PDA: LEADING THE WAY THROUGH A WORLD OF CHANGES

PDA® Parenteral Drug Association
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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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
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™ 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
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.
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 Cleanroom 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.
PDA is a volunteer driven organization—you get out of it what you choose to put in.
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 7th 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.
2014 Global Programs & Meetings

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

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


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

7th 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 9th 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
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 Global Education

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
PDA Annual Meeting Course Series San Antonio, Texas
PDA Biotechnology Week Bethesda, Maryland
PDA Knowledge Management Workshop
PDA Packaging Course Series Washington, D.C.
PDA/FDA Pharmaceutical Supply Chain Course Series Washington, D.C.
PDA/FDA Virus & TSE Safety Course Series Bethesda, Maryland
PDA Aseptic Processing Sterilization Course Series Chicago, Illinois
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 Aseptic Processing Validation Munich, Germany
Quality Systems for Aseptic Processing Bethesda, Maryland
Container Closure Integrity Course, Lebanon, New Jersey
Lyophilization Week, Bethesda, Maryland
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

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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.
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, Organo-Genesis

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 Urateani, PhD, U.S. FDA
Don E. Elinski, RPh, Lachman Consultant Services
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Harold S. Baseman, ValSource
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Jeanne Moldenhauer, Excellent Pharma Consulting
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Russell E. Madsen, The Williamsburg Group
Sabine Scheitlin
Saeed Tafreshi
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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. Gräber, Medical Products Agency Sweden
Yukio Hiyama, PhD, National Institute 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.

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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.
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- Sherry Tamura, Biogen Idec
- Elisa Yee, GlaxoSmithKline

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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

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Revenues</td>
<td>$15,968,130</td>
<td>$16,319,184</td>
</tr>
<tr>
<td>Total Expenses¹</td>
<td>$15,355,962</td>
<td>$14,292,001</td>
</tr>
<tr>
<td>Net Income Surplus (Deficit)</td>
<td>$612,168</td>
<td>$2,027,183</td>
</tr>
<tr>
<td>Net Assets at beginning of year</td>
<td>$7,655,918</td>
<td>$5,592,628</td>
</tr>
<tr>
<td>Net Assets at end of year</td>
<td>$8,363,219</td>
<td>$7,655,918</td>
</tr>
<tr>
<td>Net Asset ratio (Net Assets/Annual Expenses)</td>
<td>54%</td>
<td>54%</td>
</tr>
</tbody>
</table>

¹ 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.
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.