

70 Years of Advancing Pharmaceutical and Biopharmaceutical Manufacturing

1946 Parenteral Drug Association formed in New York City
1947 1st Publication: *The Bulletin of The Parenteral Drug Association*
1949 Introduction of PDA "News Letter"

1958 PDA Administrative Office moves to Philadelphia, Pennsylvania
1958 PDA hires 1st employee

1966 Introduction of PDA Letter

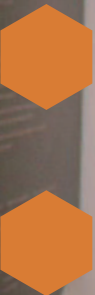
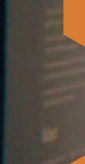
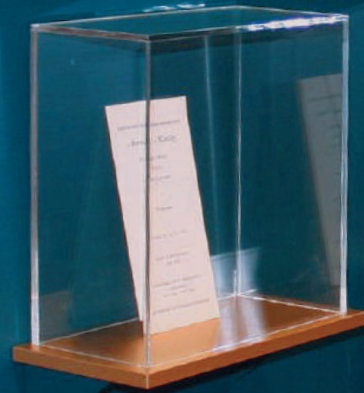
1970 1st PDA meeting outside of USA held in Mexico, Canada
1971 PDA relocates to 25th anniversary
1978 1st PDA congress in regulatory domain
1979 Publication of "Technical Progress No. 1" (collaboration of Pharm. Research Council)

1980s

1990s

2000s

2010s



PDA Then and Now

1940

1947
Bulletin of the Parenteral Drug Association (PDA Journal) issued

(PDA Journal) issued



1963
Washington Letter issued with just 4 pages



1971
PDA celebrates 25 years

1977
First two PDA Education courses developed

First two PDA Education courses developed

1990
First PDA/FDA Joint Regulatory Conference held

First PDA/FDA Joint Regulatory Conference held



1996
PDA celebrates 50 years

2007
Training and Research Institute (TRI) opens at Bethesda headquarters



Training and Research Institute (TRI) opens at Bethesda headquarters

2015
PDA Europe office moves to larger building



PDA Europe office moves to larger building

2016

2016
New Headquarters opens in Bethesda, Md.



1946
PDA Founded

1951
1st Annual Meeting at New York Academy of Sciences



1970
First non-U.S. meeting held in Montreal, Canada

1976
First set of PDA regulatory comments drafted

1978
First Technical Report published



1988
Chapters established

1992
PDA moves from Philadelphia to Bethesda, Md.

1997
Training and Research Institute (TRI) Opens

2006
PDA Europe office established in Berlin, Germany

2009
PDA Journal of Pharmaceutical Science and Technology online-only

80

members in 1946, all in U.S.



10,000

Members Worldwide in 2016



First Annual Meeting: Two days, 8 Sessions, 5 speakers, 3 panel discussions

2016 Annual Meeting:

2.5 days, 22 sessions, 40 Talks, 37 speakers

81

Technical Reports published since



Now known as the PDA Letter at 48 pages



123

courses in 2016



9 chapters in North America and Japan

PDA Today



25 International Chapters

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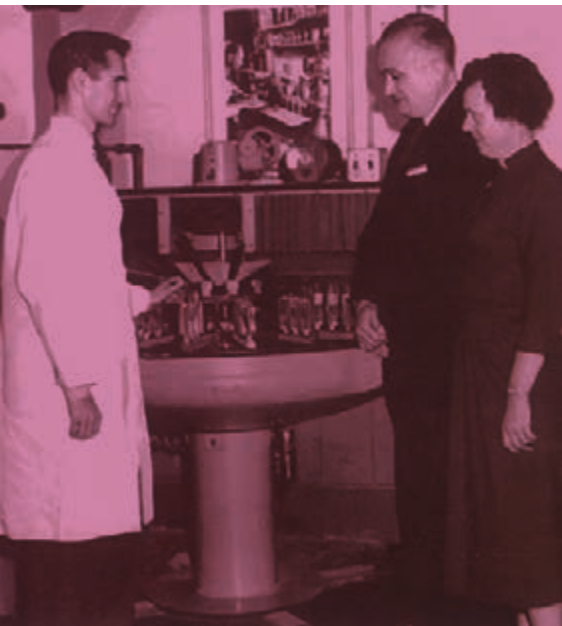


Celebrating 70 Years of Advancing Pharmaceutical and Biopharmaceutical Manufacturing

On the November 12, 1946, the Parenteral Drug Association's original six directors, **Harold London, Rudolph Price, A. Lincoln Konwiser, Max Gold, Arthur Herrick,** and **Abraham Wagner,** signed the Association's Certificate of Incorporation in New York.

According to the Charter, PDA was formed to:

- Foster and advance, in the interest of public health, the art and science of parenteral therapy, and to preserve and improve the integrity and stability of the parenteral drug industry
- Provide and disseminate information relating to parenteral drugs and parenteral therapy
- Foster and encourage a spirit of friendly cooperation among its members and the medical and pharmaceutical professions
- Cultivate and maintain cooperative relations with governmental departments and agencies, medical and pharmaceutical organizations, and other branches of the drug and related industries; and to originate and participate in cooperative enterprises and undertakings with them
- Collect and disseminate, for the benefit of members, such business and scientific information as may be of value to them
- Sponsor research projects into matters of scientific and technical interest in the field of parenteral medication
- Review the labeling and advertising of its members in the light of current regulations and advances in medical science, and dispel uncertainty in such matters
- Promote higher standards in the production of parenteral drugs



Certainly, many of those goals define the work of PDA's various volunteers 70 years later, but the original charter did not mention anything about a global industry or global challenges. That is because for its first 40 years, PDA was a U.S.-centric organization. That began changing in the 1990s, as the industry started down the road of rapid globalization with the freeing up of trade regulations around the world. PDA immediately rose to these many challenges faced by a globalizing industry. (invert this sentence with next sentence). The ramifications of rapidly expanding supply chains, marketplaces, labor forces and regulatory requirements continue to ripple through the industry and will do so for years to come.

