Strengthening the Connection between People, Science and Regulation
A Strategy for Success in 2014

- 2,329 Active Volunteers
- 10,000 Members
- 11 Regulatory Comments
- 10 Technical Documents Published
- 5,600 Conferences/Workshop Attendees
- 36 Conferences & Workshops
- 1,105 Professionals Trained
- 104 Training Courses
Strengthening the Connection between People, Science and Regulation

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Advisory Boards & Committees

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2015 Annual Report Financial Summary

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Connecting science and regulation and the people responsible for them has never been more important in the pharmaceutical/biopharmaceutical industry. Every facet of the industry is in flux, including manufacturing, regulations and quality controls. Traditional small molecule manufacturing looks nothing like it did a decade ago, with suppliers and contract operations spread all across the world doing the work for large innovator companies that once was done completely in house. Large molecule, or biologics, manufacturing has seen cell bank yields grow by leaps and bounds, even as manufacturing systems have gotten smaller, disposable and modular. Such advances in biopharmaceutical production paved the way for the onset of biosimilar, or generic, biopharmaceutical products.

Regulators are working tirelessly to keep pace, with large agencies like the U.S. Food and Drug Administration (FDA) focusing on manufacturing and quality metrics to gauge company compliance with Good Manufacturing Practice (GMP) regulations. The European Medicine Agency, the FDA and other regulators around the world are acting to prevent drug shortages, combat counterfeiting and falsified data, and create regulatory pathways for new therapies and biosimilar products.

The Parenteral Drug Association (PDA) focused all its efforts on Strengthening the Connection between People, Science and Regulation in 2015. With 20% of its 10,000 members actively involved in various activities, including meeting planning and technical report writing, PDA was at the forefront of many key areas critical to the future success of the pharmaceutical industry, including aseptic processing, data integrity and manufacturing science.

Each of these initiatives takes aim at real-life challenges faced by pharmaceutical companies that also have risen to a level of concern among the regulatory authorities worldwide.

A fundamental area of PDA member expertise is aseptic processing, a critical operation in the final stage of producing many sterile drug products, particularly biopharmaceutical products that cannot be sterilized by traditional means. PDA formed a task force of experts to monitor and participate in the commenting process as regulatory agencies worldwide released updated requirements for aseptic processing. The group’s first priority was to develop points to consider on aseptic processing, the first volume of which published in 2015.

Over the last several years, the industry has seen an increasing number of companies run afoul of regulatory expectations for the integrity of manufacturing and control data. In response, PDA formed a task force that has developed a comprehensive mitigation program.

At the heart of the various compliance and quality challenges facing the pharmaceutical industry is the persistence of aging facilities and processes. PDA’s members launched a Manufacturing Science and Operations Program to look at ways of modernizing this critical segment of the industry.

The following pages highlight PDA’s 2015 activities in these and other areas and spotlights various volunteers. Together, these demonstrate how PDA is Strengthening the Connection between People, Science and Regulation.
Volunteer Advisory Board Member

Mirko Gabriele
Technology Transfer Manager
Patheon
Member Since 2011

The most rewarding aspect of volunteering was the chance to work with experts from all over the world with different backgrounds and views on technology transfer.
Chair’s Message

PDA had another very good year in 2015. A review of the highlights would note all of the many important, interactive conferences, meetings, workshops, chapter events, and interest group meetings in the United States, Europe, and elsewhere; the continued enlightenment of industry members through new and mainstay education courses held at our Training and Research Institute in Bethesda, Md., the European Headquarters in Berlin, venues throughout the world, and in-company trainings; the industry-leading best practices on topics of interest and benefit to our members presented in technical reports, surveys, scientific books, and position papers published in the PDA Journal of Pharmaceutical Science and Technology; and regulatory participation through insightful comments on new regulations and guidances developed, collected, and posted by PDA on behalf of its membership.

