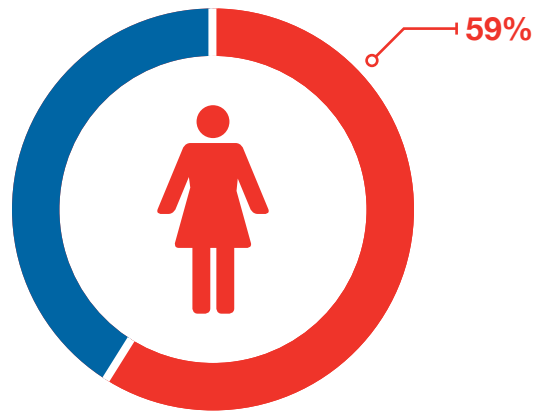


# 2018 ANNUAL REPORT PDA DIVERSITY

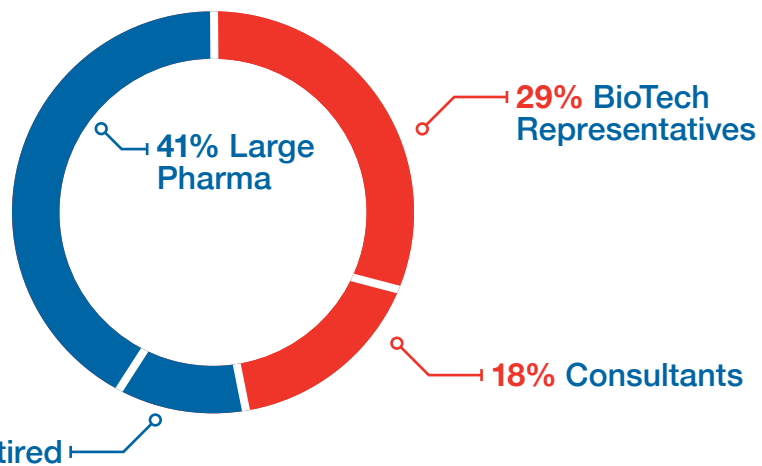


# PDA DIVERSITY

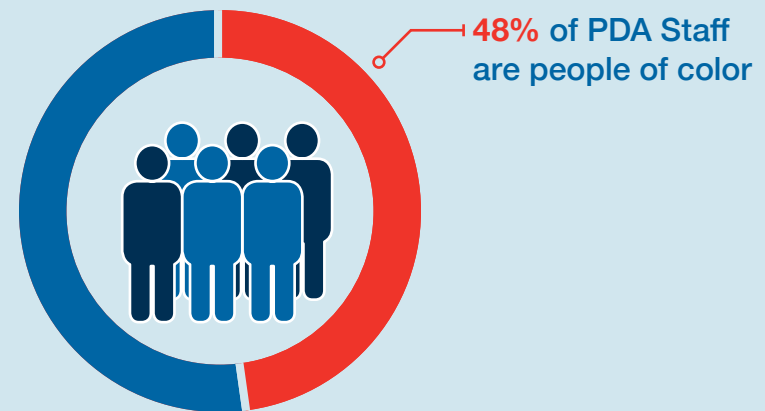
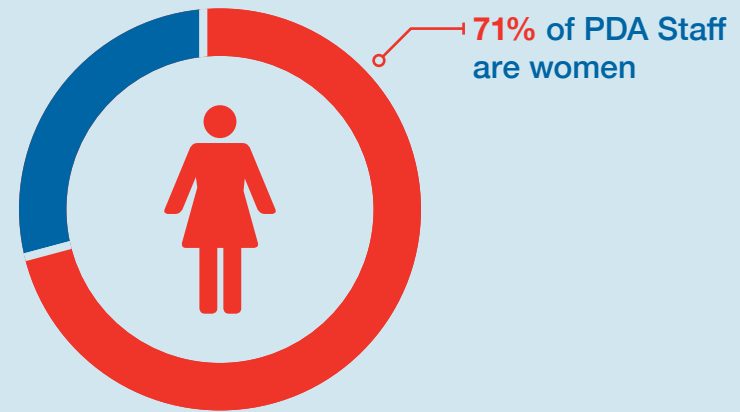
## Board of Directors: Composition



## Sectors Represented on the Board



## PDA Staff



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# PDA DIVERSITY

## PDA Leadership Reflects Diverse Membership

New leaders within PDA's professional and volunteer bodies reflect the diversity of contributors to the Association. In addition, thinking back on International Women's Day, celebrated March 8, offers the perfect opportunity to acknowledge women's roles as leaders within the organization. Starting in 2018, Becky Devine became the third female volunteer Chair. Her successor, current chair-elect Jette Christensen will continue the pattern of diversity. However, women holding positions of leadership is not a new trend for the Association. PDA pioneer Nina Demuth blazed the trail as the first woman to present at a PDA conference and serve as the Annual Meeting Program Chair during the 1970s. She also co-founded the PDA Foundation for Pharmaceutical Sciences in 1979. Following in Demuth's footsteps, Joyce Aydlett became PDA's first female Chair of the PDA Board, serving from 1998–1999.

The selection of Christensen as Chair-Elect is the first time a member volunteer from outside the United States has been slated to lead the all-volunteer Board of Directors, starting in 2020. The Board of Directors has been diversified internationally for two decades, with the 2018 board representing members in six different countries.

PDA also made changes to the process of selecting members to its Board of Directors to ensure company types throughout the pharmaceutical/biopharmaceutical supply chain are represented. Instead of selecting the entire 17-person Board of Directors by membership vote, three slots are reserved for appointment by PDA leadership to ensure equal representation among various constituencies. PDA selected Kerry Ingalls, Amgen, and Mary Oats, Pfizer, to join the Board for their experience in manufacturing operations.







# CHAIR'S MESSAGE



Looking back at 2018, PDA and our industry faced many interesting challenges. The year marked the tenth anniversary of the Heparin contamination crisis that led to a critical drug shortage. Since then, the industry has come a long way in addressing many of the complex supply chain issues that led to that crisis. As co-chair of the 2018 PDA/FDA Joint Regulatory Conference, it was exciting to see a record number of participants gather, in part, to discuss supply chain problems.

