# SoCal PDA Chapter's 6th Annual Industry Summit Expo

## IN COLLABORATION WITH

## SoCal Bio and ASQ / Food, Drug, Cosmetic Division

# "FDA 483 Trending Topics and Solutions"


**Thursday, October 06, 2016 , 4:00pm – 8:30pm**
**Hilton Irvine / Orange County Airport**

### NETWORKING, PRESENTATIONS, & EXHIBITS

- Keynote Speaker: Dr. Marlene Garcia Swider
- Technical Speakers: Barbara Unger & Susan Bain
- Table Top Exhibits
- Western Theme (Best Cowboy Attire Contest)
- Gourmet Buffet, Wine & Beer, & Cash Bar
- Raffle Prizes
- Transport from SD, LA, & Thousand Oaks

### WHO SHOULD ATTEND?

Professionals from the life science, drug, and biologics industries involved with quality, manufacturing, regulatory compliance, and laboratories.

### ABOUT PARENTERAL DRUG ASSOCIATION (PDA):

PDA is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. PDA's Mission is to develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership. http://www.pda.org

### ABOUT SOUTHERN CALIFORNIA BIOMEDICAL COUNCIL (SOCALBIO):

The Southern California Biomedical Council (SoCalBio) promotes and supports biomedical and biotechnology research, development, and manufacturing in the Greater Los Angeles region for economic development and job creation. http://www.socalbio.org

### ABOUT AMERICAN SOCIETY FOR QUALITY (ASQ) DRUG, AND COSMETIC DIVISION:

ASQ FD&C's Vision is to be recognized as the resource of choice for quality systems and leadership development in Food, Drug, and Cosmetic industries. Our Mission is to increase member value by conducting activities and involving members to fulfill the Divisions Vision. www.asq.org/fdc

### FOR REGISTRATION ASSISTANCE:

Contact PDA Event Coordinators: Ileana Ayala- iayala@PharmaBioServ.com - (310) 426-0303, or Stephanie Powers Kurtz - spowerskurtz@sterile.com - (610) 608-4142.

PDA Parenteral Drug Association Southern California Chapter

SoCalBio Southern California Biomedical Council

ASQ Food, Drug, & Cosmetic Division The Global Voice of Quality™

Hilton IRVINE/ORANGE COUNTY AIRPORT

# SPEAKERS CORNER

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**Dr. Marlene Garcia Swider,**
**Quality System Manager**
**LOS-DO, FDA- ASQ**

**Keynote Speaker:**
Dr. Marlene Garcia Swider has served in the FDA for more than 29 years in different capacities including Public Affairs Specialist (working with Congressional issues), Biotech Reviewer, Budget and Planning Analyst, Investigator, and Regulatory Project Manager. Most recently she serves as the Quality System Manager for Los Angeles District Office, FDA. She has a Bachelor in Science, a Masters in Health Services Administration, and a doctorate degree in Organizational Management. In acting capacity she has also serves as Special Assistant to the ACRA and Deputy Director for ORM, FDA, in the past. She resides in Orange County, California with her husband and 3 children. She loves square dancing, biking, hiking, gardening, and cooking. She actively volunteers in the community leading bible studies and coordinating events. She is also a professional public speaker and published author for different professional entities including ASQ, AAPS, IVT, OCRA, BioCom, and BioPharm Journal.

**Barbara Unger, President**
**Unger Consulting**

Unger Consulting

Barbara Unger formed Unger Consulting Inc. in December 2014 to provide GMP Quality consulting services to the pharmaceutical industry. She has extensive expertise in this area having led the Amgen Inc. Corporate GMP audit group that had responsibility for API and drug substance sites, Quality Systems and computers. She also developed, implemented, and maintained the GMP regulatory intelligence program for eight years at Amgen Inc. This included surveillance, analysis, and communication of GMP related legislation, regulations, guidance, and industry compliance enforcement trends. Barbara was the first chairperson of the Rx-360 Monitoring and Reporting work group (2009 to 2014) that summarized and published relevant GMP and supply chain related laws, regulations, and guidance. She also served as the chairperson of the Midwest Discussion Group GMP-Intelligence sub-group from 2010 to 2014. In 2015, Barbara participated in a Validant Inc. program of data integrity / data management assessments for a large international firm.

Before Amgen, Barbara worked for the consulting firm Don Hill and Associates, providing regulatory and quality services to the pharmaceutical industry, and for Eli Lilly and Company in quality and CMC regulatory affairs positions. She began her career in the pharmaceutical / device industry with Hybritech Inc. and received a bachelor's degree in chemistry from the University of Illinois in Urbana Illinois.

# REGISTER NOW

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**Susan Bain, SRSc, Keck Graduate Institute**

KGI
KECK GRADUATE INSTITUTE
School *of* Applied Life Sciences


Susan Bain, DRSc. is currently Professor of Practice, Clinical, Regulatory and Quality; Program Director, MBS in Clinical and Regulatory Affairs for Keck Graduate Institute's (KGI) School of Applied Life Science and Adjunct Professor of Practice and Concentration Coordinator for Clinical and Regulatory Affairs in KGI's School of Pharmacy. She is an accomplished quality and regulatory professional with experience in the medical device, pharmaceutical, and biotechnology industries. She has a diverse regulatory compliance background in a broad range of FDA-regulated industries. Her most recent corporate experience includes serving as a Vice President of Quality/Regulatory Assurance and Operations at a medical device company and has held various management positions in Quality Control/Assurance and Regulatory Affairs over the past 25 years with firms including Baxter Healthcare, Grifols, Medegen, Inc., Peregrine Corporation, and Watson Pharmaceuticals. Additionally, Susan also worked at the FDA as an Investigator, focusing on drugs and medical devices.

Susan received a Doctorate of Regulatory Science (DRSc), a Master of Science in Regulatory Science (MSc) from the University of Southern California (USC) and a Bachelor of Science in Biological Science from Cal Poly, Pomona. She holds a graduate certificate in Effective Supervision from Cal Poly Pomona and is a member of the Orange County Regulatory Association (OCRA), DIA, PDA and RAPS.

**ATTENDEE REGISTRATION INCLUDES:**

- 1 Attendee Ticket
- Parking
- Appetizers, Dinner, Dessert
- Technical Sessions
- Beer & Wine Tasting
- Exhibitor Showcase
- Commemorative Gift
- $10 Round Trip Transportation Available (From Thousand Oaks, Los Angeles, and San Diego) *Contact PDA Event Coordinators for additional details.


**REGISTER EARLY AND SAVE!**

Members $30.00
Non-Members $40.00
Student / Government $20.00

**After 9/23/16**

Members $40.00
Non-Members $50.00
Student / Government $25.00

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