



*Connecting People,
Science and Regulation®*

2012

ANNUAL
REPORT

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About PDA

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 60-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 more than 9,500 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.

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Message from the PDA Board of Directors Chair

PDA 2012: Strategically Moving Forward

With our many scientific publications, training courses, conferences and other activities, also in 2012 PDA continued to be the foremost global provider of science, technology, and regulatory information and education in the pharmaceutical and biopharmaceutical industry.

The PDA staff and hundreds and hundreds of our 9,500 members from industry and health authorities actively shared knowledge and advanced our industry.

PDA continued to grow and with revenues exceeding 15 million dollars for the first time combined with a sound cost structure we were able not only to continue many of the things we are known for in terms of signature meetings and training, but also expand into new hot topics of interest for our membership. With our strategy, which was approved a few years back, the Board of Directors has focused our activities on things we know serve our membership.

We published a record number of Technical Reports (TRs) and surveys. The TRs are used extensively by industry and health authorities to set current standards and expectations on technical topics and our process for developing and approving these ensures a high quality level.

We expanded our service and made these TRs available electronically to all members. You can now access them directly from your computer, iPad or other electronic device when you need to reference important technical topics.

We continued with our signature meetings, including the Annual Meeting, the PDA/FDA Joint Regulatory Conference, the Annual Global Conference on Pharmaceutical Microbiology, the PDA/EMA Meeting, and the Universe of Prefilled Syringes and Injection Devices.

We also covered new topics like the PDA/PICS meeting and our ICH Q10 WS and training series. We saw great attendance at these conferences both in US, Europe and Japan.

Numerous training courses were offered and attended around the world, including those at the PDA Training & Research Institute in Bethesda, where Aseptic Processing continues to be a sold out course. In our training facility, members can practice various aseptic techniques and many laboratory courses with no risk of causing a deviation when things fail – as we would in our companies.

The combination of local and global meetings continues and many of our chapters were very active in 2012 and we even decided to add two new chapters in Texas and India. Welcome!

Our members continued to significantly influence the scientific approach described in many guidelines by providing comments on a number of documents from many health authorities around the world.

Senior PDA staff and several members of the Board of Directors provided what we call “roadshows” to companies. These have proven very beneficial to both the companies and PDA through the dialog we have about current and potentially new topics.

I want to thank our outgoing Board member Martin Van Trieste and Zena Kaufman for their contributions to our organization and welcome Stephan Roenninger, and Ian Elvins to the Board.

I also want to thank Richard Johnson and his entire staff for all the great work they do every day. It is to their credit that our conferences and other activities are rated as highly as they are in terms of service level and organization.

A big thank you also to all the people from health authorities, who speak at our conferences, serve on a task force or committee or any other activity you spend time on for PDA’s membership and our industry. Trust me – the work you put into this is highly appreciated – and it helps bringing our industry forward for the benefit of patients.

Finally, I want to thank all of you – our members – for the passion and interest you bring. This is what makes PDA the world’s most rewarding and exciting organization connecting people, science, and regulation. There are so many ways of contributing to both our industry and your own personal development by taking an active career in PDA volunteer work.

PDA is moving into 2013 as a very strong organization. We will continue what we are known for and also expand our activities into new and coming hot topics that fall under our strategy.

I am looking forward to seeing you all again in 2013.



Anders Vither, Chair, PDA

Message from the PDA President



Richard M. Johnson, President, PDA

I am pleased to report that 2012 was another very successful year for your association. Our member-volunteers and PDA staff, PDA delivered great conferences and training, enhanced member benefits, and continued development and publication of a record number of industry-leading technical reports and regulatory comments. All of this activity was in continued execution of the PDA 2010-2015 Strategic Plan (published Jan. 2012 PDA News). I would like to highlight a few elements of the plan for 2012:

Focused resources to continue delivering outstanding Technical Reports and Surveys, including:

- › PDA Technical Report 52 (TR 52) Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain
- › PDA Technical Report 53 (TR 53) Guidance for Industry: Stability Testing to Support Distribution of New Drug Products
- › PDA Technical Report 22, (TR 22) Revised 2012 Process Simulation for Aseptically Filled Products
- › Risk Mitigation of Tribromoanisole (TBA)/ Trichloroanisole (TCA) Taints and Odors: A Pharmaceutical Industry Survey

Continued strong conferences and workshops, such as:

- › 66th PDA Annual Meeting in Phoenix
- › 4th PDA/EMA Joint conference in London
- › 21st Annual PDA/FDA Joint Regulatory Conference, in Baltimore, MD
- › 7th Microbiology Conference in Bethesda
- › 9th Pre-filled Syringe Conference in Las Vegas
- › ICH Q10 Meeting in Japan in cooperation with US FDA and PMDA
- › And others

Enhanced our training activities to include more high quality, hands-on training in:

pharmaceutical and biopharmaceutical technology, including aseptic processing, visual inspection, rapid microbiology methods, and more than 50 other topics. We also expanded our in-house training program, through an expanded faculty of industry experts.

Expanded our Global Impact by reaching out to emerging markets, including:

Reduced membership rates for emerging markets. Enhanced our member benefits to include a Technical Report Portal for all members.

Work effectively with global regulatory authorities to enhance pharmaceutical science and advance health of patients,

including cooperative activities with US FDA, EMA, PIC/S, PMDA, and regulators in Singapore, Russia, and throughout Europe and the Middle East.

Manage your Association's resources to assure our continued capability to deliver the value you have come to expect.

Every year seems even busier, but I want to thank you for your support and all of the volunteer efforts that make all of these activities happen. Please let us know if there are other areas you would like us to address, if you would like to volunteer in a task force, interest group or a committee, or if you would just like to stop by. Remember, this is your association. Your input is valued and appreciated.

2012 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



PRESIDENT
Richard M. Johnson

Directors



Ursula Busse
Novartis



Jette Christensen
Novo Nordisk



John Finkbohner
MedImmune



Gabriele Gori
Novartis Vaccines and
Diagnostics



Zena Kaufman
Hospira, Inc.



Michael Sadowski
Baxter Healthcare



Junko Sasaki
Dainippon Sumitomo



Sue Schniepp
Allergy Laboratories, Inc.



Lisa Skeens, PhD
Hospira, Inc.



Christopher Smalley, PhD
Merck & Co.



Martin Van Trieste
Amgen, Inc.



Glenn Wright
Eli Lilly

Scientific and Regulatory Affairs

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he Scientific and Regulatory Affairs Department (S&RA Department) 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 PDA member volunteers who collectively review current trends and develop deliverables to address industry challenges.

Work products include strategic and tactical plans, concepts for PDA meetings and workshops, PDA Training and Research Institute (PDA TRI) courses, industry surveys, position papers, comments on draft 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 S&RA 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.

In leading and supporting expansion and management of Advisory Boards, Interest Groups, Task Forces, Technical Report Teams and TRI Courses, a project manager was added in Q1, as well as the appointment of an administrative assistant in Q4. In 2012, the S&RA Department closed the year with three full-time staff: **Richard Levy**, PhD, Senior Vice President of Scientific and Regulatory Affairs, **Joshua Eaton**, Senior Project Manager, **Jahanvi (Janie) Miller**, Senior Project Manager and contractor **Morgan Holland**, Administrative Assistant. Mrs. Miller, through the Regulatory Affairs and Quality Advisory Board (RAQAB), focused on the US and European regulatory scene and contributed to the development of regulatory responses. Mr. Eaton focused on development of the Biotechnology Advisory Board (BioAB) technical projects. The two project managers dedicated a majority of their time to develop a Process Reengineering and Change Management initiative.

There were also two part-time staff members: **Vincent Anicetti**, PDA Fellow in North America, and **James Lyda**, Senior Advisor, in Europe.

Process Reengineering and Change Management

In 2012, the staff focused on the development and deployment of a new process designed to strengthen our Technical Report Development process. PDA launched a Process Reengineering and Change

Management program in quarter three of 2012. The major deliverables and volunteer tools that were products of this initiative include:

- › Launch of an official PDA team Workspace site
- › Development and deployment of a comprehensive training program on the new Technical Report development process for:
 - › Technical Report Teams
 - › Advisory Boards
- › Development of Technical Report Team Handbooks for:
 - › Volunteers
 - › Advisory Boards
- › Development and deployment of a PDA Guide for Authors: Citation Guide aimed at making the document development process more transparent and setting expectations for written deliverables
- › Rewards and recognition program

Another initiative focused on the development of PDA-owned course materials. To improve the technical content and delivery of the TRI courses, the S&RA department developed course materials based on newly published Technical Reports. The results were delivered in the form of eight new PDA-owned TRI courses using a newly developed training template.

