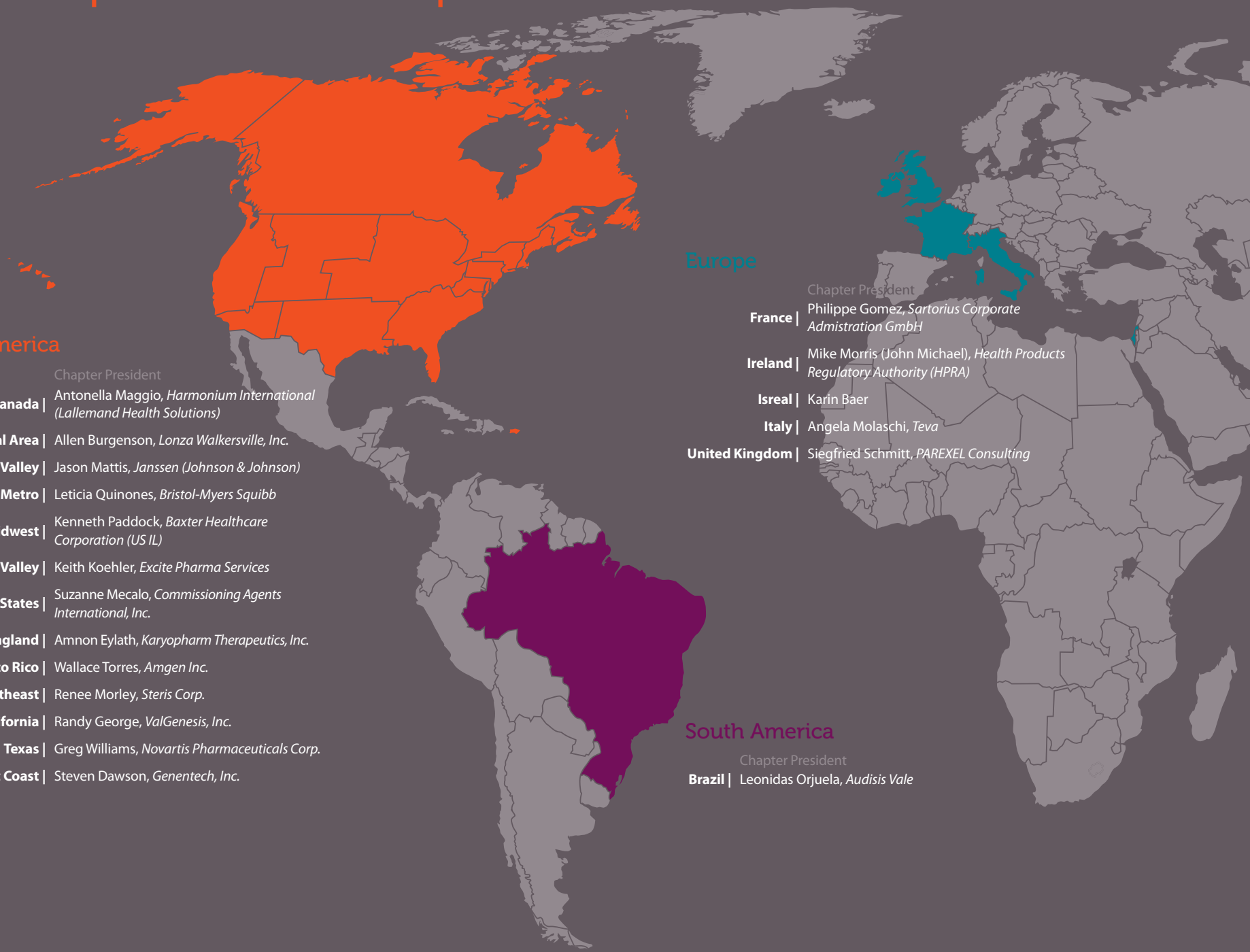
PDA Parenteral Drug Association

2017 ANNUAL REPORT

EXPANDING PDA'S INFLUENCE

PDA Chapters & Leadership



North America

Chapter President

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

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

Delaware Valley | Jason Mattis, *Janssen (Johnson & Johnson)*

Metro | Leticia Quinones, *Bristol-Myers Squibb*

Midwest | Kenneth Paddock, *Baxter Healthcare Corporation (US IL)*

Missouri Valley | Keith Koehler, *Excite Pharma Services*

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

New England | Amnon Eylath, *Karyopharm Therapeutics, Inc.*

Puerto Rico | Wallace Torres, *Amgen Inc.*

Southeast | Renee Morley, *Steris Corp.*

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

Texas | Greg Williams, *Novartis Pharmaceuticals Corp.*

West Coast | Steven Dawson, *Genentech, Inc.*

Europe

Chapter President

France | Philippe Gomez, *Sartorius Corporate Admistration GmbH*

Ireland | Mike Morris (John Michael), *Health Products Regulatory Authority (HPRA)*

