Strengthening the Connection between People, Science and Regulation

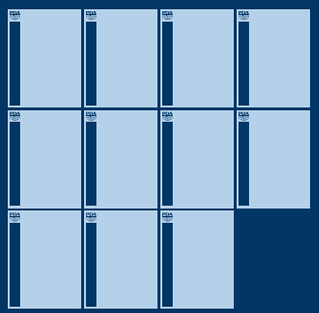
PDA®
Parenteral Drug Association

Annual Report 2015

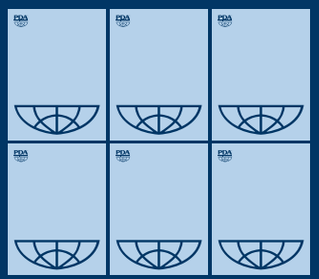
A Strategy for Success in 2014

2,329
ACTIVE VOLUNTEERS

11
REGULATORY COMMENTS

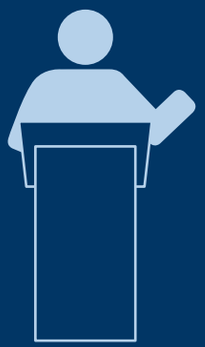


10
TECHNICAL DOCUMENTS PUBLISHED



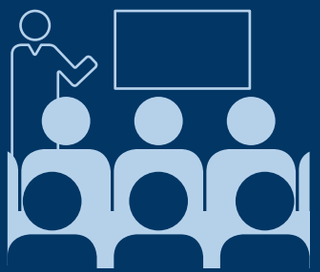
10,000
MEMBERS

5,600
CONFERENCES/ WORKSHOP ATTENDEES



36
CONFERENCES & WORKSHOPS

1,105
PROFESSIONALS TRAINED



104
TRAINING COURSES

DESIGN BY KATJA YOUNT

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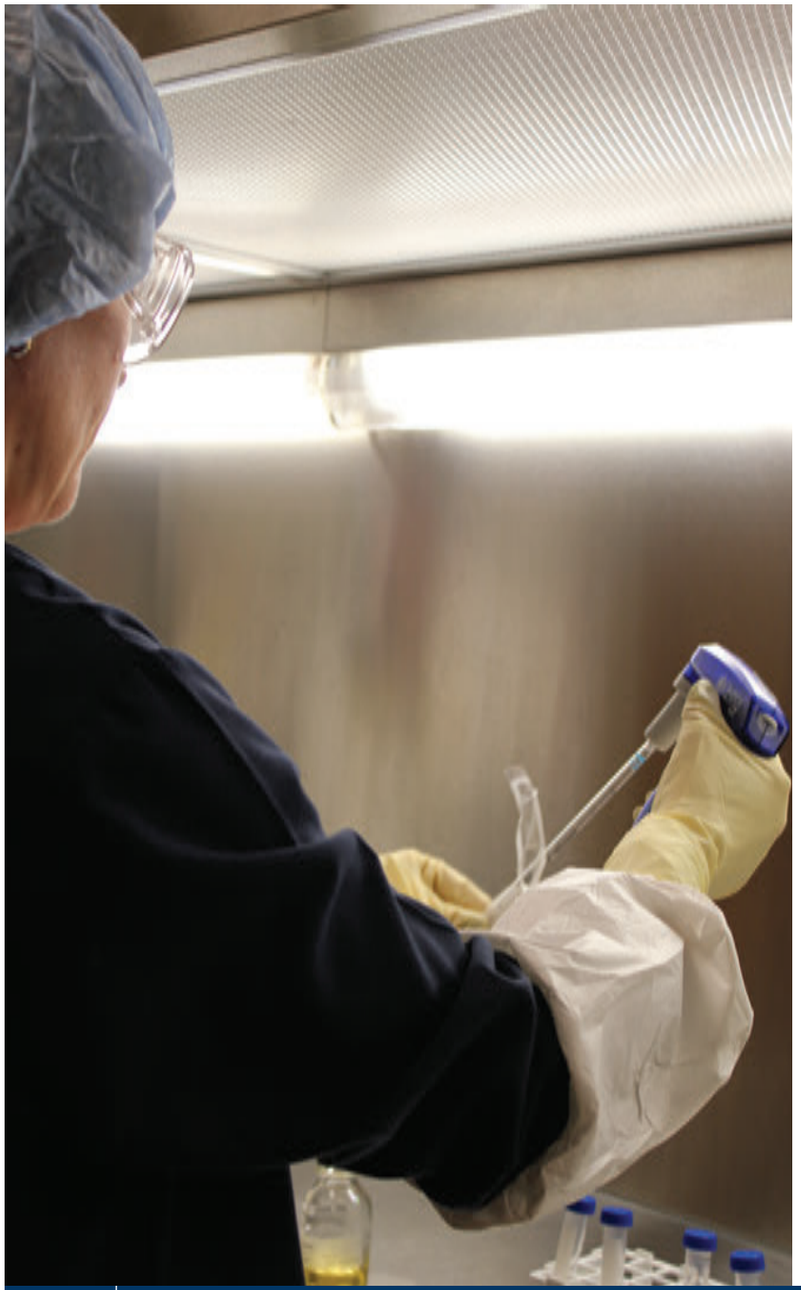
Strengthening the Connection between People, Science and Regulation