In 2011, the first projects in the PDA Paradigm Change in Manufacturing Operations (PCMOSM) initiative began to reach closure, including



Richard Levy, PhD
Senior Vice President



Joshua Eaton
Senior Project Manager



Jahanvi (Janie) Miller
Senior Project Manager



Morgan Holland
Administrative Assistant



Vincent Anicetti
PDA Fellow in North America



James Lyda
Senior Advisor in Europe

Scientific and Regulatory Affairs

“Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations (TR54),” “Application of Phase-Appropriate Quality Systems and CGMP to the Development of Therapeutic Protein Drug Substance (or API) (TR56),” and “Utilization of Statistical Methods for Production and Business Processes (TR59).” In 2012 we published these technical reports and brought to closure three supporting annexes based on Quality Risk Management Case Studies. The focus of the three annexes are as follow; Packaging and Labeling, Pharmaceutical Drug Substances and Biotechnological Bulk Drug Substances. PCMO projects are expected to facilitate knowledge transfer between the experts from industry, universities and regulators and members from the respective ICH Expert Working Groups and Implementation Working Groups.

PDA sponsored several industry surveys in 2012, including a survey examining pharmaceutical glass quality and another evaluating the business case for pharmaceutical quality. The results of those two surveys were presented at the “PDA Glass Quality Conference,” and each will be published in 2013.

The Scientific & Regulatory Affairs Department, along with members from related Interest Groups and Task Forces, contributed expertise and guidance in the development of agendas for PDA Conferences and Workshops, including the “PDA/FDA Adventitious Agents and Novel Cell Substrates,” Combination Products, and Single Use Systems Workshops.

Looking Ahead

In 2013, our departmental objective is to update the governing documents for the Scientific and Regulatory Affairs Department. The full impact of the new process is yet to be seen as existing teams begin to integrate into the new TRT development process, and newly formed teams enter the incubation phase. The PDA leadership team (Board of Directors) is in full support of the reengineered process. The Scientific and Regulatory Affairs staff is dedicated to continually improve on this initiative through feedback from our members and volunteers. Our goal is that the new technical report development process provides more timely access to relevant information for members of the pharmaceutical manufacturing community.

SCIENCE

The PDA Advisory Boards execute PDA strategic plans 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 guidance’s and directives.

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, Scientific and Regulatory Affairs, PDA

Biotechnology Advisory Board

In 2012, the BioAB was 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 Technical Report Teams, including Analytical Methods Development, Bioburden and Biofilm Management, Reprocessing of Biopharmaceuticals; two Cell Substrate related teams, Single-Use-Systems, Vaccines and a project focused on Mycoplasma.

The following technical report was approved by the BioAB in 2012:

- Ballot No. 43: Analytical Methods Validation and Transfer for Biotechnology Products

The Biotechnology Advisory Board participated in commenting on three FDA Draft Guidance’s involving biosimilars:

- Ballot No. 45: *FDA Draft Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Protein Product*
- Ballot No. 46: *FDA Draft Guidance for Industry: Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product*

Scientific and Regulatory Affairs

- › Ballot No. 47: *FDA Draft Guidance on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*

Ballots 45-47 underscore the growing importance and influence of biosimilars in the pharmaceutical arena. Significant advances have been made during recent years and the field is now starting to come of age. However, demonstrating that a proposed protein product is biosimilar to an FDA-licensed reference product manufactured by a different manufacturer is complex and will likely require more extensive and comprehensive data than simply assessing the comparability of a product before and after a manufacturing process change made by the product's sponsor. PDA contributed to make the adoption of these draft guidances more comprehensive and applicable to the manufacturers' operations.

Scientific Advisory Board

In 2012, 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 are to reach final draft stage in 2012 and are anticipated to complete their work in 2013 including the revision of TR 3 Dry Heat Sterilization, and TR 43 Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing, and TR33 Validation and Implementation of New Microbial Testing Methods. Several new technical reports such as Process Validation, Steam-in Place, Recommended Practices for Manual Aseptic Processes, and Active Temperature Controlled Systems: Qualification Guidance are also expected to come to a close in 2013.

The SAB was instrumental in managing the development, approval, and publication of five (5) PDA Technical Reports in 2012.

In 2012, the SAB approved the following 14 ballots:

- › SAB Ballot 197: Review of PDA comments RE: EMA Guideline on Process Validation
- › SAB Ballot 196: PCCIG_ Active Temperature Control Systems: Qualification Guidance
- › SAB Ballot 195: Process Validation: A Lifecycle Approach Technical Report
- › SAB Ballot 194: PDA Task Force Proposal: "Objectionable Microorganisms"
- › SAB Ballot 193: Pre-use/Post-sterilization Integrity Testing of Sterilizing Grade Filters (PUPSIT)
- › SAB Ballot 192: Technical Report No. 29 (revised) "Points to Consider for Cleaning Validation", a PDA PCMO Initiative
- › SAB Ballot 191: Appointment of Jette Christensen to the Science Advisory Board PDA Science Advisory
- › SAB Ballot 190: Memorandum of Understanding (MOU) for the Blow-Fill-Seal (BFS) Task Force
- › SAB Ballot 189: (TR 27) "Container and Closure Integrity Testing for Stability of Parenterals"
- › SAB Ballot 188: PDA TF Work Proposal re "Elastomeric Closures and Seals Defects"
- › SAB Ballot 187: Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries
- › SAB Ballot 186: Risk Management for Temperature Controlled Distribution
- › SAB Ballot 182: Re-ballot – Chuck Reed Appointment, IG Leader for the BFS IG
- › SAB Ballot 181: Re- ballot Appointment of Bill Colentro, Pharmaceutical Water Systems IG Leader

Scientific Advisory Board Members

Chair

John Shabushnig, *Insight Pharma Consulting LLC*

Co-Chair

Harold S. Baseman, *ValSource, LLC*

Members

Raphael (Raphy) Bar, PhD,
BR Consulting

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, PhD,
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

Scientific and Regulatory Affairs

Regulatory Affairs and Quality Advisory Board

The RAQAB is a major and significant source for identifying global regulatory issues of interest to PDA members. 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. During 2012, RAQAB took significant steps to increase its global representation and reach into emerging markets. New members were added representing Latin America and Brazil, China, and Russia. The board also added new liaison roles representing South Korea and India bringing the total to nine countries and regions represented. Each month RAQAB members report news of their regional regulatory authorities enhancing global regulatory awareness and leading to potential new PDA initiatives on behalf of members.

The RAQAB was instrumental in managing the development, approval, and publication of PDA Technical Report 54 Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations in 2012. This TR will be accompanied by three annexes in 2013: TR54-2, TR54-3, and TR54-4 which will cover QRM application throughout the product lifecycle. The RAQAB is also working on a Technical Report addressing Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials, set to be published quarter 3 of 2013.

The year 2012 was also one of transition for RAQAB. Longtime member, European liaison, and staff support, Jim Lyda retired. The RAQAB, Board of Directors, and all of PDA recognized Jim at the September PDA/FDA Joint Regulatory Conference for his long-term contributions to global pharmaceutical regulatory and quality affairs and his role in supporting PDA's relations with foreign regulatory agencies. Janie Miller, PDA Senior Project Manager, joined RAQAB in 2012 assuming part of Jim's role in regulatory surveillance and oversight of the regulatory commenting process to keep it in alignment with PDA's mission.

RAQAB further developed their relationships with the Interest Groups under their purview through sharing of best practices and setting expectations for communication. During 2012, IGs routinely provided updates at RAQAB monthly meetings. RAQAB also assumed global oversight for the following Interest Groups: Clinical Trial Materials, Inspection Trends, Management of Outsourced Operations, Pharmacopeial, Quality Risk Management, Quality Systems, Regulatory Affairs, and Supply Chain Management. Several RAQAB members play active roles in leading these IGs.

RAQAB spent significant meeting time on the development of a proposal for a new type of publication with the goal of a quick response directed to members on a current technical and scientific topic. After much debate on format, purpose, and title, RAQAB Chair, Stephan Roenninger, took a proposal for the PDA "Points to Consider" document to the Board of Directors in September 2012. In addition to their work on the advisory board, RAQAB members were active in planning and presenting at the signature PDA/FDA Joint Regulatory Conference in Baltimore in September and the PDA/EMA Conference in Lisbon, Spain in December as well as other regional conferences.

Regulatory Affairs and Quality Advisory Board Members

Chair

Dr-Ing Stephan Roenninger, F. Hoffman-LaRoche, Ltd.

