PDA®
Parenteral Drug Association

Connecting People, Science and Regulation®

2013 ANNUAL REPORT

www.pda.org

About PDA

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The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its more than 9,500 members worldwide.

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.

In addition to sponsoring educational conferences and training courses, PDA publishes the *PDA Journal of Pharmaceutical Science and Technology* and the *PDA Letter*, which focus on current industry and regulatory news. In keeping with its nearly 70-year history of promoting the growth of pharmaceutical science and technology, PDA introduced the PDA Training and Research Institute (PDA TRI) in May 1997.

History

PDA was founded in 1946 as the Parenteral Drug Association by a small group of pharmaceutical manufacturers who recognized the need for an organization to disseminate technical information within the industry. Today, coordinated through its headquarters and its Training & Research Institute in Bethesda, Maryland, PDA volunteers worldwide carry out its mission of promoting the exchange of rapidly evolving information on the latest technology and regulations concerning high-quality pharmaceutical production.

PDA is the recognized authoritative voice and leading technical organization in the field of parenteral science and technology. Through the development of Technical Reports and responses to regulatory initiatives, PDA and its members influence the future course of pharmaceutical products technology.

With almost 10,000 individual members worldwide, PDA draws its strength from the technical expertise of its membership. Conferences, meetings and courses bring together pharmaceutical manufacturers, suppliers, users, academics and regulatory officials to discuss issues of mutual interest. These exchanges of technical knowledge and expertise assist the advancement of pharmaceutical science and technology in the interest of public health.

Message from the PDA Board of Directors Chair

PDA 2013: Expanding from a position of strength.

Anders Vinther, Chair, *PDA*

When I think back on 2013, it was a great year for PDA and our members. Our strategy, which we have now followed for a few years, has proven to be very successful. We are focused on the core activities for which we are known within the areas of science, technology, regulatory and quality. Our focus has once again allowed us to serve our membership, with whom we continue to develop our industry, and ultimately serve patients. We published a record number of technical publications, had fantastic meetings that again moved topics forward as the industry-leading organization, and we facilitated the ability to connect as individuals.

The PDA staff, led by our PDA President Richard Johnson, did a tremendous job in putting meetings of very high quality together, helped develop technical publications, conduct training courses, and submit a number of comments to Health Authorities. We have a stable and very well-functioning organization with offices in both Bethesda, MD, USA, and in Berlin, Germany. Thank you! Also a big thank you to all of you who have been active volunteers in 2013 on committees, task forces, as speakers, advisory board members, etc. Almost 1,000 members are active in PDA or about 10 percent of the membership. That is an amazing number that shows how relevant our topics are. I also want to thank the many people from Health Authorities who take time out to attend PDA activities to both advance the industry and help lead the training of the industry in key topics.

In my 10 years on the PDA Board of Directors, our organization has never been stronger than it is now, and our infrastructure to serve the membership is very robust. This is important as we continue with our core activities and gradually expand into what we believe are new topics of interest to our membership and the industry as a whole. We set our standards high for any type of activity we do and therefore each and every one of them takes concentrated effort and time. We believe that is the way it should be as only in that way will our activities truly advance our industry, and be used as the benchmark for all. For any topic we cover, we have a tradition of taking a technical and sound science approach and to involve as many members as possible – building on our collective experience and ideas. And then, afterward, we make the output readily available to our members. This is one of the things that makes PDA unique – a tradition of which we are proud. A great example of this was the Metrics conference co-led by Russ Wesdyk, FDA, and Steven Mendivil, Amgen. The metrics topic is relatively new for our industry to discuss together. We had 300+ people attend the meeting, which by many since has been termed 'a defining conference' and together we developed PDA's position on this topic. Another example of our active meetings was the Annual Pharmaceutical Microbiology conference, where hot topics were actively discussed. In 2013 there were so many opportunities to interact and we will continue with this in 2014.

In 2013 there were also many opportunities to interact locally by attending PDA Chapter meetings – and we continued also in 2013 to expand our network of Chapters with the establishment of the Singapore Chapter.

I want to thank our outgoing Board members Sue Schniepp, Maik Jornitz, and Steve Mendivil for their contributions to our organization and welcome Veronique Davoust and Martin Van Trieste to the Board. I also want to welcome Hal Baseman as the new Chair.

The past six years have been an absolute pleasure for me to first being Treasurer, then Chair Elect and then the past two years Chairman of the PDA Board of Directors – an experience for which I am so thankful. PDA has been an important part of my life for more than 20 years now, and it will continue to be so because of the many wonderful people and because we all know that PDA is excellent at connecting people, science and regulation to advance our industry.

In 2014 PDA will continue many of its activities and add a few more as it expands from a position of strength. We will continue with the signature meetings as mentioned by Richard Johnson in his message, and we will expand in the areas of Drug Shortage, Metrics, Culture, and the life cycle of facilities and equipment amongst other things.

Thanks again for a great 2013.

Message from the PDA President

Richard M. Johnson, President, *PDA*

2013 ended up being the most successful year in PDA's history. Our conferences and workshops enjoyed higher attendance, we added more members and new chapters, and PDA completed and published a record number of publications. As important, the quality of our activities and the response from our members, attendees and readers has been very high.

In 2014 we will continue this momentum across all of our activities, maintaining our focus on our strategic plan initiatives Connecting People, Science and Regulation. We know that the world, and the pharmaceutical/biopharmaceutical industry, is changing. PDA is adapting along with these changes, and focusing our combined efforts to help lead the way to continuous improvement.

We will continue to improve our member benefits, with new tools for communication and collaboration among members; increase outreach in emerging markets; and enhance the volunteer experience.

PDA will continue to "Connect People, Science & Regulation" through our conferences and workshops worldwide, including:

- 68th Annual Meeting in San Antonio, TX in April
- Prefilled Syringe Conference in Huntington, CA in November
- Key Regulatory Conferences, including the 24th PDA/FDA Joint Regulatory Conference in September; Workshops and Conferences with US FDA, PIC/S and other Health Authorities on subjects including QbD, Supply Chain and Drug Shortage Prevention.
- PDA began as Premier Sponsor for Interphex in NYC and PR
- Other large and small events in US, Europe and Asia.

We will be expanding our training to industry and regulators worldwide, building on our prominence in Aseptic Processing and our growing portfolio in Quality Systems. We will continue to maintain the highest standards of content and educational delivery in all of these programs.

We will continue expanding our portfolio of Technical Reports that are leading the way to practical science-based implementation of technologies and quality systems, including new topics like Bioburden & Biofilms and Comparison of Global Sterile GMP Comparison. We will continue to make these invaluable resources available to members as a member benefit.

PDA has been, and will continue to be a very busy association. Our strength is in our members/volunteers. The PDA staff is committed to maintaining the high level of service that you deserve. I hope to see you soon.

2013 PDA Officers and Board of Directors

Officers

CHAIR
Anders Vinther, PhD
Genentech

CHAIR-ELECT
Harold Baseman
ValSource

SECRETARY
Steven Mendivil
Amgen

TREASURER
Rebecca Devine, PhD
Regulatory Consultant

IMMEDIATE PAST CHAIR
Maik Jornitz
G-Con

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MedImmune

Gabriele Gori
Novartis Vaccines and Diagnostics

Stephan Rönninger
Amgen

Michael Sadowski
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Sue Schniepp
Allergy Laboratories, Inc.

Lisa Skeens
Hospira, Inc.

Christopher Smalley, PhD
Merck & Co.

Glenn Wright
Eli Lilly

Scientific and Regulatory Affairs

The Scientific and Regulatory Affairs Department (SRA) manages all of PDA's scientific, quality and regulatory activities. These activities are driven by the collective efforts of Advisory Boards, Interest Groups, Task Forces, and Technical Report Teams. Each working group is made up of member volunteers who collectively review current trends and develop deliverables to address industry challenges. Work products include strategic and tactical plans, concepts for PDA conferences, meetings and workshops, PDA Training and Research Institute (PDA TRI) courses, industry surveys, position papers, comments to regulatory guidance documents and Technical Reports. Consensus documents, such as Technical Reports, are developed by Advisory Board-approved teams and provide industry with recommendations and best practices on many pharmaceutical and biopharmaceutical topics, where little or no guidance exists. The SRA Department also supports PDA members and the pharmaceutical and biopharmaceutical industries by reviewing and commenting on quality and regulatory guidance documents to assure that they are based on sound scientific principles.

The Scientific and Regulatory Affairs team faced some transition in beginning of the year, with the retirement of Jim Lyda in 2012 and the end of Vincent Anicetti's fellowship in January 2013. The SRA Department closed the year with four full-time staff and one part-time staff: **Richard Levy**, PhD, Senior Vice President of Scientific and Regulatory Affairs, **Joshua Eaton**, Senior Project Manager, **Janie Miller**, Senior Project Manager, coordinator **Morgan Holland**, and **Denyse Baker**, Senior Advisor, a new part-time staff member.

In 2013, the Scientific and Regulatory Affairs staff focused primarily on the development of technical documents for our membership. The major deliverables included:

- 17 PDA Regulatory Comments
- 10 Technical Reports
- 9 PDA TRI courses
- 4 PDA Surveys
- 1 Points to Consider document

The project managers and publications staff dedicated a majority of their time working with PDA members to develop and deliver a record of 10 PDA Technical Reports by the end of 2013. The Department, along with members from related Interest Groups, Task Forces, and Advisory Boards also contributed their expertise and guidance in the development of agendas for PDA Conferences and Workshops.

Project Managers continued their focus on the development of PDA-owned course materials based on the newly published Technical Reports. The results were delivered in the form of nine new PDA-owned TRI courses.

The four surveys in 2013 which PDA sponsored, developed, and conducted include:

- 2011-2012 PDA Glass Quality Survey – This survey was published in 2013.
- 2013 PDA Glass Quality Survey – This survey was developed and conducted in 2013; results were presented at the PDA Glass Conference in May of 2013.
- 2013 PDA (RABS) Survey – This survey was developed and conducted in 2013; Gerry Morris presented some of the results at the PDA Aseptic Conference in June of 2013.
- 2013 PDA Objectionable Microorganisms Survey – This survey was developed and conducted in 2013; Anil Sawant presented results at the PDA Microbiology Conference.

The Scientific and Regulatory Affairs staff is dedicated to continually enhancing and streamlining our internal processes, as we move forward, based on the feedback of our members and volunteers. With that in mind, in 2013, one departmental objective was to update the governing documents for the Scientific and Regulatory Affairs Department. SOPs and an Advisory Board handbook were updated and became effective in 2014.

Richard Levy, PhD
Senior Vice President

Vincent Anicetti
PDA Fellow in North America

Denyse D. Baker
Senior Advisor

Joshua Eaton
Senior Project Manager

Morgan Holland
Coordinator

Janvi (Janie) Miller
Senior Project Manager

Scientific and Regulatory Affairs

SCIENCE

The PDA Advisory Boards establish strategic direction and provide oversight for PDA's biopharmaceutical, scientific and regulatory activities through the development of guidelines, technical reports, technical bulletins and recommendations of other activities such as conferences or training courses. PDA Advisory Boards partner to interact with regulatory authorities by participating in the development of consensus responses to regulatory drafts, final guidances and directives.

Biotechnology Advisory Board

The BioAB has always been proactive in the identification of pharmaceutical and validation issues affecting biotech products, focusing on those scientific and technical areas in biotechnology that continue to evolve, develop, and affect the industry.

The BioAB managed the progress of PDA Task Forces, including Analytical Methods Development, Bioburden and Biofilm Management, Reprocessing of Biopharmaceuticals, two Cell Substrate-related task forces, Single-Use-Systems, Vaccines, and a continuing task force focused on Mycoplasma that completed a scientific article that was submitted to the *PDA Journal*.

The Biotechnology Advisory Board balloted one technical report and commented on two EMA Draft Guidances involving biological medicinal products (does not include re-ballots):

- BioAB Ballot No. 50: TR 33 (Revision) – Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods
- BioAB Ballot No. 52: *EMA Draft Guidance on the use of porcine trypsin used in the manufacture of human biological medicinal products*
- BioAB Ballot No. 54: *EMA Guideline on Similar Biological Medicinal Products*

Ballots related to the EMA draft guidances underscore the growing importance and influence of Biosimilars and drug development in the pharmaceutical arena. Significant advances have been made during recent years and the field is now starting to come of age. PDA contributed to make the adoption of these draft guidances more comprehensive and applicable to the manufacturers' operations.

Scientific Advisory Board

The Science Advisory Board (SAB) is composed of a diverse group of experts, drawn from industry, regulatory agencies and academia, who provide guidance and set strategic direction for PDA on technical topics associated with pharmaceutical manufacturing and quality. The SAB guides and supports the development of Technical Reports, Points for Consideration documents, and *PDA Journal* and *PDA Letter* articles published by the Association. It further supports the creation and ongoing activities of a range of Interest Groups where members review, discuss and advance industry understanding of numerous technical and quality topics. It contributes to PDA's educational mission through support of the Training and Research Institute (TRI), assisting with the development of curricula and the identification of instructors. The SAB works closely with its sister Advisory Boards (e.g., RAQAB and BioAB) on matters that benefit from the overlapping expertise of these groups, such as when providing a response to proposed regulations and guidance.

