

# PDA: LEADING THE WAY THROUGH A WORLD OF CHANGES



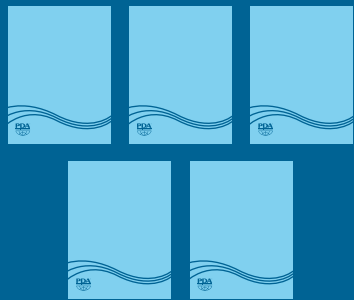
ANNUAL  
REPORT  
2014

# A STRATEGY FOR SUCCESS IN 2014

**1605**  
**ACTIVE**  
**VOLUNTEERS**  
(20% OF MEMBERSHIP)



**5**  
**TECHNICAL**  
**REPORTS**  
**PUBLISHED**

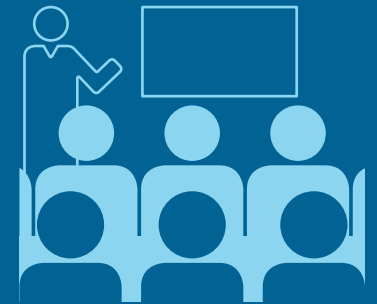


**6671**  
**ATTENDEES**  
**AT**  
**MEETINGS**



**30**  
**PROGRAMS**  
**& MEETINGS**

**61**  
**LECTURE AND**  
**LAB COURSES**



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# PDA LEADING THE WAY THROUGH A WORLD OF CHANGES

The pharmaceutical and biopharmaceutical world is changing very rapidly in many facets, including the types of therapies in development, the delivery systems required, and the manufacturing processes, technologies and controls utilized. PDA's community of over 10,000 members, representing industry and regulatory agencies, play a vital role in developing solutions for their companies and agencies so that they are better equipped to operate in this changing landscape. PDA's members are leading the way through this world of changes.

The more than 1,600 professionals who volunteered on PDA advisory boards, committees, task forces, and chapters actively contributed to finding solutions for the many challenges the industry faced in 2014. Our volunteers worked with regulatory bodies worldwide to confront head on the following three challenges:

- Risk-Based drug shortage management and prevention
- Pharmaceutical quality metrics/quality culture
- Manufacturing science

These three initiatives are playing an important role in ensuring that critical, life-saving medicines are available to patients globally. After years of grappling with a growing list of pharmaceutical products unavailable because of GMP and other regulatory compliance issues and governments around the world pushing hard for solutions, pharmaceutical companies faced the sobering fact that many of their manufacturing operations had not kept pace with modern practices and technologies. Aging facilities and processes are less likely to stand up to regulatory scrutiny, and shutdowns to bring them into compliance or outright closures are, in many cases, resulting in shortages of critical medicines.

The regulators are overwhelmed with an increasing inspection schedule. The U.S. FDA, mandated by the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA), is working with industry to identify key quality metrics that could be shared with the Agency to help it make informed, risk-based decisions as to which plants to inspect.

Recognizing PDA's proven track record of developing solutions in areas lacking regulatory and compendial guidance, regulatory agencies requested that PDA join with other industry associations to help formulate recommendations on quality metrics and formulate a solution for drug shortage mitigation. Task Forces of PDA member experts delivered documents to meet these objectives. Influenced by these efforts, the PDA Board of Directors began work on a Manufacturing Science Program that began to take shape at year's end.

Because of PDA is capable of acting quickly and can *Connect People, Science and Regulation*®, the time is now for pharmaceutical professionals around the world to join and contribute to our ongoing efforts to help companies provide high-quality medicines to patients everywhere.

## HELPING OUR MEMBERS AND INDUSTRY ADAPT TO A CHANGING LANDSCAPE

PDA had a remarkable year in 2014. PDA conducted conferences, meetings, programs, workshops, events, and added new courses for training at the TRI facility, international venues, and in-company training. We published a record number of technical reports, position papers, surveys, points to consider, books, articles and regulatory comments.

While all of these accomplishments are notable, I would like to briefly highlight a few of these to illustrate how PDA is meeting its core purpose of *Connecting People, Science, and Regulation*®.

*Connecting People:* PDA increased its international presence and membership base. PDA added or increased activities of chapters in India and Singapore. This is a reflection of the global nature of today's industry and the needs of that growing international membership base. This expansion helps our members better understand the global business expectations, challenges, and solutions.

*Connecting Science:* PDA focused efforts on helping the industry address some of its most pressing topics. These efforts included the publishing of Technical Reports, such as the *Risk Based Approach to Prevention of Drug Shortages*, the issuance of science based position papers, such as the *Medical Perspective on Visual Inspection*, and reaching out to the industry with efforts such as the *in-company training programs*. In addition, PDA began working on very important projects designed to improve the quality and reliability of health care product manufacturing, including a revision of the *Aseptic Processing Points to Consider* and the start of the *Manufacturing Science Initiative*.

*Connecting Regulation:* PDA continued to be recognized as the leader in the development and dissemination of regulatory knowledge. This leadership affords PDA with the credibility to challenge and influence the "c" in cGMP. It allows PDA and its members to take on a more active position in shaping and improving our industry, rather than merely reporting on trends. The strength of your PDA has always been the independent voice of its membership. This remains your voice – an active voice.

None of these accomplishments can happen without a strong association. And so it should be noted that PDA continued to increase its reserves. These reserves are important, because it allows the PDA the financial stability it needs to provide and to reinvest in services, programs, products and infrastructure required to serve its members and the industry they serve, for many years to come.