Vice-Chair

Susan J. Schniepp, OSO Biopharmaceuticals

Immediate Past Chair and Board Liaison: **Steve Mendevil**, Amgen

Canada Regional Liaison: **Jeffrey R. Broadfoot**, Cangene Corporation

Australia Regional Liaison: **Robert B. Caunce**, Hospira

Japan Regional Liaison: **Junko Sasaki**, Dainippon Sumitomo Pharmaceuticals

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

China Regional Liaison: **Hongyang Li**, Novartis Corporation

Russia Regional Liaison: **Elizabeth Meyers**, Amgen

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

India Regional Liaison: **Anil Sawant**, Johnson and Johnson

European Regional Liaison: **Barbara Jengtes**, PhACT GmbH

Members

Ruhi Ahmed, PhD, Ultragenyx Pharmaceutical, Inc.

Jeffrey Hartman, Merck

Karen Ginsbury, PCI Pharmaceutical Consulting Israel LTD

John Finnkbohner, PhD, MedImmune

Siegfried Schmitt, PAREXEL

Louise Johnson, Takeda Pharmaceuticals

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

Amy Giertych, Baxter

Edwin Rivera-Martinez, Sanofi-Pasteur

Janeen Skutnik-Wilkinson, NSF International

Jacqueline Veivia Panter, Abbott Laboratories

Lauren Melton, Alnylam

Hongyan Xie, Qilu Pharmaceutical Co Ltd.

Barbara Zinck, Zinck Consulting

Liaisons from other PDA Advisory Boards

SAB Liaison: Don E. Elinski, Lachman Consultant Services, Inc.

BioAB Liaison: Michael VanDerWerf, Shire Pharmaceuticals

PDA Staff Liasons

Jahanvi (Janie) Miller, Scientific and Regulatory Affairs, PDA

RAQAB was also active in regulatory commenting in 2012 submitting the following official comments to regulators:

- RAQAB Ballot 113: EMA Guideline on Process Validation
- RAQAB Ballot 111: Draft Guidance for Industry on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Action of 2009, Docket No. FDA-2011-D-0611

Scientific and Regulatory Affairs

- RAQAB Ballot 110: Draft Guidance for Industry on Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, Docket No. FDA-2011-D-0602
- RAQAB Ballot 109: Draft Guidance for Industry on Scientific Considerations in Demonstrating Biosimilarity to a Reference Protein Product, Docket No. FDA-2011-D-060D
- RAQAB Ballot 108: PDA Comments to EC, Delegated Act on Principles and Guidelines of GMP for Active Substances in Medicinal Products for Human Use

The RAQAB reviewed and approved two (2) Technical Reports to be submitted for publications and two (2) technical documents:

- RAQAB Ballot 112: Approval of Revised Proposal for ‘Gap Analysis between US and EU Sterile Manufacture (Terminal Sterilization and Aseptic Manufacture) Guidance and Regulations’
- RAQAB Ballot 107: Risk Management for Temperature Controlled Distribution (TR 58)
- RAQAB Ballot 104: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations, a PCMO Initiative (TR 54)
- Concept Paper: Guideline of Process Validation of Medicinal Products Containing Biotechnology Derived Proteins as Active Substance

Interest Groups

In 2012, the Scientific and Regulatory Affairs Department was more proactive in engaging PDA's Interest Groups, providing assistance to enhance collaboration and sharing knowledge and best practices in forums and venues outside of the two PDA signature conferences. GMP Links to Pharmacovigilance was formed as a new IG to discuss topics that straddle the interface between drug development, cGMP, Quality, Compliance, and Patient Safety. John Ayers of Eli Lilly and Company and Nikki Mehringer were named as initial leaders of this IG which kicked off in September 2012 at the PDA/FDA Joint Regulatory Conference. In 2012, PDA's Interest Groups met during the *PDA Annual Meeting* and the *PDA/FDA Joint Regulatory Conference*. In 2013 we hope to develop an open forum platform where IGs can freely discuss industry issues and collaborate more effectively.

PUBLICATIONS

PDA publications are produced under the auspices of the PDA Science and Regulatory Affairs Department. Walter Morris is the Director of Publishing and reports directly to Richard V. Levy, Sr. VP of Scientific and Regulatory Affairs. Rebecca Stauffer, Writer/Editor, works exclusively on the PDA Letter. Katja Yount, Publication Design Specialist, provides designs and layouts for the PDA Letter, PDA Technical Reports, and PDA Surveys, PDA Proceedings and other products.

PDA Technical Reports: A Record Year

2012 was the most productive year for Technical Report publication in PDA's history, with 8 total published (six new and two revised).

The reports were:

Technical Report No. 29 (Revised 2012): Points to Consider for Cleaning Validation

Technical Report No. 30 (Revised 2012): Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat

Technical Report No. 54: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations

Technical Report No. 55: Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,5-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries

Technical Report No. 56: Application of Phase-Appropriate Quality Systems and CGMP to the Development of Therapeutic Protein Drug Substance

Technical Report No. 57: Analytical Method Validation and Transfer for Biotechnology Products

Technical Report No. 58: Risk Management for Temperature-Controlled Distribution

Technical Report No. 59: Utilization of Statistical Methods for Production Monitoring

New PDA-Owned Content: Transcripts of Proceedings and Surveys

PDA expanded its collection of exclusive content with the introduction of PDA Proceedings and the publication of additional PDA Surveys in 2012.

PDA 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.

In 2012, two books were published in this category:

Transcript of the Proceedings of the 2012 PDA Innovation and Best Practices on Sterile Technology Conference

Transcript of the Proceedings of the 2012 PDA/FDA Virus and TSE Safety Conference: Proactive Approaches to Mitigate Virus & TSE Risk

PDA was planning to expand this product line with four PDA Proceedings in 2013.



Walter Morris
Director of Publishing



Rebecca Stauffer
Writer/Editor



Katja Yount
Publication Design Specialist

Scientific and Regulatory Affairs

PDA published its second survey in 2012:

PDA Survey: Business Case for Pharmaceutical Quality

Both the Proceedings and Surveys are offered as electronic books, available on the PDA Bookstore.

Electronic PDA Journal of Pharmaceutical Science and Technology

PDA's partnership with HighWire Press to host the *PDA Journal of Pharmaceutical Science and Technology* entered its third year in 2012, and the usage statistics and article sales show that the Journal is as popular as ever.

Readers access the site to retrieve articles in HTML or PDF format and to review abstracts of articles. In 2012, abstracts were viewed over 620,000 times. The HTML version of articles grew in popularity, with that form of article accessed over 10,000 times compared with only 6,900 in 2011. Nearly 50,000 pdf versions of articles were served to users during the year. Note: these statistics count every time an article or abstract is accessed; this does not discern between unique users/unique articles.

Institutional Subscriptions

116 Institutions subscribed to the online Journal in 2012.

Sponsors

Sartorius Stedim Biotech and Veltek Associates Inc. continued to support the Journal by placing banner ads on the home page.

Article Sales

The HighWire Press platform and hosting services helps bring an entirely new audience to the PDA Journal of Pharmaceutical Science and Technology. This is reflected not only in the number of users the

site receives monthly, but also the number of non-PDA members who access articles. In 2012, article sales nearly doubled from the prior year, with nearly 1200 sold.

PDA Letter

Expert Submissions

PDA members and other subject-matter experts helped make 2012 another record year for submissions to the PDA Letter. The editors published 17 feature-length articles along with many other articles in the Letter Departments, helping the publication inform members of the latest industry trends and Association news. The number and quality of articles published is a testament to the hard work of the volunteer *PDA Letter* Editorial Committee and the editorial staff. The editorial committee reviews each feature-length article and provides important feedback to ensure articles meet the needs of PDA's members.

Feature-length articles submitted by members and published in 2011:

"RMM Sessions Catch Blogger's Attention"

by Michael Miller (*January*)

"Progress of the Quality Topics at the ICH Meeting in Seville"

by Stephan Ronninger (*February*)

"USP Updates Given at PDA's 2011 Micro. Conference"

by Michael Miller (*February*)

"The Importance of Commenting on Public Standards"

by Sue Schniepp and Janeen Skutnik-Wilkinson (*February*)

"Lack of Compendia Harmony for Visible Particles Causing Confusion"

by Dan Berdovich and James Melchore (*February*)

"The Benefits and Challenges of Targeted Drug Delivery"

by Martha Folmsbee (*April*)

"EU Directive to Thwart Noncompliant APIs"

by Barbara Jentges and Karen Ginsbury (*April*)

"Rx Distribution Licenses: A Matter of State"

by Joanne Hawana (*April*)

"Considerations for Successful Design, Operation and Maintenance of an Ultrapure Water System"

by Morven McAlister (*May*)

"Rapid Microbiological Method Myths"

by Michael Miller (*June*)

"Current Sterile and Lyo Issues Discussed at Joint IG Session"

by Richard Johnson, Ken Muhvich, Edward Tidswell, and Edward Trappler (*July/August*)