In 2013, the SAB approved the following eight ballots (does not include reballot):

- SAB Ballot No. 206: QRM_R02_TR54-4 Annex 3: Case Studies in the Manufacturing of Biotechnological Bulk Drug Substances
- SAB Ballot No. 205: Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities
- SAB Ballot No. 204: Quality Requirements for Extemporaneous Preparation of Clinical Trial Materials
- SAB Ballot No. 203: TR 33 (Revision) – Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods
- SAB Ballot No. 201: TR43 (Revision)
- SAB Ballot No. 200: QRM_R04_TR54-3 Annex 2: Case Studies in the Manufacturing of Pharmaceutical Drug Products
- SAB Ballot No. 198: Recommended Practices for Manual Aseptic Processes

Biotechnology Advisory Board (BioAB)

Chair
E.J. Brandreth, *Althea Technologies*

Co-Chair
Barbara J. Potts, PhD, *Potts and Nelson Consultants, LLC*

Members

Vincent R. Anicetti, *Keck Institute*
Jeffrey C. Baker, PhD, *US FDA, CDER*
Michael R. DeFelippis, PhD, *Eli Lilly and Company*
Rebecca A. Devine, PhD, *Regulatory Consultant*
Earl S. Dye, PhD, *Genentech, Inc.*
Frank Hallinan, PhD, *Pfizer*
Kathryn E. King, PhD, *US FDA, CDER*
Robert Sitrin, PhD, *Merck & Co., Inc.*
Rodney E. Thompson, PhD, *BioPharm Process Associates*
Michael VanDerWerf, *Shire Pharmaceuticals (RAQAB Liaison)*
Michael E. Wiebe, PhD, *Quantum Consulting, LLC*
Hannelore Willkommen, PhD, *RBS Consulting*
Wendy Zwolenski-Lambert, *Abbott Laboratories*

PDA Staff Liasons
Joshua Eaton, MS, Scientific and Regulatory Affairs, *PDA*

Scientific and Regulatory Affairs

Scientific Advisory Board Members

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John Shabushnig, *Insight Pharma Consulting LLC*

Co-Chair
Harold S. Baseman, *ValSource, LLC*

Members
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Joyce E. Bloomfield, *Merck Sharp & Dohme Corporation*

Jette Christensen, *Novo Nordisk A/S*

Jean-Luc Clavelin, *Lilly France S.A.S.*

Walter De Matteo, *Institut Biochemique SA (IBSA)*

Phil DeSantis, *DeSantis Consulting Associates*

Jens Eilertsen

Don E. Elinski, RPh, *Lachman Consultant Services, Inc.*

Kristen D. Evans, *Amgen, Inc.*

Tor Gråberg, *Medical Products Agency*

Klaus Haberer, PhD, *Compliance Advice and Services in Microbiology, GmbH*

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

Joachim Leube, PhD, *Crucell Holland B.V.*

Michael A. Long, PhD, *Concordia Valsource*

Russell E. Madsen, *The Williamsburg Group, LLC*

Grace E. McNally, *US FDA, CDER*

Jeanne E. Moldenhauer, *Excellent Pharma Consulting*

Ken H. Muhvich, PhD, *Micro-Reliance, LLC*

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

Christopher J. Smalley, PhD, *Merck & Co., Inc.*

Brenda W. Uratani, PhD, *US FDA, CDER*

Glenn E. Wright, *Eli Lilly and Company*

PDA Staff Liasons
Richard Levy, PhD, Scientific and Regulatory Affairs, *PDA*

Morgan Holland, Coordinator

The Science Advisory Board also balloted the following candidates to be considered for the SAB and one candidate to Co-Chair the Process Validation Interest Group:

- SAB Ballot No. 208: SAB candidate Dr. Sylvia Pesch
- SAB Ballot No. 207: SAB candidate Scott Bozzone
- SAB Ballot No. 202: Process Validation Interest Group Co-Chair Vijay Chiruvolu

In 2013, the SAB continued to manage a large portfolio of Task Forces and Technical Report Teams with revisions of existing PDA Technical Reports and emerging projects from the PDA portfolio. Several Technical Reports that are managed by the SAB reached final draft stage and were published in 2013, including three revisions:

- TR 3 – Dry Heat Sterilization
- TR-43 Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing
- TR33 – Validation and Implementation of New Microbial Testing Methods

Also published in 2013:

- TR 60 – Process Validation
- TR 61 – Steam-in Place
- TR 62 – Recommended Practices for Manual Aseptic Processes
- TR 64 – Active Temperature Controlled Systems: Qualification Guidance.

Looking forward, Technical Reports such as TR13 (revision) Fundamentals of an Environmental Monitoring Program, Technical Transfer, Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities, Objectionable Microorganisms, Pharmaceutical Package Integrity Testing, and Prefilled Syringes, are expected to come to a close in 2014.

Regulatory Affairs and Quality Advisory Board

The mission of the RAQAB is to serve the PDA membership by influencing scientific based regulations and providing interpretation of quality and regulatory issues affecting development, manufacturing, and control of health care products. RAQAB members are a significant source for identifying global regulatory issues of interest to PDA members. The RAQAB took initiative to provide PDA comments on many global draft and new guidance documents in 2013.

The year 2013 was also one of transition for RAQAB staff support; Janie Miller, PDA Senior Project Manager, joined RAQAB in 2012 assuming responsibility in regulatory surveillance and oversight of the regulatory commenting process to keep in alignment with PDA's mission. In early 2013, Denyse Baker took on those primary liaison responsibilities as well as supporting RAQAB goals and objectives.

The regulated environment underwent a great deal of change in 2013 with the EMA revising several chapters of the European GMPs and the FDA implementing provisions of FDASIA, including the exploration of the collection of metrics on pharmaceutical quality. RAQAB was extremely active in providing regulatory comments in 2013, submitting the following official PDA comments to respective regulatory authorities. Several of these comment submissions led directly to additional interactions with FDA and EMA:

- RAQAB Ballot No. 136: EMA Guideline on Similar Biological Medicinal Products
- RAQAB Ballot No. 134: FDA Proposed Rule Administrative Detention of Drugs Intended for Human or Animal Use
- RAQAB Ballot No. 133: FDA Draft Guidance Delaying, Denying, Limiting or Refusing a Drug Inspection
- RAQAB Ballot No. 132 and 135: EMA Draft Guidance on the Use of Porcine Trypsin used in the Manufacture of Human Biological Medicinal Products

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Regulatory Affairs and Quality Advisory Board Members

Chair
Susan J. Schniepp, *Allergy Labs Ltd.*

Vice-Chair
Jeffrey R. Broadfoot, *Cangene Corporation*

Immediate Past Chair and Board Liaison:
Dr-Ing Stephan Roenninger, *Amgen*

Members
Ruhi Ahmed, PhD, *Ultragenyx Pharmaceutical, Inc.*

Alan Burns, *Sartorius-Stedium Biotech,* (U.S Regional Liaison)

Dr. Claudio Cappai Correa, F. *Hoffman-LaRoche, Ltd.* (Brazil and Latin America Regional Liaison)

Robert B. Caunce, *Hospira,* (Australia Regional Liaison)

Veronique Davoust, *Pfizer*

John Finkbohner, PhD, *MedImmune*

Jeffrey Hartman, *Merck*

Barbara Jengtes, *PhACT GmbH,* (European Regional Liaison)

Hongyang Li, *Novartis Corporation,* (China Regional Liaison)

Lauren Melton, *Alnylam*

Elizabeth Meyers, *Amgen,* (Russia Regional Liaison)

Shin-Ichiro Mohri, *Kyowa Hakko Kirin Co., Ltd.*

Heeyoung (Hailey) Park, *Republic of Korea* (Korean Regional Liaison)

Emma Ramnarine, *Genentech*

Edwin Rivera-Martinez, *Sanofi-Pasteur*

Junko Sasaki, *Eainippon Sumitomo Pharmaceuticals,* (Japan Regional Liaison)

Siegfried Schmitt, *PAREXEL*

Jacqueline Veivia Panter, *Abbott Laboratories,* (IG Liaison)

Liaisons from other PDA Advisory Boards
SAB Liaison: **Don E. Elinski,** *Lachman Consultant Services, Inc.*
BioAB Liaison: **Wendy Zwolenski-Lambert,** *Novartis*

PDA Staff Liasons
Denyse Baker, RAC, PE, Scientific and Regulatory Affairs, *PDA*
Janie Miller, MBA, Scientific and Regulatory Affairs, *PDA*

- RAQAB Ballot No. 131: FDA Draft Guidance Contract Manufacturing Arrangements for Drugs: Quality Agreements
- RAQAB Ballot No. 130: Revisions to EU GMP Chapter 6: Quality Control
- RAQAB Ballot No. 129: Revisions to EU GMP Chapter 8: Complaints, Quality Defects, and Product Recalls
- RAQAB Ballot No. 128: FDA Draft Guidance Glass Syringes for Delivering Drug and Biological Products: Technical Information To Supplement ISO Standard 11040-4
- RAQAB Ballot No. 126: Revisions to EU GMP Chapter 5: Production
- RAQAB Ballot No. 125: Revisions to EU GMP Chapter 3: Premises and Equipment
- RAQAB Ballot No. 124: EU Guideline on Setting Health Based Exposure Limits for Use in Risk Identification in the Manufacture of Different Medicinal Products in Shared Facilities
- RAQAB Ballot No. 122: EU Guidelines on the Formalised Risk Assessment for Ascertaining the Appropriate GMP for Excipients of Medicinal Products for Human Use
- RAQAB Ballot No. 121: EU Guidelines on the Principles of Good Distribution Practices for Active Substances for Medicinal Products for Human Use
- RAQAB Ballot No. 118: Revisions to the Template for the QP Declaration Concerning GMP Compliance of IMPs Manufactured in Non EU Countries
- RAQAB Ballot No. 117: FDA Drug Shortage Task Force Questions on the Use of Pharmaceutical Quality Metrics
- RAQAB Ballot No. 116: Proposed Updated Text for WHO GMPs for Pharmaceutical Products – Main Principles
- RAQAB Ballot No. 115: USP Proposal to Require Specified USP Reference Standards be used to Obtain Compendial Results

The RAQAB was instrumental in managing the development, approval, and publication of Quality Risk Management (QRM) based PDA Technical Reports on Implementation of for Pharmaceutical and Biotechnology Manufacturing Operations in 2012. Two annexes to TR54 were published in 2013: TR54-2 and TR54-3 which covered case studies on QRM application throughout the product lifecycle. The RAQAB also reviewed and approved a Technical Report addressing Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials.

The RAQAB reviewed and approved four Technical Reports, one new candidate and one task force:

- RAQAB Ballot No. 137: PCMO QRM R02 TR54-4 Annex 3: Case Studies in the Manufacturing of Bulk Drug Substances
- RAQAB Ballot No. 127: RAQAB candidate Hailey Park
- RAQAB Ballot No. 123 and 119: Extemporaneous Preparation of Clinical Trial Materials
- RAQAB Ballot No. 120: PCMO R04 Case Study Examples for QRM in Manufacturing of Pharmaceutical Drug Products (TR54-3)
- RAQAB Ballot No. 117: FDA Drug Shortage Task Force
- RAQAB Ballot No. 114: PCMO R05 Case Study Examples for QRM in Packaging and Labelling Operations (TR 54-2)

Interest Groups

In 2013, to increase the opportunities for engagement for the Interest Group members, PDA began the development of additional resources to support Interest Groups.

The primary resource, a handbook, was developed with the assistance of IG leaders and PDA staff. The purpose of this handbook is to facilitate effective participation by describing the membership attributes, governance and organizational structure, and possible

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activities as well as the roles and responsibilities of leaders and members of PDA Interest Groups (IGs). This Handbook will also define the critical elements of the IG lifecycle, and serve as a practical guide to day to day management well as promoting IG activities and member communication though planned PDA activities.

PDA also is began the search for and selection of a new online community platform for IGs. This staff-driven activity culminated in the selection of one vendor for the platform, and the development of a "go live" plan for late 2014.

Finally, Advisory Boards, led by the RAQAB, strengthened their responsibility for those Interest Groups under their responsibility through sharing of best practices and setting expectations during routine updates provided by IG leaders at AB monthly meetings.

Publications

PDA primary member benefits — Technical Reports, *PDA Journal of Pharmaceutical Science and Technology* and *PDA Letter* — are produced under the auspices of the PDA Science and Regulatory Affairs (SRA) Department, with input from PDA staff and volunteer advisory boards.

Technical Report projects are sanctioned by the advisory boards, and the resulting technical reports must be approved by the sanctioning advisory board and the PDA Board of Directors.

The *PDA Journal of Pharmaceutical Science and Technology* is a peer-reviewed online journal, published bimonthly.

The *PDA Letter* is the Association's membership magazine, put together in cooperation with an editorial committee of 16 PDA members, which includes liaisons to PDA's three advisory boards.

PDA also publishes proceedings, topical bundles and other technical books, many in in cooperation with Davis Healthcare International Publishing, Inc. (DHI). The Technical Book Committee consists of volunteers and liaisons to the three technical advisory boards and provides guidance on the PDA-DHI books.

PDA Director of Publishing Walter Morris and his staff, working in the PDA Scientific and Regulatory Affairs Department, oversees the final publication of the member-benefit and PDA-owned publications, and contributes to content development of the PDA-DHI publications.

PDA Technical Reports: Another Record Achieved

PDA broke its 2012 record of eight published Technical Reports in 2013 with 10, seven new and three revisions. This outpouring of effort by volunteers and staff brought the PDA Technical Report library to more than 66 published documents. Technical Reports continue to be the most sought-after and useful member benefits. The 2013 published reports were:

Technical Report No. 64: Active Temperature-Controlled Systems: Qualification Guidance

Technical Report No. 63: Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials

Technical Report No. 62: Recommended Practices for Manual Aseptic Processes

Technical Report No. 61: Steam In Place

Technical Report No. 60: Process Validation: A Lifecycle Approach

PDA Technical Report No. 54-3: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations:Annex 2: Case Studies in the Manufacturing of Pharmaceutical Drug Products

PDA Technical Report No. 54-2: Implementation of Quality Risk Management for Pharmaceutical & Biotechnology Manufacturing Operation:Annex 1: Case Study Examples for Quality Risk Management in Packaging & Labeling

Technical Report No. 43, Revised 2013: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing

Technical Report No. 33, Revised 2013: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods

Technical Report No. 3 (Revised 2013): Validation of Dry Heat Processes Used for Depyrogenation and Sterilization

PDA Technical Report Portal

All active PDA Technical Reports (50 by year's end) are available for online reading. This portal was launched at the end of 2012, and saw healthy usage in 2013. During the year, the website averaged 1,400 unique visitors, with 8,000 report views each month. Visitors spent an average of 40 seconds on the website.

Electronic *PDA Journal of Pharmaceutical Science and Technology*

The *PDA Journal of Pharmaceutical Science and Technology* continues to produce high-demand content under the editorship of Dr. Govind Rao. And in its fourth year on the HighWire Press online system, the Journal's content is getting wider distribution than ever before.

The Journal editorial team grew in 2013 with the addition of **Dr. Beth Junker** from Merck. This brought the team of Associate Editors to four

Walter Morris
Director of Publishing

Rebecca Stauffer
Writer/Editor

Katja Yount
Publication Design Specialist

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with plans of adding an editor from Japan in 2014. **Mia Ricci** continued curating the Journal process as Assistant Editor.

Site Access/Usage

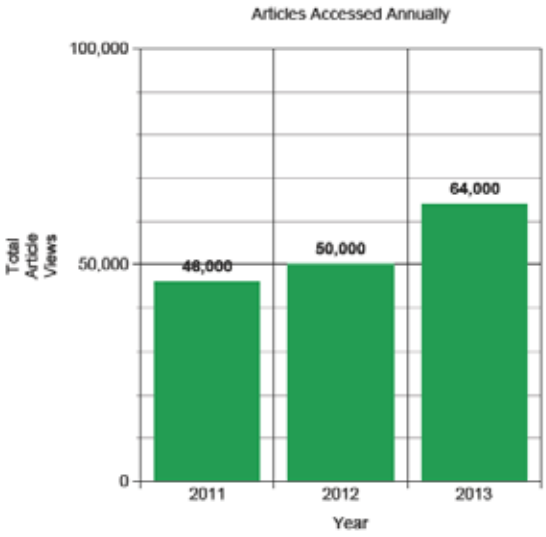
Readers access the site to retrieve articles in HTML or PDF format and to review abstracts of articles. 2013 saw continued a trend of steady growth in article access, but also saw continued explosive growth in articles sold.