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.

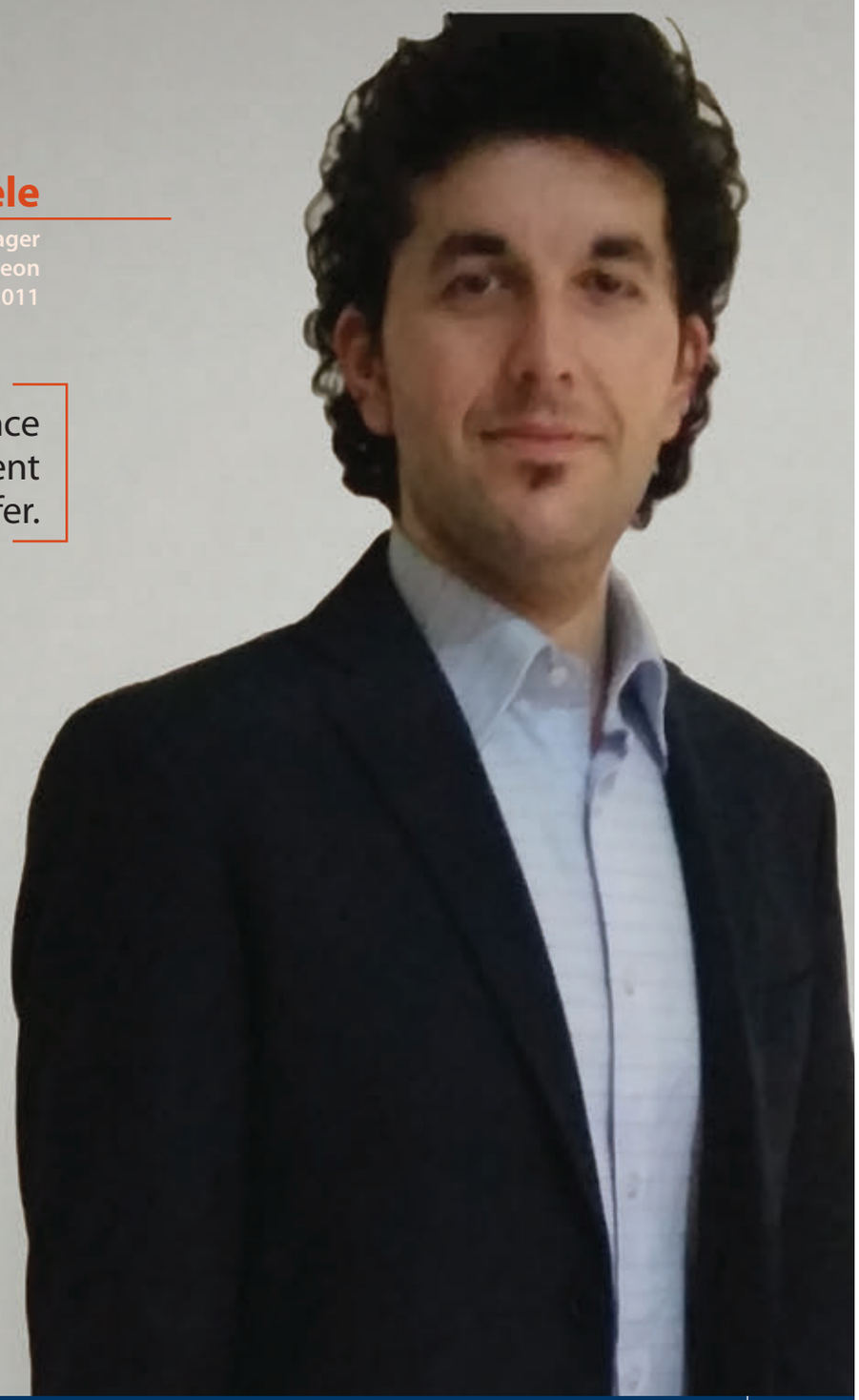
The following pages highlight PDA's 2015 activities in these and other areas and spotlights various volunteers. Together, these demonstrate how PDA is Strengthening the Connection between People, Science and Regulation.

