



# WELCOME

## SOCAL PDA Chapter Q2 2017 Program Event Biologics

### June 15, 2017





# WELCOME

- **Thank You**

SoCal PDA Program Committee

Allergan & Organogenesis

Sponsors - AES, Pace Analytical Labs and Vanrx

- **Agenda**

About PDA

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Introduction of Speakers & Presentations

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Introduction SoCal PDA Board Members

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SoCal PDA Chapter Volunteer / Board Position Opportunities

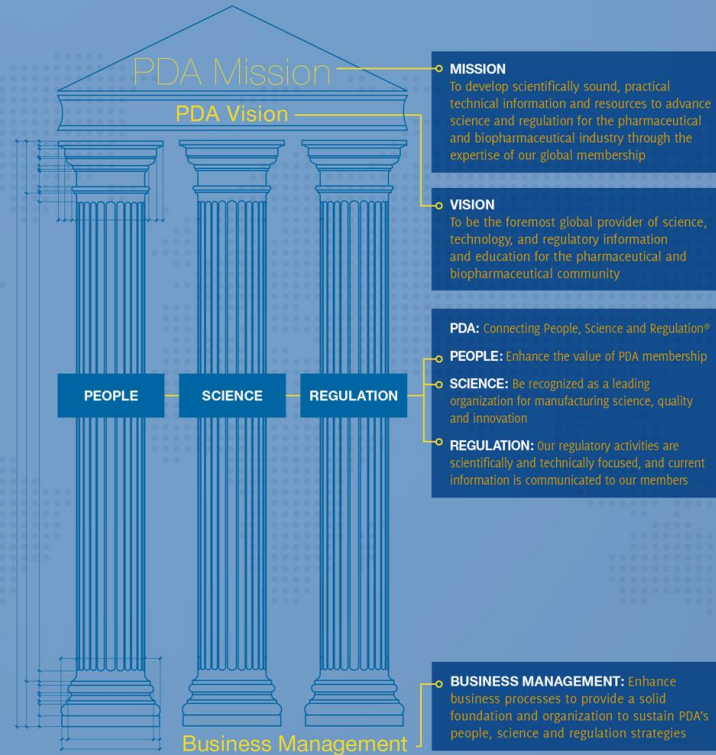
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# What Is PDA?

## What is PDA?

The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its more than 9,500 members worldwide.



PDA joins people with science and regulation to ensure members are informed of Industry “best practices”, advancements in science and current GxP regulations, to enable PDA members to provide safe and effective products for patients.



# PDA Across The Globe

SoCal  
PDA  
Chapter

**Your Local PDA Connection**

Are you curious about the issues unique to your region?

Another layer of PDA leadership resides at the grassroots level in the Chapter organizations. Regional PDA Chapters provide local services to the membership, including translations of PDA publications, networking social events, student scholarship and annual regulatory and technical conferences. Each Chapter is managed by volunteer leaders.

Get involved with your local PDA Chapter today!  
Contact [volunteer@pda.org](mailto:volunteer@pda.org)

PDA is > 10,000 members. 23 chapters worldwide. 12 chapters in the US. SoCal PDA Chapter is Venture-LA-OC-SD including HI, AZ and N.M. SoCal PDA is the second largest chapter in the US. One of the most active and innovative chapters. 2009 first chapter to do a WebEx program to 3 different locations. Greater than 500 members and 60 sponsors.





# Value & Benefits of PDA

- Stay Current With Best Practices, Regulatory and Science
- Ability To Download Technical Reports (250.00 Savings)
- Training & Educational Opportunities
- Network With Industry Peers and Colleagues
- Receiver Monthly PDA Magazine "PDA Letter" (10 per year)
- Access To PDA Programs, Events and Meetings (local to national)
- Meet New People To Expand Your Network
- Access To PDA Journal Of Pharmaceutical Science & Technology
- Opp. To Get involved in PDA Initiatives, Task Groups & Committees
- Enhance Your Personal Growth
- Advance Your Professional Career
- Access To PDA Members Worldwide Through "PDA Connect"
- Ability to Interact With FDA through the PDA/FDA Joint Conference
- Share Your Knowledge and Expertise With Others
- Give Back To Your Industry
- Opp. to participate with your Local Chapter, Programs & Initiatives



# How Do You Get Involved in PDA?

Become A PDA Member  
Join Your Local Chapter

**Volunteer!**



# PDA Volunteer Opportunities

Attend PDA Meetings & Events

Attend SoCal PDA Chapter Quarterly Events and Programs

Join the SoCal PDA Chapter "Get Involved" at the grass roots level!

Become a Survey Reviewer

Get involved with an Interest Group

Attend Training Courses

Author Articles for the PDA Letter and PDA Journal

Poster Presenter

Technical Report Peer Reviewer

Speaker

Become A Local Chapter Leader or Volunteer

Task Force Member

Interest Group Leader

Training Instructor

Join PDA Committees, Programs & Initiatives (National & Local)

Task Force Leader

Join An Advisory Board

# PDA Member Types and Benefits

		Standard/Individual	Young Professional	Emerging Economy/Academic	Student	Retired/Unemployed	Regulator/Health Authority
		\$279 per year	\$100 per year	\$100 per year	\$30 per year	\$25 per year	\$0-12 per year
Membership Benefits	PDA Letter (hard copy)	✓	NA	NA	NA	NA	NA
	Download New TRs (electronic)	✓	✓	NA	NA	NA	✓
	PDA Technical Report Portal (electronic)	✓	✓	✓	✓	✓	✓
	PDA Journal (electronic)	✓	✓	✓	✓	✓	✓
	PDA Letter (electronic)	✓	✓	✓	✓	✓	✓
	PDA Member Directory	✓	✓	✓	✓	✓	✓
	PDA Member Discounts	✓	✓	✓	✓	✓	✓
		Join PDA	Join PDA	Join PDA	Join PDA	Join PDA	Join PDA

PDA Membership is individual-based in all cases. PDA does not offer corporate membership at this time.