These activities illustrate our commitment to deploying resources to strengthen the connection of people, science and regulation in a very material way to help ensure product quality and patient safety. In 2015, PDA brought together experts at a global level from the industry, suppliers, and regulators to use true risk- and science-based approaches to address some of the most vexing and challenging issues facing today’s healthcare product manufacturing industry.

A major accomplishment of 2015 was the completion of a new, five-year strategic plan for the Association by the PDA Board of Directors. This plan ensures the continued excellence of PDA as we strive to meet member needs in a rapidly changing industry. The 2015 effort is notable because of the perspective taken by the strategic planning team. Instead of considering the state of the industry for the next five years, they envisioned what the industry might look like in a decade. This truly visionary approach has prepared the Association to meet the challenges our members will likely face years into the future, thus ensuring we will stay the course and be able to anticipate changes and facilitate improvement in our industry.

These efforts ensure that PDA members will remain a leading force in the industry. I encourage you to read the Strategic Plan (published at www.pda.org), as well as this annual report, which details many of our 2015 accomplishments. Become more engaged and participate in this very important association of your peers, colleagues, coworkers, and friends. PDA is simply the best science-based, member-driven organization for pharmaceutical and biopharmaceutical professionals on the planet.

In closing, I want to stress that our success in 2015 is due to the work of many individuals: the PDA senior leadership team, the PDA staff, the current and past Boards of Directors, and the 2300 active volunteers who participate on planning committees, advisory boards, task forces, chapters, and committees. Because of their efforts, PDA remains the standard-bearer for a generation of industry professionals and regulators endeavoring to move our industry ever forward by advancing product quality and patient safety.
The year 2015 was another successful year for PDA as we continued the execution of our newly revised 2020 Strategic Plan. We added voice to the values described in our Strategic Plan:

**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.

In 2015, we strengthened our commitment to Connecting People, Science and Regulation®:

**People:** Membership in PDA continued to grow around the world, surpassing 10,000. We launched PDA Connect™ to provide members a members-only forum for communicating. We continued to have industry leading conferences, including our most successful meeting in PDA history, the Universe of Prefilled Syringes, in Vienna, Austria. We utilized innovative techniques for connecting members in different areas of the world, including simulcasting portions of the parallel U.S. and EU Vaccines meeting to both locations and adding simultaneous translation of our PDA/FDA Joint Regulatory Conference into Japanese. We expanded the Connection, hosting our first events in Brazil, South Korea, and India—our highly successful collaboration with PIC/S on ICH Q7.

**Science:** A cornerstone and a core value of PDA. In 2015 this was evidenced by the continued excellence of our technical volunteer activities, including the publication of seven Technical Reports, one “Points to Consider,” and two Surveys. We expanded our Technical Report Portal to make all PDA Technical Reports more easily accessible to all members as a benefit of their membership.

**Regulation:** We 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 regulatory guidance, including formal written comments on 11 documents. In a spirit of collaboration and mutual interest, we worked with regulators on most of our conferences, most notably the 24th Annual PDA/FDA Joint Regulatory Conference and the aforementioned conferences on PIC/S on ICH Q7.

**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 European Headquarters to larger facilities and prepared for similar expansion in the United States in 2016. Our Education program had a record year, and we experienced our sixth consecutive year of positive revenue. In addition, our longtime member and staff leader, Bob Dana, retired at the end of the year, and we announced that Craig Elliott would assume the role to lead our Education efforts.

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 provides a unique opportunity to work with technical experts across the industry. As a member, I have the opportunity to work with experts from a very diverse network spanning large to small companies as well as innovator firms to generic manufacturers and also regulatory authorities.
PDA Vision and Mission

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

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.

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 and Regulation

PDA’s technical contributions play a central role in the Association’s ability to strengthen the connection between people, science and regulation.

In 2015, PDA expanded its library of technical reports to nearly 60 active documents with the publication of six technical reports and a Points to Consider document. These peer-reviewed, global-consensus documents are written by volunteer subject-matter experts on a wide array of technical topics.