These challenges drive PDA's members to come together on a variety of activities to help the broader global industry. In just the last few years, PDA volunteer members have formed task forces to provide guidance on the topics directly related to a globalized industry: data integrity, post-approval changes, drug shortages, and quality metrics/culture. While PDA is the leader in providing technical information and training on sterile drug processing, our members' efforts in these and other global areas make PDA a strong leader on many fronts that help drive continuous improvement in pharmaceutical/biopharmaceutical manufacturing.

Globalization is changing the demographics of PDA's membership. Thirty years ago, nearly all PDA's members were in the USA. Twenty years ago, PDA's nascent international activities were concentrated in Europe and Japan. Today, PDA hosts four chapters in Europe, one in Israel, six in the Asia Pacific region, and began developing its first in South America in 2016.

It has been an amazing and highly successful 70 years for PDA. While many of its founding goals remain relevant, the globalized industry has changed PDA's constituency and its members' impact on the industry at large for the better.

A Growing, Diverse Membership

*More than **10,000 members** from industry, government, and academia at every stage of a career reside in **79 countries** around the world. More than 2,500 of these global members support PDA's initiatives as active volunteers.*



Chair Message



It is appropriate that PDA was the first organization to receive a Johnson & Johnson Kilmer Award for leadership in the science of sterility assurance during our celebratory 70th anniversary year. Indeed, PDA's members have been leaders in this important field since its founding. As PDA President Richard Johnson said upon accepting the award, PDA's first meetings on sterility assurance were held before most of us were born!

Over the course of seventy years, PDA's efforts to advance the science of sterility assurance and aseptic processing have touched upon numerous key industry developments. PDA led the charge to improve sterilization science—an effort that gave birth to PDA's technical reports. Ensuring the promulgation of best practices in aseptic processing gave birth to PDA's first laboratory course at the Training and Research Institute. When the U.S. FDA endeavored to provide industry guidance on aseptic processing, PDA was there to serve as both a check and a partner, helping the Agency craft a scientifically sound guidance. As biotech products increased in number and importance, PDA again stepped in and developed technical documents, courses and conferences on viral filtration and removal.

With an ever-growing and internationalizing membership, PDA's activities naturally spread into other areas of importance, including supply chain security, prefilled syringes, combination products, quality systems and risk management, data integrity, cold chain shipping, cell and gene therapies, and many, many other areas.

In 2016, PDA launched major initiatives in manufacturing science, eliminating visual particulates, and post-approval changes regulations to help industry address the complicated and interconnected problems caused by aging facilities and processes and the regulatory hurdles that impede modernization. The Manufacturing Science and Operations ProgramSM was organized to highlight the ongoing focus PDA has on pharmaceutical and biopharmaceutical manufacturing.

PDA was proud to announce a significant initiative bringing together executives including CEOs and Executive Vice Presidents from biologic and pharmaceutical manufacturers with glass container and elastomeric closure suppliers. Their aspiration is through collective and collaborative continuous improvement projects to take today's world-class injectable medicine manufacturing to the next level, preparing industry for the complex products and manufacturing processes of the future by eliminating visible particles from parenteral products. The Taskforce consists of multidisciplinary members from biologic and pharmaceutical manufacturers along with suppliers of glass container and elastomeric closures with over 1,000 years of experience. This initiative will focus on the entire supply chain from raw materials to finished product.

The PDA Post-Approval Change Innovation for Access to Medicines (PAC iAM)SM is a program intent on reducing the hurdles to pharmaceutical manufacturing innovation. The group is tasked to educate the industry and regulators of the current challenges, develop science-based solutions, and encourage international regulatory cooperation.

PDA's 70th Anniversary appropriately saw PDA's members once again working to assure sound regulatory guidance on sterile drug manufacturing, but this time the focus was pending changes to the European Medicine Agency's GMP guidance, Annex 1. PDA sponsored four workshops on the topic to generate information on current best practices. PDA published a two-part Points to Consider for Aseptic Processing prior to the workshops. Earlier in the year, PDA also published a first-of-its kind comparison of sterile processing GMPs electronic book.

Many things about PDA have changed in 70 years, yet its role as a leader in pharmaceutical manufacturing and sterilization processes remains as strong as ever.

Board of Directors



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.

President's Message

Our Mission remains steadfast: *To advance pharmaceutical / biopharmaceutical manufacturing science and regulation so members can better serve patients.* PDA continues our leadership in pharmaceutical and biopharmaceutical manufacturing, and we are the benchmark that others measure themselves against. 2016 was a busy, challenging, and ultimately successful year for PDA where together we continued to *Connect People, Science and Regulation*®. Our focus remained providing service to our members and the pharmaceutical community. Together, we exemplified our values: being Science Based; demonstrating Integrity; and promoting Inclusion.

PEOPLE

Membership in PDA continued to grow around the world, with more than 41% of our members coming from outside North America. This global reach included establishment of a new chapter in Brazil.