PDA's nascent standards program adopted the related topic of purchasing controls as its first project. Led by Immediate-Past-Chair Martin Van Trieste, this group made great progress advancing the standard, which will be released for public comment in 2019.

PDA also made great strides in addressing the complex issues faced by manufacturers of emerging technologies, such as cell and gene therapy products. These revolutionary new products, which are now finding their way to commercialization, will change the landscape of patient therapy for many serious diseases and, as an industry, we need to be sure we are able to adequately manufacture and deliver these products for waiting patients. In 2018, PDA is poised to assure that technical reports, conferences, workshops, and other training and resources are available to assist those involved in manufacturing cell and gene therapy products. *Technical Report No. 81: Cell Based Therapy*—PDA's first for these product types—was approved by the Board of Directors. In addition, the PDA Biopharmaceutical Advisory Board formed the Cell and Gene Therapy Interest Group to provide a forum for our members operating in this field. During the year, PDA's Regulatory Affairs and Quality Advisory Board submitted comments on two FDA guidances for gene therapies, one on CMC and the other on testing gene therapies for RCR. PDA also sponsored the 2018 Cell and Gene Therapy Conference in Bethesda, Md., and the Advanced Therapeutic Medicinal Products Conference in Amsterdam.

As PDA moves forward into 2019, I want to say a few words about PDA's diverse community of volunteers. I believe PDA has the most dedicated, talented and leading subject matter expert volunteers, whose contributions allow PDA to succeed in its mission. Having volunteered for many years myself, I understand the commitment it takes to volunteer—giving up free time (after working a regular day job) and contributing knowledge to PDA's efforts so it can be shared by the membership and industry as a whole. I would like to thank all PDA volunteers for their time and effort. I look forward to seeing the great work that PDA's dedicated staff and valued volunteers have in store for 2019!



# BOARD OF DIRECTORS



## Chair

Rebecca Devine, PhD  
*Regulatory Consultant*



## Chair-Elect

Jette Christensen, PhD  
*Novo Nordisk*



## Treasurer

Michael Sadowski  
*Baxter Healthcare*



## Secretary

Steven Lynn  
*Lynn Consulting*



## Immediate Past Chair

Martin VanTrieste



Masahiro Akimoto  
*Otsuka Pharmaceutical  
Factory, Inc.*



Barbara M. Allen, PhD  
*Eli Lilly*



Joyce Bloomfield



Veronique Davoust  
*Pfizer*



Ghada Haddad  
*Merck*



Kerry Ingalls  
*Amgen*



Mary Oates  
*Pfizer*



Emma Ramnarine  
*Genentech/Roche*



Stephan Rönninger, PhD  
*Amgen*



Anil Sawant, PhD  
*Merck & Co./Merck  
Sharp & Dohme*



Susan Schniepp  
*Regulatory Compliance  
Associates*



Melissa Seymour  
*Biogen*

# PRESIDENT'S MESSAGE



## PDA 2018 — A Year of Challenge and Success

As I near my 10-year anniversary as PDA's President, I look back on the last decade as one of challenge and success. 2018 was typical for this, as we saw issues relating to expanding our reach, new therapies requiring new approaches to manufacturing, regulatory changes that impact our activities and evolving demographics in both our membership and our staff. Despite this, PDA continued to be successful in *Connecting People, Science and Regulation*®.

PDA focuses on People. Our members, in one way or another, work together to make safe and effective medicinal products for patients worldwide. PDA's mission is to assist our members in meeting this obligation. We completed our biannual customer survey of more than 1,600 individuals (member and nonmember) worldwide and, while the data showed that PDA is valued most highly in our credibility and value, we continue to strive for improvement. We offered 36 conferences and workshops in 2018, along with more than 110 training courses in locations around the world. Like the members we serve, we continue to adapt to the digital world, including:

- Complying with data protection and privacy requirements enacted in several countries
- Redesigning PDA's website to increase usability
- Expanding our offering of online articles and videos to keep up with the continuing migration from print to electronic access
- Increasing our efforts to translate technical reports into other languages

PDA also launched our first standards projects, which add ANSI standards to our toolkit of resources for our members. In addition, we maintained our high pace of developing PDA technical reports, research, points to consider, and regulatory comments.

PDA launched our Asia Pacific initiative, and hosted conferences in Japan, South Korea, and Taiwan. PDA also chartered a new chapter in the U.S. Pacific Northwest.

We continue to improve our unique Training and Research Institute in Bethesda and explored possible future sites in Europe and India.

Through it all, we managed the Association's assets with sustainability and service as our watchwords.

None of this could have been accomplished without the work of our many volunteers on committees and task forces, and our tireless staff who have maintained a level of excellence in execution and support of a wide spectrum of activities, whose efforts have made our accomplishments possible.

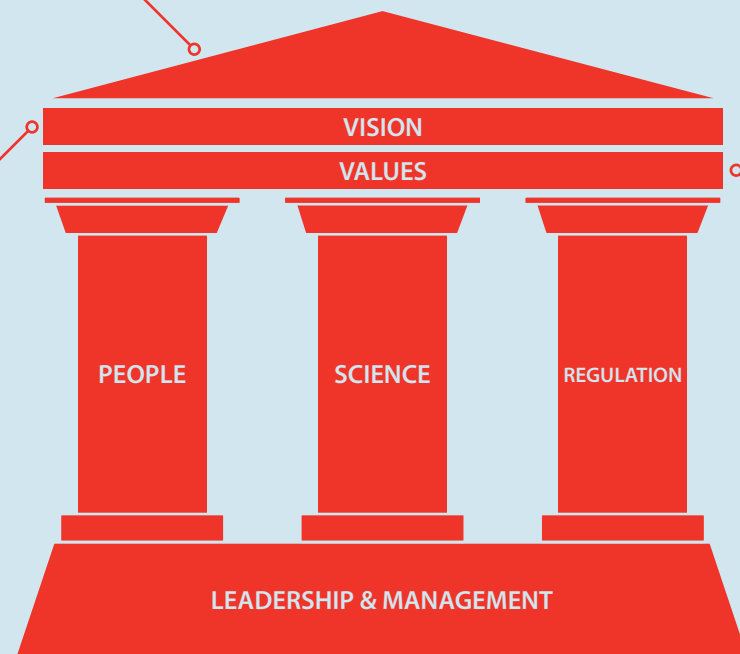


# VISION & MISSION

To advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients

To maximize product quality, availability, and value by connecting people, science, and regulation within the pharmaceutical and biopharmaceutical community so that PDA is:

- The preferred choice for professionals who seek specialized, innovative skills and knowledge enhancing their professional development
- The premier educational partner for professionals in academia, industry, and government for the advancement of manufacturing, quality, and regulatory science
- An organization that aligns its practices and resources in support of its core values of science-based, integrity, and inclusion



**Science:** Science is the foundation of our organization. We utilize a scientific approach to meet challenges and continuously improve. It is not subjective or emotional, but rather a logical, open, rational, and transparent process.