Looking forward: In 2014, the PDA Board of Directors appointed a team to revise its five year strategic plan. This is something the Board is tasked to do every five years. What made the 2014 effort notable is the perspective taken by the team. Instead of considering the state of the industry five years out, they tried to envision the industry 10 years out. The objective was to create a visionary plan, which would not only meet the needs of the association from 2015 to 2020, but prepare the association to meet the challenges its members are likely to face in the years that follow.

In closing, I want to encourage you to read the sections of this annual report which detail the accomplishments and plans of the PDA. I want you to consider what you can do to become engaged and participate in this very important association of your peers, colleagues, co-workers, and friends. And most importantly, I want to thank the PDA leadership, its Board of Directors, the staff, the volunteers, the speakers, the committees, the advisory boards, the task force members, the chapters, and the membership for the success of the PDA in 2014 and for a job very well done.



## CHAIR'S MESSAGE

Harold Baseman  
Chair of PDA



# PRESIDENT'S MESSAGE

## REDOUBLING EFFORTS TO CONNECT PEOPLE, SCIENCE AND REGULATION

2014 was a very busy and successful year for PDA. Continuing the execution of our strategic plan, we redoubled our efforts to Connect People, Science and Regulation®. We held more Conferences, workshops, and education programs than ever before, and through these efforts, along with our publications and communication tools, we reached a wider and wider audience.

### PEOPLE

PDA is a membership based organization, and in the past year we launched a new communication tool for our members, PDA Connect<sup>sm</sup> that will improve our members' interactions with each other. Our areas of focus have continued to build on our leadership in sterile manufacturing and biotechnology, and increased efforts on tools for implementing modern quality concepts in manufacturing.

### SCIENCE

Through the efforts of our many dedicated volunteers and staff, we published a record number of documents, including Technical Reports, Surveys and Points to Consider. We continue to expand our education programs, and focus on bringing world class content and instructors to an increasingly international audience.

### REGULATION

We continued robust program of engagement with international health authorities, and held ten meetings in cooperation with one or more health authorities. We continued our collaboration with PIC/S and held our ICH Q7 workshops around the world.

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.



Richard Johnson  
President of PDA



# HARALD STAHL, PHD

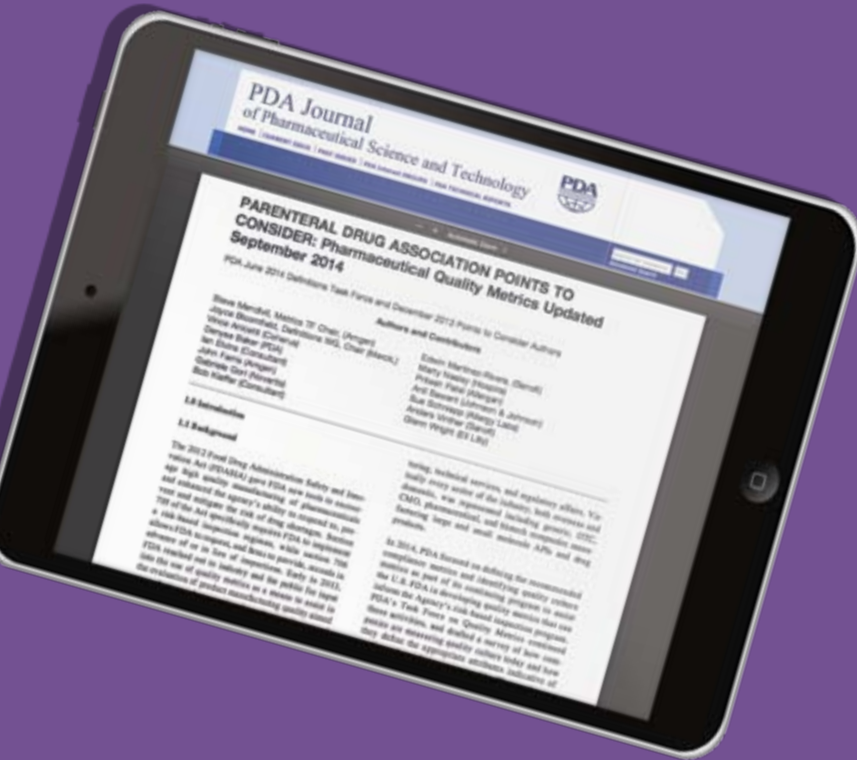
GEA Pharma Systems  
Member Since 2008

Lyophilization Interest Group Leader, PDA Europe

PDA offers access to state-of-the-art information from experts in their field. Being a PDA member also means you get to interact with the smartest and most experienced professionals in the industry. Pharmaceutical science and technology is always evolving; being involved with PDA means you're never out of touch.