Isreal | Karin Baer

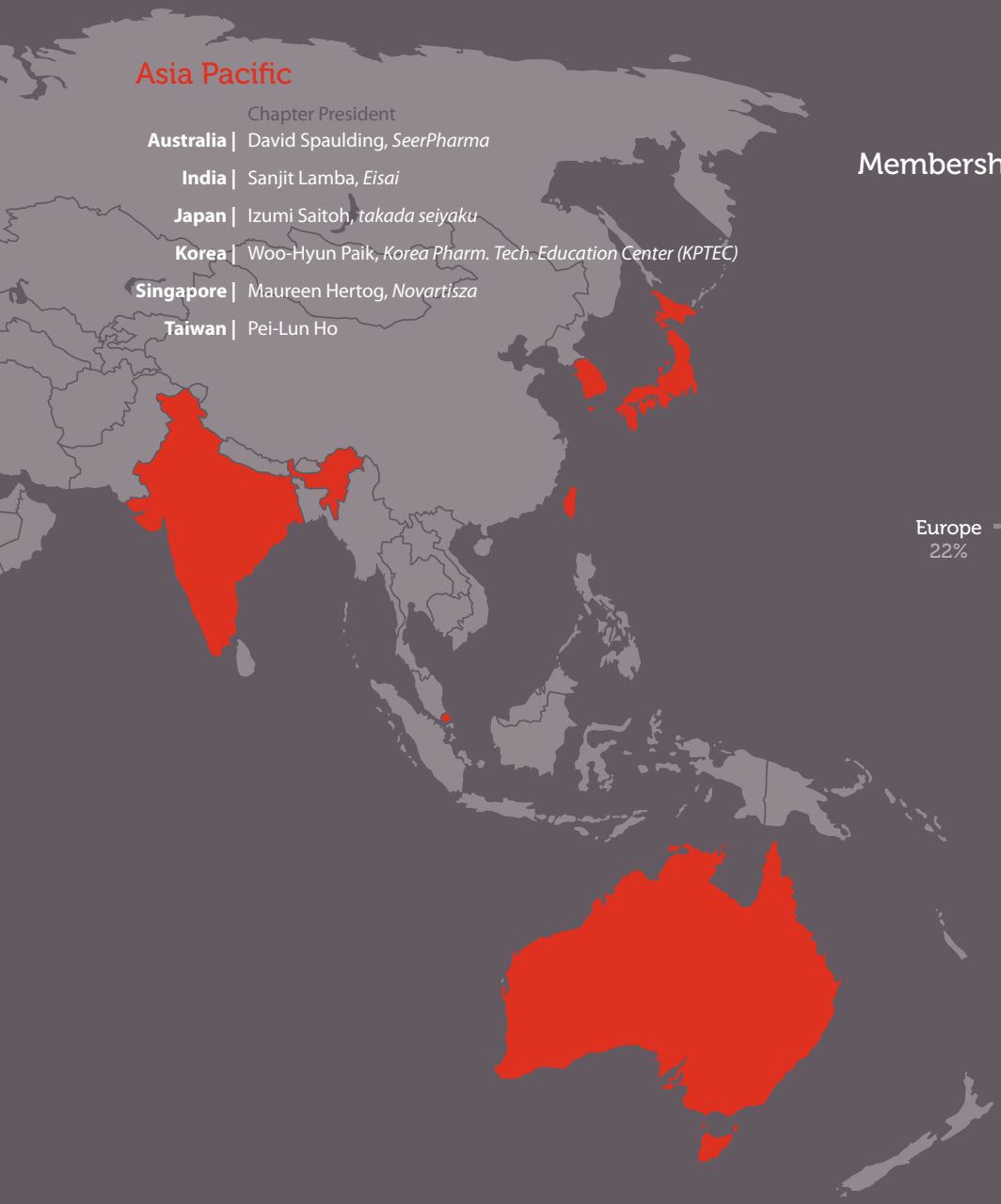
Italy | Angela Molaschi, *Teva*

United Kingdom | Siegfried Schmitt, *PAREXEL Consulting*

South America

Chapter President

Brazil | Leonidas Orjuela, *Audisis Vale*



Asia Pacific

Chapter President

Australia | David Spaulding, *SeerPharma*

India | Sanjit Lamba, *Eisai*

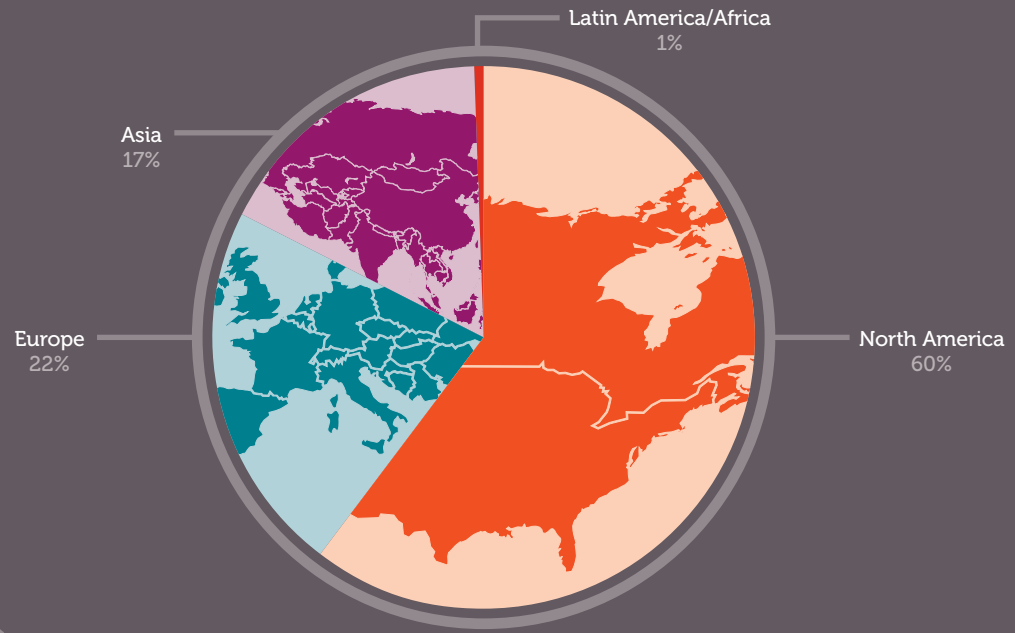
Japan | Izumi Saitoh, *takada seiyaku*

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

Singapore | Maureen Hertog, *Novartisza*

Taiwan | Pei-Lun Ho

Membership by Region



Pac iAM Technical Report Team in the PDA offices

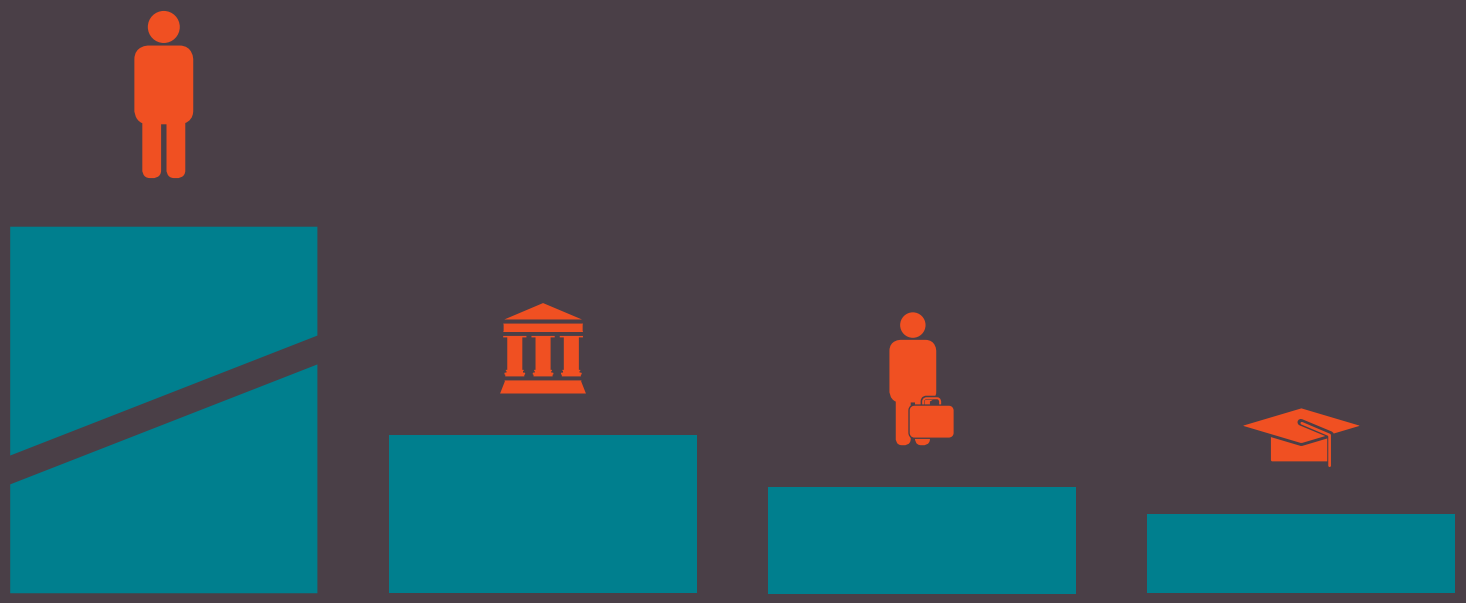
Contents

On the Cover: Attendee at the *2017 PDA Europe 2nd Annual Meeting*

Broadening Participation and Influence

The past year was one of broadening influence for the members of the Parenteral Drug Association. PDA continued to see its global footprint grow, with membership nearly equally divided between those working in the United States and those outside. In addition, PDA continued to work in a variety of important areas important to the safe manufacture of high quality parenteral and biological products. These areas include aseptic processing, manufacturing science, post-approval changes, data integrity, quality culture, and packaging science. 2017 marks a particularly important achievement for PDA and its members: acceptance as an ANSI-accredited standards developer.