In 2016 we had a record number of attendees at our conferences and our education programs, which included delivering training to more than 350 health authority members. We continued to have industry leading conferences, including our 65th Annual Meeting in San Antonio, our 25th PDA Joint Regulatory Conference, and our world leading Universe of Prefilled Syringes meeting. 2016 saw the launch of our 1st PDA Europe Annual meeting, and our focus on Aseptic Processing and Data Integrity was reflected in 4 global workshops for each topic.

SCIENCE

Science has always been a cornerstone of PDA, and is a core value. In 2016 this was evidenced by the continued excellence of our technical volunteer activities, including the publication of four (4) Technical Reports (covering topics ranging from Prefilled Syringe User Requirements to Application of Phase Appropriate Quality System and cGMP to the Development of Therapeutic Drug Substance), four (4) "Points to Consider" (on Data Integrity, Post Approval Changes, Aging Facilities and Aseptic Processing), and three (3) Surveys, and two (2) PDA books.

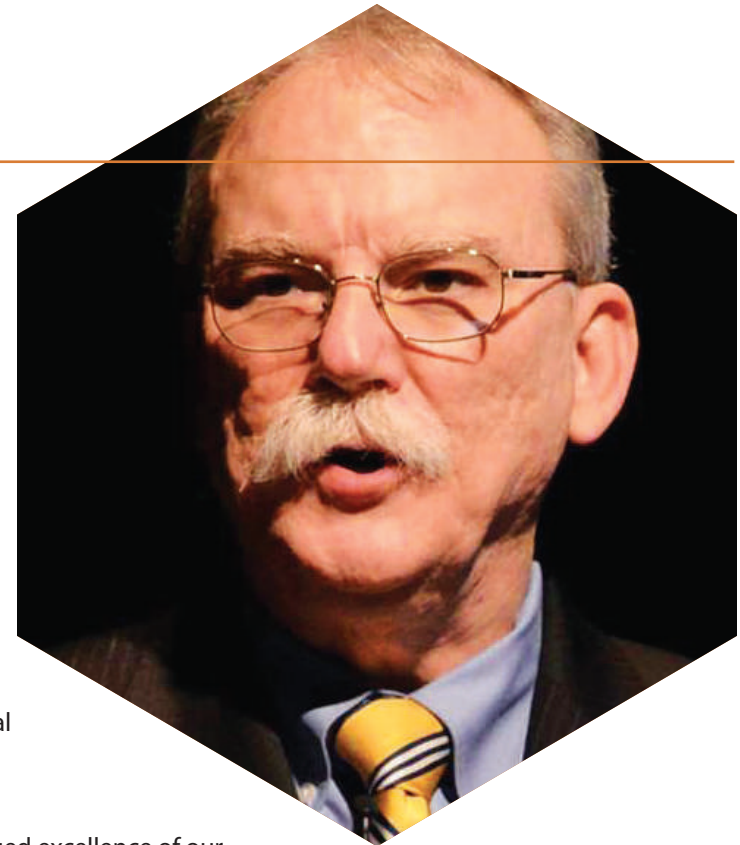
REGULATION

Ours is a highly regulated industry, and PDA continued to seek ways to inform our members of the latest regulatory expectations. We worked with Health Authorities to provide timely, technical and meaningful science-based input on draft guidance, including formal written comments on more than 15 documents. In a spirit of collaboration and mutual interest, we worked with regulators on most of our conferences, most notably the 25th Annual PDA/FDA Joint Regulatory Conference, and the highly successful ICH Q7 collaboration with PIC/S. PDA also continued our contribution to commenting on sixteen (16) draft regulatory guidances from EMA, FDA, WHO, MHRA and USP.

LEADERSHIP & MANAGEMENT

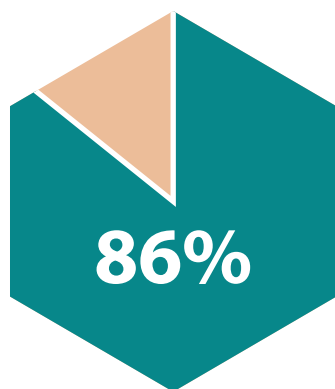
PDA as an organization must stand on a firm foundation, and as stewards of your Association, we continue to develop tools and resources to fulfill our mission, while maintaining a strong financial base. We relocated our Global Headquarters in Bethesda, MD to larger facilities, and expanded our Training and Research Institute to offer more capability to our students. All of our Education program had a record year, and we continued our 7th consecutive year of positive revenue.

In the following pages there will be much more detail about these activities. Let me take this opportunity to thank all of the many volunteers and members who made these things happen. Without you, these accomplishments would not be possible. As always, remember, this is your association. Your input is valued and appreciated.

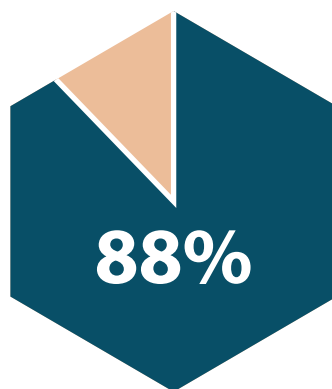


*PDA is driven by the people who support it. In 2016, the association had **2,500 volunteers** out of a membership of more than 10,000 professionals.*

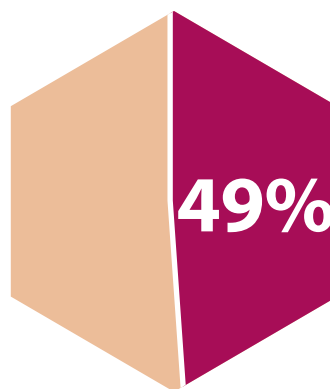
Member Satisfaction



86% of members are somewhat satisfied or very satisfied with their PDA membership



88% believe the value of membership is equal to or greater than the cost of dues



49% of PDA's members are classified as Promoters



Among the various member benefits is a free subscription to the *PDA Letter*

And the Winner is...