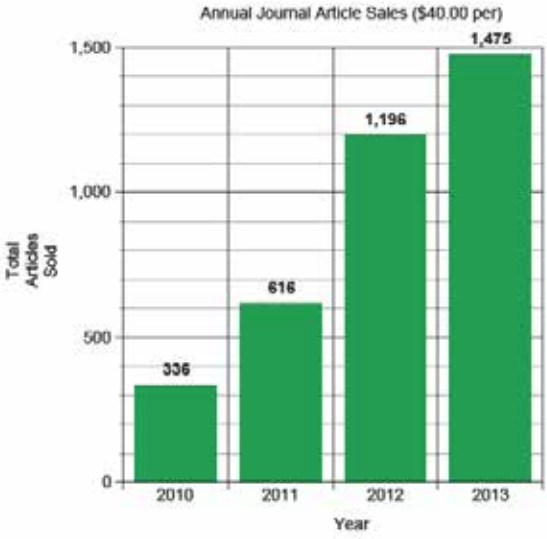
Institutional Subscriptions

109 Institutions subscribed to the online Journal in 2013.

Frederick D. Simon Award:

The Frederick D. Simon Award is presented annually for the best paper published in *the PDA Journal of Pharmaceutical Science and Technology*. This award is named in honor of the late Frederick D. Simon, a previous PDA Director of Scientific Affairs.





The 2013 Frederick D. Simon Award recipients were:

Xiaolin Cao, PhD
Gregory S. Stimpfl, P.E.
Zai-Qing Wen, PhD
Gregory T. Frank, PhD
Glenn Hunter

for the article "Identification and Root Cause Analysis of Cell Culture Media precipitates in the Viral Deactivation Treatment with High-Temperature/ Short-Time Method," which was published in January/February 2013.

PDA Letter

The *PDA Letter* is also produced by Rebecca Stauffer, PDA's writer/editor, Katja Yount, Publication Design Specialist, and Walter Morris, who serves as the publication's Managing Editor. A 16-member *PDA Letter* Editorial Committee helps review member submissions, contributes articles to the magazine and topics to the annual editorial calendar, and recruits authors.

Feature-length articles submitted by members and published in 2013:

1. "Parenterals Conference Draws 200 to Spain," Friedrich Haefele, PhD, Boehringer Ingelheim Pharma, and Stefan Merkle, PhD, Cilag AG
2. "Risk and Statistics Serve as Tools for Solving Variation Riddles and Creating Robust Processes," Michael Long

Scientific and Regulatory Affairs

3. "Industry Views on Quality-Related Shortages," Karen Ginsbury, PCI, and Tricia Griffiths, EMD Millipore
4. "Take Charge of Your Career! Practical Guidelines for Career Planning and Advancement," Winston Brown, Alcon
5. "Pharma Manufacturing Recruitment in 2013—and Beyond," Mark Lanfear, Kelly Services
6. "Should Scientific Data Determine Cytotoxic Limits?" Hank Rahe, EnGuard Systems
7. "Management, We Have a Problem," Roland Bizenek, PhD, Compass Pharma Consulting LLC
   "Roadmap to External Manufacturing Partnerships," Paul Gauthier, Shire
8. "Key Factors for Validating a Disposable System," Katell Mignot, Sartorius Stedim Biotech
9. "New Technologies Bring Device Training to Patients," Jeff Baker, Noble Rx
10. "Growing a Quality Culture," Janmeet Anant, PhD, EMD Millipore
11. "U.S. FDA, Industry Emphasize Robust Quality Systems," Kerstyn Bryce, GlaxoSmithKline
12. "Industry Faces Changing Times," Patti Rossman, Globiox

Interviews and Podcasts

The Letter Staff conducted more interviews in 2013 to bring more expert opinion to the PDA membership and launched a podcast series to coincide with articles. The following podcasts were posted online in 2013 based on these interviews (the PDA Letter article is indicated in parentheses):

1. Martin VanTrieste, Amgen, discusses the U.S. FDA's quality metrics proposal ("U.S. FDA Offering "Q" Metrics for Payers – A Good Idea," interviewed by Walter Morris, April issue)
2. Mark Sebree, BD Rx, discusses his firm's new line of generic sterile injectables ("BD Moves into Sterile Injectables Market," interview by Rebecca Stauffer, June issue)
3. Cathy Burgess, JD, greater U.S. FDA oversight of cGMPs ("cGMPs Continue to Evolve as U.S. FDA Expands Regulatory Authority under FDASIA," interview by Rebecca Stauffer, July/August issue)
4. Katja Kotter, Vetter, on new combination product rules ("Company Relies on Comprehensive Approach to Address New Combo Product Rule," interview by Rebecca Stauffer, October issue)
5. Yuexia Li, U.S. FDA, Jeffrey Baker, U.S. FDA, Cesar Matto, U.S. FDA on transitioning to U.S. FDA after years in industry ("Crossover Moves: Making a Career on Both Sides of the Government/Industry Divide," interviews by Walter Morris and Rebecca Stauffer, November/December issue)

PDA Letter InfoGraphic

In 2013, the *PDA Letter* staff introduced infographics. Katja Yount, Publication Design Specialist, works with the editors and a subcommittee of the PLEC to develop these visual editorial tools, which frequently coincided with the issue's cover story. Last year, the *PDA Letter* Infographics covered the following topics:

1. A Sampling of Sought-After Industry/U.S. FDA Jobs
2. SUS Supply Chain is a Complex Journey
3. Biopharmaceutical Manufacturing Outsourcing in 2013
4. Common Elements of a Consent Decree with the U.S. FDA
5. Sterile Product Manufacturing: A History
6. U.S. Pharma Manufacturing Jobs in 2012
7. U.S. vs EU Process Val Guidances
8. Drug Shortages in the United States: A Snapshot
9. QbD and Vaccines: PDA IG Members' View

New PDA-Owned Content

PDA published its first independent book in 2013: *Pharmaceutical Legislation of the European Union, Japan, and the United States of America,* by Barbara Jengtes, Nobuo Tateishi, Kate Denton and Michel Mikhail.

Scientific and Regulatory Affairs

Transcripts of Proceedings and Surveys

PDA expanded its collection of Transcript of Proceedings and Surveys in 2013.

PDA Transcript of Proceedings are books prepared after certain, scientific PDA conferences and include full transcripts and slides. These electronic books provide references to these key PDA events for use by the entire PDA community and are sold on PDA's Bookstore. The following Transcript of Proceedings were published during the year:

- *Transcript of the Proceedings of the 2013 PDA Aseptic Processing-Sterilization Conference*
- *Transcript of the Proceedings of the 2013 PDA/FDA Glass Packaging Conference*

PDA published the following surveys in 2013:

- *PDA Survey: Objectionable Microorganisms for Nonsterile Pharmaceutical, Consumer Health, Medical Devices, Dietary Supplement and Cosmetic Products*

PDA/DHI Books

PDA, in partnership with Davis Healthcare International Publishing, Inc. (DHI), publishes books written on topics relevant to our membership. Book proposals developed between prospective authors and DHI are vetted by the PDA Technical Book Committee, which includes liaisons to PDA's three technical advisory boards.

Janny Chua, Product Operations Manager, manages the daily retail operations and sales activities for PDA, while **Amy Davis** of DHI manages the book development, review and publication process.

The following PDA members authored or were editors of PDA/DHI books in 2013:

Paul Pluta, PhD, *Cleaning and Cleaning Validation, Volume 2*

Destin LeBlanc, *Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 3*

Lisa Hornback, *Combination Products: Implementation of cGMP Requirements*

Russell Madsen and **Jeanne Moldenhauer,** *Contamination Control in Healthcare Product Manufacturing, Volume 1*

Michael Miller, PhD, *Encyclopedia of Rapid Microbiological Methods, Volume 4*

Dr. Trevor Deeks, Karen Ginsbury and **Susan Schniepp,** *Pharmaceutical Outsourcing: Quality Management and Project Delivery*

Lynn Torbeck and **Joyce Torbeck,** *Square Root of (N) Sampling Plans: Procedures and Tables for Inspection of Quality Attributes*

Dr. Tim Sandle, *Sterility Testing of Pharmaceutical Products*

In 2013 the top five best-selling PDA/DHI books were:

- *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition, Revised & Expanded,* by **James L. Vesper**
- *Sterility Testing of Pharmaceutical Products,* by **Dr. Tim Sandle**
- *Environmental Monitoring: A Comprehensive Handbook, Volume I, II, III, IV, V, VI and Protocol CD,* edited by **Jeanne Moldenhauer**
- *Contamination Control in Healthcare Product Manufacturing, Volume 1,* edited by **Russell Madsen** and **Jeanne Moldenhauer**
- *Encyclopedia of Rapid Microbiological Methods, Volume 4,* edited by **Michael Miller,** PhD

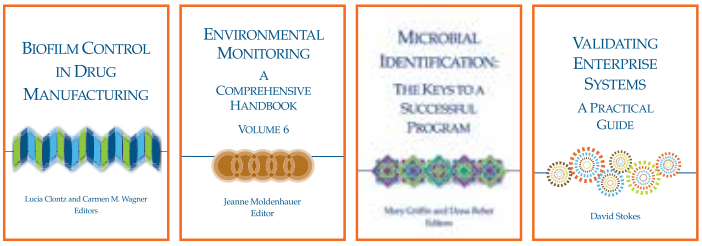
Technical Book Committee

Chair
Walter Morris, Director of Publishing, *PDA*

Co-Chair
Amy Davis, *Davis Healthcare International Publishing*

Members
Joyce Bloomfield, *Merck & Co., Inc.*
Norbert Hentschel, *Boehringer Ingelheim Pharma GmbH & Co. KG*
Jack Lysfjord, *Lysfjord Consulting, LLC*
Russell Madsen, *The Williamsburg Group, LLC*
Michael J. Miller, *Microbiology Consultants, LLC*
Jeanne Moldenhauer, *Excellent Pharma Consulting*
Siegfried Schmitt, *PAREXEL Consulting*
Steven Mendivil, *Amgen, Inc.*
Stephan Rönninger, *F. Hoffman-La Roche Ltd.*
Scott Sutton, *Microbiology Network, Inc.*
James Vesper, *LearningPlus, Inc.*

PDA Staff Liasons
Richard Johnson, President
Richard Levy, PhD, Scientific and Regulatory Affairs



PDA Training and Research Institute

The PDA Training and Research Institute (PDA TRI) was established in 1997 to provide innovative hands-on education, training and applied research opportunities in pharmaceutical and biopharmaceutical sciences and associated supporting technologies. Courses are offered at our training facility in Bethesda, Maryland, as well as in conjunction with major North American PDA Conferences, and in other select regional locations. We provide training that students can apply immediately when they return to their jobs. In order to ensure our courses continue to meet the needs of our students, we continually evaluate our curriculum and update it with new courses as appropriate.

Courses provided at our Bethesda facility take advantage of our unique laboratories, which closely duplicate a commercial clean room. This allows our students to apply in an operational setting the concepts and principles they learn in the classroom. These courses typically focus on aseptic processing technology and those systems and operations that support aseptic processing. Broadly speaking, our courses generally fall into one of the following areas:

- Aseptic Processing
- Biotechnology
- Environmental Monitoring
- Filtration
- Microbiology
- Quality/Regulatory Affairs
- Training
- Validation

In addition, specialized courses addressing topics such as Lyophilization, Prefilled Syringes and Visual Inspection are also held.

The chance for students to apply their new knowledge in a risk-free setting that mimics a commercial clean room, without jeopardizing company clean rooms or commercial products, continues to provide our students with a learning opportunity not found elsewhere in the biopharmaceutical/pharmaceutical industry.

In addition to the laboratory-based courses provided in Bethesda, we offer lecture courses in conjunction with all major PDA Conferences in North America. These courses complement the topics presented at the Conferences and offer students an economical way to expand and build on their knowledge.

2013 TRI Highlights

- More than 60 courses delivered
- 18 new courses
- 32 courses based on PDA-owned material
- More than 70 Volunteer instructors
- More than 1,300 students
- Almost 500 students trained "in house"
- 4 Training courses presented in China
- New Lab Coordinator added to staff

The third element of our educational opportunities brings the learning experience directly to client facilities. All of our lecture-based courses and some of our lab-based courses can be adapted to meet the specific needs of individual clients and delivered to a larger base of employees in a cost-effective way. In 2013, this element again resulted in our providing training to almost 500 people at various client locations.

In 2013, an off-shoot of our in-house training program resulted in PDA instructors **Harold Baseman** and **Kevin Trupp** presenting training on *Validation of Moist Heat Sterilization Processes* (PDA Technical Report 1), *Steam in Place* (Technical Report 61), *Process Validation* (Technical Report 60), and *Quality Risk Management for Aseptic Processes* (Technical Report 44) to about 200 students in Beijing, Nanjing and Shanghai, China.

In order to ensure our courses continue to meet the needs of our students, we continually evaluate our curriculum and update it with new courses as appropriate. In 2013, we offered 18 new laboratory and lecture courses focusing on topics such as *CMC Regulatory Requirements in Drug Applications, Fundamentals of Aseptic Processing, Quality Metrics: Performance Indicators* and *Risk-Based Qualification of Sterile Drug Product Manufacturing Systems.*

In 2013, we continued our initiative to develop and present courses based on PDA Technical Reports. There were more than 30 courses that were based on this PDA-owned material presented in 2013. TRI continues to be grateful to PDA Senior Vice-President for Scientific and Regulatory Affairs **Rich Levy** and his staff (**Josh Eaton**, **Morgan Holland** and **Janie Miller**), as well as TRI special assistant **Bethanne Bond** and our instructors for preparation of the materials for these courses.

2013 was one of the most successful years ever for TRI and PDA's education programs. In total, we presented more than 60 training courses to more than 1,300 industry and government regulatory personnel from the U.S. and other countries around the world in 2013.

Our courses continue to be taught by our dedicated faculty. All are subject matter experts who volunteer to teach for us. All teach in the areas in which they work; this allows the students to enjoy the richness that only personal experience can bring to the instructional setting. A separate listing of our **2013 instructors** appears on pg. 16 of this report. In addition, we are fortunate to have companies who offer support for our education programs by donating supplies and equipment used in the presentation of our courses. A listing of these **donating companies** is also included in this report. We are very grateful to all these volunteers and donors. Without them, we could not have achieved the success we did in 2013.

PDA Training and Research Institute

Bob Dana
Senior Vice President, Regulatory Affairs and Training and Research Institute

Stephanie Ko
Senior Manager, Lecture Education

James Wamsley
Senior Manager, Laboratory Education

Oscar M. Bermudez
Coordinator, Laboratory Education

And finally, a word of thanks to our loyal, hard-working staff – **Oscar Bermudez**, who joined us as Lab Coordinator in 2013, **Bob Dana, Stephanie Ko** and **James Wamsley** – and last, but by no means least, **our students**. Without them there would be no PDA TRI!