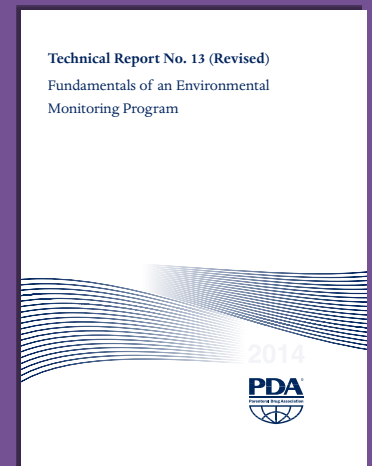
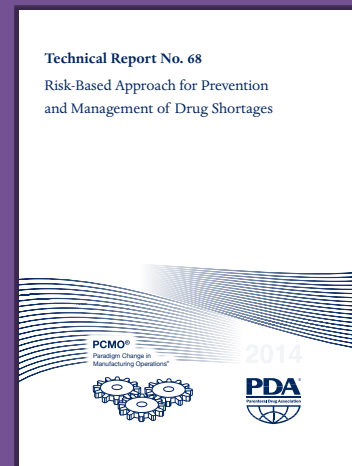
PDA Volunteer  
Spotlight

# TECHNICAL CONTRIBUTIONS



Examples of PDA Leading the Way include helping regulatory agencies like the U.S. FDA usher in a new inspection paradigm that better utilizes resources, places less burden on companies, and focus on risks to patients. PDA's members stepped up to meet the challenge in 2014 by publishing "PDA Points to Consider: Pharmaceutical Quality Metrics" in the September/October *PDA Journal of Pharmaceutical Science and Technology*. This paper defined key manufacturing metrics that companies could share with the Agency to help it monitor quality and make informed, risk-based decisions on when and where to inspect.

The task force also conducted a survey of pharmaceutical professionals at the top 100 pharmaceutical/biopharmaceutical companies to develop recommendations on what attributes constitute a strong quality culture. The team recommended to the U.S. FDA that not only should it take into account the quality metrics, but it should look at a firm's overall quality culture when making decisions to inspect or not. Questions were sent to both company executives and to quality and manufacturing personnel to measure their perceptions of quality culture. At year's end, the task force was busy preparing the final analysis of the survey for publication in 2015.





Preventing market shortages of life-saving injectable products is another serious challenge for which PDA members took responsibility. An expert task force developed risk-based guidance that manufacturers around the world can use, *PDA Technical Report No. 68: Risk-Based Approach for Prevention and Management of Drug Shortages* was published along with a drug shortage website that includes tools for companies. PDA made the unprecedented decision to make TR-68 and the tools open access, in light of the critical nature of the topic.

Members also continued the 68-year PDA tradition of solving the challenges of manufacturing sterile drug products with a variety of technical reports, books and journal articles in 2014. A task force of experts completed a revision to *PDA Technical Report No. 13: Fundamentals of an Environmental Monitoring Program* to keep up with latest in microbiological and particulate control concepts and principles. PDA and its publishing partner DHI released two titles in this area: *Contamination Control in Healthcare Product Manufacturing, Volume 3* and *Clean-room Microbiology*.

Biotechnology is the most rapidly growing area of new therapies and the issue of clearing viruses from cell-based products is one of the top manufacturing concerns. In 2014, the *PDA Journal of Pharmaceutical Science and Technology* contributed to this growing scientific field with the publication of 35 papers covering various aspects of virus detection and clearance methods.

Overall, PDA members and contributors produced 5 new technical reports, 2 PDA Surveys and a new addition to PDA's "Technical Series", Sterilization.

PDA's technical experts also assembled into teams to comment on 8 regulatory guidances issued by the U.S. FDA, Health Canada, and the EU.



# EMMA RAMNARINE

Genentech/Roche  
Member Since 2001

RAQAB  
Task Force Leader

PDA is a volunteer driven organization—you get out of it what you choose to put in.

PDA Volunteer  
Spotlight



# LEADING THROUGH EDUCATION AND INFORMATION SHARING

In order to lead the way, PDA's community of experts needs world-class training and forums where they can congregate to learn, share knowledge and develop solutions.

Advancing the PDA initiatives for Pharmaceutical Quality Metrics, Drug Shortages, and Manufacturing Science requires the interaction of PDA's expert volunteers with the rest of our community in order to gain invaluable feedback, discuss survey results, and solicit additional ideas.

The 2014 PDA Drug Shortage Workshop attracted experts from a variety of companies and the U.S. FDA to discuss solutions to this critical problem. The PDA task force that developed PDA *Technical Report No. 68: Risk-Based Approach for Prevention and Management of Drug Shortages* gained valuable information at this event that helped them complete the technical report by the end of the year.

The 2014 PDA Pharmaceutical Quality Metrics Conference was the perfect forum for PDA's task force to preview results of their 2014 survey and discuss their recently published "PDA Points to Consider: Pharmaceutical Quality Metrics" paper. Representatives of the U.S. FDA, the EMA and other regulatory bodies were on hand to consider PDA's recommendations and contribute to further work in this area.

The 2014 PDA Annual Meeting in San Antonio, Texas and the 2014 PDA/FDA Joint Regulatory Conference in Washington, DC once again stood out as PDA's signature events of the year. These two events drew nearly 1000 attendees each, and covered a wide-range of important scientific and regulatory topics that PDA members must understand in order to be leaders within their organizations. These signature conferences are where PDA member volunteers come together not only to participate in the meeting sessions, but to conduct the business of PDA through advisory board, committee, interest group and board of director meetings.

The exhibition hall at the Annual Meeting and the table top exhibits at the PDA/FDA Joint Regulatory Conference always bring out the best and latest new technologies and services that are an important part of the overall pharmaceutical supply chain. PDA also held its first Press Conference at the 2014 PDA/FDA Joint Regulatory Conference to ensure our friends in the trade press stay abreast of all the important work our members do.