Honor Award winners are those members whose contributions have most helped PDA fulfill its mission. Among the thousands of volunteers who work with PDA, these honored members are recognized for exceptional dedication and years' of service at the PDA Awards Dinner during the Annual Meeting. PDA congratulates and thanks the following recipients.

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.

Georg Roessling, PhD

Gordon Personeus Award

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

Art Vellutato

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 designated for past or present Board members.

Junko Sasaki

Anders Vinther, 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.

Roger Asselta

Martin VanTrieste Pharmaceutical Science Award

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

Kurt Brorson, PhD

Hannelore Willkommen, PhD

Distinguished Service Award

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

Ed Balkovic, PhD

Ghada Haddad

Kamikukita, PhD

Cylia Chen-Ooi

Tsutomu

Morten Munk

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.

Brigitte Reutter-Haerle

Service Appreciation Award

The Service Appreciation Award is presented annually for special acts, contributions, or services

Shannon Bellino

Melissa Morandi

David Spaulding

Gaetano

Jonathan Morse

Brian Underhill

Florentino

Susan Schniepp

Michael

Beth

John Shabushnig,

VanDerWerf

Kirschenheiter

PhD

Glenn Wright

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.

John Ludwig, PhD

Michael S. Korczynski Award

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

Gabriele Gori

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 six recipients for their contribution to the article, "Manufacturing of High-Concentration Monoclonal Antibody Formulations via Spray Drying—the Road to Manufacturing Scale," which was published in the January/February 2015 issue of the PDA Journal.

Patricia Cash, PhD

Maryam Mazaheri

Stephan Krause, PhD

Derek Murphy

Sophia Levitskaya-Seaman, PhD

Roja Narwal

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 editor of the book, *Assuring Data Integrity for Life Sciences*.

Siegfried Schmitt, 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.

Creixell Espilla-Gilart

Trevor Swan

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Japanese 25th Anniversary and Awards

The PDA Japan Chapter celebrated 25 years at its Annual Meeting, Nov. 29-30, in Tokyo. Awards were given to honor the hard work and dedication of volunteers who make PDA's largest chapter so successful. PDA President Richard Johnson was on hand to honor the chapter and these noteworthy volunteers. Pictured below are the winners of the Kawamura Award, recognizing 25 years of active service to the Japan Chapter.



Education

Training has been a core function of PDA since 1946. In the early years, most of the training occurred through the dissemination of information and best practices through PDA's publications and at conferences, but in the 1970's, training courses were introduced.

At first, PDA offered an audio tape/slide series on aseptic products, aseptic filling, cleaning, documentation of process data, and a number of other important topics. By 1978, PDA's education program expanded to include courses taught by subject matter experts like Dr. Irving Pflug on sterilization processes, temperature measurement in process validation by Dr. Clarence Kemper, particulate evaluation by Dr. Julius Knapp, and many, many more.

In 1997, PDA introduced its own hands-on Training and Research Institute, which began a major expansion at its Bethesda, Maryland home at the end of 2016.

PDA Education—Where Excellence Begins—is now the premier place for pharmaceutical professionals worldwide to go to update their skills or learn new skills in aseptic processing, visual inspection, and a host of other topics relevant to their organizations and to advancing their careers.

2016 Lectures & Lab Courses

Airflow Visualization Techniques and Practices	Biopharmaceutical Manufacturing Under Regulatory Compliance: Process Strategies, CGMP Considerations and Facility Requirements	CMC Regulatory Compliance for Biopharmaceuticals Rome, Italy	Development of a Freeze Drying Process Strasbourg, France	Establishing and Implementing an Effective GMP Auditing Program
An Introduction to Visual Inspection		CMC Regulatory Requirements in Drug Applications	Development of a Pre-filled Syringe Berlin, Germany	Establishment of a Risk Based Environmental Monitoring Program
An Introduction to Visual Inspection: A hands-on course Berlin, Germany	Biosimilar CMC and Regulatory Challenges	Container Closure Development Venice, Italy	Drug Delivery Combination Products Venice, Italy	Establishment of a Risk-Based Environmental Monitoring Program
Analytical Method Qualification, Transfer, and Validation for Biosimilars	Charting and Trending of Environmental Monitoring Data: From Microbial Counts to Contamination Recovery Rates in Controlled Rooms	Container Closure Integrity: Regulations, Test Methods, Application Venice, Italy	Elastomers Rome, Italy	Evaluation, Validation, and Implementation of Alternative and Rapid Microbiological Testing Methods
Application of Quality Risk Management to Non-Production Processes in the Pharmaceutical Quality System	Charting and Trending of Environmental Monitoring Data Berlin, Germany	Contamination Control, Clean Room Design, and Environmental Monitoring for Controlled Environments	Endotoxin Attributes, Detection, Clinical Relevance and BET — Interference Resolution	Extractables and Leachables Rome, Italy
Application of a Quality Systems Approach to Pharmaceutical CGMPs	Clean Room Design, Contamination Control, and Environmental Monitoring for Controlled Environments	Control, Validation and Monitoring of Biofilms in Water Systems Berlin, Germany	Environmental Control and Monitoring for Regulatory Compliance	Extractables and Leachables Venice, Italy
Application of a Risk-Based Approach to Freeze-Drying Processes Strasbourg, France	Cleaning and Disinfection Berlin, Germany	Design of Experiments (DoE) – The Basis of Validation Berlin, Germany	Essential Elements of Extractables and Leachables: From Material Selection to Final Report	<u>FDA On-Site Training Series</u>
Aseptic Processing Training Program			Establishing a Robust Relationship with Your Client/CMO	Advanced Steam Sterilization
				Basics of Steam Sterilization
				Media Fills