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.

President's Message

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®:*

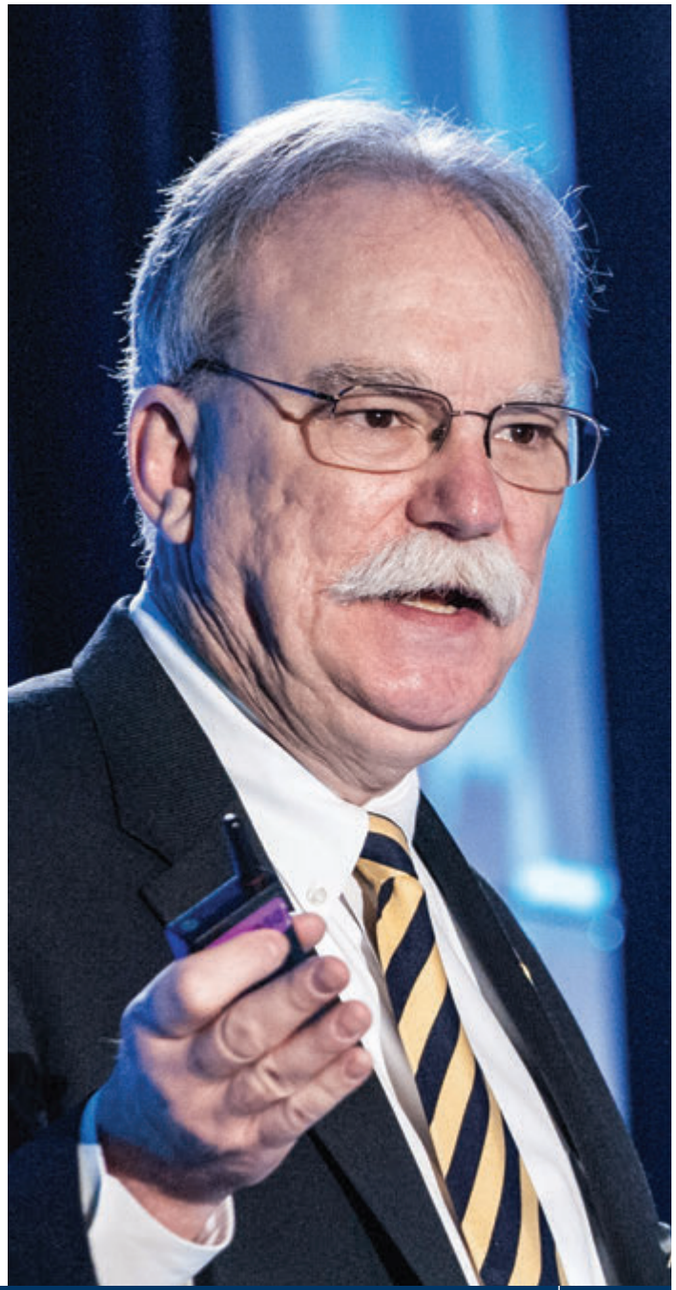
People: Membership in PDA continued to grow around the world, surpassing 10,000. We launched *PDA Connect℠* to provide members a members-only forum for communicating. We continued to have industry leading conferences, including our most successful meeting in PDA history, the *Universe of Prefilled Syringes,* 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 heath 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 ICH Q7 with PIC/S.