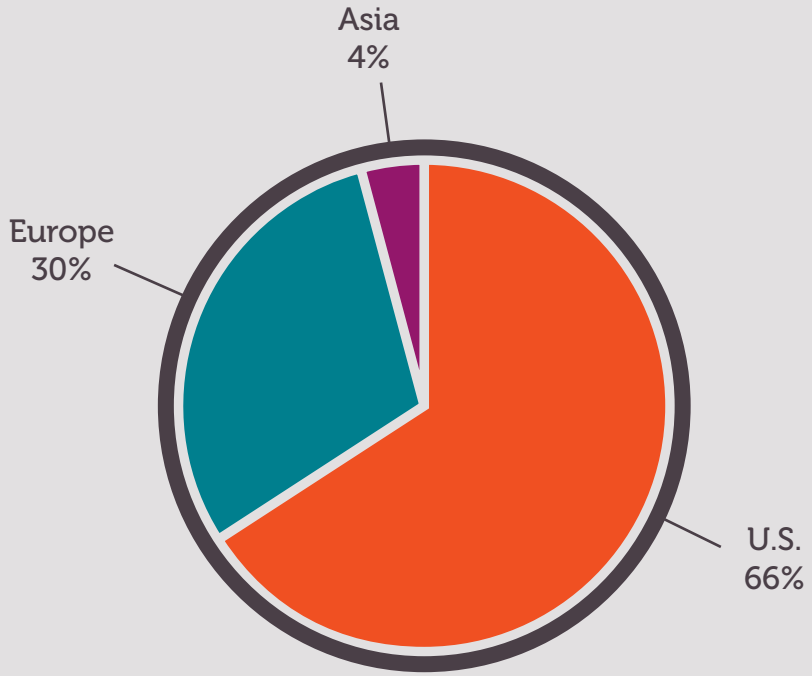
Membership by Type



10,377 Members

23% are Active Volunteers

2017 Conference & Workshop Attendees by Region



Chair Message

Martin VanTrieste, Chair

2017: A Fast-Paced Year for PDA

As Chair of the PDA Board of Directors, I am proud and honored by what PDA's staff, volunteers and over 10,000 members have accomplished in helping our industry to **serve patients.** Serving patients is a privilege, and that privilege comes with significant responsibilities. It is not easy living up to these responsibilities; PDA was created over 70 years ago to help us all live up to those responsibilities.

PDA succeeds because of the hard work, determination and diversity of its volunteers and members. In fact, PDA is one of the most diverse organizations with which I have had the privilege to be associated. This diversity allows PDA to get many different perspectives on what is needed to serve patients.

Our growing membership reflects our growing diversity. PDA added over 1,000 new members in 2017, including 424 young professionals and students. Our members are located in 78 countries with over 2,500 of them actively volunteering for PDA.

Science Has No Borders: PDA has chapters in Australia, Brazil, Canada, France, India, Ireland, Israel, Italy, Japan, Korea, Singapore, Taiwan, the United Kingdom and United States along with a European headquarters in Berlin. We are also exploring adding chapters in other countries like Cuba, Mexico and Russia. Our international activity has grown by hosting more meetings and training activities in countries outside the United States and Europe, including China, Japan, South Korea, South Africa, India and Australia. PDA also offers training courses in languages other than English. In 2017, 35% of the people attending our conferences and education offerings were from outside the United States.

PDA is working on a number of initiatives that will help manufacturers help patients. In 2017, we launched a new initiative to bring together manufacturers and glass vendors to develop best practices relating to visible particulate matter. There is a desire to have a clearly defined particle specification (e.g., size, type and quantity) based on the risk of harm to patients, so a new PDA task force has formed to align on a common, harmonized rationale across the industry to develop a practical guidance, which will be intended for use along with existing compendial, regulatory and industry standards. The Zero Defects for Visible Particles in Injectables Task Force intends to identify gaps in current risk assessments and methods used to detect and quantify visible particles. This information will then be used to develop a best practices document to potentially reduce defects related to particles.

PDA has never been more respected, strong and secure. PDA is uniquely positioned to connect people, science and regulation® to influence industry and regulatory solutions to serve patients. So, I encourage you to join your colleagues from around the world to help PDA enhance the quality and reliability of medicines so we all can live up to our responsibility to serve patients!

Board of Directors

Officers

Chair
Martin VanTrieste

Chair-Elect
Rebecca Devine, PhD
Regulatory Consultant

Secretary
Jette Christensen
Novo Nordisk

Treasurer
Michael Sadowski
Baxter Healthcare

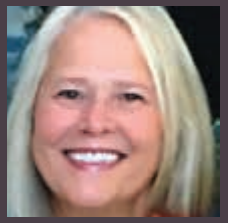
Immediate Past Chair
Harold Baseman
ValSource

Directors

Masahiro Akimoto
Otsuka Pharmaceutical Factory, Inc.

Barbara Allen, PhD
Eli Lilly

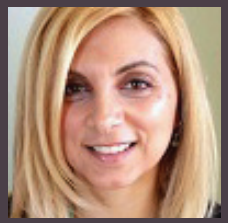
Deborah M. Autor
Mylan



Joyce Bloomfield

Ursula Busse, PhD
Novartis

Veronique Davoust
Pfizer



Ghada Haddad
Merck

Emma Ramnarine
Genentech/Roche

Stephan Rönninger
Amgen

Anil Sawant
Merck

Susan Schniepp
Regulatory Compliance Associates

Melissa Seymour
Biogen

President's Message

Richard Johnson, President and CEO

PDA Expands Global Involvement in 2017

In 1946, PDA began as a U.S. -based organization with less than 50 members. We are now a global, 10,500+ strong individual member scientific association with a mission to advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients.

Like the pharmaceutical industry, PDA is increasingly global, nearing 50% of members outside of the United States. In addition to our individual members from the spectrum of the industry, we have many members who are from government, as well as a growing academic and student cadre.

PDA continues to offer an unbiased place for interaction and education for people from across this diverse community. We offered 36 conferences and workshops in 2017 and more than 110 training courses in locations around the world. In fact, participation in PDA Education training courses was almost evenly split with 60% of attendees from the United States and the other 40% from Europe.