In addition, the 2014 Universe of Pre-Filled Syringes returned to the United States. This event brings together leading-edge experts on the growing field of drug/syringe combination products that help patients take medicines for a variety of indications, including diabetes and cancer. PDA hosts this event annually, alternating locations between the European Union and the United States. The exhibition hall at this event is truly remarkable, and stands alone as one of the busiest and most fruitful of all PDA's events.

PDA Europe sponsored a host of groundbreaking scientific forums in 2014, including Advanced Therapeutic Medicinal Products in Madrid, Spain and the 7<sup>th</sup> Workshop on Monoclonal Antibodies in Basel, Switzerland.

Understanding the value of connecting our expert members with the latest technologies, PDA became a premier sponsor of the industry leading trade show, Interphex. PDA supported Interphex New York and Puerto Rico with a PDA Member's Only Lounge and education sessions.

PDA Education continued preparing the next generation of aseptic processing leaders. The premier course offered at the PDA Training and Research Institute in Bethesda, Md. is its two-week Aseptic Processing Training Program, which was held five times in 2014.

The quality and strength of PDA's Education was recognized by the U.S. Federal Government in 2014, when a number of courses were accepted into the General Services Administration (GSA) Schedule, which makes it easier for federal employees to participate in those courses.



PDA served as a Premier Sponsor for 2014's INTERPHEX show in New York, offering members attending the meeting access to an exclusive members-only lounge.





Environmental Mycology  
Identification Workshop Bethesda,  
Maryland

2014 PDA – PIC/S Q7 Training  
Bethesda, Maryland

Joint Regulators/Industry QbD  
Workshop London, England

Pharmaceutical Microbiology  
Berlin, Germany

Parenteral Packaging Brussels,  
Belgium

2014 Interphex – PDA Premier  
Sponsor New York, NY

Trends in Aseptic Manufacturing  
Bologna, Italy

2014 PDA Annual Meeting San  
Antonio, Texas

PDA Bioburden and Biofilm  
Workshop San Antonio, Texas

Vaccines & Beyond Workshop  
Brussels, Belgium

2014 PDA Knowledge Management  
Workshop – Enabler for ICH Q8-  
Q11, WRM and Continued Process  
Verification Bethesda, Maryland

2014 PDA Packaging Conference  
Washington, D.C.

## 2014 Global Programs & Meetings

2014 PDA/FDA Pharmaceutical  
Supply Chain Conference  
Washington, D.C.

2014 PDA/FDA Virus & TSE Safety  
Conference Bethesda, Maryland

2014 PDA Aseptic Processing  
Sterilization Conference Chicago,  
Illinois

Advanced Therapy Medicinal  
Products Madrid, Spain

PDA Ireland Chapter Meeting on  
Visual Inspection Dublin, Ireland

Parenteral Manufacturing Istanbul,  
Turkey

2014 PDA/FDA Joint Regulatory  
Conference Washington, D.C.

2014 PDA Drug Shortage Workshop  
Washington, D.C.

Pharmaceutical Freeze Drying  
Technology Brussels, Belgium

7<sup>th</sup> Workshop on Monoclonal  
Antibodies Basel, Switzerland

2014 PDA Universe of Prefilled  
Syringes and Injection Devices  
Huntington Beach, California

2014 Drug Delivery Combination  
Products Workshop Huntington  
Beach, California

2014 INTERPHEX Puerto Rico PDA  
Premier Sponsor Puerto Rico

Pharmaceutical Cold & Supply  
Chain Logistics Berlin, Germany

PDA 9<sup>th</sup> Annual Global Conference  
on Pharmaceutical Microbiology  
Bethesda, Maryland

Visual Inspection Forum Berlin,  
Germany

2014 PDA/FDA Pharmaceutical  
Quality System (ICH Q10)  
Workshop on Quality Risk  
Management Baltimore, Maryland

Parenterals Munich, Germany

## 2014 Global Education

Microbial Contamination Control in the Pharmaceutical Industry Berlin, Germany

Container Closure Development Brussels, Belgium

Container Closure Integrity – Regulations, Theory, Test Methods, Application Brussels, Belgium

Interest Group Meeting Pre-filled Syringes Brussels, Belgium

Post-Conference Workshop on Extractables & Leachables Brussels, Belgium

Container Closure Systems Brussels, Belgium

Pre-Conference Workshop on Bacterial and Endotoxin Testing Berlin, Germany

Pre-Conference Workshop on Elastomeric Closures Brussels, Belgium

PDA/PICs API Training Course Johannesburg, South Africa

Modern Biopharmaceutical Manufacturing Lyon, France

Environmental Monitoring Lyon, France

Dedicated or Shared Facilities? A Risk-Based Approach Lyon, France

Interest Group Meeting on Freeze Drying Berlin, Germany

Media Fills Bologna, Italy

Manufacturing and Testing Challenges of ATMPs Madrid, Spain

Environmental Monitoring Madrid, Spain

GMP and Quality Systems for Parenterals Istanbul, Turkey

Cleaning & Disinfection Istanbul, Turkey

Fill & Finish Operations for Parenterals Istanbul, Turkey

Technology Transfer – PDA Technical Report 30 Istanbul, Turkey

Environmental Control Istanbul, Turkey

Pre-conference Workshop: Spray Drying – An Alternative to Freeze Drying? Brussels, Belgium

ICH Q9: Application of a RiskBased Approach to Freeze Drying Process Brussels, Belgium

PDA PICs Training Course on GMP for APIs Brussels, Belgium

Development of a Freeze Drying Process Brussels, Belgium

Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Basel, Switzerland

Pre-Conference Workshop: Innovations in Downscale Processing Technologies Basel, Switzerland

