout Sessions - New Breakout Session
3. Dietary Supplements Breakout Sessions

**June 4 is Half Day Breakout Sessions in the AM**
1. Medical Devices and IVDs Breakout Sessions
2. Drugs and Biologics Breakout Sessions

**Conference Chairs:**
Steven Porter, Acting District Director, FDA Los Angeles District
Evelyn De La Vega, RAC, Sr. Manager, Regulatory Affairs, Bausch + Lomb

**New Conference Format - We’ve Listened to Our Members**
You’ve told us that the break-out sessions are more beneficial and you like networking with other colleagues in your segment of the industry. This year we have eliminated some of the plenary sessions so the focus will be on the break-outs by industry sector. This allows us to shorten the overall meeting and minimize time away from the office by a half-day.

Also as costs of travel, hotel, audio visual and all expenses to produce a conference soar, we did not want to raise our registration fee (our rate is still about half the rate of many other conferences.) OCRA is committed to keeping the cost to attend this conference at an affordable rate to our Members.

We hope you like the new format. We have made it easier for you to attend the entire meeting.
Plenary Sessions

Wednesday, June 3, 2015

7:00 - 8:00 am  Registration and Continental Breakfast

8:00 - 8:45 am  Opening Remarks by FDA District Director and OCRA President
Steven Porter, Acting District Director, FDA Los Angeles District
Regina J. O’Meara, Principal IVD, Global RA Consultant

8:45 - 9:30 am  Keynote Address Speaker TBD
Moderator: Evelyn De La Vega, RAC, Sr. Manager, Regulatory Affairs, Bausch + Lomb

9:30 - 9:45 am  Break

9:45 - 10:45 am  Beyond the 483: Criminal Prosecution
Moderator: Trudy Papson, Principal Consultant, Regulatory Consultants Group
(former FDA Investigator)
Speakers: Teresa Cooper, Supervisory Special Agent, FBI
Tracey Hughes, Deputy District Attorney, County of Orange, CA

When a firm is out of compliance and has a 483 or Warning Letter, and their product is charged with misbranding and/or adulteration, this can be a charge by the District Attorney of business fraud. The jurisdictional crossover of local and federal agencies is right in your neighborhood. This session focuses on what happens when a company is taken beyond 483 actions and into criminal prosecution and how to resolve it.

10:45 am - 11:45 am  FDA Regulation of Mobile Medical Applications
Moderator: Michael Swit, Esq., Senior Director, Legal and Regulatory, Illumina
Speakers: R. William Soller, PhD, Principal, Soller Regulatory & Research Services
Dan Olivier, President, Certified Compliance Solutions

This session will focus on understanding the challenges of bringing a mobile medical app to the market. Controversy remains over how mobile medical apps should be regulated. This session will offer practical advice for regulatory and clinical professionals in the face of existing and expected regulation and guidance.

11:45 am - 1:00 pm  Lunch

1:00 - 5:15 pm  BREAKOUT SESSIONS (see following pages)

5:15 - 8:00 pm  Post Conference Reception
OCRA’s Member Appreciation Night
All attendees invited at no additional cost
1:00 - 2:00 pm  Session #1: Real World Reasons Why Proper Pharmacovigilance Matters
Moderator: Peggy Pence, PhD, RAC, FRAPS, President and CEO
Symbion Research International Inc.
Speaker: Justin A. Browne, Esq., Associate Attorney, Janet, Jenner & Suggs, LLC

The speaker will discuss the importance of pharmacovigilance from a plaintiffs’
lawyer’s perspective, including the following:
• Identify differences between regulatory and legal standards to appreciate how
adherence to industry standards and best practices can be critical preventive
and corrective measures
• Identify pitfalls to avoid and strategies for staying out of trouble
• Learn some underappreciated/unrecognized returns on compliance investment

2:00 - 3:00 pm  Session #2: Practical Approaches: How Stakeholders Can Better
Advance Clinical Trials
Moderator: Lei Zhang, PhD, Clinical Consultant
Speakers: Tara Gladwell, Vice President of Operations, Rho, Inc. (clinical CRO)

Clinical trials are evolving. It is an expensive undertaking and failure can have a
huge impact on the company sponsoring the study. Studies indicate that almost
80% of all clinical studies are not completed on time, and 20% of those are
delayed six months or longer. Un-enrolling sites, slow study start-up, and patient
drop out or non-compliance. All of these issues, and more, have been targeted
as contributors to high clinical trials costs.