**Integrity:** We are relentless in applying the highest ethical standards to our products, services, and actions. We will never compromise ethics. We will be known for living to the highest forms and standards of ethical behavior. We will honor our commitments.

**Inclusion:** We work together to create a culture of inclusion built on trust, respect, and dignity for all. We contribute to the advancement of pharmaceutical/biopharmaceutical operations by building partnerships with professionals in academia, industry, and regulatory bodies to better serve patients.

# SCIENTIFIC & REGULATORY AFFAIRS

PDA's internal Scientific and Regulatory Affairs leadership changed in 2018, with the retirement of long-time SRA Senior VP, Richard Levy, PhD, in May. A month later, Tina Morris, PhD, took over the role as VP of the department. Dr. Morris previously worked for the U.S. Pharmacopeia for fifteen years, serving as Sr. VP of Compendial Services before leaving to join PDA. Dr. Levy did not retire entirely after 13 years working for PDA; instead, he transitioned into the role of Editor for the *PDA Journal of Pharmaceutical Science and Technology*. Ruth Miller joined PDA as Director, Regulatory Affairs, taking over for Denyse Baker, who returned to industry after five years with PDA in the same role.



Tina Morris, PhD, assumed the position of PDA's VP Scientific and Regulatory Affairs in 2018



Rich Levy, PhD, became the *PDA Journal of Pharmaceutical Science and Technology's* 8<sup>th</sup> Editor

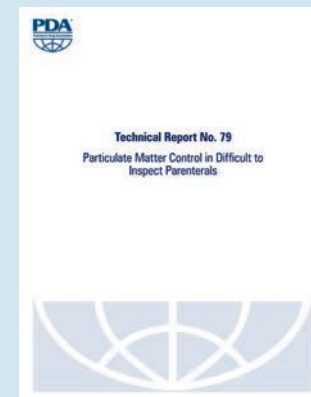
## 2018 Publications

PDA Technical Series:  
Pharmaceutical Glass

PDA Technical Report No. 79:  
Particulate Matter Control in  
Difficult to Inspect Parenterals

PDA Research: 2017 Glass Quality  
Survey

PDA Technical Report No. 80: Data  
Integrity Management System for  
Pharmaceutical Laboratories



# 13 REGULATORY COMMENTS IN 2018



PDA Response to EDQM Proposed EP 5.17.2. Recommendations on Testing of Particulate Contamination

PDA Response to EDQM Revision of EP 5.1.5 Application of F Concepts to Heat Sterilisation



Health Canada Santé Canada

PDA Response to ICH Q12 Health Canada



**U.S. FOOD & DRUG ADMINISTRATION**

PDA Response to FDA Draft Guidance on CMCs for Gene Therapy INDs

PDA Response to FDA Request for Regulation and Paperwork Reduction

PDA Response to FDA Draft Guidance on Testing Gene Therapy Products for RCR

PDA Response to FDA CMC Changes for Certain Biological Products

PDA Response to Annex 1 Revision: Manufacture of Sterile Medicinal Products



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

PDA Response to EMA EU Template for GMP Non-Compliance Statement

PDA Response to EMA QP and API Site Audit Questions



PDA Response to ANVISA Stability Revised Guidance



PDA Response to Israel MOH Draft QP SOP



PDA Response to USP Changes to COE Rules

# VOLUNTEER SPOUGHT



**Marc Hargreve, Sartorius Stedim Biotech GmbH**

Do not ask yourself if you are able to do it; just do it. Every single volunteer activity helps support our industry in its mission to enhance the future of healthcare.