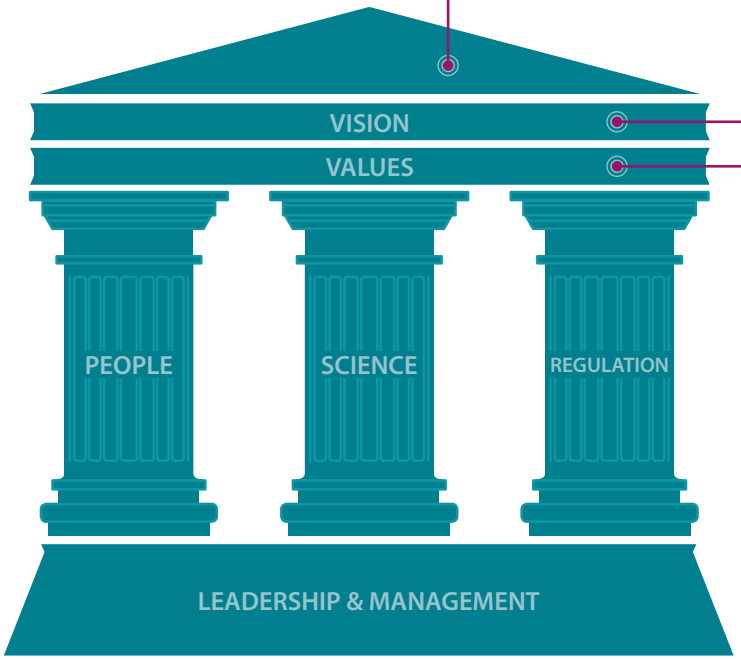
PDA continues our long tradition of leadership in scientific approaches to pharmaceutical manufacturing, with a robust development and publication program of technical reports, position papers, peer-reviewed scientific articles, and research/surveys, all of which we continue to provide to our members without charge. Of the 96 nonretired technical publications we have, 57% have been published in the last five years. In addition, PDA is embarking into new territory, becoming a standards-developing organization.

PDA continues to have a high level of interaction with Health Authorities around the world. We continue our initiatives to focus on drug shortages, data integrity, post-approval changes, and others. We have interacted with many regulatory agencies in 2017, including the U.S. FDA, ICH, Japanese PMDA, UK MHRA, EMA, WHO, Mexico's COFEPRIS and others, and provided training to 153 health authority members. We continued to provide constructive feedback on numerous draft regulatory documents to health authorities worldwide in 2017.

All of this has been accomplished through the work of our many volunteers on committees and task forces, collaborating with colleagues around the world to advance PDA's important mission. I also want to thank our tireless staff who have maintained a level of excellence in execution and support of a wide spectrum of activities. These efforts have made our accomplishments possible, and we look forward to your integral role in maintaining PDA's position as an industry leader. We will continue to value and appreciate your contributions!

PDA Vision and 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 Based: 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.

Expanding Horizons of Customer Satisfaction in 2017

PDA's customers find PDA has more value than other associations

74% in Technical Guidelines

71% in Publications

54% In-Person education events

55% in Hands-on-Training

82% of customers have used the PDA Technical Reports

70% of customers have used the *PDA Letter*

68,982 page views in 2017

Honor Awards

Each year, PDA recognizes members whose contributions have helped the Association fulfill its mission at the Awards Dinner, held during the Annual Meeting. Without dedicated volunteers like these, PDA cannot provide the highly valued services it offers the industry.

Honorary Membership

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

Rich Levy, PhD

Gordon Personeus Award

Presented in memory of the late **Gordon Personeus,** past PDA President and longtime volunteer, this award is intended to honor a PDA member, other than a Board member, for long-term acts or contributions that are of noteworthy or special importance to PDA.

Michael De Felippis, PhD

Janeen Skutnik-Wilkinson

Frederick J. Carleton Award

This award is presented as a tribute to lifetime contributor, past President, past Executive Director, and Honorary Member **Frederick J. Carleton,** and is designated for past or present Board members.

Gabriele Gori

Christopher Smalley, PhD

Martin VanTrieste Pharmaceutical Science Award

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

Michael Miller, PhD

Michael S. Korczynski Award

An award established in recognition of contributions made toward the development of PDA's international activities by **Michael S. Korczynski,** PhD

Ursula Busse, PhD

Hirohito Katayama, PhD

Edward Smith Packaging Science Award

In honor of long-time volunteer **Edward Smith,** who led PDA's packaging science activities, this award is given in recognition of extraordinary contributions to PDA and the packaging science.

Mathias Romacker

Distinguished Service Award

This award is given in recognition of special acts, contributions or services that have promoted the success and strength of PDA.

Patricia Hughes, PhD

Maria Jacobs, PhD

Stephan Krause, PhD

Hanns-Christian Mahler, PhD

Roman Mathaes, PhD

Tsuguo Sasaki, PhD

James P. Agalloco Award

The James P. Agalloco Award is presented annually to the PDA faculty member who exemplifies outstanding performance in education. The award is named for **James P. Agalloco,** in honor of his work in developing the PDA Education program.

Lee Leichter

Frederick D. Simon Award

The Frederick D. Simon Award is presented annually for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology.* This award is named in honor of the late **Frederick D. Simon**, a former PDA Director of Scientific Affairs. This year's award went to three recipients for their article, "Particulate Generation Mechanisms during Bulk Filling and Mitigation via New Glass Vial," which was published in the September/October 2017 issue of the PDA Journal.

Christopher Timmons

Stefan Merkle

Chi Yuen Liu

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 author of the book, *Method Development and Validation for the Pharmaceutical Microbiologist.*

Crystal Booth

PDA Europe Service Appreciation Award

This award is presented annually for special acts, contributions or services that have contributed to the success and strength of PDA's European activities.

Siegfried Schmitt, PhD

Service Appreciation Award

This award is presented annually for special acts, contributions or services.