"Reports from the 2012 PDA/FDA Glass Quality Conference: PDA Glass Survey Results Spark Fruitful Day 1"

by Thomas Schoenknecht (*September*)

"Reports from the 2012 PDA/FDA Glass Quality Conference: Making Glass Work the Focus of Day 2"

by Diane Paskiet (*September*)

"A Year Later, FDA Issues Updated Endotoxin Testing Guidance"

by James Cooper (*September*)

"Audit Sharing Can Lead to Fewer Supply Chain Headaches"

by Helena Champion (*October*)

"Industry Asks FDA to Look to EU for Biosimilar Regulations"

by Kathleen O'Sullivan (*October*)

"QbD Offers Opportunities and Challenges for Vaccine Makers"

by Bob Darius (*November/December*)

Journal Editorial Staff

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Associate Editors

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Antonio Moreira, PhD

Anurag Rathore, PhD

Assistant Editor

Mia Ricci

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Richard V. Levy, PhD, Senior Vice President, Scientific and Regulatory Affairs, PDA

Scientific and Regulatory Affairs

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PDA Staff

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Rebecca Stauffer, Writer/Editor, PDA

Katya Yount, Publications Design Specialist

Richard V. Levy, Senior Vice President, Scientific and Regulatory Affairs, PDA

Dona Reber and **Mary Griffin**, *Microbial Identification: The Keys to a Successful Program*

David Stokes, *Validating Enterprise Systems: A Practical Guide*

Best Editor/Author Award

Annually, PDA presents an award for the best editor/author of PDA/DHI co-published books as selected by the PDA community. The 2012 PDA/DHI Distinguished Editor/Author Award recipient is:

Editor/Author Award recipient name to come

Top Five 2011 Books (by sales)

In 2012 the top five best-selling PDA/DHI books were:

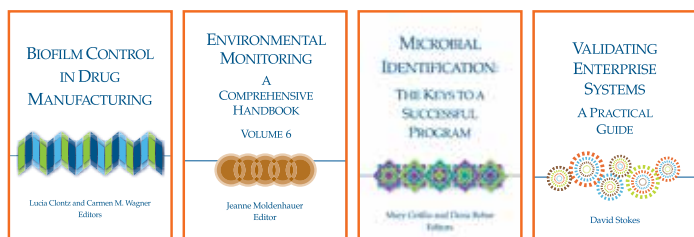
- *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition, Revised & Expanded* by **James L. Vesper**
- *Environmental Monitoring: A Comprehensive Handbook, Volume I, II, III, IV, V and Protocol CD*, edited by **Jeanne Moldenhauer, PhD**
- *Quality by Design: Putting Theory into Practice* edited by **Siegfried Schmitt, PhD**
- *Practical Aseptic Processing: Fill and Finish, Volume I and II*, edited by **Jack Lysfjord**
- *Microbiology in Pharmaceutical Manufacturing, Second Edition, Revised and Expanded, Volume I and II*, edited by **Richard Prince**

PDA/DHI Books

PDA, in partnership with Davis Healthcare International Publishing, Inc. (DHI), publishes books written on topics relevant to our membership. Authors are subject matter experts in the area, and all books are reviewed by several other experts prior to publication. **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 2012:

Carmen Wagner and **Lucia Clontz**, *Biofilm Control in Drug Manufacturing*
Jeanne Moldenhauer, PhD, *Environmental Monitoring: A Comprehensive Handbook, Volume 6*



Technical Book Committee

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Walter Morris, Director of Publishing, PDA

Co-Chair

Amy Davis, Davis Healthcare International Publishing

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Excellent Pharma Consulting

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Microbiology Network, Inc.

James Vesper,
LearningPlus, Inc.

PDA Staff Liasons

Janny Chua, Product Operations Manager, PDA

Richard Levy, PhD, Scientific and Regulatory Affairs, PDA

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, MD, 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.

By any measure, 2012 was the most successful year ever for TRI and PDA's education programs.

Laboratory Offers Risk-Free, Hand-on Experience

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.

2012 TRI Highlights

- Over 60 courses delivered
- 22 new courses
- 23 courses based on PDA-owned material
- 90 Volunteer instructors
- Over 1,400 students
- Almost 500 students trained "in house"

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.

Lecture Courses Complement Conference Topics

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.

Training on Client Sites

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 2012, this element resulted in our providing training to almost 500 people at various client locations.

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 2012, we offered 22 new courses focusing on topics such as *Implementation of Quality Risk Management, Recommended Practices for Manual Aseptic Processes, Process Validation and Verification* and *Parametric Release*.

Training Based on PDA-Owned Technical Reports

In 2012, we continued our initiative to develop and present courses based on PDA-owned Technical Reports. Instructors for these courses are drawn from the task forces that prepared the Technical Reports. This provides the student with the opportunity to "learn from the creator." In 2012, there were 23 courses that were based on this PDA-owned material. TRI owes a debt of gratitude to PDA Senior Vice-President for Scientific and Regulatory Affairs **Rich Levy** and his staff (**Vince Anicetti**, **Josh Eaton** and **Jahanvi (Janie) Miller**), as well as TRI special assistant **Bethanne Bond** and our instructors for preparation of the materials for these courses.

In total, we presented over 60 training courses to industry and government regulatory personnel from the U.S. and other countries around the world in our Bethesda facility and at our Conferences.

Expert Faculty

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

PDA Training and Research Institute

setting. A separate listing of our **2012 instructors** appears on pg. 15 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 2012.

And finally, a word of thanks to our loyal, hard-working staff – **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 2012 Contributors

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



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



Stephanie Ko
Senior Manager,
Lecture Education



James Wamsley
Senior Manager,
Laboratory Education



PDA Training and Research Institute

Last, First	Company
Adams, Carolyn	Genzyme
Akers, Michael	
Amin, Pete	FDA
Anicetti, Vince	PDA, Keck Graduate Institute
Asselta, Roger	Genesis Packaging Technologies
Baseman, Hal	Valsource, LLC
Berglund, Barbara	Jubilant HollisterStier
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Bobo, Qiao	FDA
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Bozzone, Scott	Pfizer, Inc.
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Bringslimark, Vivian	HPIS Consulting
Brorson, Kurt	FDA
Burdette, Todd	Particle Measuring Systems
Byrd, Sean	FDA
Chesney, David	Parexel Consulting
Cooper, James	Endotoxin Consulting Services
Crance, David	Particle Measuring Systems
Custard, Cheryl	Consultant
Dana, Robert	PDA
Dinowitz, Marshall	Pacific BioDevelopment
Ertel, Donald	FDA
Friedman, Barry	Barry A. Friedman, PhD, LLC
Garafola, Wayne	Sartorius Stedim Biotech
Geigert, John	Biopharmaceutical Quality Solutions
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Gross, Michael	Chimera Consulting
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Havlik, Deborah	Hospira, Inc.
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Hornback, Lisa	Hornback Consulting, LLC
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Johnson, Richard	PDA
Jornitz, Maik	G-Con
Kiang, Patty	Kiang Consultant Services
Kussow, Karl	FedEx Custom Critical
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Lasich, Joseph	Consultant
Lebowitz, Samuel	Electrol Specialties Company
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Ludwig, John	Pfizer, Inc.

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Montague, Charles	Scienta Solutions
Montalvo, Miguel	Expert Validation Consulting, Inc.
Moreira, Antonio	University of Maryland, Baltimore County
Newman, Rainer	Consultant
Novak, Wenzel	Groninger & Co GmbH
Orloff, Jason	J. Orloff & Associates, Inc.
Orlowski, Martin	Bioquell
Ostrowski, Matt	Pfizer, Inc.
Ostrowski, Matthew	Pfizer, Inc.
Paskiet, Diane	West Pharmaceutical
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Schmidt, Jennifer	FDA
Schofield, Peter	Walker Barrier Systems
Seiberling, Dale	Electrol Specialties Company
Shabushnig, John	Insight Pharma Consulting, LLC
Sullivan, Destry	FDA
Smith, Edward	Packaging Science Resources, LLC
Trappler, Edward	Lyophilization Technology, Inc.
Trupp, Kevin	Sterilization Technology and Compliance
Vadheim, Kirsten	BioCompliance Consulting
van der Schalie, Barbara	SAIC-Frederick
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Vesper, James	LearningPlus
Waites, Nancy	FDA
Watkins, Brent	Veltek Associates, Inc.
Wiebe, Michael	Quantum Consulting, LLC
Wilkins, Randy	EMDMillipore
Wolf, Allison	Eli Lilly & Company
Zwolenski-Lambert, Wendy	Abbott Laboratories

The Programs and Registration Services Department

I

n 2012, PDA conferences and workshops exceeded expectations by being true to the PDA mission and vision. The Programs, Meetings and Registration Services Department has proven to be one of PDA's critical active ingredients that keeps *Connecting People, Science and Regulation*®, by producing well-planned, thought-provoking events useful to its global members.