Many of PDA’s technical reports address ongoing industry challenges with aseptic processing and sterilization methods. In 2015, PDA’s volunteers contributed two additional reports on these hot topics. A group of aseptic processing experts collaborated to produce a much-needed revision to the 2003 PDA technical report, Points to Consider for Aseptic Processing. The goal of the revised document was to communicate PDA’s views and encourage dialogue with industry, health authorities and suppliers of technology and materials, while taking into consideration the changes and needs of the modern global sterile healthcare product manufacturing industry. Part 1 of the revision was published in 2015; Part 2 is planned for publication in early 2016.

PDA Technical Report No. 69: Bioburden and Biofilm Management in Pharmaceutical Operations was another significant contribution. Sterile drug manufacturers devote considerable resources to the control of microbial contamination, and a large component of the control strategy is the management of bioburden and biofilm in water systems. Persistent bioburden and biofilm contaminations have been directly linked to several recalls and plant shutdowns. PDA’s volunteer experts responded by developing this comprehensive technical guide, which includes five instructive case studies.
PDA volunteer task forces routinely monitor industry trends via surveys, and the results from two 2014 surveys were published in 2015: *Visual Inspection* and *Quality Culture Metrics*.

PDA’s members also were very active in regulatory processes worldwide. They commented on 11 regulatory proposals that addressed a variety of regulatory issues, including U.S. FDA guidances on human cell tissue and tissue-based products, a European Commission proposal on GMPs for cell and gene therapies, and a World Health Organization proposal to revise its good trade and distribution practices for pharmaceutical starting materials.

The *PDA Letter*, PDA’s magazine, launched a new website that allows members to access the publication online and on the go with their mobile devices, joining the *PDA Journal of Pharmaceutical Science and Technology* and the technical reports in providing members a complete online experience. The *PDA Journal* provided readers access to proceedings from the Third Viral Clearance Symposium, an industry-led effort to improve this critical step in ensuring the safety of therapeutic proteins derived from mammalian cell cultures. PDA task forces also published two “PDA Papers” in the *PDA Journal*: one on the medical risk of visible particles in injectable drugs, the other a report on the *Quality Culture Metrics Survey*. "PDA Papers" are a special contribution; they are internally reviewed by PDA and task force members and not peer-reviewed by the *PDA Journal*. 
Education Courses and Conferences

The connection between people, science and regulation is strengthened significantly at the various conferences, workshops and training courses PDA offers each year around the world. In-person learning and networking never goes out of fashion, even in the digital age. Exemplifying how PDA strengthened the connection in 2015, the Association joined with the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to conduct training for pharmaceutical professionals in Seoul, Republic of Korea; Brasilia, Brazil; and Ahmedabad and Ahmedabad, India, on the International Conference on Harmonisation Quality Guideline Q7, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients. In addition, PDA held its 24th annual PDA/FDA Joint Regulatory Conference in Washington, DC, and a Quality and Regulation Conference in the heart of the European Union, Brussels, Belgium.

PDA’s 2015 Visual Inspection Forum and 2015 Universe of Pre-Filled Syringes and Injection Devices Conference boasted the largest vendor exhibitions in their respective fields. Both events also provided excellent education opportunities through conference talks and lecture courses that featured expert speakers from industry and regulatory authorities.

PDA’s scientific conferences offer the best technical information on topics critical to industry. The PDA Annual Meeting is the premier technical conference; in 2015, it convened in Las Vegas. PDA’s Annual Global Conference on Pharmaceutical Microbiology celebrated its tenth annual installment. PDA’s European offerings highlighted a number of technical fields, including advance therapy products, virus and TSE safety, and cold chain logistics.

No organization beats PDA for hands-on training in aseptic processing techniques. Five sessions were held in 2015 at PDA’s state-of-the-art aseptic filling suite in Bethesda, Md. PDA’s expansive list of lecture and laboratory course offerings included many on aseptic processing and sterilization science.