# PDA CHAPTERS

## North America

Chapter President

**Canada** | Antonella Maggio, *Harmonium International (Lallemand Health Solutions)*

**Capital Area** | Allen Burgenson, *Lonza Walkersville, Inc.*

**Delaware Valley** | Leo Posner, PhD, (*Johnson & Johnson*)

**Metro** | Mary Huynh, *Bracco Diagnostics, Inc.*

**Midwest** | Alan Solomon, *Baxter Healthcare Corporation*

**Missouri Valley** | Gary Klaassen, *ThermoFisher Scientific*

**Mountain States** | Suzanne Mecalo, *Commissioning Agents International, Inc.*

**New England** | Laurie Masiello, *Masy Bioservices*

**Pacific Northwest** | Lisa Rutter, *Partner Therapeutics*

**Puerto Rico** | Luisette Rivera, *Johnson & Johnson*

**Southeast** | Renee Morley, *Contec, Inc.*

**Southern California** | Randy George, *ValGenesis, Inc.*

**Texas** | Greg Williams, *Novartis Pharmaceuticals Corp.*

**West Coast** | Fabio De Martino, *Genentech, Inc.*

## Asia Pacific

Chapter President

**Australia** | Eoin Hanley, *CSL Behring*

**India** | Ivy Louis, *Vienni Training and Consulting LLP*

**Japan** | Katsuhide Terada, *Takasaki University of Health and Welfare*

**Korea** | Woo-Hyun Paik, *Korea Pharm. Tech. Education Center (KPTEC)*

**Singapore** | Dinesh Khokal, *Amgen*

**Taiwan** | Wayne Wu

## Europe

Chapter President

**France** | Philippe Gomez, *Sartorius Corporate Administration GmbH*

**Ireland** | Declan Quinlan, *MSD Ireland*

**Israel** | Meir Batito, *Atox Bio*

**Italy** | Angela Molaschi, *NTC Srl*

**United Kingdom** | Siegfried Schmitt, *Parexel International Corp.*

## South America

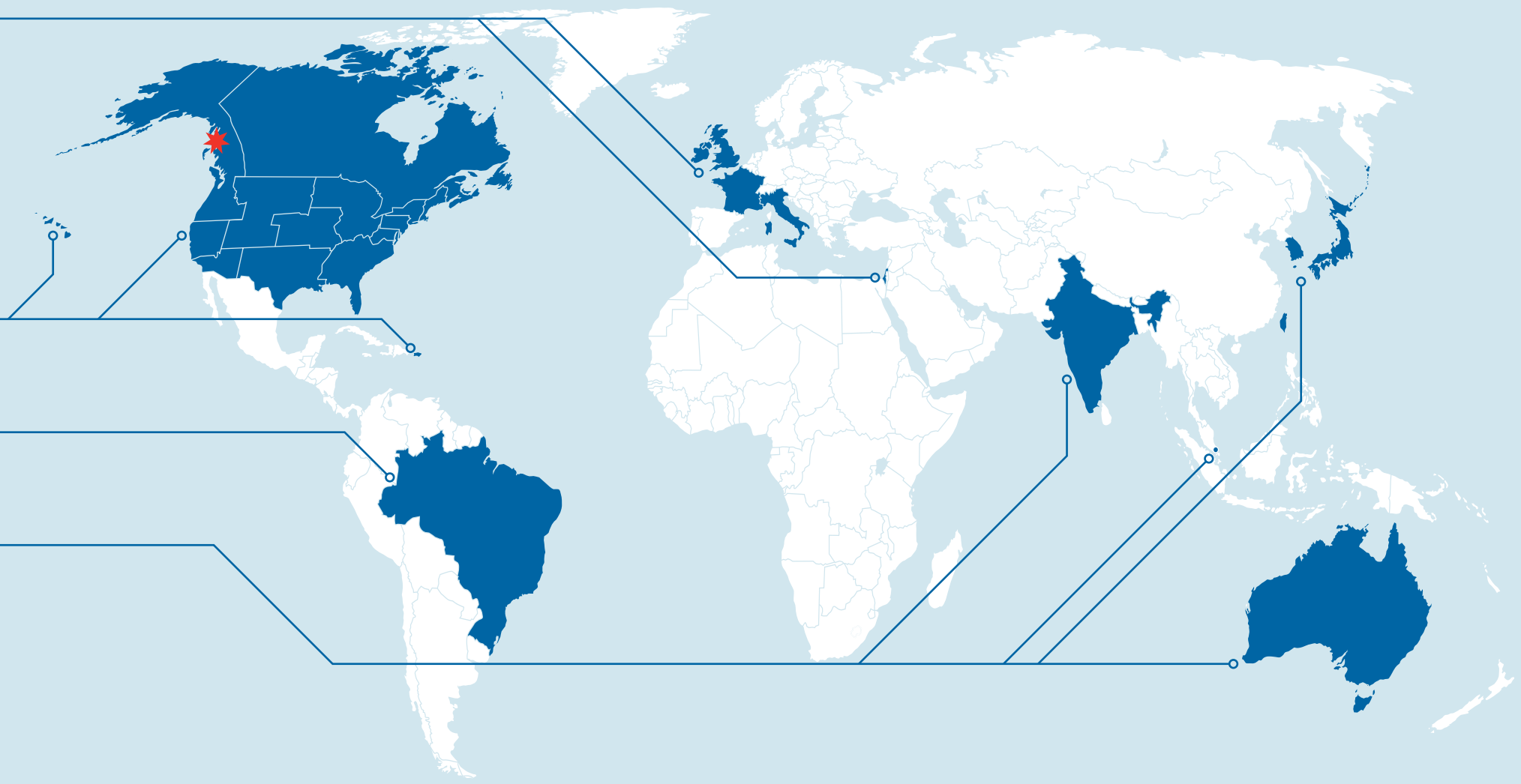
Chapter President

**Brazil** | Leonidas Orjuela, *Audisís Vale*

In 2018 PDA added a new chapter and they have already hosted their first event!



In 2018 there were **10,085 PDA members** globally



# MEMBER BENEFITS

PDA's diverse membership regularly contribute to the *PDA Letter* and *PDA Journal of Pharmaceutical Science and Technology*, two of our most popular member benefits. PDA staff produce these publications with the help and guidance from all-volunteer editorial committees. And the news *uPDATE*, an email alert PDA introduced in 2017, provides the community with a weekly snapshot of the leading industry-related news.

## news uPDATE

Total Articles  
12,338

Total News Sources  
804

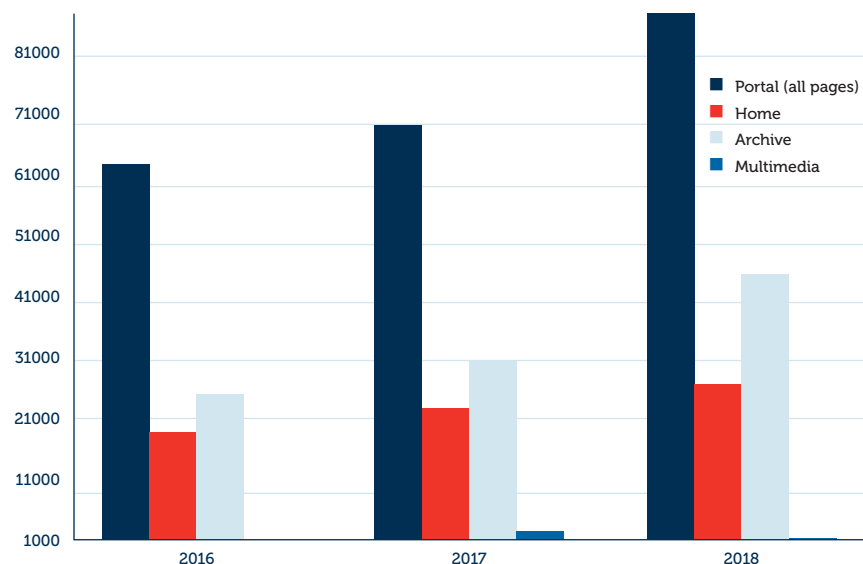
Total Subscribers  
29,087

Reads  
102,666

Readers  
42,550



## PDA Letter Portal Usage 2016–2018



*PDA Letter* website received  
88,643 page views



**Article of the Year! New Approach Suggests Continuous Lyophilization is Possible**

— Pieter-Jan Van Bockstal, Ghent University, Jos Corver, RheaVita, Thomas De Beer, Ghent University

## PDA Journal of Pharmaceutical Science and Technology 2018 Usage

Access Events to:	Home Page	Current Issue TOC	All TOCS	Searches	Abstracts	Full -Text HTML	PDFs
Total Access	299,855	18,636	59,443	40,592	397,011	33,053	51,355



# HONOR AWARDS



Each year, PDA recognizes members whose contributions have helped PDA fulfill its mission at an Awards Dinner held during the Annual Meeting. PDA congratulates each winner and thanks them for their service to PDA.

## Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient, given in recognition of long service significant in nature to PDA and requires unanimous approval from the Board of Directors.

**Maik Jornitz**

## Gordon Personeus Award

Presented in the memory of past PDA President and longtime volunteer, Gordon Personeus, this award honors a PDA member, other than a Board member, for long-term contributions of special importance to PDA.

**Shin-ichiro Mohri**

## Frederick J. Carleton Award

Presented in tribute to lifetime contributor, past President, past Executive Director, and Honorary Member, **Frederick J. Carleton**, this award recognizes past or present Board members.

**Hal Baseman**

## Martin VanTrieste Pharmaceutical Science Award

Established in honor of long-time contributor and Chair, **Martin VanTrieste**, this award honors outstanding contributions to the advancement of pharmaceutical science.

**Jeanne Moldenhauer**

## Michael S. Korczynski Award

In honor of **Michael S. Korczynski**, PhD, this award recognizes contributions made toward the development of PDA's international activities.

**James Polarine**

## Edward Smith Packaging Science Award

In honor of long-time volunteer **Edward Smith**, who led PDA's packaging science activities, this award honors extraordinary contributions to packaging science.

**Diane Paskiet**

## Distinguished Service Appreciation Award

This award is given in recognition of special contributions that have promoted the success of PDA.

**Shigeto Hirabara**

**Dayue Chen, PhD**

**Marsha Steed**

**Friedrich von Wintzingerode, PhD**

## James P. Agalloco Award

Named in honor of **James Agalloco's** work in developing the PDA Education program, this award recognizes a PDA faculty member who exemplifies outstanding performance in education.

**Horst Koller**

## Distinguished Editor/Author Award

This award recognizes the author or editor selected by PDA members for their contribution to PDA's technical books. This year's award went to the editors of the book, *Microbial Control and Identification*.

**Dona Reber**

**Mary Griffin**

## Frederick D. Simon Award

This award is presented for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology* and is named in honor of the late **Frederick D. Simon**, a former PDA Director of Scientific Affairs. This year's award went to seven recipients for their article, "Vapor Phase Hydrogen Peroxide Decontamination or Sanitization of an Isolator for Aseptic Filling of Monoclonal Antibody Drug Product—Hydrogen Peroxide Uptake and Impact on Protein Quality," which was published in the July/August 2018 issue.

**Aaron Hubbard**

**Thomas Roedl**

**Ada Hui**

**Stephanie Kneuppel**

**Kirk Eppler**

**Siegfried Lehnert**

**Yuh-Fun Maa, PhD**

## PDA Europe Service Appreciation Award

This award honors special contributions that have contributed to the success of PDA's European activities.

**Yves Mayeresse**

## Service Appreciation Award

This award is presented annually for special contributions to PDA.

**Karin Baer**

**Eoin Hanley**

**Amnon Eylath**

**Steven Dawson**

**John Geigert, PhD**

**Kerry Ingalls**

**Susan Schniepp**

**Stephan Rönninger, PhD**

## President's Award

This award recognizes a PDA staff member whose exemplary performance has contributed to PDA's success during the previous year.

**Brooke Schneider**

**Dirk Stelling**

# ADVISORY BOARDS & COMMITTEES



## SAB

Maik Jornitz, *G-Con Manufacturing Inc. (Chair)*  
 Phil DeSantis, *DeSantis Consulting Associates (Vice Chair)*  
 Masahiro Akimoto, *OTSUKA*  
 John Ayres, *Eli Lilly and Company*  
 Ed Balkovic, *MicroBio Technical Support*

Greg Bassett, *Amgen*  
 Scott Bozzone, *Consultant*  
 Jette Christensen, PhD, *Novo Nordisk*  
 Don Elinski, *Lachman Consultants*  
 Guenther Gapp, *Gapp Quality GmbH*  
 Gabriele Gori, *GlaxoSmithKline*

Dennis Guilfoyle, *Johnson & Johnson*  
 Ghada Haddad, *Merck & Co./Merck, Sharp & Dohme*  
 Norbert Hentschel, *Juno Therapeutics*  
 Kenneth Hinds, *Johnson & Johnson*  
 William Miele, *Pfizer*

Rainer Newman, *Consultant*  
 Mike Sadowski, *Baxter*  
 Siegfried Schmitt, PhD, *Parexel International Corp.*  
 Marsha Steed, *ConcordiaValsource*  
 Edward Tidswell, PhD, *Merck*  
 Wendy Zwolenski-Lambert, *Novartis*

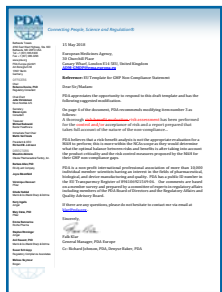
## BioAB

Michael DeFelippis, PhD, *Eli Lilly and Company, (Vice Chair)*  
 John Geigert, PhD, *BioPharmaceutical Quality Solutions (Chair)*  
 Michael Blackton, *Adaptimmune, LLC*

Vijay Chiruvolu, PhD, *Kite Pharma*  
 Olivia Henderson, PhD, *Amgen*  
 Christopher Hwang, PhD, *Just Biotherapeutics China*  
 Margit Jeschke, PhD, *Novartis*

Stephan Krause, PhD, *AstraZeneca Biologics*  
 Morten Munk, *NNE Pharmaplan*  
 Nadine Ritter, PhD, *Global Biotech Experts, LLC*  
 Jens Schletter, PhD, *Sandoz*