Pre-Conference Workshop: Automated Visual Inspection – A Practical Approach Berlin, Germany

PDA Workshop on Endotoxins and Pyrogens in Parenterals Manufacturing Berlin, Germany

Identification and Classification of Glass Defects – PDA Technical Report 43 Brussels, Belgium

The A to Zs of Biofilm Control, Monitoring, Validation, and Excursion Investigations of Pharmaceutical Water Systems Berlin, Germany

An Introduction to Visual Inspection Berlin, Germany

Rapid Microbiological Methods & An Overview of the New Technical Report 33 Berlin, Germany

2014 Aseptic Processing Training Program Bethesda, Maryland

An Introduction to Visual Inspection, Bethesda, Maryland

Recommended Practices for Manual Aseptic Processes, Bethesda, Maryland

Fundamentals of Aseptic Processing, Bethesda, Maryland

PDA Education@INTERPHEX New York, NY

2014 PDA Annual Meeting Course Series San Antonio, Texas

2014 PDA Biotechnology Week Bethesda, Maryland

2014 PDA Knowledge Management Workshop

2014 PDA Packaging Course Series Washington, D.C.

2014 PDA/FDA Pharmaceutical Supply Chain Course Series Washington, D.C.

2014 PDA/FDA Virus & TSE Safety Course Series Bethesda, Maryland

2014 PDA Aseptic Processing Sterilization Course Series Chicago, Illinois

2014 DoE Week for Process Design and Process Optimization Bethesda, Maryland

Management of Aseptic Processing Bethesda, Maryland

Validation of Moist Heat Sterilization Processes Bethesda, Maryland

Validation of Dry Heat Processes used for Depyrogenation and Sterilization Bethesda, Maryland

2014 PDA Joint Regulatory Conference Course Series Washington, D.C.

Fundamentals of an Environmental Monitoring Program Bethesda, Maryland

Strategies for Reducing Human Error Non-Conformances Bethesda, Maryland

2014 Universe of Prefilled Syringes and Injection Devices Course Series Huntington Beach, California

Single Use Systems for the Manufacturing of Parenteral Products, Bethesda, Maryland

PDA 9<sup>th</sup> Annual Global Conference on Pharmaceutical Microbiology Course Series Bethesda, Maryland

Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities Bethesda, Maryland

Validation of Biotechnology-Related Cleaning Processes Bethesda, Maryland

2014 PDA/FDA Pharmaceutical Quality System (ICH Q10) Workshop on Quality Risk Management, Baltimore, Maryland

Quality Systems for Aseptic Processing Bethesda, Maryland

Container Closure Integrity Course, Lebanon, New Jersey

Lyophilization Week, Bethesda, Maryland

2014 PDA Pharmaceutical Quality Metrics Conference, Washington, D.C.

Risk-Based Qualification of Sterile Drug Product Manufacturing Systems, Bethesda, Maryland

Mycoplasma Berlin, Germany

Mycoplasma Filtration Berlin, Germany

Good Cold Chain Practices Berlin, Germany

An Introduction to Visual Inspection Berlin, Germany

Container Closure Integrity Munich, Germany

Utilization of Statistical Methods for Pharmaceutical Production Manufacturing Munich, Germany

Aseptic Processing Validation Munich, Germany



Trainer Christa Jansen-Otten, West Pharmaceutical Services, offers hands-on-learning at the 2014 Parenteral Manufacturing Conference in Istanbul, Turkey



# IGOR GORSKY

Concordia ValSource  
Member Since 2009

Task Force Member

I had the fantastic opportunity to work on the revision of *Technical Report No. 29 (Revised 2012): Points to Consider for Cleaning Validation* under Destin LeBlanc's leadership and with a great team of professionals from around the globe. That experience allowed me to bolster my cleaning validation expertise, while simultaneously exposing me to the greater reaches of the field around the world.



PDA Volunteer  
Spotlight





# AWARDS

## 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.

**James E. Akers, PhD, Akers Kennedy & Associates**

## Gordon Personeus Award

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

**Carol M. Lampe**

## Frederick J. Carleton Award

Presented as a tribute to past President **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.

**John G. Shabushnig, PhD, Insight Pharma Consulting**

## Packaging Science Award

This award is given in recognition of extraordinary contributions to PDA and the packaging science.

**Edward Smith, PhD, Packaging Science Resources**

## Distinguished Service Award

This award is given in recognition of special acts or contributions that have contributed to the success and strength of PDA.

**David J. Cummings, U.S. FDA**

**Laurie Norwood, U.S. FDA**

**Erik van Asselt, PhD, Merck**

**Brigitte Reutter-Härle, Vetter**

**Nicholas R. DeBello, DeBello & Associates**

**Michael VanDerWerf, Organogenesis**

## Martin VanTrieste Pharmaceutical Science Award

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

**Irving J. Pflug, PhD**

## PDA Europe Service Appreciation Award

This award is presented annually for special acts or contributions that have contributed to the success and strength of PDA Europe.

**Harald Stahl, PhD, GEA Pharma Systems**

## Service Appreciation Award

The Service Appreciation Award is presented annually for special acts or contributions that have contributed to the success of PDA.

