



Preparing to Submit a Marketing Application

You are invited to a Joint Full-Day Meeting sponsored by

Orange County Regulatory Affairs Discussion Group (OCRA)

and

San Diego Regulatory Affairs Network (SDRAN)

Wednesday, November 4, 2009

Online Registration:

www.ocra-dg.org

Location:

Hilton Garden Inn Carlsbad Beach

(off the 5 Freeway at the beach in Carlsbad)

6450 Carlsbad Blvd, Carlsbad, CA 92011

Tel: 760-476-0800

Submission of a marketing application for a product is a long, complicated process with multiple obstacles. This meeting will give an overview of several key aspects to consider in the application preparation with some real-life experiences and sound advice.

Program Managers:

Cindy Fisher, PhD, RAC; Senior Manager, Regulatory Affairs, Vical Incorporated

Malcolm Lloyd-Smith; Senior VP, Regulatory Affairs and Quality Assurance, Cadence Pharmaceuticals, Inc

Radine Ganz-Pobuda, RAC; VP Programs, SDRAN

Registration fee includes breakfast, lunch, parking, and electronic access to the presentations.

Paperless Event

This OCRA meeting is a paperless event, utilizing email and the Internet to provide you with the most accurate information, whether you are in the office or on travel. A paperless format eliminates the need to transport meeting binders, saves money on the program expenses, and allows you to review material prior to the conference to maximize your learning experience.

Some of our most frequently asked questions (FAQs) are listed below:

How will I receive my registration confirmation and event communications?

All communications regarding this meeting, including your registration confirmation, will be sent by email to the address you provided on your registration form.

What materials will I receive and when will I receive them?

Approximately one week prior to the meeting, registered participants will receive an email containing links to the following:

- Preliminary agenda
- Presentation slides provided by program presenters prior to the meeting. ***Please note that hard copies of presentations will not be provided onsite, so bring your printed copies if you wish to use them for note-taking.***

If you have not received program content information five days prior to this meeting, please contact OCRA to ensure we have accurate contact information for you.

Approximately one week after the meeting, registered participants will receive an email containing links to the following:

- Final presentation slides provided by program presenters
- Program evaluation form

What content materials will I receive onsite?

At check-in, you will receive a name badge and a program agenda.

Will handouts of the presenters' slides be provided?

Presentation slides received in advance will be posted online at least one week prior to the meeting. Any new or updated slides provided after this deadline will be available following the meeting. Printed copies of the presentations will not be provided onsite, so please bring them with you if you wish to use them for note-taking.

What if I do not bring copies of the presentations?

- Most event facilities have Business Centers where you can access the Internet and print files for a small fee.
- OCRA's onsite staff can help you locate the nearest copy or print shop.
- You can download the updated presentations after the meeting to avoid carrying materials.



Preparing to Submit a Marketing Application

Wednesday, November 4, 2009

Presenters

Antoinette Azevedo

President and CEO, e-SubmissionsSolutions.com

Judy F. Gordon, DVM

President, ClinReg Consulting Services, Inc.

Malcolm Lloyd-Smith

Senior Vice President, Regulatory Affairs and Quality Assurance, Cadence Pharmaceuticals, Inc

Alessandro Lobbia

Senior Director, Regulatory Affairs, Cadence Pharmaceuticals, Inc.

Matthew Moran

Senior Director, Global Regulatory Affairs – CMC, Allergan, Inc.

Ellen Morgan

President and CEO, Synteract

Emily Onkka

Associate Director, Regulatory Operations and Submissions, Cadence Pharmaceuticals, Inc.

Cheryl Watton, MD, MBA

Executive Director, Regulatory Affairs and Global Safety, Amylin Pharmaceuticals

Leonard Wilson, MS

Special Assistant to the Associate Director for Review Management
Center for Biologics Evaluation and Research, Food and Drug Administration

Preparing to Submit a Marketing Application

Wednesday, November 4, 2009

Meeting Agenda:

- 7:00 - 8:00** **Breakfast, Registration, Networking**
- 8:00 – 8:10** **Introduction**
Cindy L. Fisher, PhD, Vical Incorporated
- 8:10 – 9:00** **eCTD**
Emily Onkka, Cadence Pharmaceuticals, Inc.
Antoinette Azevedo, e-SubmissionsSolutions.com
- 9:00 – 9:50** **Clinical Module**
Ellen Morgan, Synteract
- 9:50 – 10:00** **Break**
- 10:00 – 10:50** **Quality Module**
Alessandro Lobbia, Cadence Pharmaceuticals, Inc.
- 10:50 – 11:40** **Target Product Profiles and Labeling**
Matthew Moran, Allergan, Inc.
- 11:45 – 1:00** **Lunch**
- 1:00 – 1:50** **Advisory Committee Meetings**
Judy F. Gordon, DVM, ClinReg Consulting Services, Inc.
- 1:50 – 2:40** **FDA Review of NDAs, BLAs, PMAs, 510(k)s, and ANDAs**
Leonard Wilson, MS, Center for Biologics Evaluation and Research, FDA
- 2:40 – 2:50** **Break**
- 2:50 – 3:40** **Postmarketing Commitments**
Cheryl Watton, MD, MBA, Amylin Pharmaceuticals
- 3:40 – 4:30** **Lessons Learned**
Malcolm Lloyd-Smith, Cadence Pharmaceuticals, Inc.
- 4:30** **Adjourn and Breakdown**

***Please note that paper copies of presentations will not be distributed at the conference.**

~~~~~  
**REGISTRATION INSTRUCTIONS**

## **Preparing to Submit a Marketing Application**

**Wednesday, November 4, 2009**

### **TO REGISTER ONLINE:**

Go to [www.ocra-dg.org](http://www.ocra-dg.org) and select the **OCRA-SDRAN Joint Meeting** from the Upcoming Programs (upper right corner of homepage) or from the Programs Calendar page.

**NOTE: If you are an active OCRA member, be sure to logon to your account first, in order to benefit from the \$50 member discount.**

Click on the "Click Here to Register for this Event" link either at the top or the bottom of the meeting details page, and complete the online registration and payment process.

Payments can be made via credit card or PayPal directly on the website. Once your payment has been processed, you will receive an immediate confirmation email and receipt. An email notification is also being sent to the OCRA administration, so we know that your payment has been processed.

Alternatively, you can make your payment via company or personal check and send it in the mail. For those paying by check, please register online first, then follow up by mailing the check at least one week prior to the meeting.

### **TO PAY WITH COMPANY OR PERSONAL CHECK:**

Please complete the online registration process; select the Pay Later option, and make check payable to OCRA:

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](mailto:ksyre@cox.net)

OCRA's non-profit Federal Tax ID# 33-0630455

If paying by check, please mail your check by October 26 to ensure that it is received in time.

If you have reserved a space but do not attend, your payment **MUST** be remitted.

**OCRA REGISTRATION FORM – November 4, 2009**

**Please register online for an immediate receipt and confirmation:**  
[www.ocra-dq.org](http://www.ocra-dq.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 or (949) 387-9047 or (949) 387-9043

Please check type of card:

\_\_\_\_\_ VISA    \_\_\_\_\_ MASTERCARD    \_\_\_\_\_ AMERICAN EXPRESS

Card #: \_\_\_\_\_ Expiration 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. Submit one copy for each person attending.

Registration Rate is:

\_\_\_\_\_ \$ 135 – OCRA Members

\_\_\_\_\_ \$ 135 – SDRAN Members

\_\_\_\_\_ \$ 185 - Non-members (includes OCRA or SDRAN membership through the end of 2010)

\_\_\_\_\_ Please apply my payment to OCRA Membership

\_\_\_\_\_ Please apply my payment to SDRAN Membership

\_\_\_\_\_ \$ 75 - 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 NAME: \_\_\_\_\_

LAST NAME: \_\_\_\_\_

COMPANY: \_\_\_\_\_

TITLE: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

MAIL CODE: \_\_\_\_\_

CITY: \_\_\_\_\_

STATE: \_\_\_\_\_

ZIP: \_\_\_\_\_

PHONE: \_\_\_\_\_

FAX: \_\_\_\_\_

E-MAIL: \_\_\_\_\_

Register On-Line:  
[www.ocra-dq.org](http://www.ocra-dq.org)

## **DRIVING DIRECTIONS:**

**Hilton Garden Inn Carlsbad Beach  
(off the 5 Freeway at the beach in Carlsbad)  
6450 Carlsbad Blvd, Carlsbad, CA 92011  
Tel: 760-476-0800**

### **From Irvine**

**Take 405 Freeway South to 5 Freeway South.  
Take Exit 45 for Poinsettia Ln toward Aviara Pkwy.  
Turn right at Poinsettia Ln.  
Turn right at Carlsbad Blvd.**

### **From Downtown San Diego**

**Take 5 Freeway North.  
Take Exit 45 for Poinsettia Ln toward Aviara Pkwy.  
Turn left at Poinsettia Ln.  
Turn right at Carlsbad Blvd.**

### **From Oceanside**

**Take 5 Freeway South.  
Take Exit 45 for Poinsettia Ln toward Aviara Pkwy.  
Turn right at Poinsettia Ln.  
Turn right at Carlsbad Blvd.**

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