Michael VanDerWerf, *Halozyme Therapeutics, Inc.*  
 Karen Walker, *Seattle Genetics*  
 Keith Wonnacott, PhD, *Pfizer*  
 Earl Zablackis, PhD, *Sanofi-Pasteur*



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Jeff Broadfoot, *Emergent BioSolutions Inc. (Chair)*  
 Jacqueline Veivia-Panter, *Celgene (Vice Chair)*  
 Susan Schniepp, *Regulatory Compliance Associates (Past Chair)*  
 Karin Baer  
 Cylia Chen-Ooi, *Amgen*  
 Veronique Davoust, PhD, *Pfizer*

Mirko Gabriele, *Patheon Italia SpA*  
 Aaron Goerke, PhD, *F. Hoffmann-L Roche Ltd.*  
 Tor Graberg, *AstraZeneca*  
 Dipti Gulati, PhD, *PJI Biotech*  
 Frithjof Holtz, *Merck KGaA*  
 Hongyang Li, *Novartis*  
 Steven Lynn, *Lynn Consulting, LLC*  
 Demetra Macheras, *AbbVie, Inc.*

Luciana Mansolelli, *Novartis*  
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 Catriona Murphy, *Eli Lilly and Company*  
 Emma Ramnarine, *Genentech/Roche*

Junko Sasaki, *Sumika Chemical Analysis Service, Ltd.*  
 Anil Sawant, PhD, *Merck Sharpe & Dohme*  
 Janeen Skutnik-Wilkinson, *Biogen*  
 Gopi Vudathala, PhD, *XCell Pharma Consulting LLC*

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Claire Briglia, *MilliporeSigma*

Christine Bui, *Audentes Therapeutics*

Andrew Dick, *Johnson & Johnson*

Walid El Azab, *STERIS*

Michael De Felippis, PhD, *Eli Lilly*

Valeria Frigerio-Regazzoni, *Merck*

Mirko Gabriele, *Patheon*

Stephanie Gaulding, *DPS Engineering*

Richard Hameister, *Coherus Biosciences*

Chris Hanff, *Mallinckrodt Pharmaceuticals*

Tamer Helmy, PhD, *Microbial Vigilance*

Stephan Krause, PhD, *AstraZeneca Biologics*

Mina Mitry, *Marcyrl Pharma*

Andiyanto Sutandar, PhD, *HGP Asia Pte. Ltd.*

Wendy Zwolenski Lambert, *Novartis*

## PDA Journal Editorial

### Editor

Richard Levy, PhD

## Education AB

Harold (Hal) Baseman, *ValSource, LLC*

Bettine Boltres, PhD, *West Pharmaceutical Services Deutschland GmbH & Co. KG*

John Brecker, *VAConsultants*

Bob Dana, *Elkhorn Associates Inc.*

Marc Glogovsky, *ValSource, LLC*

Stephanie Grinan, *PDA*

Richard Johnson, *PDA*

Falk Klar, PhD, *PDA Europe*

Stephanie Ko, *PDA*

Michael Sadowski, *Baxter Healthcare Corporation (US IL)*

Janeen Skutnik-Wilkinson, *Biogen*

Marsha Steed, *bluebirdbio*

David Talmage, *PDA*

Edward Trappler, *Lyophilization Technology, Inc.*

James Vesper, PhD, *ValSource, LLC*

Brent Watkins, *Vetstek Associates Inc.*

## Technical Book Committee

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Amy Davis, *DHI (Vice Chair)*

Michael DeFelippis, *Eli Lilly and Company*

Karen McCullough, *Dendreon*

James Vesper, *LearningPlus Inc.*

Russell Madsen, *The Williamsburg Group, LLC*

Siegfried Schmitt, *Parexel International Corp.*

Steve Lynn, *Novartis*

Richard Johnson, *PDA*

Richard Levy, PhD, *PDA*

## PDA Acknowledgments

PDA would like to thank the editorial team for the *PDA Journal of Pharmaceutical Science and Technology*, 2009-2018, for their dedication and efforts. The group, led by Editor Govind Rao, helped ensure the content of the Journal was aligned with the strategic interests of the PDA community.



Govind Rao, PhD, *University of Maryland, Baltimore County*

### Associate Editors

Beth Junker, PhD, *Consultant*

Antonio Moreira, PhD, *UMBC*

Anurag Rathore, PhD, *Consultant and Faculty at Indian Institute of Technology*

### Assistant Editor

Mia Oetario





# CONFERENCES & WORKSHOPS

## North America

13<sup>th</sup> Annual Global Conference on Pharmaceutical Microbiology  
[Bethesda, MD](#)

2018 PDA Annual Meeting  
[Orlando, FL](#)

2018 PDA Biosimilars Workshop  
[Washington, DC](#)

2018 PDA Cell and Gene Therapy Conference | [Bethesda, MD](#)

2018 PDA Combination Products Workshop | [Orlando, FL](#)

2018 PDA Container Closure Performance and Integrity Conference | [Bethesda, MD](#)

2018 PDA Endotoxins Workshop  
[Bethesda, MD](#)

2018 PDA Glass Quality Conference  
[Washington, DC](#)

2018 PDA Manufacturing Intelligence Workshop  
[Orlando, FL](#)

2018 PDA/FDA Joint Regulatory Conference | [Washington, DC](#)

2018 PDA Universe of Pre-Filled Syringes and Injection Devices  
[Orlando, FL](#)

2018 PDA Sterile Medicinal Products Manufacturing Conference  
[Bethesda, MD](#)

2018 PDA Visual Inspection Interest Group Workshop  
[Bethesda, MD](#)

## Asia

2018 PDA Biopharmaceuticals Conference | [Seoul, Korea](#)

2018 PDA Annual Singapore Conference | [Singapore](#)

2018 PDA Drug Delivery of Injectables Conference  
[Taipei, Taiwan](#)

## Europe

Parenteral Packaging | [Rome](#)

Vaccines | [Malaga](#)

Virus Forum | [Florence](#)

Annex1 | [Dublin](#)

Pharmacopoeia | [Wien](#)

ATMP | [Amsterdam](#)

EU Annual | [Berlin](#)

Pharmaceutical Microbiology  
[Berlin](#)

Visual Inspection Forum | [Berlin](#)