There is little to be done when a trial fails because of safety issues or lack of
efficacy - it is the nature of investigational product development, especially for
drugs and biologics. However, sometimes, trials fail for operational reasons that
could have been prevented with proper insight and planning.

This session will focus on why clinical trials fail and practical approaches on how
to achieve effective relationship, efficient patient recruitment and data collection.

The speakers will cover some common operational and logistical elements
including:
• Relationship issues between sponsor, CRO(s), and sites
• Problems with patient recruitment
• Data capture and monitoring
• Case studies where operational issues putting the trial at risk were effectively
identified and resolved

3:00 - 3:15 pm  Break
**Clinical Trials Breakout Sessions**  
**Wednesday, June 3, 2015**

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<tr>
<th>Time</th>
<th>Session</th>
<th>Moderator</th>
<th>Speakers</th>
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| 3:15 - 4:15 pm| Session #3: US Clinical Trial Design                   | Evelyn De La Vega, RAC, Sr. Manager, Regulatory Affairs, Bausch + Lomb | Lei Zhang, PhD, Clinical Consultant  
Jihao Zhou, MD, PhD, Sr. Director, Bioinformatics Operations and Systems (BIOS), Allergan Inc. |
|               |                                                        |                                  | This session will focus on the design of clinical trials regarding medical device and pharmaceutical products. The presentations and discussion will include the important aspects to consider when creating and designing a clinical trial (protocols, endpoint selection, patient/subject selection, statistical analyses, etc.) and how to best use these in order to obtain quality data for FDA submissions and potential FDA clearance. |
| 4:15 - 5:15 pm| Session #4: Challenges in Clinical Studies (Drugs and Devices) | Shannon Stoddard, MBA, CCRA, President/CEO ProMedica International | Laurie Halloran, President, Halloran Consulting Group  
Omid Khodai, RAC, Sr. Consultant, Halloran Consulting Group |
|               |                                                        |                                  | Thought leaders will present their perspectives and innovations to address long-standing and emerging challenges in drug and device clinical studies. |
| 5:15 - 8:00 pm| Post Conference Reception                              |                                  | OCRA's Member Appreciation Night  
All attendees invited at no additional cost |
# Schedule
## Dietary Supplements Breakout Sessions
### Wednesday, June 3, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Session #1: New Product Development</th>
<th>Moderator</th>
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<td>1:00 - 2:00 pm</td>
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<td>Vicki Whitsitt, Mgr, Scientific/Regulatory Affairs, Natural Products Association</td>
<td>Hua Deng, PhD, President, Davidia Healthtech, LLC</td>
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<td>Nora Dowell, Vice President, QA/QC/RA, International Vitamin Corporation</td>
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<td>This session will discuss developing a new product for the natural marketplace and regulatory considerations. Issues and considerations of working with contract manufacturers to produce a new product will also be covered.</td>
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<td>2:00 - 3:00 pm</td>
<td>Session #2: Labeling, Advertising and Promotions</td>
<td>Mugdha Dongre, Regulatory Associate II, Edwards Lifesciences</td>
<td>James William “Will” Woodlee, JD, Associate, Kleinfeld, Kaplan and Becker</td>
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<td>Labeling is required by FDA for dietary supplements. Labeling serves as the main source of information in the world for these products. This makes these labels very critical and important part of health industry. They are regulated by FDA under the authority of the Federal Food, Drug, and Cosmetic Act, even though they are not specifically defined by law.</td>
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<td>This session will focus on the current requirements, trends, compliance issues and importance of labeling claims, investigations, non-GMO claims and will also touch base on developments regarding Proposition 65.</td>
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<td>3:00 - 3:15 PM</td>
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<tr>
<td>3:15 - 4:15 pm</td>
<td>Session #3: Clinical Studies and Design</td>
<td>Timothy Stewart, PhD, Consultant, T.S. Essential Consulting</td>
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<td>4:15 - 5:15 pm</td>
<td>Session #4: FSMA (Food Safety Modernization Act) Impact on Dietary Supplement Companies</td>
<td>Kimberly Ricks, Manager, Health Science Information, Herbalife</td>
<td>Joy Joseph, Principal Consultant, Joys Quality Management Systems</td>
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<td>This session will cover how FSMA will impact dietary supplement companies. The proposed rules will be finalized very soon and they will impact not only dietary supplement manufacturers, but also dietary ingredient suppliers. The implementation dates for bigger companies on some of these proposed rules are as early as August 2016. Smaller companies will be impacted 1-2 years after that date, but due to resource constraints in these companies, they should start looking into this as soon as possible.</td>
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<tr>
<td>5:15 - 8:00 pm</td>
<td>Post Conference Reception</td>
<td>OCRA’s Member Appreciation Night</td>
<td>All attendees invited at no additional cost</td>
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Medical device companies are regulated under various government schemes. Companies distributing product into Canada and the EU often require Notified Body or Registrar certification. Our expert speaker will present the latest information on changes that may impact the way inspections of your facilities will be conducted. Implementation of the EU MDD Regulation & 2013 Implementing Regulations, and the likely elimination of the Canadian CMDCAS program will change the certification and registration process.

