



# WELCOME

SOCAL PDA Chapter Q4 2016 Program Event

“Quality Culture & Metrics”

November 17, 2016



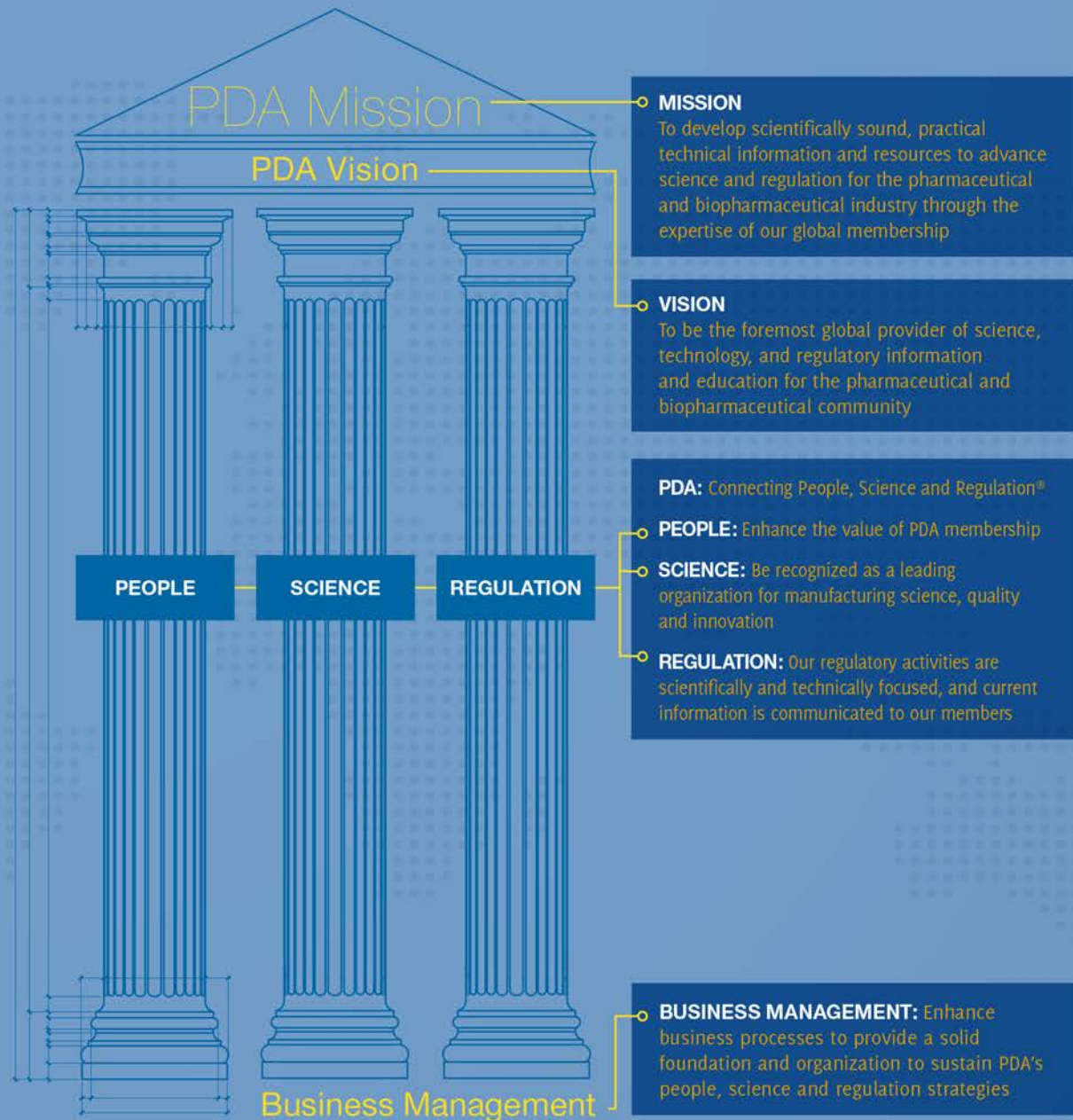


# WELCOME

- **SoCal PDA Q4 Quarterly Event**  
“Quality Culture & Metrics”
- **Thank You**  
Laurel Hacche - Manufacturing & Quality Consulting  
Anna Nguyen - Peregrine
- **AGENDA**  
About PDA & SoCal PDA Chapter  
Introduction of Sponsors  
Introduction of Speakers & Presentations  
Q&A  
Close