Outsourcing & Supply Chain  
[Seville](#)

Project Management in Pharma  
[Berlin](#)

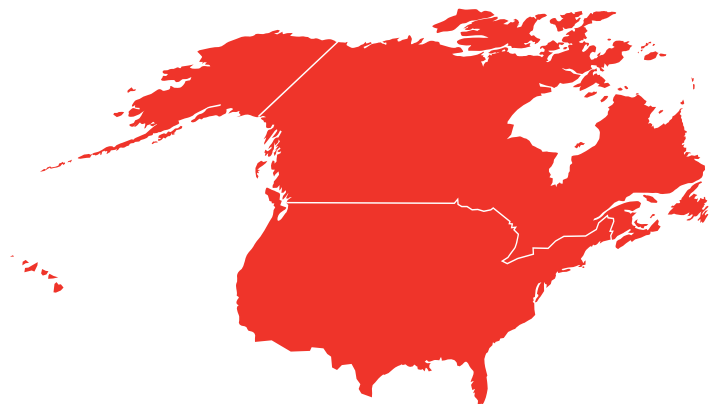
Pharmaceutical Freeze Drying Technology | [Seville](#)

Workshop on Monoclonal Antibodies | [Seville](#)

IG Meeting: Freeze Drying | [Berlin](#)

IG Meeting: Packaging Science  
[Rome](#)

IG Meeting: Prefilled Syringes | [Rome](#)





**Sateesh Yelisetti, Baxter Healthcare (Asia) Pte, Ltd.**

PDA has increased my knowledge of regulations, increased my network within the pharma industry and helped me improve my technical writing.

## Training Course Series/Programs

- Annual Meeting
- Biotechnology
- Cleaning
- Environmental Monitoring
- Human Factors
- Lyophilization
- Pharmaceutical Microbiology Conference
- Sterilization
- Regulatory
- Quality
- Quality Risk Management
- Pre-Filled Syringes and Injection Devices Conference
- Validation
- Visual Inspection
- Aseptic Processing
- Fundamentals of Aseptic Processing
- Airflow Visualization Techniques and Practices
- Isolator Technology
- Filtration Processes in the Pharmaceutical and Biopharmaceutical Industry
- Quality Culture Assessment Tool and Training

## eLearning

- FDA — Quality Culture Webinar

## Suppliers

- Aramark
- Atlantic Technical Systems
- Becton, Dickinson and Company
- BioMérieux
- Bioquell
- Colder Products Company
- Datwyler
- DuPont
- Gerresheimer
- Meissner Filtration Products, Inc.
- Mesa Labs
- Microbiologics, Inc.
- MilliporeSigma
- NewAge Industries
- Particle Measuring Systems
- PendoTECH
- Sartorius Stedim Biotech
- SCHOTT
- Shoe Inn
- SiO2 Medical Products, Inc.
- STERIS
- Stevanato Group
- Texwipe, ITW Company
- ValSource
- Veltek Associates, Inc.
- West Pharmaceutical Services, Inc.
- Wilco, Bausch + Ströbel Group
- Ypsomed Holding

# STAFF

## GLOBAL HEADQUARTERS



**Richard Johnson**  
President & CEO



**Jennifer Bell**  
VP, Finance



**Andrea Viera**  
Executive Assistant



**Faramarz Kolivand**  
Sr. Web Developer

### Global Executive Team



**Trevor Swan**  
Director, Membership & Chapter Relations



**Janny Chua**  
Manager, Bookstore Operations



**Karena Grigsby**  
Project Coordinator, Membership & Volunteers



**Shanna Morgan**  
Manager, Membership & Chapters



**Katie Ruiz**  
Coordinator, Member Relations

### Membership & Chapters



**Tina Morris**  
VP, Scientific & Regulatory Affairs



**Ruth Miller**  
Director, Regulatory Affairs



**Josh Eaton**  
Assistant Director, Scientific Affairs



**Jahanvi (Janie) Miller**  
Assistant Director, Scientific Affairs



**Christine Roberts**  
Sr. Manager, PDA Standards



**Valeria Shirvani**  
Coordinator, Science & Regulatory

### Science & Regulatory



**Walter L. Morris III**  
Sr. Director of Publishing



**Marilyn Foster**  
Technical Writer/Editor



**Rebecca Stauffer**  
Managing Editor, PDA Letter



**Katja Yount**  
Publication Design Specialist



**Rich Levy**  
Journal Editor

### Publishing



# U.S. BUSINESS UNIT



Molly Moir  
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Jason Brown  
*Assistant Director, Programs & Registration Services*