PDA Training and Research Institute 2013 Contributors

Atlantic Technical Services	Calibration Services
Aramark	Services
Becton Dickinson	Microbiology supplies
BioMerieux	Equipment, Supplies
Bioscience International	Equipment, Services
Cole Parmer	Supplies
EMDMillipore	Equipment,Supplies
EMTEK Air	Equipment, Services
General Econopak, Inc.	Supplies
ITW/Texwipe	Supplies
Kimberly Clark	Supplies
Microbiologics	Supplies
Micronova Manufacturing, Inc.	Supplies
Nuovo Ompi	Vials
PALL	Supplies
Particle Measuring Systems	Equipment, Services
PDA Metro Chapter	Laboratory Equipment
Sartorius Stedim North America	Equipment, Services, Supplies
Veltek Associates, Inc.	Equipment, Supplies
West Pharmaceutical Services	Supplies

PDA Training and Research Institute

Instructor		Company
First	Last	Company
Carolyn	Adams	Genzyme
Vince	Anicetti	Boehringer Ingelheim
Michael	Anisfeld	Globepharm
Hal	Baseman	ValSource, LLC
Barbara	Berglund	Boehringer-Ingelheim
Rafik	Bishara	
Karen	Bossert	Lyophilization Technology
Scott	Bozzone	Pfizer, Inc.
John	Brecker	Consultant
Becky	Brewer	The Dober Group
Rich	Brown	MVA Consultants
Sean	Byrd	FDA
Anne	Connors	EMD Millipore
James	Cooper	Consultant
Dave	Crance	Particle Measuring Systems
Cheryl	Custard	Consultant
Robert	Dana	PDA
Nicholas	DeBello	DeBello & Associates
Stephanie	Ferrante	EMD Millipore
Barry	Friedman	Barry A. Friedman, PhD, LLC
Wayne	Garafola	Sartorius Stedim Biotech
Marc	Glogovsky	Veltek Associates, Inc.
Tricia	Griffiths	Pall Life Sciences
Zi-Qiang	Gu	
Ghada	Haddad	Merck and Company Inc.
William	Harclerode	Forest Laboratories
Marsha	Hardiman	ConcordiaValSource
Jeffrey	Hartmann	MERCK
Deborah	Havlik	Hospira Inc.
Walter	Henkels	ConcordiaValSource
Ellen	Huang	FDA
Patricia	Hughes	Food & Drug Administration
Richard	Johnson	PDA
Maik	Jornitz	G-Gon
Robert	Kieffer	RGK Consulting
Kathryn	King	FDA

Instructor		Company
First	Last	Company
Karl	Kussow	FedEx Custom Critical, Inc.
Wendy	Lambert	Novartis Pharma AG
Carol	Lampe	Consultant
Sam	Lebowitz	Electrol Specialties, Corp.
Ron	Leversee	Perrigo
Mike	Long	ConcordiaValSource
David	Matsuhiro	Cleanroom Compliance Inc.
Mary	Miller	MVA Consultants
Michael	Miller	Microbiology Consultants
Marc	Mittelman	Exponent
Jeanne	Moldenhauer	Excellent Pharma Consulting
Charles	Montague	Scienta Solutions
Rainer	Newman	Consultant
Jason	Orloff	PharmStat
Martin	Orlowski	Bioquell, Inc.
Matthew	Ostrowski	Pfizer, Inc.
Diane	Paskiet	West Pharmaceutical
Priscilla	Pastrana	FDA
Lori	Peters	FDA
Emabelle	Ramnarine	Roche Pharma
Dona	Reber	Pfizer, Inc.
Robert	Repetto	Pfizer, Inc.
Paul	Ricciatti	BiMeda, MTC
Scott	Rudge	RMC Pharmaceutical Solutions
Dan	Sacunas	Particle Measuring Systems
Michael	Sadowski	Baxter Healthcare
Peter	Schofield	Walker Barrier Systems
John	Shabushnig	Consultant
Edward	Smith	Packaging Science Resources
Edward	Trappler	Lyophilization Technology
Kevin	Trupp	Automated Systems, Inc.
Art	Vellutato, Jr.	Veltek Associates, Inc.
Brent	Watkins	Veltek Associates, Inc.
Michael	Wiebe	Quantum Consulting
Ming	Zhou	MVA Consultants

The Programs, Meetings and Registration Services Department

In 2013, it was evident that the Programs, Meetings and Registration Services Department was on a crucial mission; to continue to provide scientifically sound, practical and technical information for the pharmaceutical and biopharmaceutical industry. With the expertise of our global members who served on planning committees, the mission was accomplished by adding four new topics to the schedule in addition to 10 other reputable PDA events.

For the first time in 2013, PDA held four new events: the PDA Human Factors and Human Error Reduction Workshop, PDA/FDA Improving Investigations Workshop, PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals, and PDA/FDA Pharmaceutical Quality Metrics Conference.

As a post-conference workshop to the 2013 Annual Meeting, the PDA Human Factors and Human Error Reduction Workshop offered a unique format of breakout sessions to maximize discussions on the challenges in advancing pharmaceutical operations and how to reduce the potential for errors. The PDA/FDA Improving Investigations Workshop allowed attendees to interact and receive feedback from key FDA figures on investigations. This co-sponsored workshop provided Interactive breakout sessions that allowed attendees to develop their own conclusions through three components of an investigation. The PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals provided attendees with a regulatory and industry perspective on currently used virus detection methods and the use of advanced molecular methods for adventitious agent detection. All sessions were highly data driven and provided elaborate approaches taken by first-hand users of most current and new technologies that addressed some of the critical issues related to sample processing, virus standards, and performance evaluation. Lastly, the PDA/FDA Pharmaceutical Quality Metrics Conference was developed to provide attendees with an open and honest dialog on all aspects of Quality Metrics and sharing experiences on what works and what doesn't work when Quality Metrics are used to drive continuous improvements. The conference explored quality metrics from different perspectives including those of outsourcing organizations, virtual companies, large companies, generic and proprietary manufacturers.

Programs, Meetings and Registration Services Department Staff

The Programs, Meetings and Registration Services Department consist of eight staff members who support Program and Speaker Management, Registration Services and Logistics (planning and execution).

Wanda Neal, CMP, Senior Vice President, Programs and Registration Services
16 Years Team Member

Tanya Allen, Programs Coordinator, Programs and Registration Services
2.5 Years Team Member

Jason E. Brown, Senior Manager, Programs & Meetings
10 Years Team Member

Patresa Day, Manager, Registration and Customer Accounts
9 Years Team Member

Leon Lewis, Director, Programs and Meetings
5.5 Years Team Member

Melissa Pazornik, Coordinator, Speaker & Logistics Assistant
3.5 Years Team Member

Andrea Viera, Assistant Manager, Programs and Speaker Management
8 Years Team Member

The Programs, Meetings and Registration Services Department

2013 PDA Conferences and Workshops

The Parenteral Drug Association (PDA) offered 14 well-planned, thought-provoking programs that provided leading science, technology and global regulatory information to the pharmaceutical and biopharmaceutical community. Listed below are the Committee members who made these conferences possible.

67th PDA Annual Meeting

April 15-17, 2013 | Orlando, FL

Hal Baseman, *ValSource, LLC (Co-Chair)*
Maik Jornitz, *G-Con Manufacturing, LLC (Co-Chair)*
Ursula Busse, PhD, *Novartis Pharma AG*
Michele Creech, *Grifols, Inc.*
Ian Elvins, *Elvins and Associates*
Jose Goin, PhD, *Genentech, Inc.*
Jeffrey Hartman, *Merck and Company*
Rickey Lu, *MedImmune*
Miguel Montalvo, *Expert Validation Consulting, Inc.*
Miguel Nogueras, *Abbott Medical Optics*
Michael Sadowski, *Baxter Healthcare*
Emily Shacter, *ThinkFDA, LLC*
Brent Watkins, *Veltek Associates, Inc.*

NEW 2013 PDA Human Factors and Human Error Reduction Workshop

April 17-18, 2013 | Orlando, FL

Christina Mendat, PhD, *Radius Product Development (Co-Chair)*
Miguel Nogueras, MTD, *Abbott Medical Optics (Co-Chair)*
Hal Baseman, *ValSource, LLC*
William Blunt, *Amgen, Inc.*
Richard Friedman, *FDA*
Karthik Iyer, *FDA*
Steven Lynn, *FDA*
Lisa Skeens, *Hospira*

2013 PDA/FDA Container Closure Components and Systems Workshop

May 14-15, 2013 | Bethesda, MD

Diane Paskiet, *West Pharmaceutical Services (Co-Chair)*
Mihaela Simianu, PhD, *Eli Lilly and Company (Co-Chair)*
Mary Foster, PharmD, *Aphena Pharma Solutions*
Heino Prinz, PhD, *Wilco*
LCDR Destry Sillivan, *FDA*
Kalavati Suvarna, PhD, *FDA*

2013 PDA/FDA Glass Packaging Conference

May 15-16, 2013 | Bethesda, MD

Ronald Iacocca, PhD, *Eli Lilly and Company (Co-Chair)*
Cesar Matto, *FDA (Co-Chair)*
Roger Asselta, *Genesis Packaging Technology*
Nicholas DeBello, *Wheaton Industries, Inc.*
Ronald Foster, *Amgen, Inc.*
Dan Haines, PhD, *SCHOTT North America, Inc.*
Snehal Patel, *Genentech, Inc.*
Thomas Schoenknecht, PhD, *SCHOTT AG*

2013 PDA/FDA Process Validation Workshop

May 20-21, 2013 | Bethesda, MD

Hal Baseman, *ValSource, LLC (Co-Chair)*
Scott Bozzone, PhD, *Pfizer, Inc. (Co-Chair)*
Vijay Chiruvolu, PhD, *Amgen, Inc.*
Rebecca Devine, PhD, *Consultant to the Biopharmaceutical Industry*
Wendy Zwolenski-Lambert, *Abbott Laboratories*

2013 PDA/FDA Pharmaceutical Supply Chain Workshop

June 3-5, 2013 | Bethesda, MD

EJ Brandreth, *Althea Technologies (Co-Chair)*
Steven Wolfgang, PhD, *FDA (Co-Chair)*
Matthew Anderson, *Merz Aesthetics, Inc.*
Lucy Cabral, *Genentech, Inc.*
Gregg Goneconto, *FDA*
Kathleen Hedland, *Council of Supply Chain Management Professionals*
Gwyn Murdoch, *Eli Lilly and Company*
Kevin Siver, PhD, *Amgen, Inc.*
Edwin Rivera – Martinez, *Sanofi Aventis*
Susan Schniepp, *Allergy Laboratories, Inc.*
Mary E. F. Storch, *Ben Venue Laboratories, Inc.*
David Ulrich, *AbbVIe*

2013 PDA Aseptic Processing-Sterilization Conference

June 20-21, 2013 | Chicago, IL

Michael Sadowski, *Baxter Healthcare Corporation (Chair)*
Thomas Arista, *FDA*
David Hussong, *FDA*
Ken Paddock, *Baxter Healthcare Corporation*
Glenn Wright, *Eli Lilly and Company*

2013 PDA/FDA Joint Regulatory Conference

September 16-18, 2013 | Washington, DC

Joyce Bloomfield, *Merck Sharp & Dohme (Co-Chair)*
Susan Schniepp, *Allergy Laboratories, Inc. (Co-Chair)*
Douglas Campbell, *Interpro QRA*
David Cummings, *FDA*
John Finkbohner, PhD, *MedImmune*
Richard Friedman, *FDA*
Maria Guazzaroni Jacobs, PhD, *Pfizer, Inc.*
Rhonda Hill, *FDA*
Colleen Hoyt, *FDA*
Mai Huynh, *FDA*
Shane Killian, *Johnson & Johnson*
Renee Kyro, *AbbVie*
Elizabeth Leininger, PhD, *Elizabeth Leininger Consultant*
Stanley Lin, *FDA*
Steven Mendivil, *Amgen, Inc.*
Kenneth Nolan, *FDA*
Laurie Norwood, *FDA*
Mahesh Ramanadham, *FDA*
Carol Rehkopf, *FDA*
Stephan Roenninger, PhD, *Amgen, Inc.*
Lonnie Warren-Henderson, *FDA*

NEW 2013 PDA/FDA Improving Investigations Workshop

September 18-19, 2013 | Washington, DC

Richard Friedman, *FDA (Co-Chair)*
Anders Vinther, PhD, *Genentech, Inc. (Co-Chair)*
Thomas Arista, *FDA*
Nicholas Cappuccino, PhD, *Pharmaceutical Intellectual Resources*
Zena Kaufman, *Hospira*
Jennifer Magnani, *F. Hoffmann- La Roche Ltd.*
Swroop K. Sahota, PhD, *Catalent Pharma Solutions*
Melissa Seymour, *Biogen Idec*
Fionnuala Walsh, PhD, *Eli Lilly and Company*

2013 PDA Analytical Methods Development & Validation Workshop

October 7-8, 2013 | Baltimore, MD

Stephan Krause, PhD, *MedImmune (Chair)*
Rajesh Gupta, PhD, *Biologics Quality & Regulatory Consultants, LLC*
Dwayne Neal, *Emergent BioSolutions*
Michael Rooney, PhD, *Jazz Pharmaceuticals*
Earl Zablackis, PhD, *Sanofi Pasteur*

The Programs, Meetings and Registration Services Department

2013 PDA Visual Inspection Forum

October 7-8, 2013 | Bethesda, MD

Markus Lankers, PhD, *rap.ID GmbH (Co-Chair)*
John Shabushnig, PhD, *Insight Pharma Consulting, LLC (Co-Chair)*
John Ayres, MD, *Eli Lilly and Company*
Roy Cherris, *Bridge Associates International*
Stephen Langille, PhD, *FDA*
Deborah Shnek, PhD, *Amgen, Inc.*

PDA 8th Annual Global Conference on Pharmaceutical Microbiology

October 21-23, 2013 | Bethesda, MD

Osama Elrashidy, *Bayer Healthcare (Co-Chair)*
Marla Stevens – Riley, PhD, *FDA (Co-Chair)*
Edward Balkovic, PhD, *Genzyme Corporation – A Sanofi Company*
Julie Barlasov, *Perritt Laboratories, Inc.*
Renee Blosser, *FDA*
Paul Dexter, *FDA*
Marsha Stabler Hardiman, *Concordia ValSource*
Chris Knutsen, PhD, *Bristol-Myers Squibb*
Michael Miller, PhD, *Microbiology Consultants, LLC*
Amy McDaniel, PhD, *Pfizer, Inc.*
John Metcalfe, PhD, *FDA*
Karen Mullen, *bioMerieux*
Cheryl Platco, *Merck Research Laboratories*
Kalavati Suvarna, PhD, *FDA*
Edward Tidswell, PhD, *Baxter Healthcare Corporation*
Kim Sobien, *Becton Dickinson Rx, Inc.*
Radhakrishna Tirumalai, PhD, *US Pharmacopeia*

NEW 2013 PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals

November 13-14, 2013 | Bethesda, MD

Arifa Khan, PhD, *FDA (Co-Chair)*
Dominick Vacante, PhD, *Janssen Research & Development, LLC (Co-Chair)*
Jean-Pol Cassart, PhD, *GlaxoSmithKline Vaccines*
Paul Duncan, PhD, *Merck and Company, Inc.*
Kathryn King, *FDA*
Laurent Mallet, PhD, *Sanofi Pasteur*
Timothy Mayall, PhD, *PaxVax*
Mark Plavsic, *Genzyme Corporation – A Sanofi Company*
Michael Wiebe, *Quantum Consulting, LLC*

NEW 2013 PDA/FDA Pharmaceutical Quality Metrics Conference

December 9-10, 2013 | Bethesda, MD

Steven Mendivil, *Amgen, Inc. (Co-Chair)*
Russell Wesdyk, *FDA (Co-Chair)*
Joyce Bloomfield, *Merck Sharp & Dohme Corporation*
Ian Elvins, *Elvins and Associates*
Richard Friedman, *FDA*
Francis Godwin, *FDA*
Karthik Iyer, *FDA*
Marty Nealey, *Hospira*
Faiad Rahaman, *FDA*
Anil Sawant, *Johnson & Johnson*
Susan Schniepp, *Allergy Laboratories, Inc.*
Alex Viehmann, *FDA*
Anders Vinther, PhD, *Genentech, Inc.*
Glenn Wright, *Eli Lilly and Company*

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Our library is comprised of recorded sessions from live 2013 events. Each recorded session includes audio synced with the presenters' PowerPoint presentations and the valuable question and answer portion of the session. A downloadable PDF handout of each presentation is also included.