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.



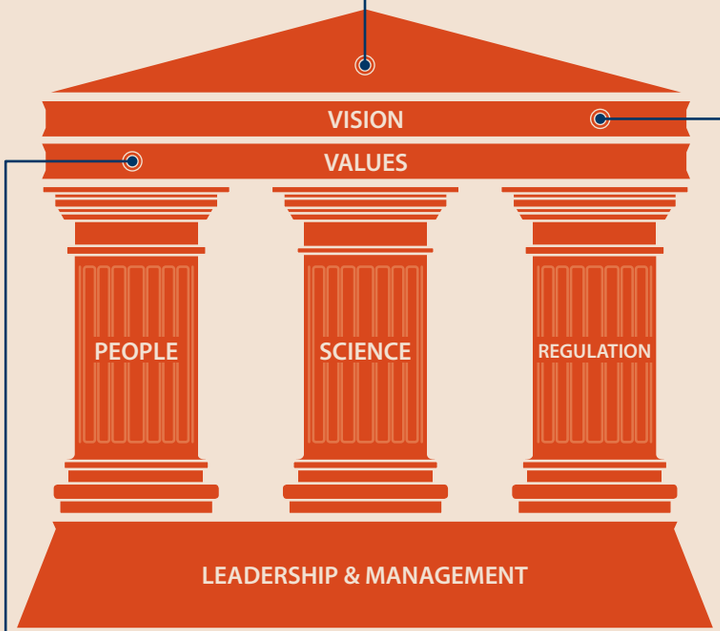
Janeen Skutnik-Wilkinson

Corporate Quality
Biogen
Member Since 2000

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



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.

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 Hyderabad 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.

A gathering of attendees at the Virus/ TSE Safety Forum in Lisbon, Portugal

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**

Particles and Injectables 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 Hyperbad and Ahmedabad, India**

Pharmaceutical Cold & Supply Chain Logistics | **Amsterdam, The Netherlands**

Pharmaceutical Freeze Drying Technology | **Munich, Germany**

Pharmaceutical Microbiology Conference | **Berlin, Germany**

Pharmaceutical Packaging Conference | **Washington, DC**

Quality & Regulation Conference | **Brussels, Belgium**

Single Use Systems Workshop | **Washington, DC**

The Universe of Pre-filled Syringes & Injection Devices | **Vienna, Austria**

Vaccines Conference | **Berlin, Germany**

Vaccines Conference | **Washington, DC**

Virus/TSE Safety Forum | **Lisbon, Portugal**

Visual Inspection Forum | **Bethesda, MD**

Visual Inspection Interest Group | **Berlin, Germany**

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 Course 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, Corrective and Preventive Action (CAPA) | **Bethesda, MD**

Fundamentals of Aseptic Processing (2 sessions) | **Bethesda, MD**

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

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

Fundamentals of Lyophilization | **Bethesda, MD**

Glass Handling in Pharmaceutical Processes including the Application of PDA Technical Report 43 | **Frankfurt/Main (Bad Soden), Germany**