Deborah Autor

Hal Baseman

Ursula Busse, PhD

Joyce Bloomfield

Stephan Rönninger, PhD

Maureen Hertog

Keith Koehler

Sanjit Singh Lamba

Jason Mattis

John Michael Morris

Kenneth Paddock

Leticia Quinones, PhD

President's Award

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

Emily Lyons

Katie Ruiz

Advisory Boards & Committees

SAB

Joyce Bloomfield, *PDA Member (Chair)*

Maik Jornitz, *G-Con Manufacturing LLC (Vice-Chair)*

Masahiro Akimoto, *OTSUKA*

John Ayers, *Eli Lilly & Company*

Ed Balkovic, *Sanofi*

Greg Basset, *Amgen*

Scott Bozzone, *Pfizer*

Jette Christensen, *Novo Nordisk*

Walter DeMatteo, *Institut Biochimique SA (IBSA)*

Phil DeSantis, *DeSantis Consulting Associates*

Gabriele Gori, *GlaxoSmithKline*

Tor Graberg, *Medical Products Agency – Sweden*

Dennis Guilfoyle, *Johnson & Johnson*

Ghada Haddad, *Merck & Co./Merck Sharp & Dohme*

Norbert Hentschel, *Boehringer-Ingelheim*

Joachim Leube, *Johnson & Johnson*

Grace McNally, *U.S. FDA*

Rainer Newman, *Consultant*

Mike Sadowski, *Baxter*

Siegfried Schmitt, *Parexel International Corp.*

Marsha Stabler Hardiman, *ConcordiaValsource*

Edward Tidswell, *Merck &Co./Merck Sharp & Dohme*

Glenn Wright, *Eli Lilly and Company*

BioAB

Michael Blackton, *Adaptimmune LLC*

Vijay Chiruvolu, *Kite Pharma*

Michael DeFelippis, *Eli Lilly and Company*

John Geigert, *BioPharmaceutical Quality Solutions*

Olivia Henderson, *Amgen*

Christopher Hwang, *Just Biotherapeutics China*

Margit Jeschke, *Novartis*

Stephan Krause, *AstraZeneca Biologics*

Joachim Leube, *Johnson & Johnson*

Morten Munk, *NNE*

Nadine Ritter, *Global Biotech Experts, LLC*

Jens Schletter, *Sandoz*

Michael VanDerWerf, *Halozyme Therapeutics, Inc*

Karen Walker, *Seattle Genetics*

Keith Wonnacott, *Pfizer*

Earl Zablackis, *Sanofi-Pasteur*

RAQAB

Karin Baer, *PDA Member*

Jeff Broadfoot, *Emergent BioSolutions Inc*

Cylia Chen-Ooi, *Amgen*

Veronique Davoust, *Pfizer*

Mirko Gabriele, *Patheon Italia SpA*

Aaron Goerke, *Roche*

Tor Graberg, *AstraZeneca*

Dipti Gulati, *PJI Biotech*

Frithjof Holtz, *Merck KGaA*

Hongyang Li, *Novartis*

Steven Lynn, *Novartis*

Demetra Macheras, *AbbVie, Inc.*

Luciana Mansolelli, *Novartis*

Anette Yan Marcussen, *NNE*

Elizabeth Meyers, *Amgen*

Shin-ichiro Mohri, *Kyowa Hakko Kirin Co., Ltd.*

Catriona Murphy, *Eli Lilly and Company*

Emma Ramnarine, *Genentech*

Junko Sasaki, *Sumika Chemical Analysis Service, Ltd*

Anil Sawant, *Merck, Sharp & Dohme*

Susan Schniepp, *PDA Member*

Janeen Skutnik-Wilkinson, *Biogen*

Jacqueline Veivia-Panter, *Consultant*

Gopi Vudathala, *XCell Pharma Consulting LLC*

PDA Letter Editorial Committee

Sharon Ayd, *Regulatory Compliance Associates*

Claire Briglia, *MilliporeSigma*

Maria Brown, *Celgene*

Winston Brown, *Phillips-Medsize*

Christine Bui, *Portola Pharmaceuticals*

Robert Darius, Michael De Felippis, PhD, *Eli Lilly*

Valeria Frigerio-Regazzoni, *Merck*

Mirko Gabriele, *Patheon*

Chris Hanff, *Mallinckrodt Pharmaceuticals*

Maik Jornitz, *G-Con*

Stephan Krause, PhD, *AstraZeneca Biologics*

Robert Lechich, *Pfizer*

Mina Mitry, *Marcyrl Pharma*

Praveen Prasanna, PhD, *Shire*

Lan Zhang, *Sanofi*

Ilana Zigelman, *Pure Med Consulting*

PDA Journal Editorial

Editor 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

Education AB

David Talmage, *PDA*

Harold (Hal) Baseman, *Valsource, LLC*

Bettine Boltres, *West Pharmaceutical Services, Inc.*

John Brecker, *JB Consulting Micro*

Bob Dana, *Elkhorn Associates, Inc.*

Marc Glogovsky, *Valsource, LLC*

Richard Johnson, *PDA*

Falk Klar, *PDA*

Stephanie Ko, *PDA*

Michael Sadowski, *Baxter Healthcare*

Janeen Skutnik-Wilkinson, *Biogen, Inc.*

Marsha Steed (Hardiman), *Valsource, LLC*

Edward Trappler, *Lyophilization Technology, Inc.*

Brent Watkins, *Veltek Associates, Inc.*

Jim Vesper, *Valsource, LLC*

Stephan Krause, *AstraZeneca*

Karen Walker, *Seattle Genetics*

Technical Book Committee

Walter Morris, *PDA (Chair)*

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*

Steve Lynn, *Novartis*

Richard Johnson, *PDA*

Richard Levy, *PDA*

Edward Balkovic, PhD

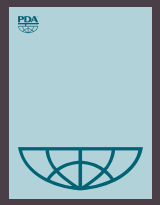
Principal Microbiologist –Contamination Control, *Genzyme – a Sanofi company*

Volunteering on PDA task forces and conference planning committees has provided me with numerous opportunities to meet and network with distinguished experts from both our industry and regulatory agencies. I have always been able to return to my job with new knowledge and a better understanding of the major issues affecting our industry.

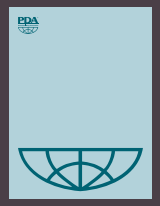
Science

The Association's growing library of technical titles and the highly valued *PDA Journal of Pharmaceutical Science and Technology* have helped manufacturers provide high quality drug products for over 70 years.

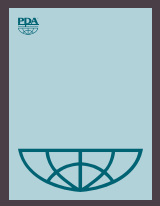
12 Technical Documents Published in 2017



Technical Report 54-5: Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems



Technical Report 60-2: Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/ Semisolid Dosage Forms



Technical Report 77: The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology

Technical Report 78: Particulate Matter in Oral Dosage Forms

Points to Consider for PAC-LCM

Points to Consider for PAC-QSE

Points to Consider for Pharmaceutical Quality Metrics Updated September 2014

Points to Consider for Aging Facilities

PAC iAM Industry Survey

Code of Conduct Survey

2017 PDA Aseptic Processing Survey

2017 PDA PUPSIT Survey

Total article reads* | **92,000**

Total abstract reads* | **417,000**

Searches conducted on site | **44,000**

* Reads indicates number of times articles/abstracts are accessed, not individual readers.

Top 10 companies (by usage)

Novartis	Sanofi Pasteur
U.S. FDA	Baxter Healthcare
Pfizer	Novo Nordisk
Merck & Co.	Chugai Seiyaku KK
Teva	LFB Biotechnologies

◄ PDA-owned book

Cylia Chen-Ooi

External Affairs Quality, *Amgen*

I have had the honor to lead the Quality Culture Task Force. It has been a pleasure to work with such a talented group of experts in the industry. I think we all have learned a lot from each other. Looking back, I am really proud of what the team accomplished over the last few years. We always go above and beyond.

9 Regulatory Comments in 2017

Health Canada / Santé Canada

GUI 0001 GMPs for Drug Products 1 May 2017

EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Concept Paper on Need for Revision of Note for Guidnace on Water for Pharmaceutical Use 6 June 2017

Q and A for Shared Facilities and HBEL Limits 30 May 2017

World Health Organization

PAC Biotherapeutics Draft September 2017

FDA U.S. FOOD & DRUG ADMINISTRATION

Interchangeability Draft Guidance — FDA Human Factors Final 20 June 2017

Draft Guidance Comparative HF studies Drug Device Combo Products for ANDA 31 March 2017

Rev Draft Guidance Quality Metrics 27 March 2017

CFDA

Guidance on Simulation testing of sterile processes 7 September 2017

Data Integrity Draft Guidance Submitted 9 March 2017

Over 70 FDA officials participate in the annual PDA/FDA Joint Regulatory Conference

2017 PDA Pharmaceutical Microbiology Conference: PDA attracts regulators to most of its events

Karin Baer

Vice President Quality-Regional Head, *Teva Pharmaceuticals*

I felt that Israel's Ministry of Health, which regulates drugs and devices for the country, needed a platform to communicate their expectations for industry. And industry needed a platform to address their concerns to regulators. To that end, I believed (and still believe) that a PDA chapter would fulfill this need.