Conferences

8th Workshop on Monoclonal Antibodies | Berlin, Germany

10th Annual Global Conference on Pharmaceutical Microbiology | Bethesda, MD

Advanced Therapy Medicinal Products | Amsterdam, The Netherlands

Aging Facilities Workshop | Las Vegas, NV

Annual Meeting | Las Vegas, NV

Aseptic Manufacturing | Berlin, Germany

Container Closure Integrity – Regulations, Theory, Test Methods, Application | Frankfurt/Main (Bad Soden), Germany

Drug Delivery Combination Products Workshop | Washington, DC

Extractables and Leachables | Frankfurt/Main (Bad Soden), Germany

Freeze Drying Interest Group | Berlin, Germany

Interphex PDA Educational Program | New York and Puerto Rico

Managing Risk in Aseptic Processing | Tel Aviv, Israel

Manufacturing Initiative Workshop | Washington, DC

Manufacturing and Testing Challenges of ATMPs | Amsterdam, The Netherlands

Metrics Conference | Washington, DC

Outsourcing/Contract Manufacturing | Copenhagen, Denmark

Parenteral Packaging | Frankfurt/Main (Bad Soden), Germany

Particulate and Injectable Conference | Berlin, Germany

PDA/FDA Joint Regulatory Conference | Washington, DC

PDA/PIC/S Training Course:ICH Q7 Guideline | Seoul, Republic of Korea; Brasilia, Brazil; and Hyderabad and Ahmedabad, India

Pharmaceutical Cold & Supply Chain Logistics | Amsterdam, The Netherlands

A gathering of attendees at the Virus/TSE Safety Forum in Lisbon, Portugal
**Lectures & Lab Courses**

2015 PDA Aseptic Processing-Sterilization Course Series | San Diego, CA
- Process Simulation Testing for Aseptically Filled Products
- Recommended Practices for Manual Aseptic Processes
- Validation of Moist Heat Sterilization Processes

2015 PDA Pharmaceutical Packaging Conference Series | Baltimore, MD
- Implementing QRM for Pharma & Biotech Manufacturing Operations: Case Studies in Packaging & Labeling Drug Products
- Selection and Utilization of Glass Containers in Pharma Packaging
- Technical Development of Prefilled Syringes, Autoinjectors & Injection Pens

2015 PDA/FDA Joint Regulatory Conference Course Series | Washington, DC
- CMC Regulatory Requirements in Drug Applications
- Process Validation and Verification: A Lifecycle Approach
- Quality Metrics: Performance Indicators
- Risk-Based Product Development Basics for Combo Products
- Root Cause Investigation for CAPA

The A to Z’s of Biofilm Control, Monitoring, Validation, and Excursion Investigations of Pharmaceutical Water Systems | Berlin, Germany

Airflow Visualization Techniques and Practices | Bethesda, MD

Application of ICH Q9 | Berlin, Germany

Application of Phase-Appropriate GMP to the Development of Protein Bulk Drug Substances | Bethesda, MD

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

Aseptic Processing Training Program (5 two-week sessions) | Bethesda, MD

Assessing Packaging and Processing Extractables and Leachables | Bethesda, MD

Cleaning and Disinfection | Berlin, Germany

CMC Regulatory Compliance Training | Berlin, Germany

Container Closure Development | Frankfurt/Main (Bad Soden), Germany

Container Closure Integrity | Frankfurt/Main (Bad Soden), Germany

Current Challenges in Vaccines | Bethesda, MD

Designing/Presenting GXP Training Programs to Meet FDA Requirements | Bethesda, MD

Development and Manufacturing of a Prefilled Syringe | Vienna, Austria

Development, Manufacturing and Handling of Primary Packaging Containers, Drug Delivery Device Formats and Actual Market | Bethesda, MD

Development of a Freeze-Drying Process | Berlin, Germany

Elastomers (2 sessions) | Frankfurt/Main (Bad Soden), Germany

Endotoxins and Pyrogens in Parenterals | Berlin, Germany

Environmental Monitoring | Berlin, Germany

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

Extractables & Leachables | Berlin, Germany

Filtration Week | Bethesda, MD

Filters and Filtration in the Biopharm Industry: Advanced

Filters and Filtration in the Biopharm Industry: Basics

Foreign Particulate Examination, Isolation, & Analysis | Bethesda, MD

A Former Investigator’s Perspective on Conducting Effective Deviation Investigations, Root Cause Investigations,