Filtration Processes in the Pharmaceutical and Biopharmaceutical Industry	Good Glass Handling Practices Venice, Italy	Investigating Microbial Data Deviations	Preparing for Regulatory Inspections for the FDA and EMA	Steam Sterilizers: Getting it Right from the Beginning
Foreign Particulate Examination, Isolation, and Analysis (2 sessions)	Good Qualification Practice of Pharma Storage and Transportation Equipment Amsterdam	Investigations - Best Practices	Process Simulation Testing for Aseptically Filled Products	Sterile Pharmaceutical Dosage Forms: Basic Principles
Fundamentals of an Environmental Monitoring Program (2 sessions)	How to find the right GMP for APIs Berlin, Germany	Isolator Technology	Virus Filtration Berlin, Germany	Strategies for Reducing Human Error Nonconformances
Fundamentals of Aseptic Processing	Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing	Knowledge Management Applied in Facilities & Engineering to Improve Manufacturing in Reliability	Quality by Design for Biopharmaceuticals Barcelona, Spain	Technology Transfer
Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities	The Impact of cGMPS on Biomanufacturing Facility Design	Management of Aseptic Processing	Quality Metrics and Quality Culture New England Chapter	Test Methods for Pre-filled Syringe Systems Berlin, Germany
Fundamentals of Lyophilization	Implementing Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations	Managing the QC and R+D Laboratory in a GMP Compliant Manner	Quality Metrics: Performance Indicators	Track und Trace – Implementierung von Serialisierung, Fälschungssicherheit und Verifizierung für pharmazeutische Produkte Leipzig, Germany
From Gene to Product – Tailormade Strategies for High Level Expression of Biologicals Rome, Italy	In-house Training Abbott Biologicals I Olst	Microbiological Risk Assessment of a Pharmaceutical Manufacturing Process	Quality Risk Management for Facilities and Equipment	Introduction to Aseptic Processing Principles Rome, Italy
GMPs for Manufacturers of Sterile and/or Biotechnology Products	In-house Training Abbott Biologicals II Olst	The Metrics of Process Monitoring & Understanding the Risks of Variation Rome, Italy	Quality Systems for Aseptic Processing	Training Effectiveness: What's Your Design Strategy?
Going Deeper than Human Error: Finding More Specific Root Causes to Incidents involving people		Outsourcing, Technology Transfer and CMO Client Relationships Barcelona, Spain	Recommended Practices for Manual Aseptic Processes	Understanding and Addressing Technical, Quality, and Regulatory Challenges for Drug Delivery Combination Products - NEW
		Particle Identification in Parenterals Berlin, Germany	Rapid Microbiological Methods Berlin, Germany	Understanding Product options, User Needs and Fill-Finish Requirements for Nested Format Syringes
		Pharmaceutical Water Systems Berlin, Germany	Risk Based Approach for Prevention and Management of Drug Shortages Barcelona, Spain	Understanding Variation and the Metrics of Process Monitoring
		Praxis der Pharmazeutischen Gefriertrocknung Osterode, Germany	Risk Based Qualification of Sterile Drug Product Manufacturing Systems	Validation of Biotechnology-Related Cleaning Processes
		Practical Application of GMP for Development of ATMPs Berlin, Germany	Risk Management in Technology Transfer Barcelona, Spain	Validation of Lyophilization
		Practical Aspects of Aseptic Processing	Role of the Quality Professional in the 21 st Century	Validation of Moist Heat Sterilization Processes
		Practical Guide for Root Cause Investigations — Methodology & Tool Kit Barcelona, Spain	Root Cause Investigation for CAPA Berlin, Germany	Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Validation and Ongoing Control
			Single Use Systems for the Manufacturing of Parenteral Products	
			Secure Cold Chain Amsterdam	



Trainees in the TRI lecture room

Conferences/Workshops

Over the last 70 years, there has been no better place for industry suppliers and manufacturers to network than PDA's signature conferences. The Annual Meeting, the PDA/FDA Joint Regulatory Conference, the Universe of Prefilled Syringes, and the Pharmaceutical Microbiology Conference are four of PDA's signature events that collectively draw thousands of participants and exhibitors each year, including healthy representation from regulators from around the world.

In 2016, PDA Europe held its first Annual Meeting and plans to build this event into another signature event that members and the industry can count on. The first event led with topics on leading-edge manufacturing technologies, Industry 4.0, and novel therapies.