This informative presentation will help you to prepare for the changes that have already occurred and to plan for those that are still pending.

When the revisions to the Medical Device and Active Implantable Medical Device Directives, modified by Directive 2007/47/EC became effective on March 21, 2010, the requirement for performing clinical evaluations became a stark reality. No longer could manufacturers get away with providing no clinical data, cursory summaries of existing clinical data or literature on equivalent devices.

The implementation of the MEDDEV 2.7.1 guidelines for performing clinical evaluations and structuring clinical evaluation reports, while not legally binding, provided a structure by which manufacturers and notified bodies would be expected to follow. This has presented challenges for manufacturer’s compliance and assessment by notified bodies. In particular, the provision in the guidance for demonstrating clinical equivalence has been too often misunderstood and as a consequence, misapplied, resulting in rejection of equivalence arguments and delays in issuance of the CE Mark.

This session will feature a noted and seasoned product expert with one of the most prominent and respected notified bodies, BSI, and will discuss current regulatory guidance and provide practical examples to illustrate what is expected when developing a clinical equivalence argument and clinical evaluation report.
### International Breakout Sessions

**Wednesday, June 3, 2015**

<table>
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<tr>
<th>Time</th>
<th>Session #4: Regulatory International Updates in Times of Crisis</th>
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<tr>
<td>4:15 - 5:15 pm</td>
<td>Session #4: Regulatory International Updates in Times of Crisis</td>
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<tr>
<td>Moderator:</td>
<td>Christine Posin, RAC, Consultant</td>
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<td>Speaker:</td>
<td>Debra Yeskey Pharm D. Director, Regulatory &amp; Quality Affairs Division</td>
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<td>Biomedical Advanced Research &amp; Development Authority</td>
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<td>Office of the Assistant Secretary for Preparedness and Response</td>
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<td>U.S. Department of Health and Human Services</td>
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Those who operate in the pharma world, and those who are part of a patient world, will be interested in the challenges being battled in the international world. The Office of the Assistant Secretary for Preparedness and Response (ASPR, BARDA, HHS), the World Health Organization (WHO) and country regulators are facing many diseases that have the potential for a crisis situation. Just a few of them are SARS in Asia, MERS in the Middle East, and most recently Ebola in West Africa and other countries.