Education

2017 Lectures & Lab Courses

Aseptic Processing | **Bethesda, MD**

Fundamentals of Aseptic Processing | **Bethesda, MD**

Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing | **Bethesda, MD**

An Introduction to Visual Inspection | **Bethesda, MD**

Foreign Particulate Examination, Isolation and Analysis | **Bethesda, MD**

Analytical Method Qualification, Validation, Verification, and Transfer for Biotechnological Products | **Bethesda, MD**

Design, Operation, and Qualification of Pharmaceutical Water Systems | **Bethesda, MD**

Quality Strategy for Biopharmaceuticals | **Anaheim, CA**

Quality Metrics and Quality Culture | **Anaheim, CA**

Container Closure Systems and Integrity Testing | **Anaheim, CA**

Cleanroom Management | **Anaheim, CA**

Validation of Biotechnology-Related Cleaning Processes | **Bethesda, MD**

Airflow Visualization Techniques and Practices | **Bethesda, MD**

Technical and Regulatory Challenges of Combination Products, Drug Delivery Products – Prefilled Syringes, Autoinjectors and Injection Pens | **Bethesda, MD**

Training Courses by Region

Fundamentals of Lyophilization | **Bethesda, MD**

Single Use Systems for the Manufacturing of Parenteral Products | **Bethesda, MD**

Validation of Lyophilization | **Bethesda, MD**

Validation of Moist Heat Sterilization Processes | **Bethesda, MD**

Isolator Technology | **Bethesda, MD**

Biotechnology: Overview of Principles, Tools, Processes and Products | **Bethesda, MD**

Fundamentals of an Environmental Monitoring Program | **Bethesda, MD**

The Impact of cGMPS on Biomanufacturing Facility Design and Operation | **Bethesda, MD**

Biopharmaceutical QA/QC Strategy for Senior Management | **Bethesda, MD**

Establishment of a Risk-Based Environmental Monitoring Program | **Bethesda, MD**

The Common Sense of Quality Auditing | **Bethesda, MD**

Application of a Quality Systems Approach to Pharmaceutical CGMPs | **Bethesda, MD**

Quality Metrics and Quality Culture | **Bethesda, MD**

Sterile Pharmaceutical Dosage Forms: Basic Principles | **Bethesda, MD**

Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities | **Bethesda, MD**

Assessing Packaging & Processing Extractables/Leachables | **Bethesda, MD**

Quality Metrics & Quality Culture – Australia Chapter | **Melbourne, Australia**

Quality Culture and Investigations: Best Practices | **Washington, DC**

Preparing for Regulatory Inspections for the FDA and EMA | **Washington, DC**

CMC Regulatory Requirements in Drug Applications | **Washington, DC**

CMC Regulatory Compliance for Biopharmaceuticals | **Washington, DC**

Quality Metrics & Quality Culture – Singapore Chapter | **Suntec City, Singapore**

Quality Metrics & Quality Culture – India Chapter | **Hyderabad, India**

Steam Sterilizers: Getting it Right from the Beginning | **Bethesda, MD**

Filtration Processes in the Pharmaceutical and Biopharmaceutical Industry | **Bethesda, MD**

Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Validation and Ongoing Control | **Bethesda, MD**

Validation of Dry Heat Processes | **Bethesda, MD**

Safety Assurance Cases for Combination Products | **Bethesda, MD**

Radiation Sterilization | **Bethesda, MD**

Regulatory Aspects of Microbiology in a Non-Sterile Environment | **Bethesda, MD**

How to Use and Interpret Data for Particle Counter and Microbial Air Samplers | **Bethesda, MD**

Mold Identification for Quality Control | **Bethesda, MD**

Bioburden and Biofilm Management | **Bethesda, MD**

Application of Quality by Design and ICH Q9 rules to Aseptic Processes and their impact to Sterility Assurance | **Bethesda, MD**

An Introduction to Visual Inspection | **Bethesda, MD**

Strategies for Reducing Human Error Nonconformances | **Bethesda, MD**

Temple University Training | **Bethesda, MD**

Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Testing Methods | **Bethesda, MD**

Foundations of Quality Risk Management | **Bethesda, MD**

Quality Risk Management: Risk Control and Risk-Based Decision Making | **Bethesda, MD**

Practical Application of Quality Risk Assessment Tools | **Bethesda, MD**

Rapid Microbiological Methods | **Porto, Portugal**

Practical Guide for Root Cause Investigations—Methodology & Tool Kit | **Porto, Portugal**

Secondary Packaging for Parenterals | **Barcelona, Spain**

Elastomers | **Barcelona, Spain**

Container Closure Development | **Barcelona, Spain**

Container Closure Integrity: Regulations, Test Methods, Application | **Barcelona, Spain**

Extractables & Leachables | **Barcelona, Spain**

Track and Trace: How to implement Pharma Serialization, Tamper | **Barcelona, Spain**

Evidence and the EU-Falsified Medicines Directive | **Barcelona, Spain**

Particle Identification in Parenterals | **Berlin, Germany**

An Introduction to Visual Inspection: A hands-on course | Berlin, Germany

Praxis der Pharmazeutischen Gefriertrocknung | **Osterode, Germany**

Basics of Successful Auditing | Berlin, Germany

Cleaning & Disinfection | Berlin, Germany

Supply Chain Strategies for API and Drug Product | Berlin, Germany

Quality by Design for Biopharmaceuticals | Berlin, Germany

Introduction to Aseptic Processing Principles | Berlin, Germany

Quality Culture | Berlin, Germany

Application of a Risk-Based Approach to Freeze-Drying Processes | Cologne, Germany

Development of a Freeze-Drying Process | **Cologne, Germany**

Particle Identification in Parenterals | **Berlin, Germany**

An Introduction to Visual Inspection: A hands-on course | Berlin, Germany

From Gene to Product – Tailor-made Strategies for High Level | Berlin, Germany

Expression of Biologicals | Berlin, Germany

Testmethoden für vorbefüllte Spritzen | Berlin, Germany

Best Compliance Practices im GMP Prüflabor | Berlin, Germany

CMC Regulatory Compliance for Biopharmaceuticals | Berlin, Germany

Extractables and Leachables | Berlin, Germany

DoE Basics for Validation by Design | Berlin, Germany

Mary W. Carver

Senior Consultant, *Pharma Microbiology Consulting, LLC*

Mary is passionate in sharing her knowledge and expertise with others. Recently she helped PDA develop the Fundamentals of Aseptic Processing training course, which she also teaches. She even goes on the road for PDA, conducting lectures at company facilities. In 2017 Mary starred in a *PDA Letter* On the Issue video on cleaning and disinfection. Her dedication, enthusiasm, and support are exceptional and can be seen through her interactions with students and PDA staff.