The continued success of these events offered is largely due the 240+ volunteers who serve on the program planning committees and lend their knowledge and expertise to the development of our unique programs. Having such volunteers participating in a PDA event constitutes an evolving learning process in tailoring the program to the needs and concerns of today's professions in industry and regulatory authorities. The planning committee volunteers commit to:

- Face-to-face meetings and teleconferences up to one year prior to the conference and provide input/action items prior to the meeting.
- Assist with coordination and moderating sessions.
- Meeting deliverables for the promotion of events.
- Defining topics and recommending speakers.

In addition, feedback that is provided from our global membership continues to address the PDA Mission and Vision to be the foremost global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industry.

2012 Program Planning Committee Chairs and Co-chairs

Each PDA program committee is led by dedicated pharmaceutical professionals that are a driving force behind the vision and content of events.

Vince Anicetti, *Keck Graduate Institute of Applied Life Sciences*

Norman Baylor, PhD, *Biologics Consulting Group, Inc.*

Rafik Bishara, PhD

Joyce Bloomfield, *Merck and Company*

Kurt Brorson, PhD, *FDA*

Lucy Cabral, *Genentech, Inc.*

John Finkbohner, PhD, *MedImmune, LLC*

Richard L. Friedman, *FDA*

Tim Gillum, PhD, *Baxter Healthcare Corporation*

Marsha Hardiman, *Medtronic, Inc.*

Yu Hu, PhD, *Eli Lilly and Company*

Steven Lynn, *FDA*

Steven Mendivil, *Amgen, Inc.*

Morten Munk, *CMC Biologics A/S*

Adalberto Ramirez, *Amgen, Inc.*

Robert Repetto, *Pfizer, Inc.*

Marla Stevens - Riley, PhD, *FDA*

Michael Sadowski, *Baxter Healthcare Corporation*

Junko Sasaki, *Dainippon Sumitomo Pharma*

Susan Schniepp, *OSO BioPharmaceuticals*

Edward Tidswell, PhD, *Baxter Healthcare Corporation*

Michael VanDerWerf, *Shire Regenerative Medicine, Inc.*

Martin VanTrieste, *Amgen, Inc.*

Anders Vinther, PhD, *Genentech, Inc.*

Hannelore Willkomenn, PhD, *RBS Consulting*

Joyce Winters, *Lachman Consulting, Inc.*

Steven Wolfgang, PhD, *FDA*

Programs and Meetings Staff

The Programs and Meetings Department consists of seven staff members who support Program and Speaker Management, Registration Services and Logistic (planning and execution). With so many components to attend, there is no shortage of "T's" to cross and "i's" to dot too. Teamwork is a vital ingredient in reaching our goals for each event. Meet our team:



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



9 Years Team Member:
Jason E. Brown, Senior
Manager, Programs
and Meetings



7 Years Team Member:
Patresa Day, Manager,
Registration and
Customer Accounts



5 Years Team Member:
Andrea Viera, Senior
Coordinator, Programs
and Registration
Services



4.5 Years Team Member:
Leon Lewis,
Director, Programs
and Meetings



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



2.5 Years Team Member:
Melissa Pazornik,
Coordinator, Speaker
and Logistics
Assistant

The Programs and Registration Services Department

2012 PDA Conferences and Workshops

PDA offered 16 programs covering a wide range of topics to suit the focus and varying interests of pharmaceutical professionals within the US and Japan.

2012 PDA Annual Meeting

April 16-18, 2012, Phoenix, AZ

PDA Single Use Systems Workshop

April 18-19, 2012, Phoenix, AZ

Applying QbD Principles in Vaccines Development: PDA/FDA CMC Workshop

May 14, 2012, Bethesda, MD

2012 PDA/FDA Virus and TSE Safety Conference

May 15-17, 2012, Bethesda, MD

PDA/FDA Glass Quality Conference

June 4-5, 2012, Washington, DC

2012 PDA Innovation & Best Practices on Sterile Technology Conference

June 18-19, 2012, Chicago, IL

2012 PDA/FDA Joint Regulatory Conference

September 10-12, 2012, Baltimore, MD

2012 PDA/FDA Pharmaceutical Quality System Workshop

September 12-13, 2012, Baltimore, MD

2012 PDA Biennial Training Conference

October 8-9, 2012, Bethesda, MD

2012 Universe of Pre-filled and Injection Devices

October 15-17, 2012, Las Vegas, NV

PDA's 7th Annual Global Conference on Pharmaceutical Microbiology

October 22-24, 2012, Bethesda, MD

Understanding Requirements for Cleanrooms Workshop

October 24, 2012, Bethesda, MD

Pharmaceutical Quality System (ICH Q10) Conference

November 5-6, 2012, Tokyo, Japan

2012 PDA/FDA Pharmaceutical Supply Chain Conference

November 13-14, 2012, Bethesda, MD

2012 Cold Chain Management/Good Distribution Practice Conference

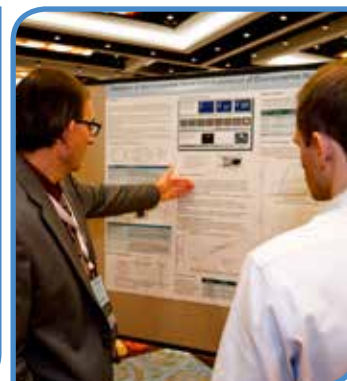
November 15-16, 2012, Bethesda, MD

2012 PDA/FDA Vaccine Conference

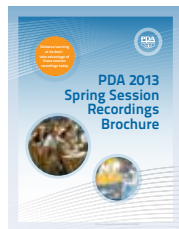
December 3-4, 2012, Bethesda, MD

- › 2012 PDA/FDA Joint Regulatory Conference
- › Responsibilities of Executive Management (Operations & Quality) – Implementing the Principles of ICH Q10: 2012 PDA/FDA Pharmaceutical Quality Systems Workshop
- › 2012 PDA Universe of Pre-filled Syringes and Injection Devices
- › PDA 7th Annual Global Conference on Pharmaceutical Microbiology
- › 2012 PDA/FDA Pharmaceutical Supply Chain Conference Recordings
- › 2012 PDA Cold Chain Management/Good Distribution Practice Conference
- › 2012 PDA/FDA Vaccines Conference

2012 Event Photos



The PDA Online Learning Library - Distance Learning at its Best.



Each recorded session includes audio synced with the presenters' PowerPoint presentation 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/onlinelearning.org for a list of recent recordings.

PDA 2012 Session Recordings:

- › 2012 PDA Annual Meeting
- › 2012 PDA Single Use Systems Workshop
- › 2012 PDA Applying QbD Principles in Vaccine Development: PDA/FDA CMC Workshop
- › 2012 PDA/FDA Virus & TSE Safety Conference
- › 2012 PDA/FDA Glass Quality Conference
- › 2012 PDA Innovation & Best Practices on Sterile Technology Conference



Membership and Chapters



Membership and Chapter's Accomplishments

In 2012, PDA saw its third consecutive year of membership growth. In an effort to continue this growth, PDA focused on increasing member value by:

- > Increasing number of published Technical Reports (\$3.0M in technical reports downloaded by members)
- > Introducing free access to all Technical Reports through the Technical Report Portal
- > Forming new chapters and increasing chapter support
- > Upgrading membership database

Support for chapters around the globe was characterized by an increased presence of both PDA Staff and Board Members, and by continuing the high level of support that was established in previous years. Highlights of these efforts include:

- > Visits to India, Taiwan, China, Japan, Russia, Singapore and Europe by the PDA President
- > 27 different chapter events that were supported by either a direct staff or BoD presence
- > Maintaining a high level of support for the Japan Chapter, which continues to be the largest and most active chapter outside the United States
- > A new chapter which was formed in India
- > The revised Chapter Points Program entered its second year of production and was avidly contested

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*

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 Treasurer: **Ivy Louis**, *Vienni Training and Consulting LLP*
 Secretary: **Amit Sharma**, *Sartorius Stedim India Pvt Ltd*

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 Management & Planning: **Masashi Imamura**, *Nichi-iko Pharmaceutical Co. Ltd*
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 Treasurer: **Young Kou Jeong**, *Pall Korea 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*

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 President Elect: **Alice Redmond**, *Commissioning Agents, Inc.*
 Treasurer: **Joan Fitzgerald**, *Allergan, Inc.*
 Secretary: **Ann Greene**, *Academic Institute*

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 President Elect: **Rachel Karpel**, *PCI Pharmaceutical Consulting Israel*
 Treasurer: **Karin Baer**, PhD, *Omrrix 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*