How do you ethically develop vaccines and treatments and test on human subjects in third world countries? When there is a health crisis, what regulations might be waived to provide critical patients with experimental drugs? With so many differing country regulations, how do you navigate the hurdles to save lives? The ASPR and World Health Organization are making diligent efforts toward addressing many potential global health crises.

This session will discuss activity updates to address these situations on the international front.

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<tr>
<th>Time</th>
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<tr>
<td>5:15 - 8:00 pm</td>
<td>OCRA’s Member Appreciation Night</td>
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<td>All attendees invited at no additional cost</td>
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<td>Time</td>
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<tr>
<td>7:00 - 8:00 am</td>
<td>Attendees Arrive - Continental Breakfast Available</td>
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| 8:00 - 9:00 am | **Session #1: After the FDA comes to visit: From a 483 to What We Do Today**  
Moderator: Trudy Papson, Principal Consultant, Regulatory Consultants Group (former FDA Investigator)  
Speakers: Andrew Balo, Vice President, Regulatory & Clinical, Dexcom  
Trent Davalos, Director of Quality Assurance, Dexcom  
This presentation will cover the following:  
· Unannounced agency inspections (i.e. dealing/preparing for the FDA during and after audits)  
· Dexcom’s warning letters and the circumstances surrounding them  
· What is a holistic response (i.e. understanding the regulations, containment, addressing and documenting changes from identified root causes at the company and/or suppliers)  
· Ongoing monitoring  
· Use of expert training and continuous improvement projects |
| 9:00 - 10:00 am | **Session #2: Comparison of Early Stage Start-Up Entities to Established Big Business**  
Moderator: James (Rusty) Lusk, Principal, Quality Systems International  
Speaker: TBD  
Various stages of company development have unique expectations for value creation. Start-up and large companies have requirements for completing critical activities, resource allocation, talent assessment, project and risk management and metrics. The medical device industry recognizes that start-ups generate new platform technologies with fewer resources and often-greater efficiency, while typically big business struggles with organic growth and usually takes longer to capitalize new product development.  
This talk will discuss:  
· Resource management  
· Credible, competent and responsible employees  
· Hat’s versus Silo’s  
· Risk taking and aversion  
· Transition from start-up to larger company via acquisition |
| 10:00 - 10:15 am | Break                                                                   |
10:15 - 11:15 am  Session #3: Strategic Planning for Product Registration: Tips and Tools for Class II and Class III Devices
Moderator: Eri Hirumi, RAC, Consultant
Speakers: Eri Hirumi, RAC, Consultant
FDA Invited
This session will cover FDA challenges, timelines, things to consider, logistics, agreements and labeling.

As global opportunities expand, strategic planning for product marketing becomes more complex. Being aware of global requirements and developing flexible strategies will enable companies to maximize their development and validation dollars. This session will discuss key elements for strategy development and available resources.

Speaker #1 - Key elements and resources available to develop flexible global strategies.

Speaker #2 - Strengthening the Medical Device Clinical Trial Enterprise

11:15 am - 12:15 pm  Session #4: U.S. Pre-Market Submissions: Hot Topics and FDA Update
Moderator: Kim Walker, MS, RAC (US & EU), Global RA & QA Consultant
Kim Walker Consulting
Speaker: FDA Invited

During this session, FDA will provide updates on the various pre-market submission pathways. Topics related to the Refuse to Accept Policy, the new Substantial Equivalence Guidance implementation, the difference between a reference device and a predicate, updates on the De Novo process, updates on HDEs, and updates on PMAs will be covered. Additionally, review times, new policies, 2015-2016 CDRH/ODE goals, and anticipated new guidance documents will be discussed.