Please visit **www.pda.org/online-learning** for a list of recent recordings.

PDA 2013 Session Recordings:

- 2013 PDA Annual Meeting
- 2013 PDA/FDA Glass Packaging Conference
- 2013 PDA/FDA Process Validation Workshop
- 2013 PDA Aseptic Processing Sterilization Conference
- 2013 PDA/FDA Joint Regulatory Conference
- 2013 PDA/FDA Improving Investigations Workshop
- 2013 PDA Visual Inspection Forum
- PDA 8th Annual Global Conference on Pharmaceutical Microbiology

Membership and Chapters

In 2013, PDA had its fourth year of consecutive member growth – 1.5 percent increase in members. In an effort to continue this positive growth, PDA introduced three new programs: a new member type aimed at young professionals (under 30), free membership for regulators, and a discount for renewing members. To complement this, PDA increased member value in the following ways:

- New investments in volunteer recruitment and development:
  - Volunteer Development Program introduced
  - New staff position: Volunteer Coordinator
- Chapter support:
  - New chapters in Singapore and Texas to support local member activities
- Improvements in Membership Marketing:
  - Career Articles in *PDA Letter* highlighting the volunteer/career trajectory of influential PDA members
  - Introduction of the first monthly volunteer email and online volunteer application
  - Rebranding of volunteer spotlights and recognition
  - Redesign of PDA Membership Brochure

Hassana Howe
8 Years Team Member:
Director, Membership & Chapters

Trevor Swan
7 Years Team Member:
Manager, Membership & Chapters

Megan Kuhman
Newly Added Team Member
Volunteer Coordinator

Katie Ruiz
4 Years Team Member:
Customer Service Representative

Alison Caballero
5 Years Team Member:
Sr. Sales Coordinator

PDA Global Chapters and Leaders

ASIA – PACIFIC

Australia Chapter

President: **Greg Jordan,** *Box Hill Institute: Centre for Biotechnology and Animal Science*
President Elect: **Kim Waters,** *GlaxoSmithKline*
Treasurer: **Paul Kerr,** *SeerPharma P/L*
Secretary: **Anna Corke,** *Genera Biosystems*

India Chapter

President: **Sanjay Singh,** *Aurobindo Pharma*
President Elect: **Sanjit S. Lamba,** *Eisai Pharmatechnology & Manufacturing P., Ltd*
Treasurer: **Ivy Louis,** *Vienni Training and Consulting LLP*
Secretary: **Vishal Sharma,** *Vienni Training and Consulting LLP*

Japan Chapter

President: **Katsuhide Terada,** PhD, *Toho University*
Vice President: **Shigeo Kojima,** PhD, *Pharmaceuticals and Medical Devices Agency*
Treasurer: **Yukio Hiyama,** PhD, *National Institute of Health Sciences*
Management & Planning: **Masashi Imamura,** *Nichi-iko Pharmaceutical Co. Ltd*
Management & Planning: **Izumi Saitoh,** PhD, *Takada Seiyaku*

Membership and Chapters

Korea Chapter

President: **Woo-Hyun Paik,** PhD, *Korea Pharm. Tech. Education Center*
Treasurer: **Young Kou Jeong,** *Pall Korea Life Sciences*

Singapore Chapter

President: **Maureen Hertog,** *Novartis Singapore Pharmaceutical Manufacturing Pte Ltd*
President Elect: **Sateesh Yelisetti,** *Baxter*
Treasurer: **Chia Phei Kok,** *Visentec Solutions Pte Ltd*
Secretary: **Wayne Lee,** *Pall Life Sciences*

Taiwan Chapter

President: **Lain-Tze Lee,** *Industrial Technology Research Institute*
Secretary-General: **Yi-Yin Lu,** *PDA Taiwan Chapter*

EUROPE & ISRAEL

France Chapter

President: **Philippe Gomez,** *Sartorius Stedim Biotech*
President Elect: **Jean-Luc Clavelin,** *Eli Lilly and Company*
Treasurer: **Sorin Haias,** *Lives International Corporation*
Secretary: **Christian Renaux,** *Baxter Healthcare Corporation*

Ireland Chapter

President: **Alice Redmond,** *Commissioning Agents, Inc.*
President Elect: **John Michael Morris,** *Irish Medicines Board*
Treasurer: **Ann McGee,** *McGee Pharma International*
Secretary: **Ann Greene,** *Dublin Institute of Technology*

Israel Chapter

President: **Rina Yamin,** *Rina Yamin Pharmaceutical Consulting*
President Elect: **Rachel Karpel,** *PCI Pharmaceutical Consulting Israel*
Treasurer: **Karin Baer,** PhD, *Omrix biopharmaceuticals, LTD*
Secretary: **Karen S. Ginsbury,** *PCI Pharmaceutical Consulting Israel*

Italy Chapter

President: **Walter De Matteo,** *Institut Biochemique SA*
President Elect: **Vincenzo Tarantino,** *KEDRION S.p.A.*
Treasurer: **Gaetano Fiorentino,** *Italfarmaco S.p.A.*
Secretary: **Massimo Golia,** *Pall Italia Srl*

United Kingdom Chapter

President: **Siegfried Schmitt,** *PAREXEL Consulting*
Treasurer: **Mark Gibson,** *AstraZeneca*
Secretary: **Sarah Newell,** *ThermoFisher, Ltd.*

NORTH AMERICA

Canada Chapter

President: **Sabrina Ullah,** *SNC-Lavalin Pharma Inc.*
Secretary: **Antonella Maggio,** *Generex Biotechnology*

Capital Area Chapter

President: **Allen Burgenson,** *Lonza Walkersville*
Treasurer: **Barry Friedman,** PhD, *Barry A. Friedman, PhD, LLC*
Secretary: **Stephen Rochelle,** *Rochelle & Associates*

Delaware Valley Chapter

President: **Arthur Vellutato, Jr.,** *Veltek Associates, Inc.*
President Elect: **Jason Mattis,** *GlaxoSmithKline*
Treasurer: **Marlene Raschiatore,** *Johnson & Johnson*
Secretary: **Stephen S. Trombetta,** *Veltek Associates, Inc.*

Metro Chapter

President: **Lara Soltis,** *Texwipe*
President Elect: **Leticia Quinones,** *Bristol-Myers Squibb*
Treasurer: **Mary Ly Huynh,** *Independent*
Secretary: **Maggie Filipowicz,** *Laureate Biopharmaceutical*

Midwest Chapter

President: **Jeanne Moldenhauer,** *Excellent Pharma Consulting*
President Elect: **Kenneth Paddock,** *Baxter Healthcare*
Treasurer: **Alan Solomon,** *Baxter Healthcare*
Secretary: **Angela Coon,** *Baxter Healthcare*

Missouri Valley Chapter

President: **Eldon Henson,** *Covidien*
President Elect: **Jeff Hargroves,** *ProPharma Group*
Treasurer: **Keith Koehler,** *Certified Energy Labs*
Secretary: **Gary Klaassen,** *Bayer AG Pharma*

Mountain States Chapter

President: **Suzanne Mecalo,** *Commissioning Agents, Inc.*
Treasurer: **Leah Choi,** *RMC Pharmaceutical Solutions*
Secretary: **Sheri Glaub,** *RMC Pharmaceutical Solutions*

New England Chapter

President: **Roland Bizanek,** PhD, *Compas Pharma Consulting*
President Elect: **Jonathan Morse,** *Complya Consulting Group*
Treasurer: **Mark Plucinsky,** *Alexion*
Secretary: **Jeffrey Anderson,** *Biogen Idec Inc.*

Puerto Rico Chapter

President: **Melba Clavell,** *Quantic*
President-elect: **Myriam Sosa,** *Novartis*
Treasurer: **Yaritza Martinez**
Secretary: **Ruth Toledo,** *Amgen, Inc.*

Southeast Chapter

President: **Melissa Seymour,** *Biogen Idec*
President Elect: **Shannon Bellino,** *Doe & Ingalls*
Treasurer: **Sherry Nelson,** *Mangan, Inc.*
Secretary: **Renee Morley,** *Steris Corporation*

Southern California Chapter

President: **Saeed Tafreshi,** *Intelitec Corporation*
President Elect: **John Holmgren,** *Allergan, Inc.*
Treasurer: **William Nichols**

Texas Chapter

President: **Beth Kirschenheiter,** *Hospira, Inc.*
Treasurer: **Winston Brown,** *Alcon*
Secretary: **Patricia Rossman,** *Globiox*

West Coast Chapter

President: **Elaine Eborall,** *Genentech, Inc.*
President Elect: **Melissa Morandi,** *Acceleron Pharma*
Treasurer: **Milan Crnogorac,** *Genentech, Inc.*
Secretary: **Steven Dawson,** *Genentech, Inc.*

PDA Europe

Program & Events

PDA Europe, based in Berlin, Germany, conducts well-established conferences, workshops, Interest Groups meetings and post-conference training courses all over Europe and beyond, as well as in-house trainings in companies and universities.

In 2013, PDA Europe organized more than 40 events in Europe. Additional events outside Europe were set up with the support of the PDA Chapters, such as PDA Chapter Japan for a seminar on Pre-filled Syringes with more than 200 participants, PDA Chapter Israel for a Training Course on Visual Inspection and a PDA Europe Training Course organized for the Saudi Food & Drug Authority in Riyadh, Saudi Arabia.

The cooperation with PIC/S and the presence of regulators, health authorities and inspectors at PDA conferences and training courses provide content and panel discussions appreciated by individuals active across the pharmaceutical sector.

During this busy year, the programs, events & exhibition team held approximately 400 telephone meetings with committees, sent out more than 500 invitations and confirmation letters to speakers, shipped more than 5,000 kg of conference materials across the world and organized event locations, networking dinners and the accompanying exhibitions for round about 250 exhibiting companies.

A flavor of PDA Europe´s successful events might be reflected by highlighting the 2013 "The Universe of Pre-Filled Syringes and Injection Devices" Conference held in Basel, Switzerland. With more than 800 attendees and 100 exhibitors, this event exceeded all expectations and became the most successful event in the history of PDA.

Exhibition & Sponsoring

As is typical in most PDA conferences, PDA Europe also offers vendors the opportunity to present their companies in a complimentary exhibition. Exhibiting at PDA events provides attendees with hands-on experience regarding technological and scientific trends such as new machinery, materials and application systems.

Presenting and talking at PDA meetings about their novel technology and solutions is essential for distinguishing themselves from competitors.

PDA exhibitions have become a popular way for companies to support the conference while investing in another opportunity for image transfer. Exhibitors can sponsor in a variety of ways, starting with packages focused on delegate materials through producing special gifts for attendees, or co-hosting a Networking Event. PDA Europe, in turn, supports the exhibitors by offering them creative and appropriate ideas for an effective company promotion within the non-profit sector, helping them achieve the highest impact at the most reasonable price.

The tremendous success of PDA Europe in 2013 could not have been realized without:

The Finance & Administration Department

The Accounting and Controlling Department takes care of all financial matters of concern including bookkeeping, payments, reporting and budgeting. Additionally, matters of Human Resources and IT are taken care of.

The Registration, Membership & Chapters Department

In 2013, the Registration, Membership & Chapters Team received approximately 3,000 phone calls, 7,000 Emails and sent approximately 2,000 invoices to participants and members around the world. Antje represents the PDA Europe contact to members. Together with the PDA board members, supported PDA Europe the chapter activities in 2013.

The Marketing Department:

PDA Europe´s website has been visited by more than 53,000 people in 2013. More than 80 ads, flyers and brochures were created and four videos were produced. The Marketing Team developed partnerships with new media partners and coordinated the communication and promotion for all PDA Europe events.

