



The Quality  
Leadership  
Network

Local Regulatory Policy  
Graduate Programs

# **FDA, Academia, and Industry** Working Together to Improve Quality

**Free Workshop**

Friday, April 8th, 2016  
10:00 am – 3:30 pm

**Registration Deadline**

April 1, 2016, or  
until spaces are filled

## Free Workshop

In an effort to ensure full transparency with the medical product and dietary supplement industries, the FDA Los Angeles District Office is hosting a **Regulatory Policy Lecture Series** on how FDA goes about improving product, processes, and service quality through the use of quality tools. During cGMP investigations and through import inspections, FDA has noted several areas where industry could improve product quality. We will share our observations with future regulatory policy professionals and graduate students from local regulatory policy graduate programs. The audience for these lectures includes graduate program students from *USC, UCI, Tech Graduate Institute, Chapman University* and *Cal Poly Pomona*. Many of these students are pursuing careers with FDA as employees or quality interns. These workshops will include presentations by FDA quality interns and FDA subject matter experts discussing our current challenges with product quality and use of quality tools to address these quality issues.

This first lecture will act as a kick-off meeting for a proposed quarterly Lecture Series where FDA and Academia come together to provide regulatory topics and real applicable cases. A primary goal will be exploring how best to resolve these case studies. Registration is limited to FDA employees, local university professors and regulatory program graduate students. This facility can only accommodate 85 students and their professors.

Future Discussion Group meetings will be open to other students and may be held at various locations to accommodate the convenience of the attendees

## Location

Main Lobby Conference Room  
L.A. District FDA Office  
19701 Fairchild  
Irvine, CA 92612

Register by **April 1** to attend this event. **No walk-ins** are allowed due to security requirements at this facility.

Lunch for the event is sponsored by the *University of Southern California, Regulatory Science Program*.

## Program Managers

*Niedre Heckman*, MS, MPH, Sr. Mgr., Global Regulatory Affairs, Baxalta US Inc.  
*Frances Richmond*, PhD, Director International Center for Regulatory Science.  
*Marlene Swider*, PhD, Quality Systems Manager, Los Angeles District Office, FDA.

## Schedule of Presentations

9:45 a.m.	Registration and Networking
10:00 - 10:10 a.m.	Opening Remarks – Goals of This Workshop Speaker: <b>Marlène Garcia Swider</b> , PhD, Quality Systems Manager, FDA Los Angeles District
10:10 – 10:50 a.m.	Internship Projects at FDA Speakers: <b>Jordan Adajar</b> , USC: "CAPA Nonconformances in the Medical Device Industry" and <b>Robin Quon</b> , CSU Pomona: "Major Non-Conformances on Nationwide FDA-Regulated Biotechnology Products."
10:50 – 11:00 a.m.	Break
11:00 – 11:30 a.m.	Reusing Single Use Devices: Three Perspectives Speaker: <b>David Locke</b> , DRSc, Doctoral graduate, USC
11:30 – 12:30 p.m.	FDA Mission and Vision Speaker: <b>William Martin</b> , PhD, Acting Director for Pacific Region, FDA
12:30 – 1:00 p.m.	Lunch
1:00 – 1:20 p.m.	FDA Imports Speaker: <b>Dan Solis</b> , Director of Import Operations, Los Angeles District title : "How FDA Conducts Import Operations at the US Ports and its role in Consumer Protection."
1:20 – 1:30 p.m.	Break
1:30 – 1:50 p.m.	FDA Regulatory Policy Process and Current Trends Speaker: <b>Marlène Garcia Swider</b> , PhD, Quality System Manager, FDA Los Angeles District
1:50 – 2:30 pm	Open Q&A, Discussion on Potential Discussion Group, and Polling of Topics for Next Discussion Group Meetings

## Event Registration



### On-line Registration

The USC website will be used for registrations. Online Registration:

<https://goo.gl/4kFnG7>



Final confirmation of your attendance will be sent by **April 5**. If you have any questions, please call or email, **Randa Issa** at 323-442-2018, [rissa@usc.edu](mailto:rissa@usc.edu) or **Frances Richmond** at 323-442-3531, [fjr@usc.edu](mailto:fjr@usc.edu)



### Email Registration

Please complete this registration form and email it to [fjr@usc.edu](mailto:fjr@usc.edu)

Name: \_\_\_\_\_

Role: \_\_\_\_\_

School: \_\_\_\_\_

Address: \_\_\_\_\_

City/State/Zip: \_\_\_\_\_

Email: \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

# Security Instructions, Parking, and Driving Directions



**FDA Los Angeles District Office**  
19701 Fairchild, Irvine, CA 92612

## Security

Please be aware that there is increased security at the FDA Irvine building, similar to that of security screening at an airport. All bags will be checked and ID's must be shown. You will enter the facility through a metal detector.

## Parking

When arriving at the address, please pull up to the security guard booth. You will be asked for your identification and your vehicle license plate number will be taken by the guard. There is plenty of on-site parking. **If you do not pre-register for this event by April 1st, you will not be allowed through the security gate.**

## Driving Directions



We recommend you look up driving directions from your own starting point.

### From **San Diego**

Take the 5 Freeway North to the 405 Freeway North.  
Take the JAMBOREE RD Exit.  
Turn LEFT onto JAMBOREE RD.  
Turn LEFT onto FAIRCHILD RD.  
The FDA facility will be on the LEFT-hand side of the road.

### From **Long Beach**

Take the 405 Freeway South.  
Merge onto CA-73 S toward CA-55/ SAN DIEGO VIA TOLL RD.  
Stay on the 73 Toll Road going South.  
Take the JAMBOREE RD Exit.  
Stay straight to go onto SE BRISTOL ST.  
Turn LEFT onto JAMBOREE RD.  
Turn RIGHT onto FAIRCHILD RD.  
The FDA facility will be on the LEFT-hand side of the road.

### From **Anaheim**

Take the 57 Freeway South.  
Merge onto the 5 Freeway South.  
Merge onto the 55 Freeway South toward NEWPORT BEACH.  
Merge onto the 73 Toll Road South.  
Take the JAMBOREE RD Exit.  
Stay straight to go onto SE BRISTOL ST.  
Turn LEFT onto JAMBOREE RD.  
Turn RIGHT onto FAIRCHILD RD.  
The FDA facility will be on the LEFT-hand side of the road.