Quality Leadership Network Lecture Series  
FDA, Academia, and Industry Working Together to Improve Quality  
Medical Devices Best Practices

You are invited to a Workshop with  
U.S. Food and Drug Administration  
and  
Local Regulatory Policy Graduate Programs

Friday, October 21, 2016  
7:00 A.M. – 2:00 P.M.

FDA LOS-DO Main Conference Room at  
19701 Fairchild Drive, Irvine, CA  92612

Registration Deadline: October 14, 2016 or until spaces are filled

Workshop Description:

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. The audience for these lectures includes industry participants and graduate students from USC, UCI, Tech Graduate Institute, Chapman University and Cal Poly Pomona. **You must pre-register to attend this event. No walk-ins will be allowed due to security requirements at this facility.**

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

Cost:

This event is free to all participants. Breakfast is sponsored by Keck Graduate Institute and BB Medical & Surgical. Lunch for the event is sponsored by the University of Southern California, Regulatory Science Program. Registration is required; no onsite registration permitted.

Registration:

All attendees are required to register online. Click here to register.  
[https://uscpharmacy.az1.qualtrics.com/SE/?SID=SV_8J7dEA3TYmJDGTz](https://uscpharmacy.az1.qualtrics.com/SE/?SID=SV_8J7dEA3TYmJDGTz)
Questions/More Information:

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Randa Issa, PhD (through October 7th)  
(323) 442-2018  
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Schedule of Presentations:

7:00 AM  
Registration & BREAKFAST  
(Sponsored by Keck Graduate Institute and BB Medical &Surgical)

7:45 AM  
Opening Remarks  
FDA QLN and LOS-DO Senior Management

8:00 AM  
It's Time to Reimagine CAPA  
Glenn D. Yeik  
President & CEO, Trimeyde, Inc.

8:30 AM  
Medical Device Injuries: FDA Data Reveals Increasing Risk  
Christina Bernstein,  
Founder and President, BB Medical Surgical  
Joseph O'Neill,  
Senior Associate, Marketing, The Expert Institute

9:00 AM  
Quality Metrics Tools ensuring Quality Practices  
Joseph Humm  
Vice President, Sales Operations, Sparta Computer Systems

9:30 AM  
BREAK

10:00 AM  
Making Decisions Defensible  
Kelly Black, Statistician and President, Neptune & Company, Inc.

10:30 AM  
Medical Devices Regulatory Submissions - Best Practices  
Niedre Heckman, Senior Manager, Global Regulatory Affairs  
Shire

11:00 AM  
 Been There; Done That – Past and Present Medical Device Field Observations Panel Discussion
Eri Hirumi, Auditor, TUV SUD – Field observations from ISO 13485 audits, harmonizing terminology and definitions with ISO standards, and tips on how to “prove state of the art” to help keep your Technical Files updated.

Kim Walker, Global RA & QA Consultant and SDSU/CSUF Instructor – Field observations from 21 CFR 820 audits, tips on becoming successful regulatory professionals, and Warning Letter case study and related project management skills needed.

Trudy Papson, President, Regulatory Consultants Group, LLC – Review of publicly available prosecution case studies of non-compliant companies.

Susan Bain, Professor, Keck Graduate Institute – Field observations of 21 CFR 820 FDA inspections and compliance best practices for new regulatory professionals.

11:40 AM

Compliance at LOS-DO
Kelly Sheppard, Director,
LOS-DO Compliance Branch

Noon

LUNCH (Sponsored by USC)

1:00 PM

Benefit-Risk Guidance and the CDRH strategic Priorities (including Case for Quality)
Robin Newman, Director CDRH Office of Compliance, FDA
Ann Ferriter, Director for Division of Analysis and Program Operations, Office of Compliance, Center for Devices and Radiological Health

2:00 PM

Where Do We Go from Here & Adjournment
Dr. Marlène Garcia Swider, Quality Manager, LOS-DO, FDA
(Acting QSM for the PA Biologics Program, ORA, FDA)

Security, Parking and Driving Directions:

You must pre-register to attend this event. No walk-ins will be allowed due to security requirements at this facility.

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 October 14, you will not be allowed through the security gate.
**DRIVING DIRECTIONS** - We recommend you look up driving directions from your own starting point.

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

**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.