Georg Roessling, PhD, Senior Vice President PDA Europe

Ailyn Kandora, Director Events & Exhibitions

Melanie Decker, Director Events & Exhibitions

Creixell Espilla-Gilart, Exhibition & Sponsorship

Elke von Laufenberg, Exhibition & Sponsorship

Lu Yang, Assistant Event Management

Sylvia Becker, Program Coordinator

Dirk Stelling, Director, Finance & Administration

Ilona Frank, Accountant

Antje Petzholdt, Registration, Membership, Chapters

Iryna Funke, Registration Coordinator

Nadine Gold, Marketing Manager

Frederike Mohme, Marketing Assistant

PDA Europe

2013 PDA Europe Activities

15-16 January – Milano | Italy
Single Use Systems for Pharmaceutical Applications
Scientific Planning Committee
Massimo Golia, *Pall Italy*
Walter De Matteo, *IBSA*

5-6 February – Lyon | France
Modern Biopharmaceutical Manufacturing
Scientific Planning Committee
Thierry Ziegler, *Sanofi-Aventis, Chair of the Conference*

7 February
Freeze Drying of Vaccines
Faculty: **Georg Frinke,** *Cilag AG*

26-27 February – Berlin | Germany
Pharmaceutical Microbiology
Scientific Planning Committee
Michael Miller, *Co-Chair, Microbiology Consultants, LLC*
Jette Christensen, *Co-Chair, Novo Nordisk A/S*

28 February
Microbial Contamination Control in the Pharmaceutical Industry
Faculty: **Karen Ginsbury,** *PCI Pharma*

28 February – 1 March
The A to Z's of Biofilm Control, Monitoring, Validation, and Excursion Investigation of Pharmaceutical Water Systems
Faculty: **Teri C. Soli,** *Soli Pharma Solutions, Inc.*

28 February – 1 March
Rapid Microbiological Methods
Faculty: **Michael Miller,** *Microbiology Consultant, LLC*

12-13 February 2013 – Ulm | Germany
Parenteral Drug Development
Scientific Planning Committee
Ingo Presser, *Boehringer Ingelheim, Conference Co-Chair*
Karoline Bechtold-Peters, *F. Hoffmann-La Roche, Conference Co-Chair*

19-21 March – Berlin | Germany
An Introduction to Visual Inspection: A hands-on training course
Faculty: **John G. Shabushnig,** *Insight Pharma Consulting* & **Markus Lankers,** *rep.ID*

19 March
Interest Group Meeting Visual Inspection – Automated Inspection

5-7 March – Prague | Czech Republic
Parenteral Packaging
Scientific Planning Committee
Claudia Petersen, *Co-Chair, Gerresheimer Bünde*
Mihaela Simianu, *Co-Chair, Eli Lilly*

Development of a Freeze Drying Process
Faculty: **Georg Frinke,** *Cilag AG*

7 March
Interest Group Meeting Pre-filled Syringes

Container Closure Development
Faculty: **Jörg Zürcher,** *Bayer HealthCare AG*

Selection and Utilization of Glass Containers in Pharmaceutical Packaging
Faculty: **Roger Asselta,** *Genesis Packaging*

Interest Group Meeting Freeze Drying: Cost Optimization in the Lyophilization Process

4-6 June – Berlin | Germany
Virus & TSE Safety Forum
Scientific Planning Committee
Kurt Brorson, *CDER, FDA, Co-Chair*
Hannelore Willkommen, *Regulatory Affairs & Biological Safety Consulting, Co-Chair*

3 June
Virus Spike Characterization and Virus Removal by Filtration: New Trends and Developments
Moderators: **Hannelore Willkommen,** *Regulatory Affairs & Biological Safety Consulting*
Qi Chen, *Genentech*
Brian Hubbard, *Amgen*

25-26 June – Florence | Italy
Advanced Therapy Medicinal Products
Scientific Planning Committee
Wilfried Dalemans, *TiGenix, Co-Chair of Conference*
Giovanni Migliaccio, *Istituto Superiore di Sanità, Co-Chair of Conference*

9-10 July – Dublin | Ireland
Current and Emerging EU Regulations and Inspection Trends
In Cooperation with the Irish Medicines Board
Scientific Planning Committee
Frank Hallinan, *Biopharmaceutical Consultant, Co-Chair*
John Lynch, *IMB, Co-Chair*

11 July
Managing Outsourced Operations
Faculty: **Karen Ginsbury,** *PCI Pharma*

GDP – The new EU Good Distribution Guideline
Faculty: **Richard Peck,** *Sensitech Inc.*

11-12 July
An Introduction to Visual Inspection: A hands-on Training Course
Faculty: **John G. Shabushnig,** *Insight Pharma Consulting* & **Markus Lankers,** *rep.ID*

23 September
Selection Considerations for Manufacturing Freeze Dryers
Moderators: **Georg Rössling,** *PDA Europe,* **Harald Stahl,** *GEA Pharma,* **Georg Frinke,** *Cliag AG* & **Stefanie Trudel,** *Boehringer Ingelheim*

24-25 September – Düsseldorf | Germany
Pharmaceutical Freeze Drying Technology
Scientific Planning Committee
Hans Hörmann, *Boehringer Ingelheim, Conference Co-Chair*
Oliver Ruetsch, *Cilag, Conference Co-Chair*

26 September
ICH Q9: Application of a Risk-based Approach to Freeze Drying Processes
Faculty: **Yves Mayeresse,** *GSK Vaccines*

26-27 September
Development of a Freeze Drying Process – From Formulation to a Robust Process
Faculty: **Georg Frinke,** *Cilag AG*

11-12 September – Basel | Switzerland
6th Workshop on Monoclonal Antibodies
Scientific Planning Committee
Juan Giménez, *Co-Chair, GSK Biopharmaceuticals*
Ilona Reischl, *Co-Chair, BASG/AGES*

10 September
Process Validation for the Manufacture of Biotechnology-Derived Active Substances
Chair of the Workshop: **Steffen Gross,** *PEI*

9-10 September
Implementation of Quality Risk Management for Commercial Pharmaceutical and Biotechnology Manufacturing Operations
Faculty: **Roland Guinet,** consultant

8-9 October – Berlin | Germany
Pharmaceutical Cold Chain Integrity
Scientific Planning Committee
Rafik Bishara, *Technical Advisor, Co-Chair*
Erik van Asselt, *MSD, Co-Chair*

7 October
Challenges of Cold Chain Logistics in Russia
Moderators: **Georg Rössling,** *PDA Europe,* **Anatoly Ushakov,** *Termo-Cont MK Ltd.,* **Elizabeth Meyer,** *Amgen,* **Rafik Bishara,** *PCCIG*

10-11 October
PDA Good Temperature-Controlled Management Practices
Faculty: **Rafik H. Bishara,** *PCCIG* Erik van Asselt, *MSD,* **Richard Harrop,** *Topa Packaging* & **Richard Peck,** *Sensitech*

5-6 November – Basel, Switzerland
The Universe of Pre-filled Syringes and Injection Devices
Scientific Planning Committee
Michael Betz, *F. Hoffmann-La Roche, Co-Chair*
Mathias Romacker, *Amgen, Co-Chair*

7 November
Glass – The Packaging Material for Parenterals
Faculty: **Bettine Boltres,** *SCHOTT*

7-8 November
Development and Technical Requirements for Combination Injection Products
Faculty: **Lee H. Leichter,** *IG Leader Combination Products US, P/L Biomedical*

Development of a Pre-filled Syringe: A hands-on Training Course
Faculty: Manfred Holzer, *SKAN,* **Christa Jansen-Otten,** *West Pharma,* **Horst Koller,** *Schott,* **Markus Lankers,** *rap. ID,* **Silvia Lorenz,** *Groninger,* **Wenzel Novak,** *Groninger,* **Heinz Prinz,** *Wilco,* **Ian Thompson,** *Ypsomed*

Honor Awards

Honorary Membership Award: James E. Akers, PhD

Dr. Akers is President of Akers Kennedy & Associates, Inc., located in Leawood, KS (Greater Kansas City). He has 33 years of experience in the Pharmaceutical industry and has worked at various director level positions within the industry and for the last two decade as a consultant. Dr. Akers served as President of the PDA from 1991 to 1993 and as a member of the PDA Board of Directors from 1986-1999. Currently, he is Chairman of the USP Committee of Experts Microbiology as well as a Co-Chair of the USP Expert Panel on Sterile Pharmacy Preparations and Chair of the Expert Panel Alternative Antibiotic Assay Methods. Dr. Akers is also a member of the United States Delegation to ISO T/C209 Working Group 2. He has lectured worldwide, and taught numerous pharmaceutical technology courses and moderated workshops in Europe, Asia and North America. Dr. Akers has also authored 29 textbook chapters in print and a 30th chapter in preparation. He has also edited two books, one on isolation technology and a second on advanced aseptic processing technology, and he has also authored more than 100 technical and review articles on a variety of subjects, including validation, aseptic processing, contamination control, environmental monitoring and control, biotechnology, isolator technology, sterilization and disinfection, sterility testing, media fill testing, HACCP analysis, pharmaceutical microbiology and regulatory compliance.

Frederick J. Carleton Award: John G. Shabushnig, PhD

Dr. Shabushnig is the founder and Principal Consultant of Insight Pharma Consulting, LLC, having recently retired from Pfizer after 28 years in both Quality and Manufacturing Operations. Dr. Shabushnig holds a BS in Chemistry and a PhD in Analytical Chemistry. He is an active member of the Parenteral Drug Association, having served as Chair of the Board of Directors and currently as Chair of the Science Advisory Board and the leader of the Visual Inspection Interest Group. He is also an instructor at PDA's Training and Research Institute.

Gordon R. Personeus Award: Carol M. Lampe

Carol Lampe is currently an independent consultant. She retired from Baxter Healthcare's Corporate Sterility Assurance Group, where she worked for more than 30 years and was a subject matter expert on aseptic processing. She was the co-chair for TR#62 on "Recommended Practices for Manual Aseptic Processes," which was issued in 2013, and is the trainer for a PDA course on the subject. She served on the PDA task force for the original and recently revised (2013) TR#22 on process simulation testing of aseptically produced products and was a member of the PQRI Committee that evaluated the FDA draft guidance on aseptic processing. She was on the PDA training team, who along with the FDA, provided training and interpretation of the 2004 FDA guidance to industry on aseptic processing. Lampe currently is a member of the training cadre for course work relating to fundamentals of aseptic processing. She works with a team of professionals from industry and PDA staff, teaching courses both at the TRI and on site. The on-site coursework is tailored to meet individual company needs related to aseptic processing, cleanroom fundamentals, support sterilization and cleanroom behavior.

***Michael S. Korczynski Award: Tor G. Gråberg**

Tor G. Gråberg has been with the Medical Products Agency since 1996 as a Pharmaceutical Inspector. In 2004 he was appointed as Head of Drug Inspectorate. Before joining the MPA, he was working as a production manager during 13 years in the pharmaceutical industry. He holds a MSc degree in Pharmacy from the University of Uppsala. During 2010 and 2011 Gråberg was the Chairman of PIC/S (Pharmaceutical Inspection Co-operation Scheme). He is still the Swedish delegate at PIC/S and member of its Executive Bureau. Since April 2011, he has been a member of PDA Science Advisory Board.

***Michael S. Korczynski Award: Yukio Hiyama,** PhD

Dr. Yukio Hiyama is Visiting (and retired) Scientist at National Institute of Health Sciences. He received PhD degree in Chemistry from the University of Tokyo in 1979. He leads MHLW's study groups to draft GMP related guidance and to propose the regulatory framework. Dr. Hiyama led an industry-government Human Science project on evaluation methods for pharmaceutical development and manufacturing control, and he is involved in JP Committees. He has been involved in the ICH discussion for Q8, Q9 and Q10. His work experiences include positions in Upjohn Co., scientist at National Institutes of Health, USA and post-doctoral fellow at University of Illinois.

** **New Description:** Award established in recognition of contributions made toward the development of PDA's international activities by Michael S. Korczynski, PhD.*

James P. Agalloco Award: Joseph J. Lasich

Joseph J. Lasich is President of JJL Global Pharma Services, LLC. He has provided aseptic processing consulting services to firms in Brazil, Canada and Germany, and has served as one of the instructors in aseptic processing at PDA. He retired from Alcon Laboratories after 33 years, where he last held the position of Director in Corporate Quality Assurance. Held management positions in Production, Technical Services, Validation and Quality Assurance. Former member of AAMI and ISO aseptic processing working groups.

James P. Agalloco Award: Rainer Newman

Rainer Newman has nearly 40 years of experience in aseptic processing. He is an independent expert providing aseptic processing consulting and training services. He served many years with Bristol-Myers-Squibb and Johnson & Johnson as well as several years with PA Consulting and in other consulting roles. Newman received his BS and MS degrees in Environmental and Radiation Science from Rutgers University.

James P. Agalloco Award: Brent Watkins

Brent Watkins is currently the South East Technical manager for Veltek Associates, Inc., supporting the pharmaceutical and biotech industries in contamination control. Prior to Veltek, he worked in several positions within SVP manufacturing for Abbott Laboratories (now Hospira). Watkins also serves on the faculty at the Parenteral Drug Association Training and Research Institute in Bethesda, Maryland. He is also a committee member for PDA's technical report on Cleaning and Disinfection. He holds a Bachelor's degree in Chemistry from Wake Forest University.

Honor Awards

Martin Van Trieste Pharmaceutical Science Award:
Professor Irving J. Pflug, PhD

Professor Irving J. Pflug, PhD, has been part of the University of Minnesota and the Parenteral Drug Association for more than 40 years, working in the area of Microbial Control and Technology. He and his collogues carried out research to integrate Microbial-Control Science into Sterilization Process Design and Validation, also in the statistical treatment of sterilization microbial calculations. One contribution was the development of the Holcomb-Spearman-Karber Method for DT-value calculation which makes the DT-value concept more understandable and usable. Nat Kirsch and Captain Sol Pflag worked with Professor Pflug in the development of the PDA "Teaching Sterilization" program that was carried out intensively for many years. This activity evolved into the PDA Training and Research Institute. One of the major advances in pharmaceutical product manufacturing is the move of the industry to Isolator Technology. Professor Pflug was part of a team led by Jack Lysfjord who shepherded that development through the regulatory channels into today's wide usage in the pharmaceutical industry.

*PDA Packaging Science Award: **Edward J. Smith,** PhD

Dr. Smith is a long-term member of the PDA where he leads the Packaging Science Interest Group and teaches for the TRI. He is also a former Board Member and served on the Steering Committee of the Pharmaceutical Cold Chain Interest Group. Dr. Smith is Principal Consultant at Packaging Science Resources, LLC which provides consulting and training in the packaging of injectable drug products for the pharmaceutical, biotechnology and medical device industries.

**New Award:* *Presented in recognition of contributions to PDA and the packaging science. Edward J. Smith, PhD is the inaugural recipient of this award.*

Distinguished Service Award: **Erik van Asselt,** PhD

Dr. Erik van Asselt, PhD, studied Chemistry at the University of Amsterdam, The Netherlands (cum laude). After his study he went to the University of Groningen where he received his PhD in Mathematics and Natural Sciences by the elucidation of 3D protein structures using X-ray crystallography. Since 2000, he has worked at Merck, Sharp & Dohme (MSD) in Haarlem, The Netherlands. He started as a Stability Coordinator and subsequently he became Supervisor of the stability laboratory. In 2007 he moved to the position of Improvement Engineer where he is responsible for cold chain management, logistics, budgets, and improvement projects. Van Asselt is a certified Black Belt. In February 2009, he became the chairman of the PDA Pharmaceutical Cold Chain Interest Group (PCCIG) European Branch. From December 2009 to June 2011 he led the PDA PCCIG Task Force on Risk Management for Temperature Controlled Distribution with more than 30 volunteers from the pharmaceutical industry, suppliers, and logistics service providers. This resulted in the publication of PDA Technical Report 58 in September 2012. In addition he contributed to PDA Technical Reports 53 and 64, which were published in August 2011 and October 2013, respectively. Since 2009 he is one of two co-chairs at the annual PDA Pharmaceutical Cold Chain Management conference in Berlin, Germany.

Distinguished Service Award: **David J. Cummings**

David J. Cummings is the Associate Director for Quality in CDER's Office of Pharmaceutical Science. He holds a degree in Chemistry from the University of North Carolina at Pembroke. He was employed as an analytical chemist in the pharmaceutical industry for 11 years and has 16 years of service with FDA in the areas of review, program and policy development, and quality management systems. Cummings is certified by the American Society for Quality as a Certified Manager of Quality/ Organizational Excellence and Certified Quality Auditor. He is also a member of the US Technical Advisory Group (TAG) 176 for ISO 9001 on Quality Management Systems.