2016 Conferences

11th Annual Global Conference on Pharmaceutical Microbiology | **Arlington, VA**

Annex 1 | **Berlin, Germany**

Annex 1 | **Dublin, Ireland**

Annex 1 Workshop | **Arlington, VA**

Annex 1 Workshop | **San Diego, CA**

Annual Meeting | **San Antonio, TX**

Annual Meeting | **Berlin, Germany**

ATMP | **Berlin, Germany**

Biosimilars Conference | **Baltimore, MD**

Cold/Supply Chain | **Amsterdam, Netherlands**

Critical Demands on Modern Pharmaceutical Packaging | **Bern, Switzerland**

Data Integrity | **London, Great Britain**

Data Integrity | **Berlin, Germany**

Data Integrity Workshop | **San Diego, CA**

Data Integrity Workshop | **Washington, DC**

Drug Delivery Combination Products Workshop | **Huntington Beach, CA**

Freeze Drying | **Strasbourg, France**

IG PFD | **Berlin, Germany**

IG VI | **Berlin, Germany**

IG UPS | **Venice, Italy**

Iran Meeting | **Tehran, Iran**

Manufacturing Science Workshop | **San Antonio, TX**

Microbiology | **Berlin, Germany**

Monoclonal | **Rome, Italy**

Outsourcing | **Barcelona, Spain**

Outsourcing/CMO Conference | **Washington, DC**

Parenteral Packaging | **Venice, Italy**

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

PDA-PIC/S Training Course on GMPs for APIs | **San Juan, Puerto Rico**

Universe of Pre-filled Syringes & Injection Devices | **Huntington Beach, CA**

Visual Inspection | **Berlin, Germany**

Visual Inspection Interest Group | **Washington, DC**

Sponsors of PDA 2016 Conferences

Sponsor	Package Level	Sponsor	Package Level
2016 Annual Meeting		2016 PDA Universe of Pre-filled Syringes & Injection Devices	
Associates of Cape Cod, Inc.	Platinum Sponsor	BD Medical – Pharmaceutical Systems	Platinum Sponsor
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2016 PDA Biosimilars Conference		West Pharmaceutical Services, Inc.	Gold Sponsor
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2016 PDA/FDA Joint Regulatory Conference		APTAR Stelmi	Bronze Sponsor
Quality Executive Partners	Diamond Sponsor	11th Annual PDA Global Conference on Pharmaceutical Microbiology	
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Amgen	Silver Sponsor	Charles River	Silver Sponsor
2016 PDA Data Integrity Workshop			
Sparta Systems	Platinum Sponsor		



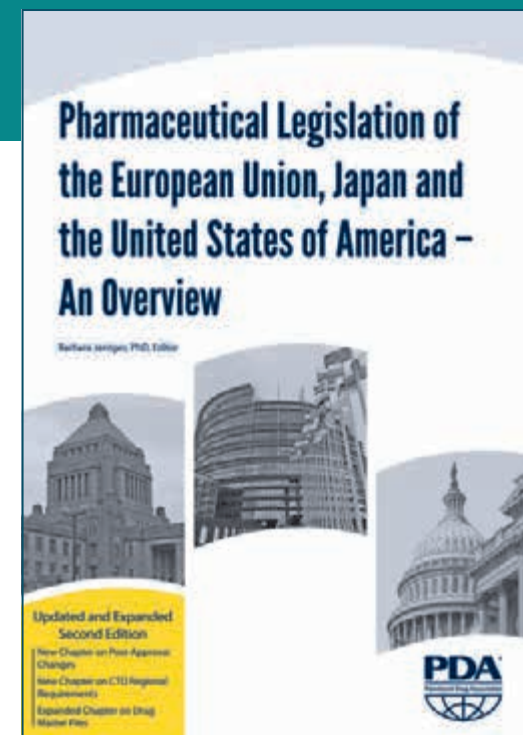
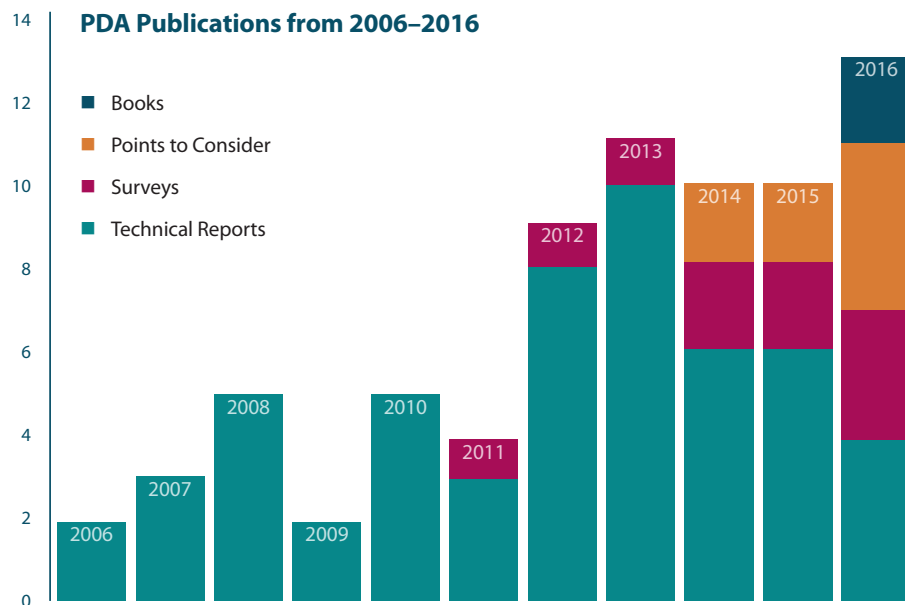
Big Data was on the agenda for the 1st PDA Europe Annual Meeting

PDA is known and respected for the scientific and technical contributions it has made to the industry. Sound science is the foundation of PDA's education, programming and regulatory activities.