Attendees converse in the lobby at the Packaging Combo Conference
Identifying and Classifying Nonconformities in Molded and Tubular Glass | Bethesda, MD
Implementing QRM for Pharma and Biotech: Case Studies in Manufacturing of Biotech Bulk Drug Substances | Bethesda, MD
Implementing QRM for Pharma and Biotech: Case Studies in Manufacturing of Pharma Drug Products | Bethesda, MD
Implementing QRM for Pharmaceutical & Biotech Manufacturing Operations | Bethesda, MD
Innovative Combination Products | Vienna, Austria
Introduction to Aseptic Processing Principles | Berlin, Germany
An Introduction to Visual Inspection (3 sessions) | Berlin, Germany and Bethesda, MD
Learning, Knowledge Management, and Impact: Moving from Theory to Practice | Bethesda, MD
Lyophilization Week | Bethesda, MD
Management of Aseptic Processing | Bethesda, MD
Manufacturing and Testing Challenges: ATMPs | Berlin, Germany
Modern Manufacturing and Trend Monitoring | Bethesda, MD
Moist Heat Sterilization Week | Bethesda, MD
Mylan Training | Bangalore, India
Outsourcing: Technology Transfer | Berlin, Germany
Particle Identification | Berlin, Germany
PDA 10th Annual Global Conference on Pharmaceutical Microbiology Course Series | Bethesda, MD
Process Simulation Testing for Aseptically Filled Products | Bethesda, MD
Qualifying Your SMEs as Trainers | Bethesda, MD
Quality Systems | Berlin, Germany
Quality Systems for Aseptic Processing | Bethesda, MD
The Quality Culture and Its Measurement | Bethesda, MD
Rapid Microbiological Methods & an Overview of the Technical Report 33 | Berlin, Germany
Recommended Practices for Manual Aseptic Processes | Bethesda, MD
Recommended Practices for Manual Visual Inspection | Berlin, Germany
Risk-Based Approach for Prevention and Management of Drug Shortages | Bethesda, MD
Risk-Based Qualification of Sterile Drug Product Manufacturing Systems | Bethesda, MD
Secondary Packaging | Frankfurt/Main (Bad Soden), Germany
Single Use Systems for the Manufacturing of Parenteral Products | Bethesda, MD
Smart Medication | Vienna, Austria
Statistics of Pharmaceutical Production Monitoring and Capability | Berlin, Germany
Steam In Place | Bethesda, MD
Steam Sterilizers: Getting It Right from the Beginning | Bethesda, MD
Tale of Two Materials | Berlin, Germany
Technical Development of Prefilled Syringes, Autoinjectors and Injection Pens | Baltimore, MD
Test Methods for Prefilled Syringes | Vienna, Austria
Train the Trainer Week | Bethesda, MD
Utilization of Statistical Methods for Production Monitoring | Bethesda, MD
Validation of Biotechnology-related Cleaning Processes | Bethesda, MD
Validation of Dry Heat Processes Used for Sterilization and Depyrogenation | Bethesda, MD
Validation of Lyophilization | Bethesda, MD
Validation of Moist Heat Sterilization Processes (Lab) | Bethesda, MD
Validation of Moist Heat Sterilization Processes (Lecture) | Bethesda, MD

Opening plenary session of the 2015 PDA/FDA Joint Regulatory Conference
I think that the Visual Inspection Forum is probably at the top of my list of most enjoyable PDA experiences. Here, good science from manufacturing control and inspection strategies, visual inspection technologies, and the impact those factors have on patient safety all seem to come together in a very tangible fashion.
Tony Cundell, PhD
Consultant
Microbiological Consulting
Member Since 1985