**Maik W. Jornitz, G-Con Manuf**

**Arthur Vellutato, Jr., Veltek**

**Barbara Jentges, PhD, PhACT GmbH**

**Brenda Uratani, PhD, U.S. FDA**

**Don E. Elinski, RPh, Lachman**

**Consultant Services**

**Greg Jordan, Box Hill Institute**

**Harold S. Baseman, ValSource**

**Janeen A. Skutnik-Wilkinson, NSF**

**Jeanne Moldenhauer, Excellent**

**Pharma Consulting**

**Karen S. Ginsbury, PCI**

**Lothar Hartmann, PhD**

**Rina Yamin, Rina Yamin Pharma-**

**ceutical Consulting**

**Robert Sitrin, PhD, SitrinSolutions**

**Russell E. Madsen, The Williamsburg**

**Group**

**Sabine Scheitlin**

**Saeed Tafreshi**

**Steven Mendivil, Amgen**

**Susan Schniepp, Allergy Laboratories**

## James P. Agalloco Award

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

**Joseph J. Lasich**

**Rainer Newman**

**Brent Watkins, Veltek**

## Michael S. Korczynski Award

An award established in recognition of contributions made toward the development of PDA's international activities.

**Tor G. Gråberg, Medical Products**

**Agency Sweden**

**Yukio Hiyama, PhD, National Insti-**

**tute of Health Sciences, Japan**

## 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.

**Bob Collier, PDA**

**Nadine Gold, PDA**

# PDA BOARD OF DIRECTORS



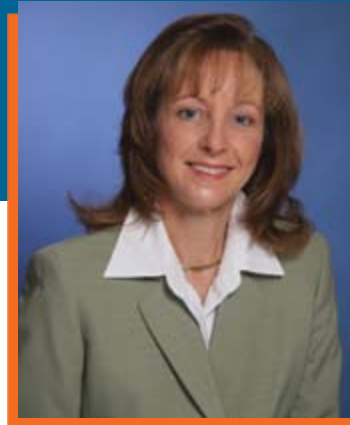
**Chair**  
Hal Baseman, *ValSource*



**Chair-Elect**  
Martin VanTrieste, *Amgen*



**Secretary**  
Michael Sadowski, *Baxter Healthcare*



**Treasurer**  
Rebecca Devine, PhD,  
*Regulatory Consultant*



**Immediate Past Chair**  
Anders Vinther, *Genentech*



Joyce Bloomfield  
*Merck*



Ursula Busse, PhD  
*Novartis*



Jette Christensen  
*Novo Nordisk*



Veronique Davoust  
*Pfizer*



Ian Elvins  
*Elvins & Associates*



John Finkbohner, PhD  
*MedImmune*



Gabriele Gori  
*Novartis*



Stephan Rönninger,  
PhD, *Amgen*



Junko Sasaki  
*Dainippon Sumitomo  
Pharma*



Lisa Skeens, PhD  
*Hospira*



Christopher Smalley, PhD  
*Merck*



Glenn Wright  
*Eli Lilly and Company*



# KIM WATERS

GlaxoSmithKline Australia  
Member Since 2008

Australia Chapter President

PDA offers many opportunities, but the first step is to say, "I want to make a difference." By sharing your knowledge and experience, you are helping our industry.



PDA Volunteer  
Spotlight



# ADVISORY BOARDS & COMMITTEES

## SAB

Raphael Bar, PhD, *BR Consulting*  
 Hal Baseman, *Valsource, LLC*  
 Joyce Bloomfield, *Merck*  
 Scott Bozzone, PhD, *Pfizer*  
 Jette Christensen, *Novo Nordisk*  
 Jean-Luc Clavelin, Dr.-Ing, *Consultant*  
 Walter De Matteo, *Institut Biochimique SA (IBSA)*  
 Phil DeSantis, *DeSantis Consulting Associates*  
 Kris Evans, *Amgen*  
 Tor Graberg, *Medical Products Agency-Sweden*  
 William Harvey, *U.S. FDA*  
 Norbert Hentschel, *Boehringer-Ingelheim*  
 Maik Jornitz, *G-Con LLC*  
 Joachim Leube, *Johnson & Johnson*  
 Mike Long, Dr. LP, *ConcordiaValsource*  
 Grace McNally, *U.S. FDA*  
 Jeanne Moldenhauer, *Excellent Pharma Consulting*  
 John Shabushnig, PhD, *Insight Pharma Consulting, LLC*  
 Christopher Smalley, *Merck*  
 Marsha Stabler Hardiman, *ConcordiaValsource*  
 Edward Tidswell, PhD, *Baxter*  
 Glenn Wright, *Eli Lilly and Company*