Glass Quality, Visual Inspection and Foreign Material Identification Week | **Bethesda, MD**

GMP Week | **Bethesda, MD**

- GMPs for Manufacturers of Sterile and/or Biotech Products

Good Cold Chain Practices | **Berlin, Germany**

Attendees converse in the lobby at the Packaging Combo Conference

Identification and Classification of Noncomformities 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**

- Evaluation, Validation, and Implementation of Alt & Rapid Microbio Testing Methods
- Investigating Microbial Data Deviations
- Regulatory Aspects of Microbiology in a Non-Sterile Environment

PDA Annual Meeting Course Series | **Las Vegas, NV**

- Applying Six Sigma Techniques to Process Validation Lifecycle
- Developing a Robust Supplier Management Process
- Sterile Pharmaceutical Dosage Forms
- The Quality Culture and Its Measurements
- Technical and Regulatory Challenges of Combination Drug Delivery Products

Practical Aspects of Aseptic Processing (Regulatory) | **Bethesda, MD**

Opening plenary session of the *2015 PDA/FDA Joint Regulatory Conference*

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**

Volunteer Task Force Member

John Ayres

Senior Director, Product Safety Assessments
Eli Lilly
Member Since 2003

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.

AWARDS

Each year, PDA recognizes members whose contributions have helped the Association fulfill its mission. Honored members are recognized at the PDA Awards Dinner, held during the Annual Meeting. PDA congratulates each winner and thanks them for their service to the Association.

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) Elrashidy
Michael DeFelippis, PhD**,** Eli Lilly
Anthony Cundell, PhD, Microbiological Consulting
Robert Repetto, Pfizer
Steffen Gross, Paul-Ehrlich-Institut

James P. Agalloco Award

The James P. Agalloco Award is presented annually to the PDA faculty member who exemplifies outstanding performance in education.

John Geigert, PhD, BioPharmaceutical Quality Solutions
Piet Christiaens, PhD, Toxikon Europe

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 Australia
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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 Maa, 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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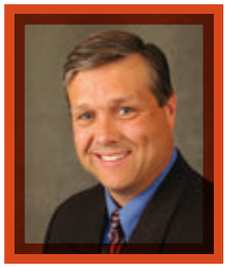

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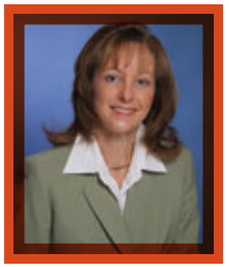