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



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



3 Years Team Member:
Katie Ruiz
 Customer Service Representative



4 Years Team Member:
Alison Caballero
 Sales Coordinator

Membership and Chapters

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*

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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

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 Treasurer: **Mary Ly Huynh**, *Independent*
 Secretary: **Maggie Filipowicz**, *Laureate Biopharmaceutical*

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 Treasurer: **Alan Solomon**, *Baxter Healthcare*
 Secretary: **Angela Coon**, *Baxter Healthcare*

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President: **Eldon Henson**, *Covidien*
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 Treasurer: **Keith Koehler**, *Certified Energy Labs*
 Secretary: **Gary Klaassen**, *Bayer AG Pharma*

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President: **Suzanne Mecalo**, *Commissioning Agents, Inc.*
 Treasurer: **Leah Choi**, *RMC Pharmaceutical Solutions*
 Secretary: **Karrin Hogan Kelly**, *Scientific Resources*

New England Chapter

President: **Russell J. Morrison**, *Protein Sciences Corporation*
 President Elect: **Roland Bizanek**, PhD, *Compas Pharma Consulting*
 Treasurer: **Mark Plucinsky**, *Shire*
 Secretary: **Jonathan Morse**, *Complya Consulting Group*

Puerto Rico Chapter

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



Southeast Chapter

President: **Shelley Preslar**, *ProPharma Group*
 President Elect: **Melissa Seymour**, *Biogen Idec*
 Treasurer: **Sherry Nelson**, *Mangan, Inc.*
 Secretary: **Shannon Bellino**, *Doe & Ingalls*



Southern California Chapter

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

West Coast Chapter

President: **Elizabeth Leininger**, PhD, *Elizabeth Leininger Consulting*
 President Elect: **Elaine Eborall**, *Genentech/Roche*
 Treasurer: **Milan Crnogorac**, *Genentech/ Roche*
 Secretary: **Beth Keij**, *Novartis Diagnostics*



Chapter Council Meeting Participants

2012 PDA Europe Activities

7-8 February, Clinical Trial Materials

This conference provided current regulatory trends related to IMPs, state-of-the-art clinical manufacturing of IMPs and discuss primary packaging and devices used for testing combination products in clinical trial R&D. A highlight was the tour of the brand new clinical production area of F.Hoffmann-La Roche in Basel.

28-29 February, Microbiology/ Endotoxins/ RMM

Delegates from international regulatory agencies, global industry experts and representatives from technology met in Berlin to discuss current inspection trends, recent case studies and future trends in the field of pharmaceutical microbiology and manufacturing control.

6-7 March, Quality by Design

This one of a kind workshop provided a great chance to actively shape the QbD initiative and to participate in direct debate with all the players from Pharmacopoeia, EDQM, EMA, FDA, USP, industry and suppliers.

13-15 March, Parenteral Packaging

This conference, taking place in Berlin, offered a comprehensive program focusing on trends in parenteral packaging, materials and components, new devices, production technology case studies and container closure integrity methodology updates.

20-22 March, Visual Inspection Interest Group Meeting and Training Course

This year's Interest Group Meeting concentrated on the subject "How to deal with rejects from Visual Inspection" which led to interesting discussions among the participants. Following this IG meeting Markus Lankers and John Shabushnig hold their successful and always sold-out hands-on training course "An Introduction to Visual Inspection".

27 March, Interest Group Meeting Prefilled Syringes

The question "What is the best choice for your product: Glass or Polymer?" was actively discussed during the interest group meeting prefilled syringes in Berlin. Like always at Interest Group Meetings, a lively discussion among the participants and speakers and an active exchange of expertise and experience made this meeting a great success.

28-30 March, Freeze Drying Interest Group Meeting and Training Course

The focus on "Controlled Nucleation" made this Interest Group Meeting a very interesting meeting which was followed by a two-day training course on "Development of a Freeze Drying Process". This training course covers the whole range of aspects which are needed to develop a freeze drying cycle.

9-10 May, Workshop in Cooperation with PIC/S

In cooperation with PIC/S, PDA organized this workshop to create an interactive discussion between inspectors and industry sharing experiences gained in GMP inspections.

5-6 June, Advanced Therapy Medicinal Products

This meeting was dedicated to the most recent scientific developments and challenges, as well as burning regulatory issues on ATMPs. Numerous experts from academia, industry and regulatory bodies around the world shared their knowledge on how to improve successful development paths for ATMPs.

12-13 June, Monoclonal Antibodies

This fifth workshop on monoclonal antibodies offered a deeper look at the emerging trends influencing major aspects of the development continuum for monoclonal antibodies. In four interactive sessions participants gained knowledge in Development and Regulatory Considerations for IMPs and Commercial Registration, Molecular Approaches to Monoclonal Antibody Optimization, Late-Stage Process Development Strategies and the Development and Regulatory Considerations for Monoclonal Antibody Related Products.

18-21 September, Pharmaceutical Freeze Drying Technology

Numerous new developments in the freeze drying industry were thoroughly discussed during this year's conference on pharmaceutical freeze drying technology. In-depth discussions and active Q&A sessions completed this successful conference.

25-28 September, Visual Inspection Forum

This annual event alternating between the USA and Europe has grown into the leading event for those working in visual inspection. This year's forum took place in Berlin and concentrated on inspection of biopharmaceutical drug products with the challenge of differentiation protein aggregates and air bubbles.

9-12 October, Pharmaceutical Cold Chain Management & Good Distribution Practice

Thermal protection and supply chain integrity were the two central themes of this year's conference on Pharmaceutical Cold Chain Management. The conference was followed by the successful "four module training course" on "Good Temperature-Controlled Management Practices" which gave trainees the opportunity to learn the best cold chain practices from international industry experts.

6-9 November, Parenterals 2012

About 200 international delegates from regulatory agencies and industry came together to discuss manufacturing, quality control, technologies and regulations of biologic drug products. The two-day event served as a forum to network and as an opportunity for knowledge exchange amongst the experts.

4-7 December, PDA/EMA Joint Conference

After the positive outcome of the 2011 PDA/EMA Joint Conference in London, the Scientific Planning Committee developed a program which encompassed a full range of topics related to GMP and to quality of both chemical and biological products. The unique concept of this PDA/EMA Joint conference created a great forum for regulatory and industry experts from around the world to exchange knowledge and gave participants many opportunities to talk directly to speakers and to participate in panel discussions and Q&A sessions.

Honor Awards

Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award has usually been given in recognition of very long service, of a very significant nature, to PDA. The award requires unanimous approval of the PDA Board of Directors, and honorary members are not eligible for other awards in the same year.

JIM LYDA Jim Lyda, who retired from PDA in September 2012 after almost 20 years of service, became a key promoter of PDA's Influence with regulators. Mr. Lyda joined the PDA staff in July 1992 after 21 years with the FDA. In 1998 he moved to Switzerland to start PDA's staff operations in Europe. After a brief detour in consulting, he rejoined the 'new' PDA Europe staff in 2005. He moved back to the USA in late 2008, working for both the US and Europe offices. Mr. Lyda retired in September 2012 after almost 20 years of service.

Frederick D. Carleton Award

Presented as a tribute to lifetime contributor, past President, past Executive Director, and Honorary Member Frederick J. Carleton, this award is designated for past or present Board members

AMY SCOTT-BILLMAN Amy Scott-Billman is currently the VP, Global Regulatory Strategy for Immunotherapeutics in GlaxoSmithKline Biologicals (GSK Bio) where she leads a global team responsible for all regulatory strategy and operations relevant to the development and commercialization of immunotherapeutic products and companion diagnostics for cancer and chronic disorders. Ms. Scott-Billman has been with GSK for over 17 years in various capacities in the pharmaceutical and vaccines businesses. Prior to GSK, she held various positions over nearly 9 years at the FDA/CBER, including senior management, reviewer and inspector. Ms. Scott-Billman has been a member of PDA for nearly 20 years and her contributions have included; 2-term Board Member, Chair of Regulatory Affairs and Quality Control, Chair of PDA/FDA Committee, Awards Committee and member of Biotechnology Advisory Board. Ms. Scott-Billman received her B.S. in Microbiology from the Pennsylvania State University in and her M.S. in Biotechnology from Johns Hopkins University.

Gordon Personeus Award

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

KURT BRORSON, PhD Kurt Brorson, Ph.D. is a Research Biologist in CDER's Division of Monoclonal Antibodies, Office of Biotech Products. Dr. Brorson received a B.A. in biology from the University of Chicago (Chicago IL) in 1984 and Ph.D. in molecular biology from the California Institute of Technology (Pasadena CA) in 1990. After a 2-year postdoctoral fellowship at the NIH, he joined FDA as a fellow in 1992 and rose through the ranks to senior investigator in 2012. In addition to review, inspection, training and policy activities, he conducts research on bioprocess monitoring and viral safety of biotechnology products.