Conferences/Workshop

2017 U.S. & Asian Conferences/Workshops

12th Annual Global Conference on Pharmaceutical Microbiology | **Bethesda, MD**

Annex 1 Workshop | **Washington, DC**

Annual Meeting | **Anaheim, CA**

Cell & Gene Therapy Workshop | **Anaheim, CA**

Cell & Gene Therapy Conference | **San Diego, CA**

Combination Products Interest Group Meeting | **Washington, DC**

Container Closure, Devices and Delivery Systems: Compatibility and Material Safety Workshop | **Washington, DC**

Endotoxins Workshop | **Bethesda, MD**

Modern Biopharmaceutical Processing Conference | **Singapore, Singapore**

PAC iAM Workshop | **Washington, DC**

PDA/FDA Biosimilars Conference | **Bethesda, MD**

PDA/FDA Joint Regulatory Conference | **Washington, DC**

Pharmaceutical Quality Metrics & Quality Culture Conference | **Bethesda, MD**

Pre-filled Syringe Interest Group Meeting | **Washington, DC**

Quality Risk Management for Manufacturing Systems Workshop | **Chicago, IL**

Visual Inspection Forum | **Bethesda, MD**

2017 Europe Conferences/Workshops

2017 PDA Europe Pharmaceutical Microbiology Conference | **Porto, Portugal**

2017 PDA Europe Workshop: Secondary Packaging | **Barcelona, Spain**

2017 PDA Europe Interest Group Meeting Pre-filled Syringes | **Barcelona, Spain**

2017 PDA Europe Parenteral Packaging Conference | **Barcelona, Spain**

2017 PDA Europe Interest Group Meeting Visual Inspection | **Berlin, Germany**

2017 PDA Europe Interest Group Meeting Freeze Drying | **Berlin, Germany**

2017 PDA Europe Current Trends in Aseptic Fill & Finish of Pre-filled Syringes, Conference | **Lindau (Bodensee), Germany**

2017 PDA Europe The Principles of Viral Safety for Biologics and Vaccines | **Dubrovnik, Croatia**

2017 PDA Europe Virus & TSE Safety Forum | **Dubrovnik, Croatia**

2017 PDA Europe Workshop Business Opportunities in Iran | **Berlin, Germany**

2017 PDA Europe Workshop: Annex 1 | **Berlin, Germany**

2017 PDA Europe 2nd Annual Meeting | **Berlin, Germany**

2017 PDA Europe ATMP Conference | **Valencia, Spain**

2017 PDA Europe Freeze Drying Conference | **Cologne, Germany**

2017 PDA Europe Particles in Injectables Conference | **Berlin, Germany**

2017 PDA Europe 10th Monoclonal Antibodies Workshop | **Berlin, Germany**

2017 PDA Europe Cold & Supply Chain Logistics Conference | **Prague, Czech Republic**

2017 PDA Europe Workshop on Innovative Drug Delivery Systems/ Combination Products | **Vienna, Austria**

2017 PDA Europe Workshop on Connected Health & Drug Delivery – Improved Patient Convenience and Adherence | **Vienna, Austria**

2017 PDA Europe Impact of Pre-filled Syringe Packaging Components on Biopharmaceuticals | **Vienna, Austria**

2017 PDA Europe Universe of Pre-filled Syringes Conference | **Vienna, Austria**

2017 PDA Europe Workshop on Drug Delivery Systems: Global Technical, Regulatory and Quality Challenges | **Vienna, Austria**

2017 PDA Europe Outsourcing & Contract Manufacturing Conference | **Munich, Germany**

Attendees at the Europe Annual Meeting

Plenary Speakers at the 2017 Annual Meeting

32 Events around the world*

* Not including Chapter Meetings

Visibility Program

PDA launched a visibility program in 2017 to promote strategic initiatives in manufacturing science, post-approval changes, and aseptic processing/Annex 1. The comprehensive program included social media, press releases, articles, advertisements, and presentations.

PDA PAC iAM Task Force Publishes Two Papers Journal of Pharmaceutical Science and Technology

For Immediate Release: March 2, 2017
Media Inquiries: Walt Morris, 301-656-5900, x. 148; morris@pda.org

Bethesda, Md., March 2, 2017 – The Parenteral Drug Association (PDA) today announced the availability of two "PDA Papers" authored by the Post-Approval Changes for Innovation in Availability of Medicines (PAC iAM) Task Force in the "Accepted Articles" section of the *PDA Journal of Pharmaceutical Science and Technology (PDA Journal).*

The papers, "PDA Points to Consider: Technical Product Lifecycle Management: Communication and Knowledge Exchange between Marketing Authorization Holders and Health Authorities" and "PDA Points to Consider: Technical Product Lifecycle Management Pharmaceutical Quality System Effectiveness For Managing Post-Approval Changes", are "open access" manuscripts. The two papers are part of an extensive work plan by the PAC iAM Task Force that was announced on September 19, 2016.

The Task Force is conducting a survey and has begun work on a PDA Technical Report. The group will meet at the upcoming PDA Annual Meeting in April.

PDA Journal and represent the official viewpoint of PDA.
...les that have been accepted for publication

PDA Assists Pharma Manufacturing Upgrades with *Points to Consider for Aging Facilities*

For Immediate Release: August 31, 2017
Media Inquiries: Walt Morris, 301-656-5900, x. 148; morris@pda.org

Bethesda, Md., August 31, 2017 – The Parenteral Drug Association (PDA) published *Points to Consider for Aging Facilities* as part of an ongoing focus on manufacturing improvements. In some cases, noncompliant, aging facilities are a reason forcing companies to cease manufacturing, which may exacerbate drug shortages.

Points to Consider for Aging Facilities reflects the general thoughts and suggestions of the pharmaceutical manufacturing industry on how to identify and modernize aging facilities. It covers eight critical areas to help companies avoid the traps encountered by other companies: Recognizing an Aging Facility; Impediments to Modernization; Business Case for Modernization; Impact of Changing Standards; Slowing the Aging Process; and Regulations.

A team of industry experts developed this document, based on responses to a PDA workshop held in March 2015 and a survey of PDA members conducted in late 2015:

Ghada Haddad, MBA, Merck & Co./Merck, Sharp & Dohme, Co-Chair
Maik Jornitz, ... Inc., Co-Chair

PDA @PDAonline | 27 Sep 2017

Read a summary of highlights from the Annex 1 Workshop that occurred at the 2nd PDA Europe Annual Meeting #PDALetter http://ow.ly/qTMG30fiJDe

PDA @PDAonline | 3 Oct 2017

We've reviewed the results of the survey and discussed aseptic processing, so where do we go from here? #2017Annex1

PDA @PDAonline | 18 Oct 2017

Did you miss #2017PAC? Read a summary of the Workshop from PDA Board Member @UrsulaBusse. http://ow.ly/ulsf30fPXnV