# Sponsor Presentations





## Sponsor

**AES**

**Janet Wittbrodt**



**AES is a full-service engineering company with expertise in the Life Sciences industry. Our experienced team, assembled from within the industry, are experts in Process Sciences, Operations, Automation and Process Engineering, Maintenance, Commissioning, and Qualification/ Validation as well as Data Management and System/ MES Integration, resulting in a true one-stop integrator. Our process knowledge spreads across both upstream and downstream processing as well as fill/ finish/ packaging for both fixed and single use facilities at any scale. Our software and automation hardware strengths, including panel and instrumentation design and fabrication, represent depth with numerous platforms including Emerson DeltaV, Rockwell Automation, Wonderware, and GE. Large or small, our team handles all projects ranging from new facility construction and design to maintaining/ upgrading/ optimizing existing facilities on time and on budget.**



# Sponsor

## Pace Analytical

### Renee Klein



Pace Analytical Life Sciences is a full service, cGMP-compliant, contract analytical testing providing chemistry and microbiology services: sterility testing, bioburden, microbial limits, antimicrobial effectiveness, environmental monitoring, bacterial endotoxins, microbial identification, methods development and validation, assays, drug release profiles, dissolution, impurities, residual solvents, and elemental impurities. Three FDA-registered laboratories: Minnesota, New Jersey, and Puerto Rico.



# Sponsor

**Vanrx**

**Troy Simmons**



**Vanrx Pharmasystems makes the most technologically advanced sterile filling solutions for the pharmaceutical industry. Vanrx fill-finish machines use isolated robotics and machine vision to automate the packaging of injectable drugs into nested vials, syringes, or cartridges. The company was founded by pharmaceutical industry veterans to create the systems needed to make the next generation of innovative therapies. Vanrx has created the first gloveless robotic isolator—the SA25 Aseptic Filling Workcell—an ideal production tool for the current and future pharma market. The SA25 can support aseptic filling into vials, syringes and cartridges using highly repeatable robotic processes. As a standard product, it can be built and installed faster than conventional systems. Pharmaceutical companies can bring drug products to market faster by partnering with Vanrx.**



# Speakers

**Mihaela C. Simianu, Ph.D.**

Director, Regulatory Compliance, Pharmatech Associates

**“Product and Process Design for Biologics”**

**Bikash Chatterjee**

President and Chief Science Officer, Pharmatech Associates

**“All Things Considered: CMC and QMS Intersection in Process Development”**





# Q & A





# Board Members & Members-at-Large

Randy George - **Chapter President**

Laurel Hacche - **Program Chair**

Stephanie Powers Kurtz - **Philanthropy Chair / Co-Chair 2017 VN**

Ileana Ayala - **Venue / Event Chair / Co-Chair 2017 VN**

Ruchika Raval - **Corporate Outreach Chair**

Susan Bain - **Student Chapter Advisor**

Madelyn Low - **Student Chapter President**

Anna Nguyen - **Member-at-Large – Program / Treasury Support**

Vicky Southard - **Member-at-Large - Data Support**

Amy Stanton - **Member-at-Large – Program Support / FDA Liaison**

Joan Akleh - **Member-at-Large – Vendor Outreach / Vendor Night Support**

Renee Klein - **Member-at-Large – Program / Vendor Night Support**

Geared Pearce - **Board Advisor - Social Networking / Marketing**

John Holmgren - **Board Advisor - Programs / Past President**

Brian Underhill - **Immediate Past President**



# SoCal PDA Volunteer Opportunities

- Chapter Administrator / Event Coordinator – external position to board
- Program Planning Support - committee members
- Event / Vendor Night Planning Support - committee members
- Vendor Relations / Outreach - Chairperson Opp. Available
- Corporate Relations / Outreach - committee members
- Philanthropy Relations Initiative - committee members
- Membership Relations / Outreach - Chairperson Opp. Available
- Student Chapter / Young Professionals - Chairperson Opp. Available
- Communication / Social Media / Marketing - Chairperson Opp. Available
- Chapter Secretary - Board Position Available
- IT / WebEx / Website / Mobile App. Support - Chairperson Opp. Available
- Speakers-SME's, Technical, Regulations, Quality, etc...for programs / events
- **Committee volunteer opportunities available for all above programs and initiatives**



# SoCal PDA Upcoming Events

- **August 17, 2017 – Networking Event “Membership Appreciation” / Dave & Busters, Irvine Spectrum, Irvine, CA**
- **September 28, 2017 – 7th Annual Industry Summit and Exhibitor Showcase (Vendor Night) / Richard Nixon Library, Yorba Linda, CA**
- **November 16, 2017 – Aging Facilities / Evening Lecture / Kite Pharma Los Angeles, CA; Peregrine, Tustin, CA; 3rd Location to Be Added**



# SoCal Volunteer Opportunity

## SoCal PDA Chapter Contact

Randy George

SoCal PDA Chapter President

949-632-1802

[r.george@rescop.com](mailto:r.george@rescop.com)

## PDA USA Contact

Katie Ruiz

Member Relations Coordinator

[ruiz@pda.org](mailto:ruiz@pda.org)

301-656-5900 ext. 110





**From SoCal PDA Chapter**

**“Thank You”**

**To Our Sponsor's, Speakers & Attendees**

**For Supporting and Attending**

**Today's Program**

**“Drive Safe”**