Dr. Brorson served on the PDA Biotechnology Advisory Board from 2005-2007. During his 7 years of PDA membership he has contributed to numerous Task Forces and Technical Reports including the Microplasma Task Force, Technical Report 56 – Application of Phase-Appropriate Quality Systems and CGMP to the Development of Therapeutic Protein Drug Substance, and Technical Report 50 – Alternative Methods for Mycoplasma Testing.

Michael S. Korczynski Award

Grant established in recognition of contributions made toward the development of PDA's international activities by Michael S. Korczynski, PhD. The grant funds travel expenses for an international guest to deliver the "Korczynski Paper" at a PDA Meeting.

MAIK W. JORNITZ is Vice President Business Development at G-CON LLC. He is active member and Immediate Past Chair of PDA. He has published multiple books, book chapters and papers. He holds a variety of patents and is founder of Bioprocess Resources LLC. Mr. Jornitz received his Diploma in Bioengineering at the College for Advanced Technology in Hamburg, Germany and accomplished his PED at the IMD Business School, Lausanne, Switzerland. In 2012 he was instrumental in helping carry the message of PDA to India, leading to establishment of a new PDA India Chapter. He has also been the primary contributor to opening new contacts with regulators in China.

James P. Agalloco Award

This award is presented annually to the PDA TRI faculty member who exemplifies outstanding performance in education. The selection is based on student and faculty evaluations and is named for James P. Agalloco in honor of his work in developing the PDA education program.

JAMES F. COOPER, PharmD James F. Cooper, PharmD, was Professor of Pharmacy at the Medical University of South Carolina before founding Endosafe, Inc., an LAL-reagent producer, in 1987. He is a 40-year PDA member and was a Board member (1983-85). For the PDA Training and Research Institute, as one of the highest rated instructors, he has taught LAL, endotoxin and depyrogenation topics and the endotoxin component for the aseptic processing course from the outset (1999). His thesis work at The Johns Hopkins University in 1971 led to innovation of the bacterial endotoxin test for parenterals. His publications span the history of LAL technology. He is a frequent speaker and Technical Report participant for PDA. Now retired, he continues consultation, teaching, publishing related to endotoxin issues and PET-drug GMPs.

DALE A. SEIBERLING Dale A. Seiberling received a B.Sc. (1950) and M.Sc. with engineering emphasis (1951), in Dairy Technology at Ohio State University, where he taught from 1951-1957. In 1957 he joined Klenzade Products as Engineering Consultant and, following acquisition of Klenzade by Economics Laboratory, Inc., became VP/General Manager of the Equipment Engineering Division. He left Ecolab, forming Seiberling Associates, Inc. in 1976 to continue designing fully automated Clean-In-Place processes. His initial work in the pharmaceutical industry in 1974 was followed by intensive work in both pharmaceutical and biotech projects from 1987-2007. He has supported the PDA Training

Honor Awards

and Research Institute (TRI) education program continuously and actively since 1992. During that time he designed, built, and donated a Clean-In-Place (CIP) skid to PDA that will allow TRI to continue teaching students the principles of COP cleaning. He also provided PDA TRI with equipment and design donations that have allowed TRI to greatly expand course offerings beyond Aseptic Processing Training.

Martin Van Trieste Pharmaceutical Science Award

Presented as a tribute former Board Member and long-time PDA contributor Martin Van Trieste, this award is for outstanding contributions to the advancement of pharmaceutical science.

JOHN SHABUSHNIG, PhD John Shabushnig, PhD, 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 B.S. in Chemistry and a Ph.D. 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.

PDA Distinguished Service Awards

Given for special acts, contributions or service that has contributed to the success and strength of PDA.

BARBARA ALLEN, PhD Barbara Allen, PhD, is currently the Senior Director of Global Quality Systems at Eli Lilly and Company, and she has been a PDA Member since 2003. During that time she was a speaker, session moderator, and on the Planning Committee for ICH Q 10 Japan 2012, US and Brussels in 2011. She also served on the 2010 Pharmaceutical Supply Chain Program Planning Committee.

KENNETH NOLAN Kenneth Nolan is a Senior Advisor within the Office of the External Relations, he provides executive level policy and program direction for the U.S. Food and Drug Administration's (FDA) interactions, information exchanges and liaison activities to a variety of domestic and international trade associations to increase understanding of the agency's regulations, policies, and initiatives. Mr. Nolan served on the PDA/FDA Joint Regulatory Conference Planning Committee for 10 years as the FDA Liaison for the Centers for Disease Control. He played a significant role in developing the relationship with the FDA by facilitating co-sponsorship agreements, federal register notices, regulatory speakers for PDA globally, and communicating the policies of the FDA.

ELIZABETH LEININGER, PhD Elizabeth Leininger, PhD, is the Principal Consultant at E Leininger Consulting, LLC. She is a Regulatory Affairs and Quality professional involved in the global strategic development and licensing of biologics and bio-pharmaceutical products. She has over 20 years of experience at CBER, the Bio-pharmaceutical Industry and as a Consultant. Dr. Leininger began her professional career as a Staff Fellow and Product Reviewer at the Center for Biologics Evaluation and Research at the FDA. Prior to establishing her own group in Regulatory Affairs and Quality consulting,

Dr. Leininger has held positions of Vice President of Regulatory Affairs and Quality at StemCells, Inc and BAS Medical. She also was a Director of Regulatory Affairs at GlaxoSmithKline and Chiron Corporation, and a Senior Consultant with Biologics Consulting Group. Dr. Leininger has been a member of the Parenteral Drug Association (PDA) since 1992. During that time she was a long time contributor to the PDA/FDA Joint Regulatory Conference Planning Committee, a frequent speaker at PDA conferences, and was the President of the PDA West Coast Chapter Board (2008-2012).

EMABELLE RAMNARINE Emabelle Ramnarine is the Head of Biologics QC Network at Roche Pharma and is accountable for the Biologics QC Network strategy including lifecycle management of methods, analytical technology, stability, raw materials and adventitious agent testing. Prior to this Ms. Ramnarine was Head of Quality Risk Management and led the design, deployment, and governance of a harmonized QRM program at Roche Pharma. She has applied her extensive QRM experience in actively influencing industry QRM best practices, leading the Task Force on Technical Report 54, and speaking and training on QRM for the PDA Training and Research Institute and PDA Conferences. Her other experience includes validation, change control, QC testing, and laboratory controls management.

IZUMI SAITOH, PhD Izumi Saitoh, PhD, started his long career in pharmaceutical sciences in 1974 after graduating from Tokyo University. He took a position in a lab where he studied sterile products & external use products for over 20 years. He acquired his PhD from Tokyo University in 1994, and received awards from multiple pharmaceutical academies. After a short time as the head of a clinical supply division, he was promoted to general manager of one of Shionogi's major plants in 2002. Finally in 2012, he was selected as Takata Seiyaku's executive director. Dr. Saitoh has been a PDA member since 1996. As an active Japan Chapter Board member he has contributed to the PDA Q10 Conference in Tokyo and the 2012 PDA Japan Annual Meeting.

WENDY ZWOLENSKI LAMBERT Wendy Zwolenski Lambert has over two decades of diverse experience in the pharmaceutical and medical device industries. Her experience includes roles in analytical chemistry, process and quality engineering, quality management and regulatory affairs. Her current role is focused on enhanced approaches to biopharmaceutical drug development, and implementation of the process validation lifecycle. She has been a PDA Member since 2004 and significantly contributed to the Process Validation Task Force. She is currently a member of both the Biotechnology Advisory Board and the 2013 PDA/FDA Validation Workshop.

Frederick D. Simon Award

Chosen by the Fred Simon Award Committee. This award is presented annually for the best paper published in the PDA Journal and is named in honor of the late Fred Simon, a previous PDA Director of Scientific Affairs.

Considerations for Design and Use of Container Challenge Sets for Qualification and Validation of Visible Particulate Inspection (May/June 2012, Vol 66 no. 3 273-284)

JAMES A. MELCHORE James A. Melchore received his BS degree from Rutgers University and his MS degree in Microbiology from Seton

Honor Awards

Hall University. He began his career at Novartis where he served as Section Supervisor of Packaging and then Manufacturing. He then served as Section Head of Sterile Packaging and Team Leader for Automated Inspection Validation at Bristol-Myers Squibb. He provided technical assistance to other BMS sites while serving as Manager of World Wide Validation. As Director of Technical Operations at Bracco Diagnostics, he was actively involved in the Technology Transfer of multiple products. He then became Associate Director of Validation at Enzon Pharmaceuticals. In 2008, he established Melchore Consulting, which specializes in inspection strategies, corrective actions and training. Mr. Melchore has two other publications on manual and automated inspection.

