59% of PDA Board is made up of women

71% of PDA Staff are women

48% of PDA Staff are people of color

41% Large Pharma

29% BioTech Representatives

18% Consultants

12% Retired

Sectors Represented on the Board

PDA Staff
<table>
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<td>TRI</td>
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<td>Staff</td>
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<td>Women in Pharma</td>
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<td>Volunteer Spotlights</td>
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<td>Marc Hargreve</td>
<td>9</td>
</tr>
<tr>
<td>Sateesh Yelisetti</td>
<td>17</td>
</tr>
<tr>
<td>Renee Morley</td>
<td>19</td>
</tr>
</tbody>
</table>
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.
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!
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.
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.
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.

### 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

**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* 8th Editor.
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.
In 2018 PDA added a new chapter and they have already hosted their first event!

In 2018 there were 10,085 PDA members globally.
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

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**PDA Letter Portal Usage 2016–2018**

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**PDA Journal of Pharmaceutical Science and Technology 2018 Usage**

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<td>51,355</td>
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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

Kirk Eppler

Thomas Roedl

Siegfried Lehnert

Ada Hui

Yuh-Fun Maa, PhD

Stephanie Knueppel

**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

John Geigert, PhD

Eoin Hanley

Kerry Ingalls

Amnon Eylath

Susan Schniepp

Steven Dawson

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

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- Maik Jornitz, G-Con Manufacturing Inc. (Chair)
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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

13th 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.
GLOBAL HEADQUARTERS

Global Executive Team

Richard Johnson  
President & CEO

Jennifer Bell  
VP, Finance

Andrea Viera  
Executive Assistant

Faramarz Kolivand  
Sr. Web Developer

Trevor Swan  
Director, Membership & Chapter Relations

Janny Chua  
Manager, Bookstore Operations

Karena Grigsby  
Project Coordinator, Membership & Volunteers

Shanna Morgan  
Manager, Membership & Chapters

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Coordinator, Member Relations

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Director, Regulatory Affairs

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Patres Day
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Nichole Davis
Director of Finance

Ana Vallenas
Accounts Payable Analyst

Arinie Williams
Accounts Receivable Specialist

Feng Chen
Director of Information Systems

Bob Collier
Sr. Systems Analyst

Frank Wang
IT Specialist

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Sylvia Becker
Manager, Programs & Events

Teresa Schubach
Manager, Programs & Events

Elke Von Laufenberg
Manager, Training & Education

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Manager, Exhibitions & Sponsorship

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Coordinator, Europe Program

Dirk Stelling
Director of Finance & Administration

Antje Petzholdt
Manager, Registration, Members, Chapters

Iryna Funke
Coordinator of Events & Registration

Creixell Espilla-Gilart
Manager, Marketing

Patresa Day
Assistant Director, Programs & Registration Services

Falk Klar
General Manager, Vice President PDA Europe

Kerstin Wilken
Manager, Programs & Education

Sylvia Becker
Manager, Programs & Events

Elke Von Laufenberg
Manager, Training & Education

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Director, Events & Exhibitions

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Coordinator, Europe Program

Dirk Stelling
Director of Finance & Administration

Antje Petzholdt
Manager, Registration, Members, Chapters

Iryna Funke
Coordinator of Events & Registration

Creixell Espilla-Gilart
Manager, Marketing
## Financials

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<td>Total Expenses¹</td>
<td>$16,986,590</td>
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<td>$(90,759)</td>
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<td>Increase (Decrease) in Net Assets</td>
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<td>$9,149,791</td>
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¹ 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.

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### Revenue

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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.