Distinguished Service Award: **Nicholas R. DeBello**

Nicholas DeBello was employed with Kimble Glass for more than 30 years, holding various positions in the field of Personnel, Industrial Engineering, Quality, Technical Service, Warehouse and Distribution. Prior to his retirement in May 2003, DeBello was the Director of Quality Management Systems for Gerresheimer-Kimble Glass where he held that position for more than 12 years. In September 2003, DeBello became the Director of Quality Management Systems for Alcan Global Pharmaceutical Packaging, Inc. Wheaton Science Products which is now Wheaton. Prior to his retirement in December 2013, DeBello held the position of Vice President, Quality Management Systems. In this capacity he was responsible for Quality, Technical Services, Engineering Services and the ISO program. Today with more than 40 years of experience with glass manufacturing, quality and packaging involving the Pharmaceutical, Diagnostics and Life Science Markets, DeBello is the now Principal Consultant for DeBello & Associates, LLC. He is a PDA Member, Chairs the Glass Task Group and Co-Chairs the Glass Task Group for TR-43 Revision that includes Molded Bottles, Tubular Vials, Ampoules, Cartridges and Syringes. DeBello is also a Senior ASQ Member and Certified Quality Auditor with a B. A. Degree in Economics from St. Francis University.

Distinguished Service Award: **Laurie Norwood**

Laurie Norwood is the Deputy Director for the Division of Manufacturing and Product Quality (DMPQ) in the Office of Compliance and Biologics Quality/ CBER/FDA. Norwood received her B.S. Degree in Biology from Baker University and her M.S. Degree in Neurophysiology from the University of Maryland. She joined CBER in 1986 and worked in a research development lab for nine years, receiving two patents for her work on in vitro potency testing for Oral Polio Virus Vaccine. Since joining OCBQ in 1995, her responsibilities have included review of INDs for emerging Cellular and Gene Therapy products, license applications, and supplements for viral vaccines, hematologic recombinants, in vitro diagnostic kits and blood fractionation products, as well as inspection of biological manufacturing facilities. She has managed reviewers within the division and in addition to her Deputy Director responsibilities is currently involved in policy and development of guidance documents related to the review and inspection of products regulated by CBER.

Honor Awards

Distinguished Service Award: Brigitte Reutter-Härle
Brigitte Reutter-Häerle is the Director of Corporate Marketing for Vetter, a leading contract development and manufacturing organization that serves the global pharma/biotech industry. Appointed in 2004, she is responsible for the company's international marketing activities and product and service management. In 2009, she led the communications program for Vetter's U.S. expansion. Reutter-Häerle earned a B.A. and degree in business administration from Baden-Wuerttemberg Cooperative State University. She has served as leader of the PDA's Prefilled Syringe Interest Group/Europe since 2007, as well as in other PDA global and national capacities.

Distinguished Service Award: Michael VanDerWerf
Michael VanDerWerf is celebrating nearly 30 years in the biotech business, where he has seen a broad range of biological products and a wide sample of companies, such as GSK, evolve from an early stage. Now working on combination products for regenerative medicine applications, VanDerWerf continues to be challenged. But the one right choice that he made many moons ago was joining PDA, a forum to share experiences – both good and not so good – with others in the industry, and allowed him to mature as a professional. Thanks for everything.

Frederick D. Simon Award: Xiaolin Cao, PhD
Dr. Xiaolin Cao is a principal scientist in the department of drug product development, Amgen Inc., California, where he employs a number of analytical techniques to support formulation studies, cell sciences and technology and pilot plant manufacturing. Dr. Cao received his PhD in Chemistry from the Australian National University and has authored more than 60 peer-reviewed research papers. He is a member of American Chemical Society and the Society for Applied Spectroscopy.

Frederick D. Simon Award: Gregory T. Frank, PhD
Dr. Frank completed graduate studies at Stevens Institute of Technology and the University of Delaware, after which he has had a variety of roles in the pharmaceutical industry, the latest as Principal Engineer at Amgen. His experience has included responsibility for process and technology development for small molecule NCEs and biopharmaceuticals, as well working with environmental, safety and other regulatory agencies. His publications range from crystallization, physiological pharmacokinetics, oligonucleotides, membrane science, and bioreactors to a variety of biochemical unit operations.

Frederick D. Simon Award: Glen Hunter
Glenn Hunter graduated with a B.Sc. in Chemical Engineering from the University of California, Los Angeles in 1991. While at Amgen, he obtained M.Sc. degrees in Mechanical Engineering and Chemical Engineering from the USC. Joining Amgen in 1991, Hunter supported Amgen's Epogen® Manufacturing Plant as a process engineer. From 1995 through 1999, he supported the design and construction of many of Amgen's subsequent commercial manufacturing facilities in Colorado and Thousand Oaks. In 1999, Hunter became the Engineering Manager for Amgen's Pilot Plant facility, becoming its Director in 2002. The Amgen's Thousand Oaks Pilot Plant that comprises two distinct buildings and is operated by approximately 50 engineers and scientists.

Frederick D. Simon Award: Gregory S. Stimpfl, P.E.
Greg Stimpfl is currently a principal engineer in the pilot plant engineering group at Amgen, Inc. in Thousand Oaks, CA, USA. Stimpfl is a licensed professional engineer with more than 20 years of experience in pharmaceutical and bioprocess engineering. His attention for the past 10 years at Amgen has been focused on mammalian cell culture and recovery process engineering with an emphasis on process equipment design, pilot testing, and optimization.

Frederick D. Simon Award: Zai-Qing Wen, PhD
Dr. Zai-Qing Wen is a Principal Scientist in the Department of Formulation and Analytical Resources at Amgen. He obtained his PhD. from the University of Glasgow, U.K. His major interest is to apply vibrational spectroscopy including Raman and FTIR as well as electronic and optical imaging technique to characterize protein pharmaceuticals in pre-filled syringes and vials as well as to study the mechanism of protein interaction with container materials.

Distinguished Editor/Author Award: Michael J. Miller, PhD
Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical microbiology and the design, validation and implementation of rapid microbiological methods. He is currently the President of Microbiology Consultants, LLC (http://microbiologyconsultants.com). In this role, he is responsible for providing scientific, quality, regulatory and business solutions for the pharmaceutical industry and suppliers of new microbiology technologies. Over the past 23 years, Dr. Miller has held numerous R&D, manufacturing, quality, consulting and business development leadership roles at Johnson & Johnson, Eli Lilly and Company, Bausch & Lomb, and Pharmaceutical Systems, Inc.

Service Appreciation Award: Brenda Uratani, PhD
Dr. Uratani served as Assistant Country Director for FDA's China Office (2009- 2011), and held responsibility as FDA's primary senior technical and regulatory expert on issues related to pharmaceuticals. Before joining FDA's China Office, she worked as the Senior Compliance Officer in the Office of Compliance within FDA's Center for Drug Evaluation and Research (CDER) for more than 12 years. Dr. Uratani has extensive FDA working experience in Chemistry, Manufacturing, and Control (CMC) review, and current Good Manufacturing Practice (CGMP) and compliance both in sterile and biotech drugs. She plays a key role in the writing of the PET drug GMP regulations (21 CFR 212) and guidance, as well as several GMP guidances on sterile drug manufacturing, including the 2004 FDA Guidance on Sterile Drug Produced by Aseptic Processing.

Honor Awards

Service Appreciation Award: Barbara Jentges, PhD

Dr. Barbara Jentges, Senior Drug Regulatory Affairs Expert and Managing Director of PhACT GmH Switzerland, is a pharmacist with more than 22 years of experience in Drug Regulatory Affairs. Among other positions, she worked as an expert/assessor of the Federal Institute for Drugs and Medical Devices (BfArM = Bundesinstitut für Arzneimittel und Medizinprodukte) in Germany. She is also teaching at the ETH (Swiss Federal Institute of Technology) in Zurich/Switzerland in the Master curriculum Medicinal and Industrial Pharmaceutical Sciences (MIPS) and at the University of Applied Sciences and Arts Northwestern Switzerland, Basel. Additionally, she is member of PDA's Regulatory Affairs and Quality Advisory Board (RAQAB) and co-author of the book Pharmaceutical Legislation of the European Union, Japan and the United States of American — An Overview as published by PDA in 2013.

Service Appreciation Award: Maik W. Jornitz

Maik W. Jornitz, Chief Operating Officer of G-CON, LLC is a distinguished technical expert with close to 30 years of experience in bioprocesses, especially sterilizing grade filtration and single-use technologies, including regulatory requirements, integrity testing, systems design, and optimization. Jornitz has published multiple books, book chapters and over 100 scientific papers. He is a member of the PDA Science Advisory Board and Audit Committee, as well as an advisory board member of Artemes Technologies, Biotechnology Industry Council and multiple scientific publciations. He received his M.Eng. in Bioengineering at the University of Applied Sciences in Hamburg, Germany and accomplished the PED program at IMD Business School in Lausanne, Switzerland

Service Appreciation Award: Susan J. Schniepp

Susan Schniepp has more than 24 years of experience in quality assurance for both the food and pharmaceutical industries and is currently the Manager of Specifications and Test Methods for Hospira, Inc. She has a degree in microbiology from Northern Illinois University and began her career in 1980 as a microbiologist in the food industry for Quaker Oats and M&M/Mar where she first used the USP. In 1984 she transitioned to the pharmaceutical industry as an R&D Microbiologist. During her career she has had responsibilities for complaints, labeling and other quality systems but her primary focus has been establishing communications with compendial authorities.

Service Appreciation Award: Steven Mendivil

Steven Mendivil is Executive Director of International Quality External Affairs for Amgen, Inc. He has worked in the Biotech/Pharmaceutical/ Medical Device Industry for more than 30 years with Svya, Syntex, Genentech and Amgen. As an active member of PDA, Mendivil was Chair of RAQAB and Executive Officer (Secretary) for PDA's Board of Directors. He has Co-Chaired a number of PDA conferences and most recently lead the Quality Metric Conference and PDA's Points to Consider on Quality Metrics.

Service Appreciation Award: Saeed Tafreshi

Saeed Tafreshi began his professional career in 1980 as a machinist by day and a mechanical engineering student at night. In the early days of rapid advancement of technology where traditional electro-mechanical designs where being replaced by processors, Tafreshi entered the machine design arena. In his 10 years as a designer, he recorded number of manufacturing machinery and assembly line design advancements employing the use of CNC, EDM, CAD, CAM, and Control Processors. In 1992 Tafreshi began applying his manufacturing systems expertise to help Pharmaceutical, Biotech and Medical Device Industry meet the regulatory compliance challenges. The last eight years of his career he served as Management Consultant and Process Designer focusing on Quality and Efficiency. His involvement with PDA started in early 1990s. He served as the president of Southern California chapter for three terms. His current project is called "retirement."

Service Appreciation Award: Sabine Scheitlin

After graduating, Sabine Scheitlin made her apprenticeship in Roche and has been with the company for the 20 years since. Scheitlin had responsibilities in managing Safety, Efficacy and Quality-parts of the regulatory filings for drug registration for several countries and companies. She has several years of experience in managing the internal and external communication as well as in organizing international meetings, events and exhibitions. In her current position as operational support manager in Global Quality at Roche, she is responsible in addition for all technical and administrative aspects of the monthly GMP Newsletter as well as for the research and oversight on new regulations and requirements as well as related literature. For the PDA project on "Paradigm Change in Manufacturing Operations (PCMO)," Scheitlin was supporting Dr. Stephan Roenninger, who is one of the founders and co-chair, in for coordination and project managing aspects from the beginning in 2008 till 2013.

Service Appreciation Award: Russell E. Madsen

Russell Madsen is President of The Williamsburg Group, LLC. Prior to forming The Williamsburg Group, he had served PDA as Acting President and was Senior VP Science and Technology. Before joining PDA, he was employed by Bristol-Myers Squibb Company as Director, Technical Services, providing technical and general consulting services to Bristol-Myers Squibb operations, worldwide. He is Vice-Chairman of ASTM E55.03 General Pharmaceutical Standards, a member of the USP Microbiology Expert Committee, Chairman of the USP Visual Inspection of Parenterals Expert Panel, a member of Pharmaceutical Technology's Editorial Advisory Board, and an Honorary Member of PDA.

Service Appreciation Award: Arthur Vellutato Jr.

Art Vellutato, Jr. is the President and CEO of Veltek Associates, Inc. (an EPA and FDA registered facility), founded in 1981. He is also the President and Senior Consultant of Aseptic Processing, Inc., the consulting division of Veltek Associates, Inc. He is a frequent industry speaker with more than 50 industry publications, and he is one of the leading consultants in the pharmaceutical and biotechnology industry specializing in contamination control, cleaning, disinfection, gowning and environmental monitoring. He lends more than 26 years of valuable experience that include his tenure as the Director of Quality Assurance at VAI for nine years, the Director of Manufacturing for six years. Vellutato conducted cGMP training on Cleaning/Disinfection/Contamination Control/EM to FDA (CDER and CBER) in 2002 through 2009. He also conducted training for the EMEA in 2004, 2006, 2007, 2009, 2010 and to the Kazakhstan (Russian) Regulatory Agency in 2005. In his tenure in the industry, he has trained more than 500,000 industry professionals.

Honor Awards

Service Appreciation Award: Rina Yamin

Rina Yamin served as President of the Israeli PDA in 2012-2013. She holds a Pharmacy degree and an MBA in Health Systems Management. She has more than 35 years of industrial Pharmaceutical and Biotechnological experience in R&D, regulatory and clinical studies. Currently, Yamin is an examiner of the Israeli Chief Scientist.

Service Appreciation Award: Don Elinski, RPh

Don Elinski was most recently a Principal Consultant with Lachman Consulting Services. In that role, he served as an expert consultant in the areas of Manufacturing, Quality, Compliance, and Validation. Over the past nine years, Elinski has worked on projects of a global and national level. He has previously held positions of responsibility in Validation, Quality, and Technical Services for Eli Lilly, Johnson & Johnson, Merck, Genentech, Sterling Winthrop, Zeneca, and Geneva (Sandoz) Pharmaceuticals. He has worked with both solids technology, biotechnology, and parenterals. Elinski has been active in PDA for most of his career, serving in the past as the Section Leader for the PDA Manufacturing Sciences Interest Groups, and a charter member of the Science Advisory Board and the Regulatory Affairs Quality Advisory Board. He has further contributed to the PDA and ISPE through past technical reports, presentations and task forces, and program committees, He was the recipient of the PDA Distinguished Service Award in 2003. Elinski holds degrees in both Biophysics and Microbiology, and Pharmacy from the University of Pittsburgh. He is a Registered Pharmacist in Virginia and Pennsylvania.