## RAQAB

Susan Schniepp, *Allergy Laboratories (Chair)*  
 Jeff Broadfoot, *Emergent BioSolutions Inc (Vice-Chair)*  
 Ruhi Ahmed, Ph.D, *RAC, Ultragenix Pharmaceutical Inc.*  
 Robert Counce, *Hospira*  
 Claudio Correa, Ph.D, *Roche*  
 Veronique Davoust, *Pfizer*  
 John Finkbohner, *AstraZeneca*  
 Mirko Gabriele, *Patheon Italia SpA*  
 Karen Ginsbury, *PCI Pharmaceutical Consulting Israel, Ltd.*  
 Jeffrey Hartman, *Merck*  
 Hongyang Li, *Novartis*  
 Elizabeth Meyers, *Amgen*  
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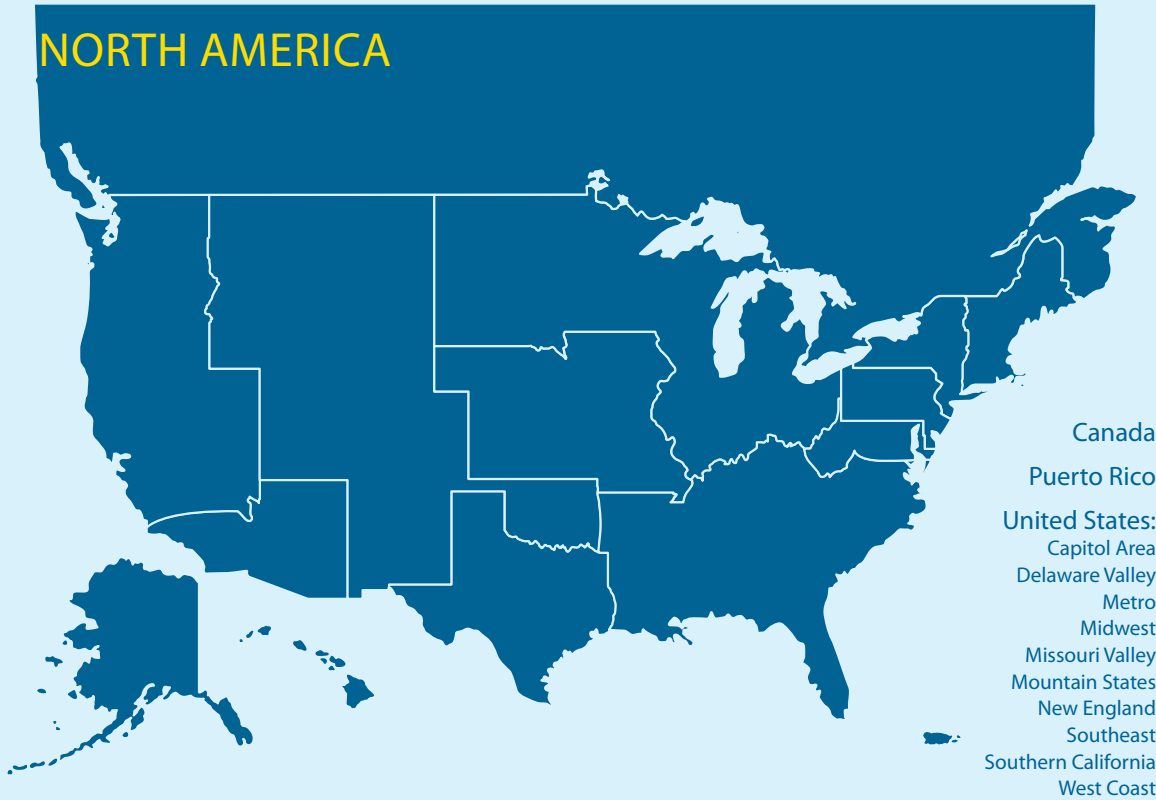
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Leon Lewis >  
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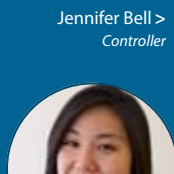
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Operations



< Andrea Viera  
Assistant Manager, Programs  
& Speaker Management



< Tanya Allen  
Coordinator, Program &  
Speaker Management



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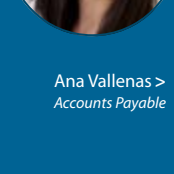
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Coordinator, Member  
Relations



< Christine Searles  
Executive Assistant



< Rebecca Stauffer  
Writer/Editor



Ana Vallenias >  
Accounts Payable



Frank Wang >  
IT Specialist



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Katja Yount, Publication Design Specialist

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President PDA Europe



< Falk Klar, PhD  
Senior Director Training &  
Education



< Nadine Gold  
Manager Marketing

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Members, Chapters  
Iryna Funke, Registration Coordinator  
Frederike Mohme, Coordinator Marketing



# PDA VISION AND MISSION

## PDA Vision

To be the foremost global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industry.

## PDA Mission

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership.