12:15 pm  End of Conference
## Schedule of Breakout Sessions

**Drugs and Biologics Breakout Sessions**  
**Thursday, June 4, 2015**

<table>
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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Moderator(s)</th>
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<tr>
<td>7:00 - 8:00 am</td>
<td>Attendees Arrive - Continental Breakfast Available</td>
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<tr>
<td>8:00 - 9:00 am</td>
<td>Session #1: Pricing and Reimbursement</td>
<td>Cindy Fisher, PhD, RAC, Director, Regulatory Affairs, Vical Inc.</td>
<td>TBD</td>
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| 9:00 - 10:00 am | Session #2: Recalls and Market Withdrawal Processes | Amy Stanton, Quality Systems Specialist, Amgen Inc.                           | Rochelle Roinik, District Recall Coordinator, FDA Los Angeles District  
Thanh Tran, District Recall Coordinator, FDA Los Angeles District |

This session focuses on the recall and market withdraw process specific to biologic and pharmaceutical products. FDA recall coordinators share their expertise on what challenges companies face with dealing with recalls and how to handle them in a method acceptable to the US Food and Drug Administration.

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<td>10:00 - 10:15 am</td>
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| 10:15 - 11:15 am | Session #3: Strategic Planning for Product Registration | Tammy Vu, Sr. Regulatory Affairs Specialist, Abbott Medical Optics (AMO)  
Paul Stone PhD, Sr. Director, Global Regulatory Affairs, Allergan |                                                                            |

This session focuses on the challenges that may occur when preparing for product registration for pharmaceutical and biotechnology products. It will offer tips and tools on preparation and approval strategies.

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<th>Time</th>
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<th>Speaker(s)</th>
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</table>
| 11:15 AM - 12:15 pm | Session #4: New Regulatory Updates                  | Dr. Raymond W. Bruullo, DPM, Compliance Officer  
FDA Los Angeles District | Michelle Butler, Director, Hyman, Phelps & McNamara, P.C.  
Claire Gilligan, Senior Vice President of Global Quality, Actavis |

This session will cover food and drug laws, both domestic and international. It will focus on any recent changes or additions to the laws.

It will also cover:
- FDA and regulatory authority policies and industry adaptations
- Regulatory framework and requirements: domestic and international
- Regulatory actions typically taken in pharma or biologics
- Future trends considering FDA realignment as to regulatory actions

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<th>Speaker(s)</th>
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<tr>
<td>12:15 pm</td>
<td>End of Conference</td>
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Please register online for an immediate receipt and confirmation: https://ocra-dg.org

Online Registration Instructions: If you have an account on the OCRA website, please log on. If you do not have an account, you will need to create one. All OCRA meetings and conferences require that you join OCRA. While creating an account, you can pay for membership ($50) if you are not already a member or need to renew. Once you have an account and have set a user name and password, you can continue with the conference registration process (you do not need to wait for an email from OCRA).

**Group Registrations**: This conference is priced to break even, as such, we do not offer discounts for group registrations. Please complete the registration form for each attendee.

If you prefer to use this form to register, please fax it with your credit card payment to: (949) 266-8461. See next page for paying by check.

**NAME of REGISTRANT**: 
Submit one copy for each person attending.
Registration Fee includes the following: Access to available speaker presentations to download prior to the conference, breakfast, lunch on first day, breaks and parking.

Please check type of card: ______Visa ______ Master Card ______ American Express

Card #: ____________________________ Exp Date:______________
Name on Card: ____________________________
Signature: ____________________________

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 On-Line or Pay Pal payment option.

**Conference Registration Rate**

___$ 725 - OCRA Members
___$ 775 - Non-members (includes OCRA membership for one year)
___$ 475 – FDA/Government/Students*

___$ 475 - Wednesday Only - For Dietary Supplement Industry Attendees Only**

* Student Rate is for individuals enrolled full time in a Regulatory or Quality related academic program at an accredited institution. The Student Rate does not apply to working professionals taking one or two courses on the side. Student ID and copy of current class schedule are required to register at this rate. Final eligibility determined by OCRA. We do not offer online registration at this rate as it requires approval. Please fax this form with payment and items described above (if applicable).