The *PDA Journal of Pharmaceutical Science and Technology* has published every year of PDA's existence, so also celebrated its 70th year. A highlight of 2016 was the addition of a "publish-ahead-of-press" function to the Journal's website, which allows the editors to post "accepted papers" prior to official publication in a future edition.

Prompted by the 1976 draft FDA guidance on GMPs for large volume parenterals, PDA's members mobilized and provided technical guidance to the Agency, the U.S. Pharmacopeia and the industry on a number of pressing topics, including container/closures, visual inspection, particulate matter, Limulus Amebocyte Lysate testing, and terminal sterilization. It was this latter topic that became the focus of PDA's first technical report in 1978 (known as "technical monographs" then): "Validation of Steam Sterilization Cycles."

By the end of 2016, the library of PDA-owned technical documents produced by member volunteers has grown to nearly 100 technical reports, surveys and points to consider. In a remarkably busy year, PDA published 13 volunteer-driven documents: five technical reports, a points-to-consider document, three surveys, and two books, as well as two papers in the PDA Journal.



PDA Journal
of Pharmaceutical Science and Technology

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Accepted Articles
August 15, 2017

Current Issue : July/August 2017

Editor's Note

John Sculley's Noble Cause: Disruptive Innovation to Transform Healthcare
By Editor-in-Chief Govind Rao

As Congress currently struggles with legislation around Obamacare, I had the privilege of speaking with John Sculley, legendary marketing genius and former CEO of Pepsi and Apple. "The healthcare industry is the only technology-driven industry where we spend more each year and get less for our money. I intend to do something about it." With those words, he laid out his vision over a couple of conversations.

John was headed out to meet with six senators in Washington DC, after just having met with Governor Scott Walker (Wisconsin) and John Kasich (Ohio). "I'm doing this as a citizen—anyone who has ideas about how you can transform healthcare needs to get those ideas in front of the government leadership." John took off the current problems in rapid-fire succession.

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January

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Global Sterile Manufacturing Regulatory Guidance Comparison
With link to Comparison Spreadsheet

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PDA Survey

2015 Particulate Matter in Oral Dosage Forms

PDA Survey

2015 Particulate Matter in Difficult to Inspect Parenterals

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2015 Aging Facilities

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Technical Report No. 73
Prefilled Syringe User Requirements for Biotechnology Applications

Technical Report No. 74
Reprocessing of Biopharmaceuticals

Technical Report No. 75
Consensus Method for Rating 0.1µm Mycoplasma Reduction Filters

Technical Report No. 76
Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging

Technical Report No. 56 (Revised 2016)
Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance)

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Points to Consider for Aseptic Processing
Part 2
May 2016

PCMO®
Pharmaceutical Change in Manufacturing Operations®



A speaker addresses the large audience at the 2016 PDA/FDA Joint Regulatory Conference

In PDA's Certificate of Incorporation, filed on November 12, 1946 in New York, one of the Association's primary purposes was to:

“Cultivate and maintain cooperative relations with governmental departments and agencies...and to originate and participate in cooperative enterprises and undertakings with them.”

PDA issued its first comments to a regulatory proposal in 1976 in response to the U.S. FDA request for comment on the proposed “Good Manufacturing Practices for Large Volume Parenterals.” The comments were prepared by the PDA “Research Committee,” reviewed by interested PDA members, and shown to FDA officials, before final submission to the proposed GMP's docket. The Association has proffered comments on hundreds of regulatory proposals since.

In the forty years since, the process for commenting on regulatory proposals has been formalized:

The Regulatory Affairs and Quality Advisory Board (RAQAB) identifies current regulatory and quality issues affecting the development, manufacturing and quality of healthcare products:

- advises PDA on the impact of such issues
- recommends a plan of action for PDA response
- and develops and makes recommendations to the PDA Board of Directors on association positions

In 2016, PDA's regulatory participation activities were at the busiest level yet, with 16 comments prepared and submitted throughout the year. Reflecting the growing international influence of PDA, half of the regulatory comments were on proposals issued to regulatory bodies outside the United States. PDA members also commented on a proposal by the U.S. Pharmacopeia's new General Chapters pilot program.



GxP Data Integrity Definitions and Guidance for Industry Draft Version for Consultation



Questions and answers on production of water for injections by non-distillation methods – reverse osmosis and biofilms and control strategies

Guideline on the sterilization of the medicinal product, active substance, excipient, and primary container

Guideline on manufacture of the finished dosage form



Guidelines on procedures and data requirements for changes to approved biotherapeutic products

Guidelines on Validation

Guidelines on Validation: Appendix 4 Analytical Method Validation

Guidelines On Validation — Appendix 6: Validation On Qualification Of Systems, Utilities and Equipment



Draft Guidance: Insanitary Conditions at Compounding Facilities

Quality Metrics Technical Conformance Guide Technical Specifications Document

Draft Guidance: Assay Development for Immunogenicity Testing of Therapeutic Proteins

Draft Guidance Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information

Draft Guidance for Industry: Data Integrity and Compliance with CGMP

Draft Guidance for Industry Implementation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009

Draft Guidance for Industry: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development

Electronic Common Technical Document Technical Conformance Guide Technical Conformance Guide