Service Appreciation Award: Lothar Hartmann, PhD

Dr. Lothar Hartmann obtained his Diploma and PhD in Technical Chemistry from the Technical University of Berlin. He joined Hoffmann-La Roche in 1988 and served in numerous functions in the global Quality Department. Dr. Hartmann acted as Head of External Relations interacting with regulatory health authorities and associations for more than a decade before being assigned as Head of Knowledge Management. Since 2011, he has served as Head of Quality at Crucell Berne, a Johnson & Johnson Group of Companies. He served for approximately 10 years on the board of APIC/CEFIC as Vice-Chairman. In this function, he was nominated for the ICH Q7a Expert Working Group setting up world-wide harmonized GMPs for APIs. His work was also recognized with an award from the FDA in May 2004. Dr. Hartmann is co- and lead-author of various documents published by CEFIC/APIC and EBE (European Biopharmaceutical Enterprises). Dr. Hartmann also served on the Board of Directors of PDA from 2008 until 2010 and was initiator of PDA's PCMO project.

Service Appreciation Award: Harold S. Baseman

Hal Baseman is the Principal and Chief Operating Officer for ValSource LLC and ConcordiaValsource. He has more than 33 years of diverse experience in the pharmaceutical, biotechnology, and medical device industry. He has held technical and executive management positions with several operating and consulting companies. Aside from his present position, Baseman's executive management positions included President and CEO of Vital Pharma and BFS Technologies, founder and President of The Validation Group Inc., and President of Day & Zimmermann Biopharm Technologies Division. Baseman has been an active member of the PDA for more than 25 years and has been a member of the Board of Directors since 2008 and Treasurer through 2010 and 2011. He has been the co-chair of the PDA Science Advisory Board and co-leader for the PDA Process Validation Interest Group since 2005. He was the co-lead for the PDA Technical Report #44: Risk Management for Aseptic Processing Task Force and the co-lead for the Technical Report #22 (Aseptic Process Simulation) revision team. Baseman is a member of the PDA TRI Faculty and a frequent presenter at PDA conferences and meetings. He holds a Bachelor of Science Degree in Biology from Ursinus College in Collegeville, PA and a Masters in Business Administration in Management from La Salle University in Philadelphia, PA.

Service Appreciation Award: Robert Sitrin, PhD

Dr. Sitrin has been with Merck Research Labs since 1987 in Bioprocess Research and Development, responsible for analytical development, characterization and preclinical regulatory filings of numerous vaccines including VAQTA®, RECOMBIVAX HB®, PedvaxHIB®, COMVAX®, GARDASIL®, PNEUMOVAX 23®, Proquad®, RotaTEQ®, and ZOSTAVAX®. Most recently, he managed a group in Manufacturing Commercialization responsible for providing analytical support to vaccine products during late development and post licensure. Today Dr. Sitrin is responsible for managing the Analytical Life Cycle project in Vaccine Commercialization for modernizing vaccine assays for current products as well as providing internal support for troubleshooting current analytical and process issues. He holds a B.S. in Chemistry from MIT and a PhD in synthetic organic chemistry from Harvard.

Service Appreciation Award: Greg Jordan

Greg Jordan graduated from the Victorian College of Pharmacy in 1975 and gained a Master's Degree in 1977. He has more than 30 years of experience in the pharmaceutical industry, both as a consultant and employed in Product Development, Quality Control and Regulatory Affairs departments for major international pharmaceutical companies. His areas of interest are in analytical chemistry and quality systems. Jordan is a Senior Educator at Box Hill Institute in Melbourne responsible for delivery of Pharmaceutical Manufacturing training in China and a Senior Quality Auditor with SQA Services Inc. He is currently a Board member of 'Racing Analytical Services Limited.' He first joined the PDA in 1998.

Service Appreciation Award: Janeen A. Skutnik-Wilkinson

Janeen Skutnik-Wilkinson is Vice President of NSF Health Sciences, Pharma Biotech at NSF- International, a non-profit International Public Health Organization that provides education, consultancy and auditing to the pharmaceutical sector. Previously, she was Director of Quality Strategy at Pfizer, responsible for working with various trade associations and also developing Pfizer Positions on Quality and CMC issues on a global scale. She has more than 18 years experience and expertise in excipients, QA/QC, compendial affairs, quality and regulatory policy, change control and documentation, analytical method development and validation, and product launch spanning two companies.

Honor Awards

Service Appreciation Award: Jeanne Moldenhauer

Jeanne Moldenhauer has more than 25 years of experience in sterile process validation, regulatory affairs and microbiology. She is now the Vice President of Excellent Pharma Consulting, Inc. Moldenhauer is an Interest Group Leader for Microbiology and Environmental Monitoring at PDA, Chair of the Rapid Microbiology User's Group and a member of the Scientific Advisory Board of PDA. Moldenhauer is a published author and editor of four previous PDA-DHI books: *Environmental Monitoring: A Comprehensive Handbook*, *Steam Sterilization: A Practitioner's Guide*, *Laboratory Validation: A Practitioner's Guide*, and *Systems Based Inspection for Pharmaceutical Manufacturers*. She is the winner of the 2005 PDA/DHI Distinguished Editor/Author Award.

Service Appreciation Award: Karen S. Ginsbury

Karen Ginsbury is a London trained pharmacist, with a Masters degree in Microbiology. Expert in all aspects of cleanrooms and microbiology, she has a second area of expertise in the GMP manufacture of investigational drugs and is currently co-editing a PDA Technical Report on the topic. With more than 20 years of experience in the industry, Ginsbury has hands-on experience in Quality Assurance and setting up GMP compliant Quality Systems. She regularly lectures around the world on related topics.

Service Appreciation Award: Eldon Henson

Eldon Henson currently serves as the Vice-President, Quality Operations at Mallinckrodt Pharmaceuticals in St. Louis where he has responsibility for all quality and compliance activities at Mallinckrodt's 10 manufacturing facilities in North America and Europe. These facilities manufacture a variety of APIs, solid dosage forms, parenteral products, and nuclear imaging products. He serves as a member of IVT's Editorial Advisory Board and has had a number of publications on a variety of GMP compliance topics, such as IVT's Auditing Handbook, Quality Improvement Handbook, Topic of the Day GMP Training Program, the GMP Toolbox, contamination control, GXP Excellence by Design (XbD), the role of integrity in a GXP environment, supplier quality, and creating a culture of compliance. Henson holds BA and MA degrees in Microbiology from Southern Illinois University – Carbondale. He has worked in various quality and manufacturing roles at Abbott Laboratories, Novartis, Boehringer-Ingelheim, KV Pharmaceutical, and Sigma-Aldrich and is the immediate Past President of the Missouri Valley Chapter of PDA.

Europe Service Appreciation Award: Dr. Harald Stahl, PhD

Dr. Harald Stahl is the Senior Pharmaceutical Technologist at GEA Pharma Systems and the leader of PDA's Lyophilisation Interest Group. He has held various positions at GEA since 1995 and previously worked for Schering AG, Germany, where he focused on aseptic powder processing. With a diploma in physics and a PhD in chemical engineering, Dr. Stahl is an experienced trainer, presenter and author, having published more than 100 papers on various aspects of pharmaceutical processing.

PDA President Award: Robert Collier

Before the name "Information Technology" was invented, Bob was using computers. He wrote his first computer program as a college student in 1970. After graduation, he became a professional Software Engineer starting at NASA, moving on to Aramco in Saudi Arabia, and finally returning to the U.S. to work in Telecommunications and Online Services. Collier would say that a love of science sent him to NASA, a love of travel sent him to Saudi Arabia, but it was Lady Luck that brought him to PDA.

PDA President Award: Nadine Gold

Nadine Gold has been working for PDA for 5 years in marketing and communications. She lives above the office, which came in handy the first three years working for PDA because she only has to climb two stairs at night and fall right into her bed. She loves nature; she walks, bikes and exercises outside in order to clear her head and come up with creative ideas for PDA Europe. She originally wanted to become a teacher but her voice is too quiet. Luckily, she does not need a loud voice working for PDA!

Special Recognition: Jack Levin, MD

Presented by the Parenteral Drug Association (PDA) in recognition of the 50th anniversary of Dr. Levin's pioneering work and discovery of Limulus Amebocyte Lysate (LAL) reagent, which revolutionized the way we test for bacterial endotoxin. PDA further recognizes Dr. Levin as a leader in research related to the physiological effects of endotoxin and chronic diseases associated with Gram-negative bacteria.

2013 Annual Financial Report

PDA is a financially independent, not-for-profit organization. The association's primary sources of revenue are programs (meetings and conferences), education and training, publication sales and membership dues.

PDA has Fifth Consecutive Year of Financial Growth

PDA continued to see strong demand from our members. This is a testament to the value of the products and services PDA offers. Global revenue grew 4 percent from $15.7 million in 2012 to $16.3 million in 2013. Revenue was driven by strong growth in our Programs and Meetings and customized in-house training offered by our Training and Research Institute. Membership also had another record year, marking our fourth year of consecutive increases in PDA members.

Financial Reserve Targets achieved in 2013

As outlined in the 2015 strategic plan, PDA is committed to rebuilding its financial reserves while also investing in new capital projects. PDA's financial reserves are now fully funded – two years ahead of plan. PDA's unrestricted net assets grew 37 percent in 2013 from $5.6 million in 2012 to $7.7 million. PDA's cash and investments increased from $7.5 million in 2012 to $9.9 million in 2013 — a 33 percent increase. These cash reserves help provide long term stability for PDA.

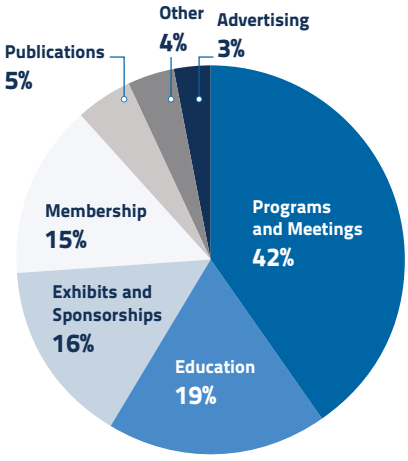
The following is a summary of the audited financial statements for the year ending December 31, 2012. The full audit report is available upon request from PDA headquarters in Bethesda, Maryland.

2013 Annual Report Financial Summary

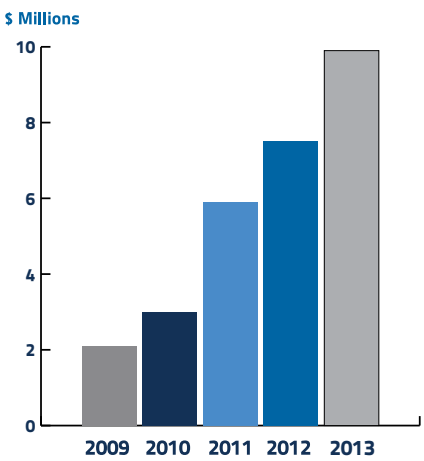
	2013	2012
Total Revenues	$ 16,319,184	$ 15,731,233
Total Expenses[1]	$ 14,292,001	$ 14,149,531
Net Income Surplus (Deficit)	$ 2,027,183	$ 1,581,702
Net Assets at beginning of year	$ 5,592,628	$ 4,010,926
Net Assets at end of year	$ 7,655,918	$ 5,592,628
Net Asset ratio (Net Assets/Annual Expenses)	54%	40%

[1] *Foreign currency translation adjustments account for a decrease of $8,540 in 2013 expenses and a decrease of $14,671 in 2012 expenses. See Note F of the 2013 audited financial statements for additional detail.*

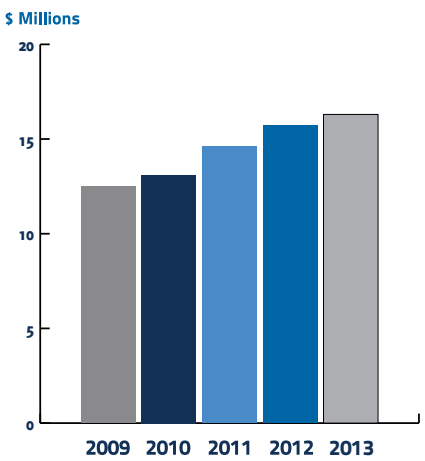
2013 Revenue Sources



Cash & Investments



Revenue



2013 PDA Staff

Executive Office

Richard M. Johnson, President
Tess Birch, Administrative Assistant

Scientific and Regulatory Affairs

Rich V. Levy, PhD, Senior Vice President, Science and Regulatory Affairs
Walter Morris, Director, Publishing
Denyse Baker, Senior Advisor, Science & Regulatory Affairs
Josh Eaton, Senior Project Manager, Science & Regulatory Affairs
Morgan Holland, Coordinator, Science & Regulatory Affairs
Janie Miller, Senior Project Manager, Science and Regulatory Affairs
Rebecca Stauffer, Writer/Editor
Katja Yount, Publication Design Specialist

Membership Services

Hassana Howe, Senior Manager, Membership Services and Chapters
Trevor Swan, Manager, Membership Services and Chapters
Megan Kuhman, Volunteer Coordinator
Katie Ruiz, Customer Services Representative

Sales

David Hall, Vice President Sales, Contractor
Alison Caballero, Sales Coordinator

PDA Training and Research Institute

Robert L. Dana, Senior Vice President, Training and Research Institute
Stephanie Ko, Senior Manager, Lecture Education
James Wamsley, Senior Manager, Laboratory Education
Oscar Bermudez, Coordinator, Laboratory Education

Marketing Services

Adrienne Fierro, Vice President, Marketing Services
Amelia Townsend, Marketing Director
Emily Hough, Marketing Coordinator
Jessica Almonte, Marketing Coordinator
Morgan Predieri, Marketing Coordinator
Faramarz Kolivand, Webmaster
Janny Chua, Manager, Bookstore

Programs and Registration Services

Wanda Neal, CMP, Senior Vice President, Programs and Registration Services
Jason E. Brown, Senior Manager, Programs and Meetings
Patresa Day, Manager, Registration
Leon Lewis, Senior Manager, Programs and Web Seminars
Andrea Viera, Senior Coordinator, Programs and Registration Services
Tanya Allen, Senior Coordinator, Programs and Registration Services
Melissa Pazornik, Coordinator, Program and Registration Services
Aja Schorr, Coordinator, Program and Registration Services

Administration

Craig Elliott, Senior Vice President, CFO
Michelle Lax, US Controller
Jennifer Bell, Controller
Ana Vallenas, Accounts Payable Analyst
Shanna Morgan, Accounts Receivables Specialist
Feng Chen, Senior Manager, Information Technology
Frank Wang, IT Specialist
Bob Collier, Database Administrator

PDA Europe

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Nadine Gold, Marketing Manager
Frederike Mohme, Marketing Assistant
Ailyn Kandora, Director Events & Exhibitions
Melanie Decker, Director Events & Exhibitions
Antje Petzholdt, Manager, Membership & Chapters, EU Event Registration
Dirk Stelling, Director, Finance/Controlling
Ilona Frank, Accountant
Iryna Funke, Registration Coordinator
Sylvia Becker, Program Coordinator
Creixell Espilla-Gilart, Exhibition & Sponsorship Management
Elke von Laufenberg, Exhibition & Sponsorship Management
Lu Yang, Assistant Event Management

PDA®
Parenteral Drug Association

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