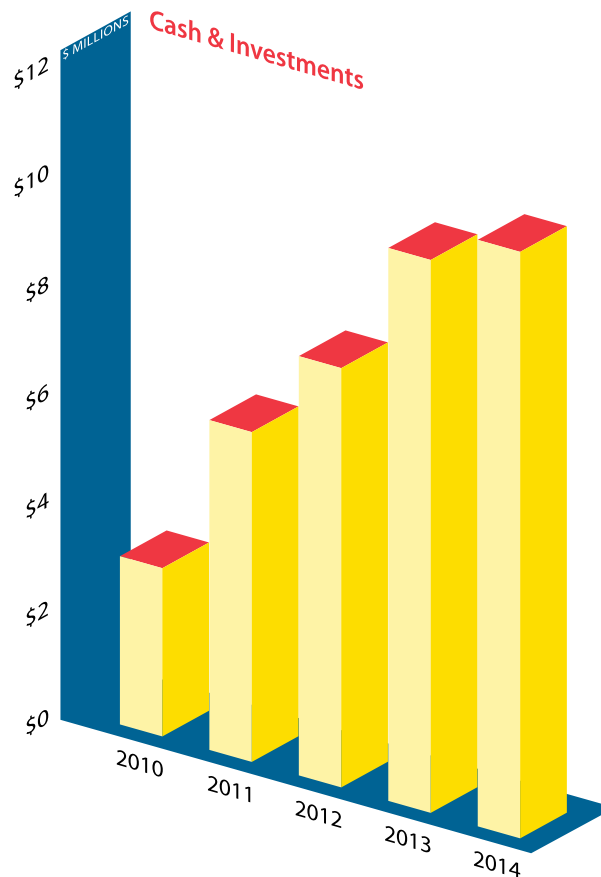
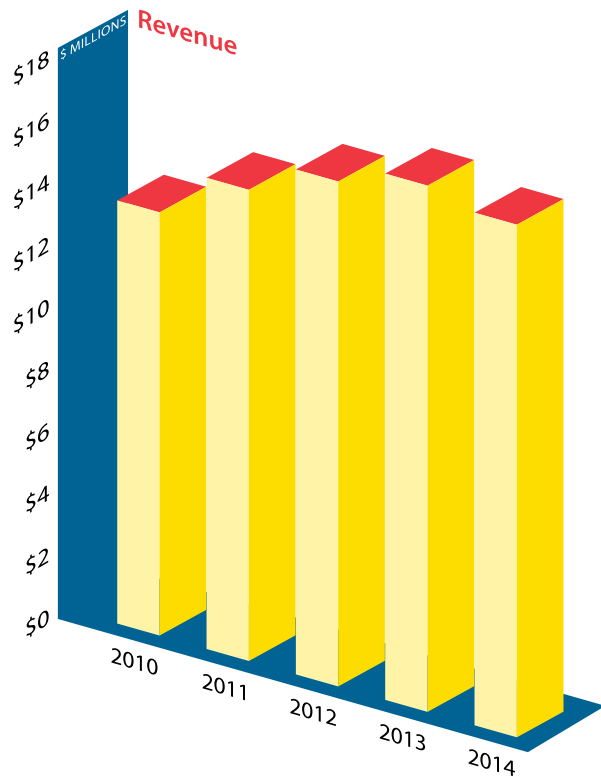
## PDA Mission Elements

- Promote advances in pharmaceutical and biopharmaceutical science
- Provide global forums for the scientific community, regulators and industry professionals
- Facilitate development, testing and qualification of new technologies
- Facilitate training and education on global level
- Deliver unique hands-on training through PDA's Training and Research Institute
- Foster Career-long Learning and professional development
- Enable scientific information sharing with industry peers
- Continue to be a leading and influential contributor of information for the global regulatory and harmonization processes.

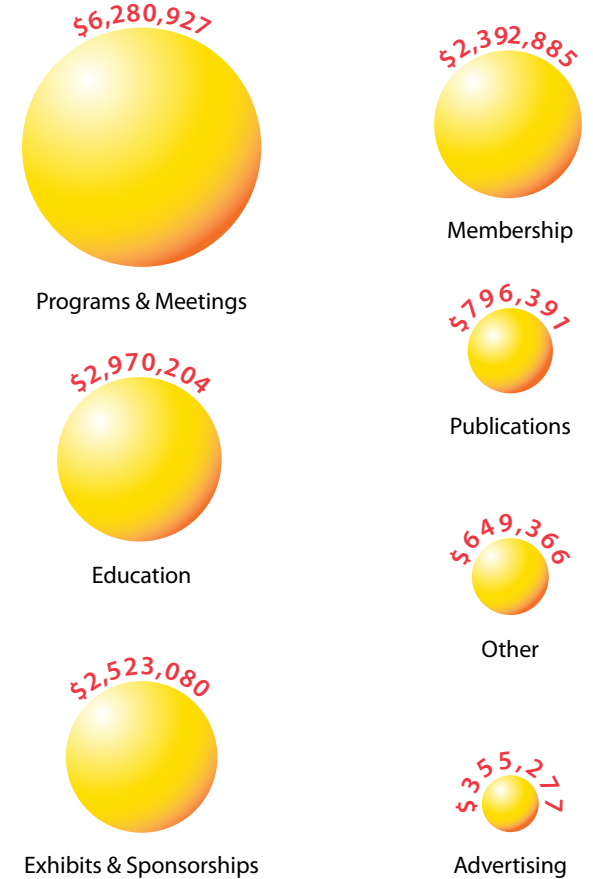
# 2014 ANNUAL REPORT FINANCIAL SUMMARY

	2014	2013
Total Revenues	\$ 15,968,130	\$ 16,319,184
Total Expenses <sup>1</sup>	\$ 15,355,962	\$ 14,292,001
Net Income Surplus (Deficit)	\$ 612,168	\$ 2,027,183
Net Assets at beginning of year	\$ 7,655,918	\$ 5,592,628
Net Assets at end of year	\$ 8,363,219	\$ 7,655,918
Net Asset ratio (Net Assets/ Annual Expenses)	54%	54%

<sup>1</sup> Total expense includes the foreign currency translation adjustment of (\$207,862) in 2014 and \$8,540 in 2013. This is considered a non-operating expense item.



## 2014 Revenue Sources



# STEVE MENDIVIL

Amgen  
Member Since 1991

RAQAB  
Board of Directors  
Executive Committee  
Pharma Quality Metrics Task Force

I remember attending my first PDA conference in San Francisco being very confused, and not understanding many of the presentations. I kept attending conferences, reading, and eventually developed a small network, which lead to a job at Genentech. After moving to Amgen, I became more involved in PDA's RAQAB and eventually was nominated to be co-chair under Zena Kaufman.



PDA Volunteer  
Spotlight