## 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.







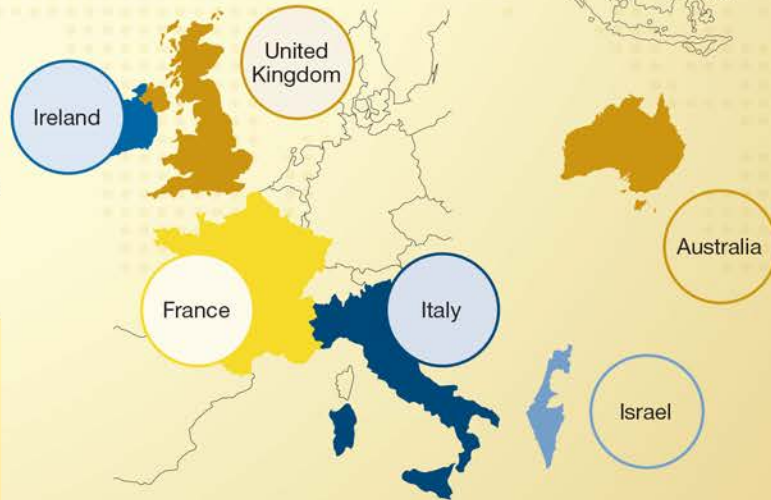
## Your Local PDA Connection

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)





# It's easy to see the value of membership in PDA

- PDA Technical Reports
  - Now all Standard and Government members can view the complete collection of PDA Technical Reports for free at the online TR Portal. Visit the PDA homepage for access.
  - They are global technical documents, prepared by member-driven Task Forces comprised of content experts.
  - Membership includes free 30 day download of each new PDA Technical Reports (each valued at \$250)
- *PDA Letter*
  - Main written communication link to membership
  - Mailed to all members 10 times per year – available online too
- *PDA Journal of Pharmaceutical Science and Technology*
  - Peer reviewed journal focusing on member interests
  - Free access includes current and previous volume year.

# Volunteer Opportunities at PDA

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

## Leadership

- ◉ PDA Executive Officers

- ◉ Director

- ◉ Scientific Advisory Board
- ◉ Biotechnology Advisory Board

- ◉ Regulatory Affairs and Quality Advisory Board

- ◉ PDA Committee Chair/Co-Chair
- ◉ Task Force Co-Chair

- ◉ Author/Contributor to the *PDA Letter*
- ◉ Author/Contributor to the *PDA Journal*
- ◉ Poster Presenter
- ◉ Attend Chapter Committee/Planning Meetings
- ◉ Technical Report Peer Reviewer

- ◉ Speaker
- ◉ Chapter Leader
- ◉ Task Force Member
- ◉ TRI Instructor
- ◉ Interest Group Leader

### PDA Committees:

- ◉ Program Planning Committee
- ◉ PDA Letter Committee
- ◉ Membership Committee
- ◉ Education Committee
- ◉ Audit Committee

- ◉ PDA Membership
- ◉ Attend Global PDA Meetings

- ◉ Attend Chapter Events
- ◉ Survey Reviewer

- ◉ Interest Group Member
- ◉ Attend TRI Courses

1,000

Over 1,000  
volunteers  
worldwide  
actively carry out  
PDA's Mission

## Getting Involved





# SoCal PDA Board & Programs

## Quarterly Programs

### Laurel Hacche

Forum for industry experts to stimulate discussion and networking through trending educational content, which fosters participation and increases chapter revenue to support ongoing programs

## PDA Signature Event (Annual Vendor Night)

### Randy George

PDA annual signature event that attracts thought leaders and industry experts to provide a platform for vendors to share products and services as a means to increase and enhance their customer base

## Philanthropy

### Stephanie Powers-Kurtz

Compassionate advocates that provide time, money, visibility and/or mentorship/education to maximize the impact on social sectors



# SoCal PDA Broad & Programs

## Corporate Outreach

**Ruchika Raval**

To provide a channel connecting corporations and members of the PDA Chapter so as to provide technical expertise and increase participation