At a Microbiology Interest Group meeting I was asked if I would lead a PDA task force to write a technical report on the validation of alternative microbiological test methods. This resulted in PDA Technical Report No. 33 in 2000.
Honorary Membership
This is PDA’s most prestigious award, conferring lifetime membership benefits to the recipient. The award is usually given in recognition of very long service of a significant nature to PDA.
John Shabushnig, PhD, Insight Pharma Consulting

Gordon Personeus Award
Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award is intended to honor a PDA member, other than a member of the PDA Board of Directors, for long-term acts or contributions that are of noteworthy or of special importance to PDA.
Hannelore Willkommen, PhD, RBS Consulting
David Matsuhiro, Cleanroom Compliance

Packaging Science Award
This award is given in recognition of extraordinary contributions to PDA and the packaging science.
Nicholas DeBello, DeBello & Associates

Frederick J. Carleton Award
Presented as a tribute to lifetime contributor, past President, past Executive Director and Honorary Member Frederick J. Carleton, this award is designated for a past or present member of the PDA Board of Directors whose services on the Board are determined by his/her peers as worthy of such recognition.
Susan Schniepp, Regulatory Compliance Associates
Steven Mendivil, Amgen

Distinguished Service Award
This award is given in recognition of special acts, contributions or services that have contributed to the success and strength of PDA.
Osama (Sam) Elshahidy
Michael DeFelippis, PhD, Eli Lilly
Anthony Cundell, PhD, Microbiological Consulting
Robert Repetto, Pfizer
Steffen Gross, Paul-Ehrlich-Institut

James P. Agalanco Award
The James P. Agalanco Award is presented annually to the PDA faculty member who exemplifies outstanding performance in education.
John Geigert, PhD, BioPharmaceutical Quality Solutions

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.
Derek Duncan, PhD, Lighthouse Instruments

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.
Maik Jornitz, G-Con Manufacturing

Service Appreciation Award
The Service Appreciation Award is presented annually for special acts, contributions or services.
Kim Ngan Waters, GlaxoSmithKline
Lara Soltis, Ansell Healthcare
Roland Bizanek, PhD, Compass Pharma Consulting
Melissa Seymour, Biogen Idec
Elaine Eborall, Genentech
John Finkbohner, PhD, AstraZeneca-Medimmune
Junko Sasaki, Sumitomo Dainippon Pharma Co., Ltd.
Christopher Smalley, PhD, Merck

Michael S. Korczynski Award
An award established in recognition of contributions made toward the development of PDA’s international activities.
Junko Sasaki, Sumitomo Dainippon Pharma Co., Ltd.
Karen Ginsbury, PCI Consulting

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.
Yuh-Fun Ma, Wendy Shieu, Sarah Torhan, Edwin Chan, Aaron Hubbard, Benson Gikanga, and Oliver Stauch, for the March/April 2014 paper, “Filling of High Concentration Monoclonal Antibody Formulations into Pre-Filled Syringes: Filling Parameter Investigation and Optimization”

Distinguished Editor/Author
This award recognizes the author or editor selected by PDA members for their contribution to PDA’s technical books.
Kevin O’Donnell for his book Cold Chain Chronicles

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.
Melissa Pazornik and Sylvia Becker
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- Rodney Thompson, PhD, BioPharm Process Associates
- Mike Wiebe, PhD, Quantum Consulting, LLC
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- Earl Zablackis, Sanofi-Pasteur
- Wendy Zvolenski-Lambert, Novartis Pharma AG

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- Laurie Graham, U.S. FDA
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- Steven Mendivil, Amgen
- Animamie Moeritz, PhD, Novartis
- Rodney Thompson, PhD, BioPharm Process Associates
- Mike Wiebe, PhD, Quantum Consulting, LLC
- Hannelore Willkommen, PhD, RBS Consulting
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- Wendy Zvolenski-Lambert, Novartis Pharma AG

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- Michele Creech, Grifols
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- Robert Dream, HDR Company
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- Maik Jornitz, G-Con
- Youwen Pan, Roche/Genentech
- Leticia Quinones, Bristol-Myers Squibb
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- Rebecca Stauffer, PDA
- Sherry Tamura, Biogen Idec

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- Richard Johnson, PDA
- Dave Matsushiro
- Georg Rössling, Amgen
- John Shabushnig, Insight Pharma Consulting, LLC
- Mike Sadowski, Baxter Healthcare
- Jim Vesper

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- Fredericke Mohme, PDA
- Christina Braden-Moore, BD
- Steven Kaufman, Bespak | A Consort Medical Company
- Patricia Stancati, Sartorius Steimdom North America Inc.

