EXPANDING PDA’S INFLUENCE
PDA Chapters & Leadership

North America

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.

South America

Brazil | Leonidas Orjuela, Audisie Vale

Europe

France | Philippe Gomez, Sartorius Corporate Administration GmbH
Ireland | Mike Morris (John Michael), Health Products Regulatory Authority (HPRA)
Israel | Karin Baer
Italy | Angela Molaschi, Teva
United Kingdom | Sigfried Schmitt, PAREXEL Consulting
Membership by Region

North America 60%
Asia 17%
Europe 22%
Latin America/Africa 1%

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, Novartis
Taiwan | Pei-Lun Ho
Pac IAM Technical Report Team in the PDA offices
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On the Cover: Attendee at the 2017 PDA Europe 2nd Annual Meeting
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.
10,377 Members

23% are Active Volunteers

2017 Conference & Workshop Attendees by Region

- U.S. 66%
- Europe 30%
- Asia 4%
Chair Message

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
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.
People

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
Chi Yuen Liu
Stefan Merkle

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 Grabberg, Medical Products Agency – Sweden
Dennis Guiffoyle, 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, ConcordiaVatsource
Edward Tidwell, Merck &Co./Merck Sharp & Dohme
Glenn Wright, Eli Lilly and Company

BioAB

Michael Blackton, Adapimmune 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 Grabberg, 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 Rammarine, Genentech
Junko Sasaki, Sumika Chemical Analysis Service, Ltd
Anil Sawant, Merck, Sharp & Dohme

Susan Schniepp, PDA Member
Janee 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-Medisize

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
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.
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

<table>
<thead>
<tr>
<th>Report/Title</th>
<th>Document Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Points to Consider for PAC-LCM</td>
<td>Points to Consider</td>
</tr>
<tr>
<td>Points to Consider for PAC-QSE</td>
<td>Points to Consider</td>
</tr>
<tr>
<td>Points to Consider for Pharmaceutical Quality Metrics Updated September 2014</td>
<td>Points to Consider</td>
</tr>
<tr>
<td>Points to Consider for Aging Facilities</td>
<td>Points to Consider</td>
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<tr>
<td>PAC iAM Industry Survey</td>
<td>Survey</td>
</tr>
<tr>
<td>Code of Conduct Survey</td>
<td>Survey</td>
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<tr>
<td>2017 PDA Aseptic Processing Survey</td>
<td>Survey</td>
</tr>
<tr>
<td>2017 PDA PUPSIT Survey</td>
<td>Survey</td>
</tr>
</tbody>
</table>
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

- GUI 0001 GMPs for Drug Products 1 May 2017
- Concept Paper on Need for Revision of Note for Guidance on Water for Pharmaceutical Use 6 June 2017
- Q and A for Shared Facilities and HBEL Limits 30 May 2017
- PAC Biotherapeutics Draft September 2017
- 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
- Guidance on Simulation testing of sterile processes 7 September 2017
- Data Integrity Draft Guidance Submitted 9 March 2017
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.
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

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

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

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

Training Courses by Region

Europe 40% U.S. 60%
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.
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

Events around the world*

* Not including Chapter Meetings
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

The papers, “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 @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
Financials

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

\(^1\) 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.
# Sponsors & Contributors

## Top PDA Sponsors

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>Contribution Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amgen</td>
<td>OMPI</td>
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<td>Associates of Cape Cod, Inc.</td>
<td>Owen Mumford</td>
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