## Vendor Outreach

**Randy George**

To provide a channel to increase vendor sustained support for the PDA Chapter

## NEXUS Publication

**Shaleen Parekh**

To provide a unique perspective connecting academia and industry

## Keck Graduate Student PDA Chapter

**Ileana Ayala**

To grow a community that influences KGI students and the Bioscience Industry while also providing development opportunities





# Sponsors

- **PLATINUM SPONSOR**  
SQA Services, Inc. - Amgen  
Parexel International - Peregrine
- **WEBEX SPONSOR**  
RPA – Peregrine  
Paramount Science - Peregrine  
Contac - Peregrine



# Sponsor

- **PLATINUM SPONSOR**



SQA provides global supplier quality services for quality-critical industries. With quality, manufacturing, and regulatory experts located in over 50 countries, SQA provides a cost-effective, local supplier presence. Managed, on-demand services include supplier quality audits, supplier remediation, quality engineering, source inspection, corrective action management, and real-time supplier quality data via SQA's world-class STEPQ technology.



# Sponsor

- **PLATINUM SPONSOR**



PAREXEL is a global biopharmaceutical services company focused on integrated solutions – from product strategy and clinical development through market access and lifecycle management. By applying the best minds, we simplify the journey between science and new treatments through innovation and problem-solving, so new products can reach patients sooner



# Sponsor

- **WEBEX SPONSOR**



RPA is a professional sales organization conceived on the premise that technology is successfully sold as much by the integrity of the individuals presenting it as the substance of the company producing it. Partner with us for the specialized cleanroom furniture and equipment you require for efficient operations and welcome success. We connect you to the cleanroom builders, as well as manufacturers that make the furnishings to fill that space. With all the right equipment, your controlled environment functions exactly as it should.





# Sponsor

- **WEBEX SPONSOR**



Paramount Sciences assists manufacturers in providing a safe, quality product. We support companies in three key areas: Decontamination, Contamination Control and Environmental Monitoring. Whether you need to make your environment clean after an incident, maintain its routine cleanliness through contamination control measures or monitor with active air sampling, we provide solutions. We have extensive business experience coupled with a science focus and are passionate about linking the two for the success of your business operations. We represent quality products and services backed by people and organizations with integrity.



# Sponsor

- **WEBEX SPONSOR**



Contec, Inc. is a leading manufacturer of contamination control products for mission-critical cleaning in manufacturing environments worldwide. For more than 27 years, Contec has provided solutions to customers across many industries including biomedical, pharmaceutical, medical device, microelectronics, optics, semiconductor, automotive OEM and aerospace.

Our extensive cleanroom product line includes knitted, woven and nonwoven wipes, presaturated wipes, sterile and non-sterile products, mopping systems, disinfectants and swabs for cleanrooms and controlled environments.



# Speakers / Presentations

- **Cylia Chan**

Sr. Manager Quality Assurance External Affairs Amgen  
PDA Quality Culture Team

**“PDA Quality Cultural Program Overview”**

- **Carmen Medina, MPH, Ph.D**

Vice President, Technical, Parexel International  
28 Years FDA Experience

**“Enterprise-Wide Quality Metrics”**



# Q & A





# News, Notes & Future Events

## **PDA Future Events-**

- **San Diego - 2016 PDA Data Integrity Workshop**  
Dec 07 - Dec 08, 2016 / San Diego, CA
- **2017 PDA Pharmaceutical Quality Metrics and Quality Culture Conference**  
Feb 21 - Feb 22, 2017 / Bethesda, MD
- **2017 PDA Annual Meeting**  
Apr 03 - Apr 05, 2017 / Anaheim, CA



# News, Notes & Future Events

- **SoCal PDA Events-**

  - Q1 2017 Quarterly Event**

  - Full Day Event - TBD

  - Date/Location - TBD

- **Networking Event As Host Chapter/PDA Annual Meeting**

  - Apr 03 - Apr 05, 2017 / Anaheim, CA

- **Vendor Sponsorship Program**

  - Roll Out Nov. – Dec. 2016

  - Begin January 2017



# SoCal Volunteer Opportunity

## CONTACT

Chapter President Brian Underhill

909.714.3155

[bunderhill@socalpda.org](mailto:bunderhill@socalpda.org)

President Elect Randy George

949-632-1802

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



**Thank you for your attendance**

**Happy Thanksgiving  
to you and your families**

**From  
SoCal PDA**