2017 PDA Staff

U.S. Staff

European Staff

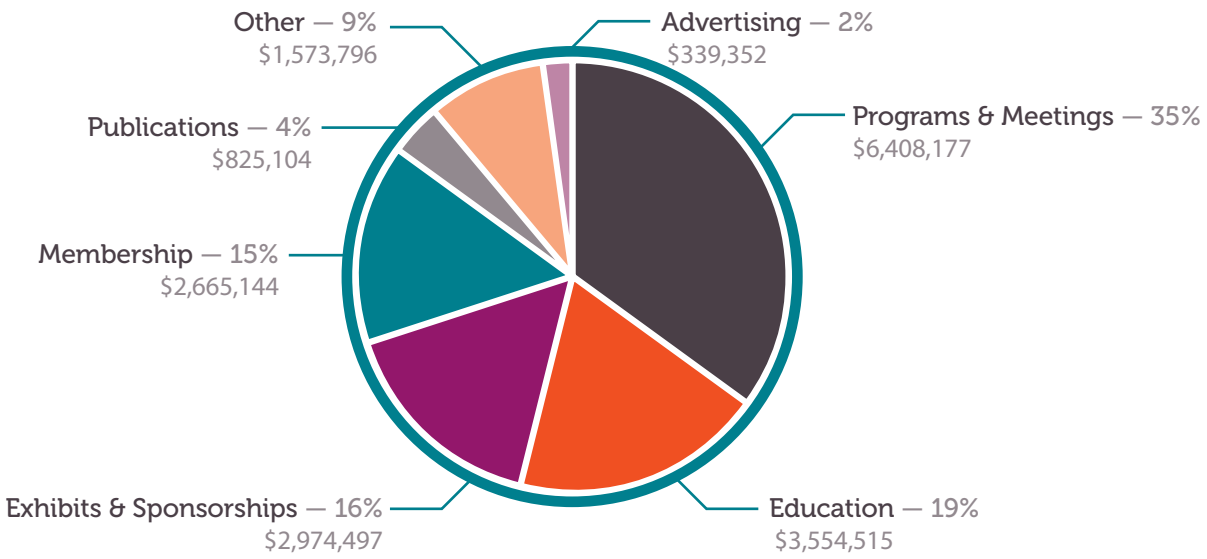
Not Pictured

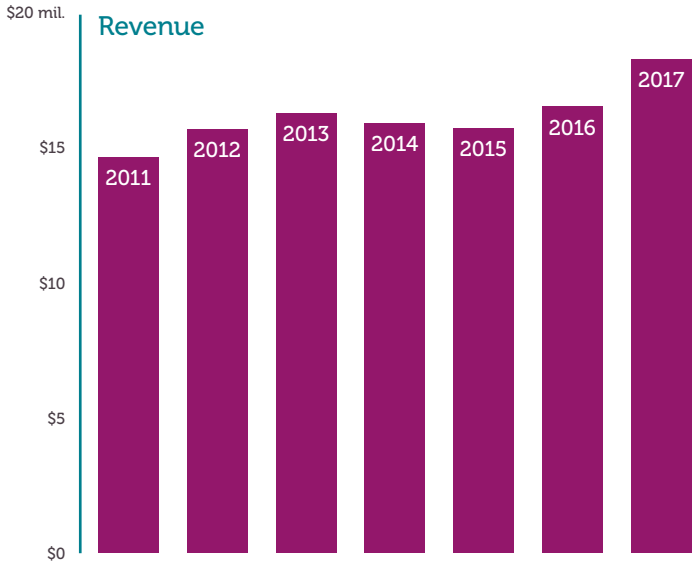
Traci Royal
Manager, Programs

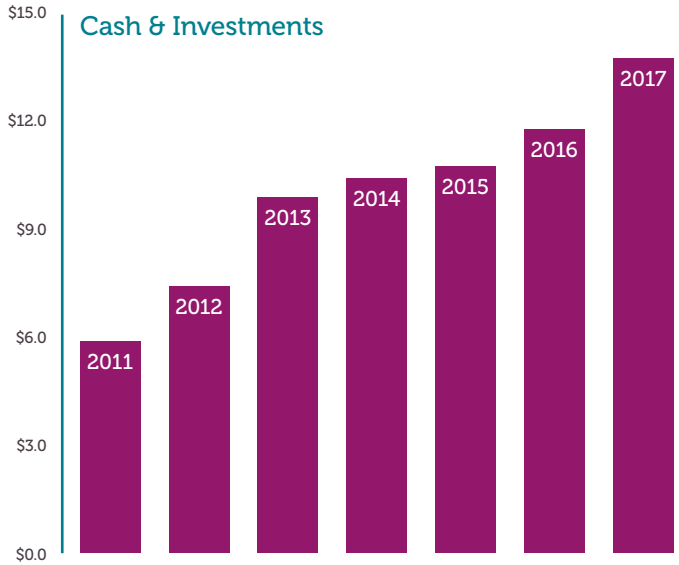
Financials

	2017	2016
Total Revenues	$ 18,340,585	$ 16,573,562
Total Expenses[1]	$ 17,945,639	$ 16,161,723
Net Income Surplus (Deficit)	$ 394,946	$ 411,839
Increase (Decrease) in Net Assets	$ 394,946	$ 411,839
Net Assets at beginng of year	$ 8,754,845	$ 8,343,006
Net Assets at end of year	$ 9,149,791	$ 8,754,845
Net Asset ratio (Net Assets/ Annual Expenses)	51%	54%

[1] Total expense includes the foreign currency translation adjustment of $244,102 in 2017 and ($50,745) in 2016. This is considered a non-operating expense item.







Sponsers & Contributors

Top PDA Sponsors

Amgen	OMPI
Associates of Cape Cod, Inc.	Owen Mumford
BD	Quality Executive Partners
Bespak	Roche
bioMerieux	Sartorius
BioServ	SCHOTT
Biothermal LLC	Sensile Medical
Bormioli Rocco	SHL
Bosch Inspection	Sparta Systems, Inc.
Datwyler	Terumo
FDAZilla	ValSource
IMA Life	Veeva Systems
Insulet	Veltek Associates, Inc.
Lachman Consultant Services	Vetter
Lonza	W.L. Gore & Associates
MasterControl	West Pharmaceutical Services
Mitsubishi Gas Chemical Company	Ypsomed
Noble	

PDA would like to thank its contributors

TRI Sponsors

Supporters	Contribution Type
Aramark	Supply and Service
Becton Dickinson	Supply
BioMérieux	Supply and Service
Bioquell	Supply and Service
MilliporeSigma	Supply and Service
Texwipe	Supply
DuPont	Supply
Mesa Laboratories, Inc.	Supply
Microbiologics	Supply
Pall Corporation	Supply
Particle Measuring Systems	Supply and Service
S2 Media	Supply
Sartorius	Supply and Service
Shoe Inn	Supply
STERIS	Supply
Veltek Associates, Inc.	Supply and Service
Fedegari Technologies, Inc.	Service
Ohio Medical Corporation	Service
Atlantic Technical Services	Service
Filamatic	Service
Meissner	Supply
PendoTECH	Supply
Dow Corning Corporation	Supply
Nuovo Ompi	Supply
Denville Scientific	Supply
West Pharmaceutical Services	Supply
Datwyler	Supply
Hardy Diagnostics	Supply
Ansell	Supply

PDA®

Parenteral Drug Association

Bethesda Towers
4350 East West Highway
Suite 600
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
E-mail: info@pda.org
Web site: www.pda.org

PDA Europe
Am Borsigturm 60
13507 - Berlin
Germany
Tel: +49 30 436 55 08-0 or -10
Fax: +49 30 436 55 08-66