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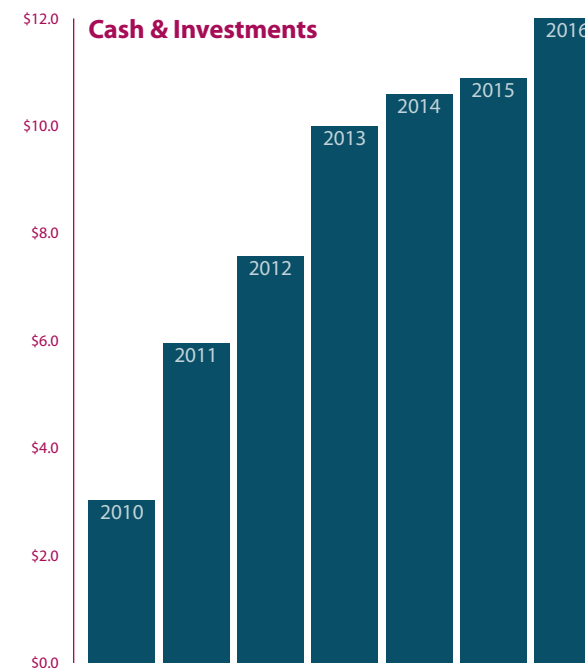
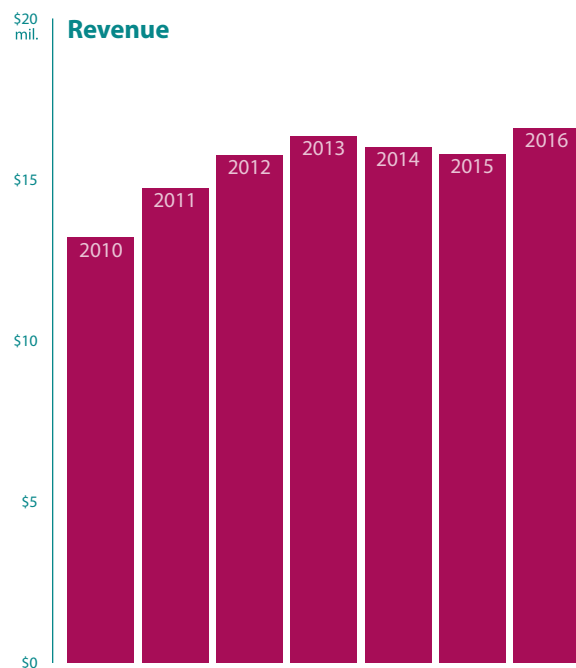
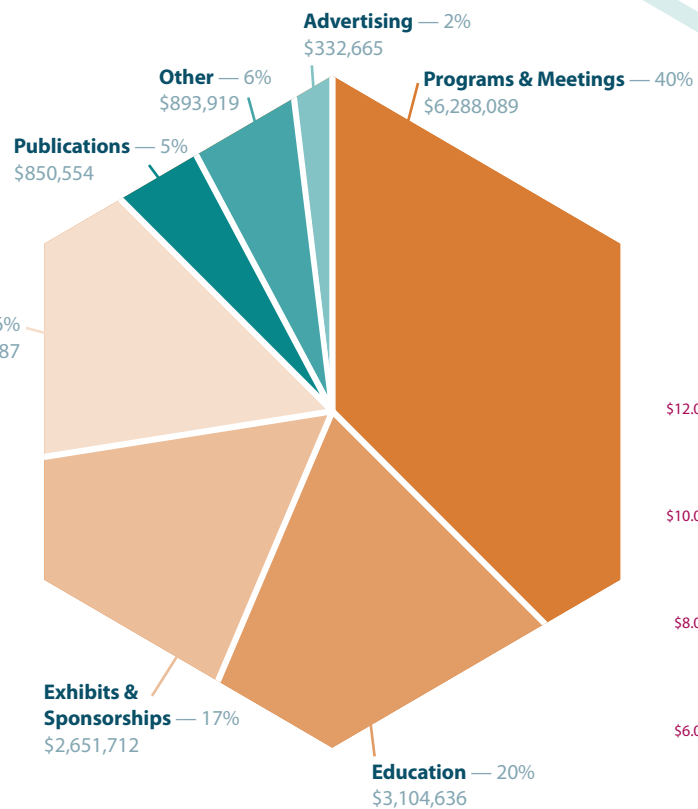
Julie Tchuya
Coordinator, Program + Events



Financials

	2016	2015
Total Revenues	\$ 16,573,562	\$ 15,761,671
Total Expenses ¹	\$ 16,161,723	\$ 15,781,884
Net Income Surplus (Deficit)	\$ 411,839	\$ (20,213)
Increase (Decrease) in Net Assets	\$ 411,839	\$ (20,213)
Net Assets at beginning of year	\$ 8,343,006	\$ 8,363,219
Net Assets at end of year	\$ 8,754,845	\$ 8,343,006
Net Asset ratio (Net Assets/ Annual Expenses)	54%	53%

¹ Total expense includes the foreign currency translation adjustment of (\$50,745) in 2016 and (\$174,442) in 2015. This is considered a non-operating expense item.



PDA/FDA JOINT REGULATORY CONFERENCE

From humble beginnings in 1991, the PDA/FDA Joint Regulatory has become PDA's consistently largest signature meeting and a truly must-attend event for pharmaceutical/biopharmaceutical manufacturing community around the world.

25TH

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The 1962 PDA Annual Meeting Banquet