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Manager, Global Quality Risk Management
Genzyme Corporation
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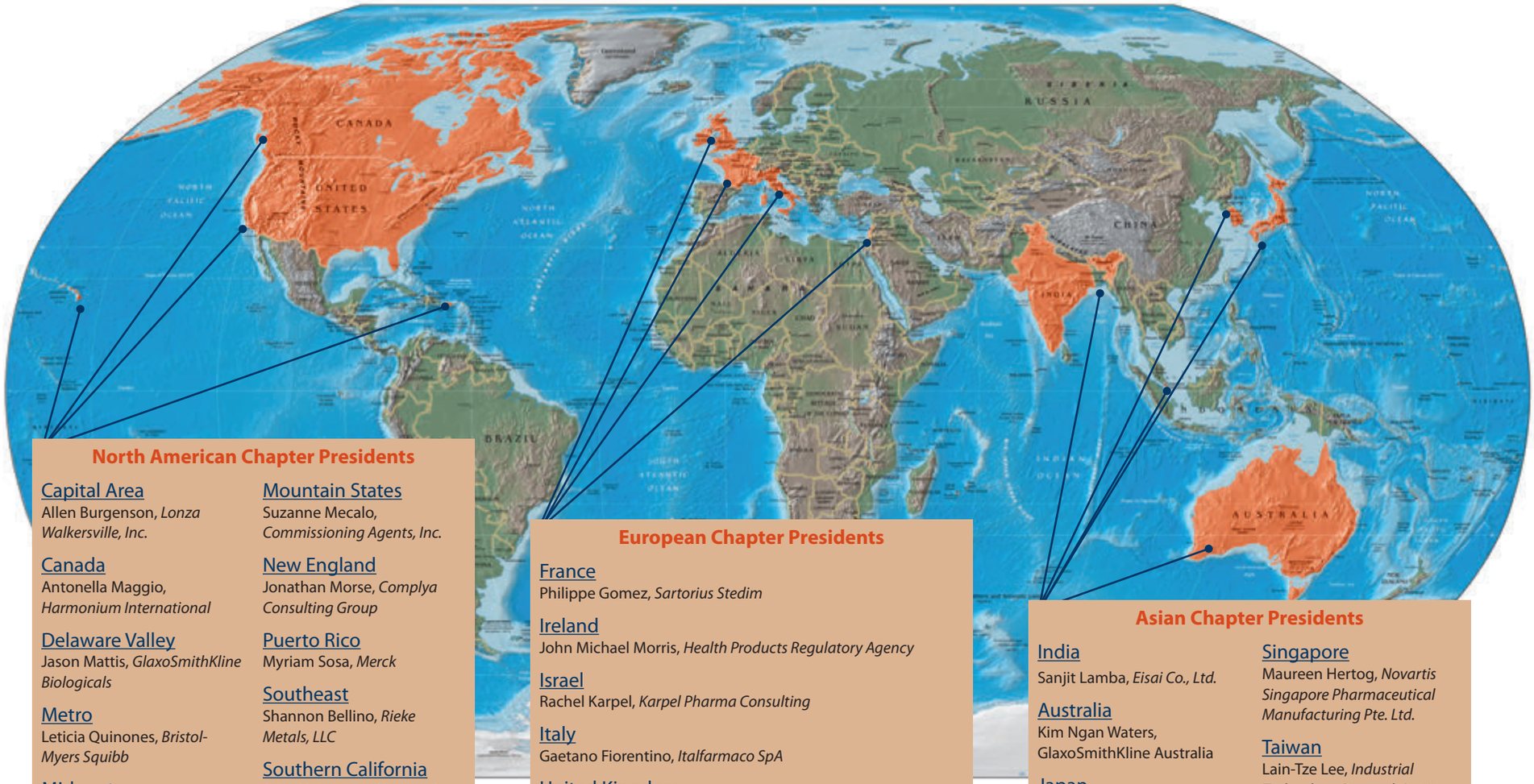
The volunteer opportunities available at PDA are unlike any other. You're offered the opportunity to meet both like-minded and different-minded people within PDA. I have been able to learn and contribute by volunteering.

PDA Chapters



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Volunteer Task Force Member

Jim Polarine

Technology Service Manager
STERIS
Member Since 2011

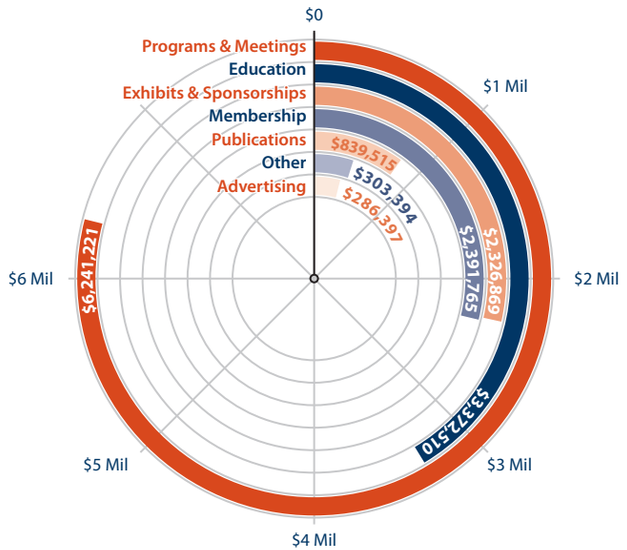
As a PDA member, I benefit from interacting with my peers and colleagues in the industry. I also enjoy reading the *PDA Letter,* the *PDA Journal of Pharmaceutical Science and Technology,* and the latest PDA/DHI technical books.