Patresa Day  
*Assistant Director, Programs & Registration Services*

Marisa Sterling-Abram  
*Assistant Director, Logistics*

Brooke Schneider  
*Manager, Programs & Meetings*

Tanya Allen  
*Coordinator, Program & Speaker Management*

## Programs & Meetings



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*VP, Education*

Stephanie Ko  
*Sr. Manager, Lecture Education*

Kim McIntire  
*Manager, Educationns*

Ghislain Batama  
*Laboratory Assistant*

David Hall  
*VP, Sales*

Alison Caballero  
*Manager, Sales Administration*

## Education

## Exhibits & Sponsorship



Debbie Goldstein  
*VP, Marketing*

Jill Litwin  
*Sr. Marketing Manager*

Lindsay Navin  
*Sr. Marketing Coordinator*

Roxene Edwards  
*Sr. Marketing Coordinator – Digital*

Brandon Smolen  
*Manager, Human Resources*

Tehya Enger  
*Receptionist*

## Marketing

## Human Resources



Nichole Davis  
*Director of Finance*

Ana Vallenias  
*Accounts Payable Analyst*

Arneice Williams  
*Accounts Receivable Specialist*

Feng Chen  
*Director of Information Systems*

Bob Collier  
*Sr. Systems Analyst*

Frank Wang  
*IT Specialist*

## Finance & IT

# EUROPEAN BUSINESS UNIT



Falk Klar  
*General Manager, Vice President PDA Europe*  
**General Manager**



Kerstin Wilken  
*Director, Programs & Education*

Sylvia Becker  
*Manager, Programs & Events*

Teresa Schubach  
*Manager, Programs & Events*

Elke Von Laufenberg  
*Manager, Training & Education*

## Programs & Education



Melanie Decker  
*Director, Events & Exhibitions*

Nadjeschda Gomez-Stahl  
*Manager Exhibition & Sponsorship*

Julie Tchuya  
*Coordinator, Europe Program*

## Logistics & Exhibits



Dirk Stelling  
*Director of Finance & Administration*

Antje Petzholdt  
*Manager Registration, Members, Chapters*

Iryna Funke  
*Coordinator of Events & Registration*

Creixell Espilla-Gilart  
*Manager, Marketing*

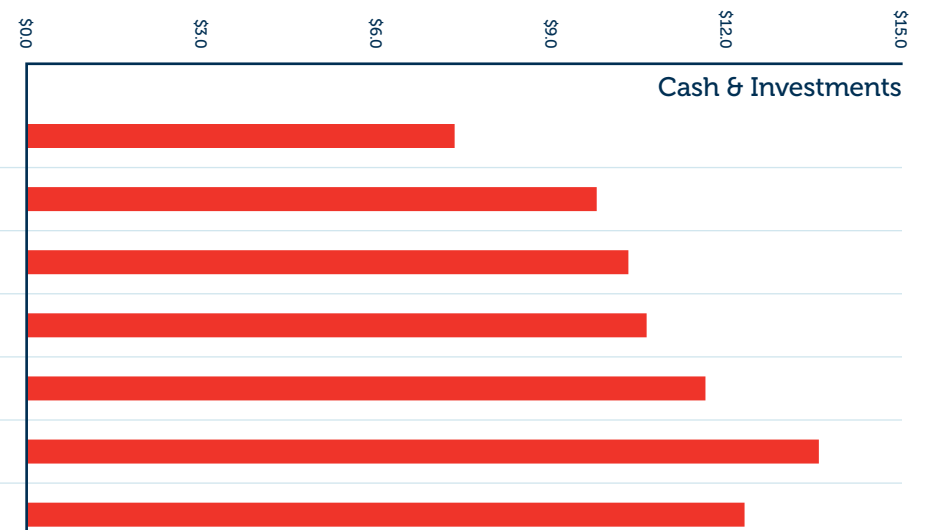
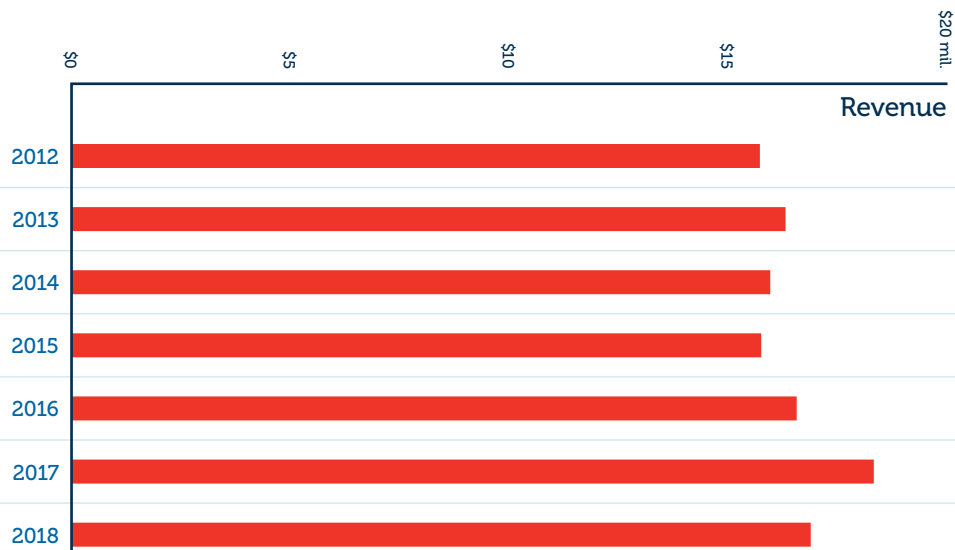
## Finance & Registration

## Marketing

# FINANCIALS

	2018	2017
Total Revenues	\$ 16,895,831	\$ 18,340,585
Total Expenses <sup>1</sup>	\$ 16,986,590	\$ 17,945,639
Net Income Surplus (Deficit)	\$ (90,759)	\$ 394,946
Increase (Decrease) in Net Assets	\$ (90,759)	\$ 394,946
Net Assets at beginng of year	\$ 9,149,791	\$ 8,754,845
Net Assets at end of year	\$ 9,059,032	\$ 9,149,791
Net Asset ratio (Net Assets/Annual Expenses)	53%	51%

<sup>1</sup> Total expense includes the foreign currency translation adjustment of (\$68,996) in 2018 and \$244,102 in 2017. This is considered a non-operating expense item.



# WOMEN IN PHARMA

# VOLUNTEER SPOTLIGHT

## PDA Chapters Celebrate the Impact of Women

In August, the West Coast Chapter held its third annual Women in the Biopharmaceutical panel. Over 150 participants from all over Northern California came to hear panelists Catherine Kavanagh, Mandy Sharma, Stephanie Yonker, Pat Hancock, Ziva Abraham and Lori Richter discuss their career journeys and what they learned as they moved ahead. Each panelist's experience was unique—some had even lived and worked abroad for periods of time. The panel represented a range of industry roles and sectors.

Common themes emerged during the discussions and Q&A session:

- The importance of taking risks; going beyond the comfort zone
- Ignoring negative thoughts that hold you back
- Learning new things constantly, as growth is fundamental to career satisfaction
- Finding a mentor and developing that relationship
- Without risks, there are no rewards
- Taking a leap in your career may be the most challenging and most fulfilling move you make

The number one advice embraced by all of the speakers? "Get comfortable with being uncomfortable."

This event continues to gain in popularity each year. Now, other PDA chapters are holding similar events, using this as a model.



## Renee Morley, Contec, Inc.

After being a member for almost eight years, PDA has been a big contributor to my professional career in many ways. I have had opportunities to network with the top leaders in pharmaceutical manufacturing and learn how they are overcoming challenges to provide safe drugs for patients. I have strengthened my technical knowledge by attending conferences, interest group meetings and networking events. And I have been able to give back by helping provide programs and scholarships for students. PDA has helped shape me into a well-rounded technical professional.



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