**Due to the change in format, we are only offering a one day rate to Dietary Supplement industry attendees. This option is not available for online registration as it requires approval. Please fax this form with payment. All one day registrations will be reviewed by OCRA to determine eligibility.

Scholarships available to all OCRA Members: See OCRA’s website for the application (Professional Development/Educational Grants). **Deadline for applications: May 1, 2015. Click on the link below to download the form: [https://ocra-dg.org/index.php/en/professional-development/educational-grants](https://ocra-dg.org/index.php/en/professional-development/educational-grants)
Please register online for an immediate receipt
and confirmation: https://ocra-dg.org

To Register With Company or Personal Check:
Please complete the registration form and fax it to (949) 266-8461. If paying by check, please make
your check payable to: “OCRA” and mail to 5319 University Dr., Suite 641, Irvine, CA  92612.
OCRA’s non-profit Federal Tax ID:# 33-06304553. Only paid attendees will be able to attend. If a check
has not been received prior to the conference, you will be asked to provide a credit card as a hold until
the check is received. Phone: (949) 387-9046.

Receipts for Payment:
By using the On-Line Registration or PayPal option, you will receive an automatic receipt.

Parking validation, name badges and any conference materials will be provided
at the on-site registration desk.

Cancellations: Cancellations must be received in writing (via email to: ksyre@cox.net or via fax to
949-266-8461) by May 15, 2015. After May 15, if you have reserved a space but do not attend, your
payment MUST be remitted (due to our commitment with the hotel). However, an alternate person may
attend in your place (non-member replacements will be required to become members for an additional
$50 fee.)

Please Provide Complete Contact Information for Each Attendee:

FIRST NAME: ____________________________________________________________
LAST NAME: ____________________________________________________________
COMPANY: ______________________________________________________________
TITLE: __________________________________________________________________
ADDRESS: ______________________________________________________________
MAIL CODE: _____________________________________________________________
CITY: __________________________________________________________________
STATE: __________________________________________________________________
ZIP: __________________________________________________________________
PHONE: ________________________________________________________________
FAX: ___________________________________________________________________
E-MAIL: _________________________________________________________________
Please register online for an immediate receipt and confirmation: https://ocra-dg.org

NAME of REGISTRANT: ___________________________________________________

______I Plan To Stay for Lunch on Day 1

______I Plan To Stay for Member Appreciation Reception End of Day 1

All attendees are invited for an after-conference reception free of charge on June 3 from 5:15-8:00 pm

______Vegetarian Meal Requested or List Other Dietary Restrictions (please be specific and provide examples of what you can eat):

__________________________________________________________________________
__________________________________________________________________________

SELECT BREAKOUT SESSIONS
Please select one for each breakout.

Note: To assist with assuring adequate space in each breakout session, please make your selections below. Your selections do not need to be in the same category. Should you decide to change your selection, you can do so on the day of the conference.

<table>
<thead>
<tr>
<th>June 3 Breakout Sessions</th>
<th>Clinical Trials</th>
<th>Dietary Supplements</th>
<th>International</th>
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Items are needed for attendee giveaway bags
If you would like to provide a giveaway for the conference, we would be happy to include useful promotional items such as bags, notepads, electronic gadgets, commuter mugs or other items. Plan to provide 400 of each item.