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- Siegfried Schmitt, PAREXEL
- Mike Defilipis
- Steve Lynn, Novartis
- Richard Johnson, PDA
- Richard Levy, PDA
The volunteer opportunities available at PDA are unlike any other. You’re offered the opportunity to meet both like-minded and different-minded people within PDA. I have been able to learn and contribute by volunteering.
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Antonella Maggio, Harmonium International

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Jason Mattis, GlaxoSmithKline Biologicals

Metro
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Midwest
Kenneth Paddock, Baxter Healthcare Corporation

Missouri Valley
Jeff Hargroves, ProPharma Group

Mountain States
Suzanne Mecalco, Commissioning Agents, Inc.

New England
Jonathan Morse, Complya Consulting Group

Puerto Rico
Myriam Sosa, Merck

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Hassana Howe > Senior Director, Membership & Chapters
Richard Levy > Senior Vice President, Scientific & Regulatory Affairs
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Falk Klar, PhD > Senior Director, Training & Education
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Jahanvi (Janie) Miller > Senior Project Manager
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Almeda Hardy > Director, Meetings & Registration Services

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Hanna Morgan > Accounts Receivable
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Bob Collier > Database Administrator

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Hassana Howe > Senior Director, Membership & Chapters
Trevor Swan > Senior Manager, Membership & Chapters
Denise D. Baker > Senior Advisor
Jason E. Brown > Program Manager, Programs & Registration Services

Antje Petzholdt, M.P.A > Manager Registration, Chapters & Membership
Morgan Holland > Coordinator
Andrea Viera > Executive Assistant

Sylvia Becker, Manager Programs & Events
Melanie Decker, Director Events & Exhibitions
Crexell Espilla-Gilart, Manager Exhibition & Sponsorship
Linna Funke, Registration Coordinator
Frederike Mohme, Marketing Assistant
Antje Petzholdt, Manager Registration, Chapters & Membership
Dirk Stelling, Director, Finance & Administration
Elke Von Laufenberg, Manager, Training & Education

U.S. Staff Not Pictured
Patrick Pelz, Marketing Manager
Katja Yount, Publication Design Specialist
Jim Polarine
Technology Service Manager
STERIS
Member Since 2011

As a PDA member, I benefit from interacting with my peers and colleagues in the industry. I also enjoy reading the PDA Letter, the PDA Journal of Pharmaceutical Science and Technology, and the latest PDA/DHI technical books.
2015 Annual Report
Financial Summary

2015 Revenue Sources

<table>
<thead>
<tr>
<th>Source</th>
<th>2015</th>
<th>2014</th>
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<tbody>
<tr>
<td>Programs &amp; Meetings</td>
<td>$6.0 M</td>
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<tr>
<td>Education</td>
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<tr>
<td>Exhibits &amp; Sponsorships</td>
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<td>Membership</td>
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<tr>
<td>Publications</td>
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<tr>
<td>Other</td>
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</tbody>
</table>

Total Expenses includes the foreign currency translation adjustment of ($174,442) in 2015 and ($207,862) in 2014. This is considered a non-operating expense item.
Volunteer Interest Group Leader

Brigitte Reutter-Haerle
Vice President, Marketing/Corporate Communications
Vetter Pharma International GmbH
Member Since 2005

Honestly, I know of no other organization that offers all that PDA does in regard to cutting-edge discussions and insight on scientific topics, as well as extensive networking opportunities with leading experts in the field. PDA’s international community has cultivated an environment of sharing and exchange of valuable information.