2015 Annual Report Financial Summary

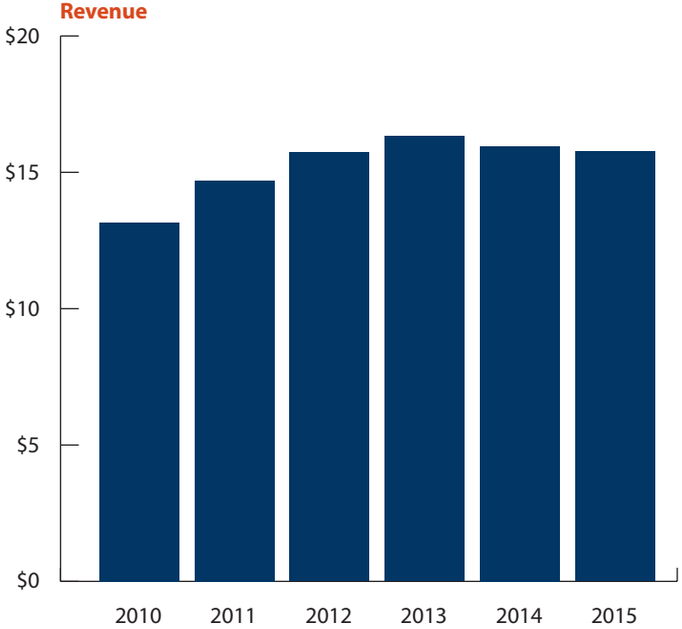
	2015	2014
Total Revenues	$ 15,761,671	$ 15,968,130
Total Expenses[1]	$ 15,855,711	$ 15,355,962
Net Income Surplus (Deficit)	$ (94,040)	$ 612,168
Net Assets at beginng of year	$ 8,363,219	$ 7,655,918
Net Assets at end of year	$ 8,343,006	$ 8,363,219
Net Asset ratio (Net Assets/ Annual Expenses)	53%	54%

[1] Total expense includes the foreign currency translation adjustment of ($174,442) in 2015 and ($207,862) in 2014. This is considered a non-operating expense item.

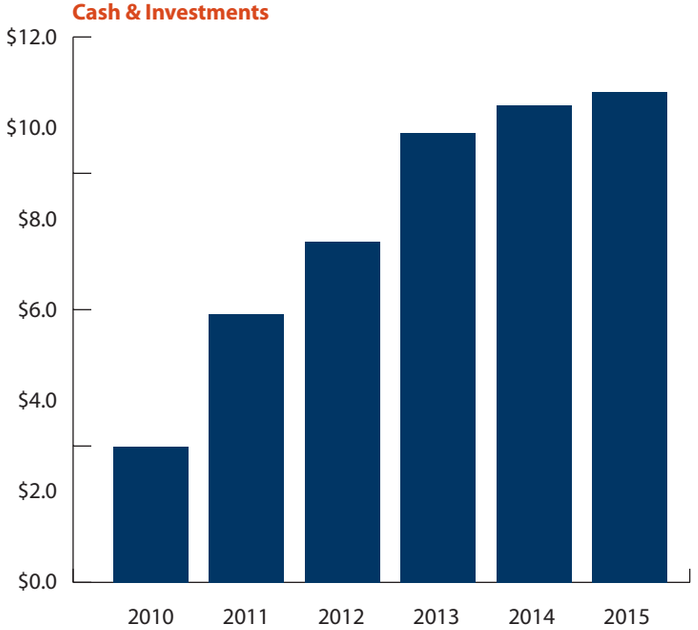
2015 Revenue Sources



Revenue



Cash & Investments



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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.

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