Contact Kimberly Syre at ksyre@cox.net to inquire
The 18th Annual FDA-OCRA Educational Conference
The Current Regulatory Landscape: Opportunities and Challenges
June 3-4, 2015

Conference Chairs:
Evelyn De La Vega, RAC, Sr. Manager, Regulatory Affairs, Bausch + Lomb
Steven Porter, Acting District Director, FDA Los Angeles District

Annual Conference Committee:
Dr. Raymond W. Brullo, DPM, Compliance Officer, FDA Los Angeles District
Evelyn De La Vega, RAC, Sr. Manager, Regulatory Affairs, Bausch + Lomb
Mugdha Dongre, Regulatory Associate II, Edwards Lifesciences
Cindy Fisher, PhD, RAC, Director, Regulatory Affairs, Vical Incorporated
Eri Hirumi, RAC, Consultant
Gustavo “Gus” Kobrin, President, Strategic Regulatory Solutions, Inc.
Paul Kramsky, President, Rockin’ Regulatory, Inc.
James (Rusty) Lusk, Principal, Quality Systems International
Regina J. O’Meara, Principal IVD, Global RA Consultant
Trudy Papson, Principal Consultant, Regulatory Consultants Group
Peggy Pence, PhD, RAC, FRAPS, President and CEO, Symbion Research International Inc.
Christine Posin, RAC, Consultant
Kimberly Ricks, Manager, Health Science Information, Herbalife
Amy Stanton, Quality Systems Specialist, Amgen
Timothy Stewart, PhD, Consultant, T.S. Essential Consulting
Shannon Stoddard, MBA, CCRA, President/CEO, Promedica International
Michael A. Swit, Esq., Senior Director, Legal and Regulatory, Illumina
Tammy Vu, Sr. Regulatory Affairs Specialist, Abbott Medical Optics (AMO)
Kim Walker, Global Regulatory Affairs and Quality Assurance Consultant, Kim Walker Consulting
Vicki Whitsitt, Manager, Scientific and Regulatory Affairs, Natural Products Association
Lei Zhang, PhD, Clinical Consultant

About OCRA
Orange County Regulatory Affairs Discussion Group (OCRA) is a non-profit volunteer organization comprised of Regulatory Affairs professionals who are interested in participating in educational programs and networking with one another. Our membership includes individuals who work in Life Sciences industries such as medical devices, pharmaceuticals, biologics, in-vitro diagnostic and dietary supplements.

OCRA has nearly 800 members representing more than 225 companies. While the majority of our members are in Orange County, California, and surrounding areas, our membership is nationwide. Our members are employed by small-to-large size manufacturers, service providers, consultants and legal offices.

OCRA meetings provide an educational forum and a means for the regulatory community to network. While our focus is regulatory in nature, our programs can also provide timely information for individuals involved in Management, Clinical Trials, Engineering (e.g., software validation and product development), Marketing (e.g., advertising and labeling), Quality (e.g., Quality System Regulation), and other related fields. As a result, our meetings consistently draw participants from the entire West Coast region and elsewhere, including speakers and attendees from FDA district and headquarters offices.

OCRA Board of Directors:
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Driving Directions and Sleeping Room Reservations

Irvine Marriott
18000 Von Karman Avenue
Irvine, CA 92612
(949) 553-0100

HOTEL RESERVATIONS
Call (800) 228-9290

OCRA has a block of rooms at the Irvine Marriott from June 1 through June 4 at the rate of $175.00 for Single or Double Occupancy (available until May 24, 2015). Book your room online at:
http://www.marriott.com/meeting-event-hotels/group-corporate-travel/groupCorp.mi?resLinkData=FDA/OCRA 18th Annual Educational Conference%5ELAXIR%60fdafdaa%60175.00%60USD%60false%606/2/15%606/4/15%605/24/15&app=resvlink&stop_mobi=yes

If calling please ask for the “OCRA Group Rate”.

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 Michelle 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 or Long Beach Airport: Take 405 South (San Diego Freeway). Exit Jamboree and turn Right off ramp. Turn Right onto Michelle 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 Michelle 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 Michelle 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 Michelle 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 Bernadino/Riverside: Take 91 West (Riverside Freeway) to 55 South Freeway (Newport Beach Freeway). Take 55 south to 405 South Freeway (San Diego Freeway). Exit Jamboree Road, turn right off ramp. Turn Right onto Michelle 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.

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