DANIEL BERDOVICH Daniel Berdovich started Micro Measurement Laboratories in February of 1998 to offer his 25 years of experience in particle science. MMLabs offers custom challenge sets for qualification of human or machine visual inspection, and performs many particle tests in the visible, sub-visible and sub-micron range, using the latest instruments and imaging systems.

PDA Service Appreciation Awards

Chosen by the PDA President and Senior Staff. (Includes retiring PDA Board of Director Members and Chapter Leaders). This award is given in recognition of special services performed on behalf of PDA.

BRENDAN CAHILL Brendan Cahill is an employee of Pfizer Ireland Pharmaceuticals, where he is part of the Quality Leadership Team at the Grange Castle Biotech facility. He has worked in the parenterals business for 25 years, holding roles of increasing responsibility in Validation and Quality. Mr. Cahill became involved with the PDA Ireland Chapter soon after its establishment in 2006, and assumed the role of Chapter President from 2011-2012.

JOSE COTTO, PhD Jose Cotto, PhD, joined Amgen in 2001 and for the past 12 years he has held roles of increasing responsibilities within the quality and operations organization. During this time, he played a key role in the startup of the Amgen Puerto Rico expansion and continuous improvement initiatives. He currently is the Executive Director for the company working at Amgen Thousand Oaks, CA as a Global Operations Leader. Prior to Amgen, Dr. Cotto worked at Abbott Laboratories where he worked for over 15 years in the areas of technical support, process development, compliance, quality assurance and quality control. He holds a bachelor degree in Biology from the University of Puerto Rico and a Ph.D. in Biochemistry and Molecular Biology from Northwestern University. Dr. Cotto also conducted his postdoctoral studies in Biochemical Engineering at the University of Texas at Austin. Dr. Cotto's interest to influence the pharmaceutical industrial environment in Puerto Rico led him to participate in PDA where he served several times as a speaker and elected president of the PDA Puerto Rico Chapter, 2010-2012.

ROBERT L. DANA Robert L. Dana is Senior Vice President of Education for the Parenteral Drug Association. He is currently responsible for the planning, operation and administration of PDA's educational programs and training facility. He is a former Director of PDA and is a member of the University of Connecticut Pharmacy School Advisory Board. He has a BS in Pharmacy and is a licensed Registered

Pharmacist in Connecticut. Mr. Dana stepped down as the Inspection Trends Interest Group Leader in 2012.

MORDECHAI IZHAR, PhD Mordechai Izhar, PhD, is currently the Quality assurance and Validation Department manager at Ludan Engineering Co. Beer Sheva, Israel. His past positions include Validation and Calibration Department Manager with Interpham Laboratories, Ness-Ziona, Israel and Research Associate in R&D, Biotechnology and Research associate in hormone department at the Veterinary Institute, Bet Dagan, Israel. He received his Ph.D. in Biophysics at Weizmann Institute of Science, Feinberg Graduate School, Rehovot, Israel. Dr. Izhar has been a PDA member since 2008 and served as President of the PDA Israel Chapter 2009-2011 and is currently a PDA Israel Chapter Committee Member.

ROBERT JOHNSON Robert Johnson is currently the Global Quality Assurance Head LCMC at Lonza AG. He has been a PDA member since 1997. He served on the Technical Report 33 team and the 2009 Microbiology Program Planning Committee. Mr. Johnson also served as the 2011-2012 PDA Metro Chapter President.

ZENA KAUFMAN Zena Kaufman is currently Senior Vice President of Global Quality at Hospira. Prior to that, Ms. Kaufman was at Abbott in quality roles in the Global Pharmaceutical Operation's corporate division for 6 years. Ms. Kaufman has been a strong voice in the external quality environment, having served as Chair of the Technical Leadership Committee of PhRMA, and participating in the Expert Working Group of the ICH Q10. She served as chair of the PDA Regulatory Affairs Quality Advisory Board 2006-2007 and the PDA Board of Directors 2010-2012.

FRANK S. KOHN, PhD Frank S. Kohn, PhD, is president of FSK ASSOCIATES, INC., an international consulting company providing services to the pharmaceutical, biotechnology, and vaccine industry. Dr. Kohn worked for Wyeth, where he was Director of Manufacturing at the Sanford, N.C. location. Kohn has more than thirty years of industry experience working in various technical, quality, and management positions for Schering Plough Corp., Armour Pharmaceutical, Sanofi, and Wyeth Vaccines. He holds graduate degrees in environmental microbiology and operations management. Also, he was chair for the Vaccine Interest Group for PDA and Section Head for Biopharm Development Interest Groups for PDA. Dr. Kohn is the co-author of the book, "Isolation Technology in Pharmaceuticals: Selection, Validation and Use" and has presented numerous technical papers, seminars, and lectures. He is a frequent speaker and course leader in the U.S. and Europe. After Dr. Kohn's many PDA contributions, he stepped down as the PDA Vaccines Interest Group Leader in 2012.

ELIZABETH LEININGER, PhD Elizabeth Leininger, PhD is the Principal Consultant at E Leininger Consulting, LLC. She is a Regulatory Affairs and Quality professional involved in the global strategic development and licensing of biologics and bio-pharmaceutical products. She has over 20 years of experience at CBER, the Bio-pharmaceutical Industry and as a Consultant. Dr. Leininger began her professional career as a staff fellow and product reviewer at the Center for Biologics Evaluation and Research at the FDA. Prior to establishing her own group in Regulatory Affairs and Quality consulting, Dr. Leininger has held positions of Vice President of Regulatory Affairs and Quality at StemCells, Inc and BAS Medical. She also was a Director

Honor Awards

of Regulatory Affairs at GlaxoSmithKline and Chiron Corporation, and a Senior Consultant with Biologics Consulting Group. Dr. Leininger has been a member of the Parenteral Drug Association (PDA) since 1992. During that time she was a long-time contributor to the PDA/FDA Joint Regulatory Conference Planning Committee, a frequent speaker at PDA conferences, and the President of the PDA West Coast Chapter Board (2008-2012).

RUSSELL MORRISON Russell Morrison is the Director of Process and Technical Services for Commissioning Agents, Inc., where he is responsible for the sales, marketing, and execution of process validation, technology transfer, and facility/utility commissioning and qualification projects. Mr. Morrison has a BS in chemical engineering with honors from the University of Minnesota and an MBA in Information Systems from Rensselaer Polytechnic Institute, and served as a submarine officer in the United States Navy. Mr. Morrison is currently a Board Member at Large for the PDA New England Chapter, and is in his ninth year of chapter board service. In 2005-2006 he co-served as the chapter's Secretary and Treasurer; in 2007-2008 he served as Treasurer; in 2009-2010 he served as President-Elect; and Mr. Morrison just finished his term as Chapter President for 2011-2012. During his term as Chapter President, 2001-2012, the New England Chapter finished 1st and 2nd in PDA Global's Chapter Points program. Other notable accomplishments during his term as president include a block-buster meeting in March 2012 on Process Validation, with 170 guests and members in attendance; and a strengthening of the relationship with the PDA New England's student chapter, including awarding of \$12,000 in scholarships.

THOMAS PAMUKCOGLU Thomas Pamukcoglu, MBA, currently is the Sr. Director Commercial Quality Assurance at MedImmune. Mr. Pamukcoglu has been a member of PDA since the early 1990s active in the areas of aseptic processing and a member of the Visual Inspection Task Force. In 2010, he was a co-founder and founding president of the Missouri Valley Chapter of PDA (2010-2012). Recently, he has been a PDA Glass Task Force member working to help develop the new glass container lexicons.

SHELLEY PRESLAR Shelley Preslar is Co-Chair of the Chapter Council and is the immediate Past President of the PDA Southeast Chapter (First Place Chapter in 2012!). Over the past ten years, she has supported the PDA Southeast chapter in several roles including Student Outreach Committee Chair, Secretary and President and has been involved at the National level. When not volunteering, Ms. Preslar is an area manager for ProPharma Group, supporting companies in the life science industry.

MARTIN VANTRIESTE Martin VanTrieste is the senior vice president of Quality at Amgen. He is responsible for all aspects of Quality Assurance, Quality Control, Compliance, Operational Excellence, Environment, Health and Safety, along with Training at Amgen. Prior to joining Amgen, VanTrieste was with Bayer HealthCare's Biological Products Division as vice president of Worldwide Quality and Abbott Laboratories as the vice president of Quality Assurance for the Hospital Products Division. While at Abbott, Mr. VanTrieste held various positions in Quality, Operations, and Research and Development. He started his career at Abbott in 1983 after obtaining his Pharmacy degree from Temple University School of Pharmacy. Mr. VanTrieste has been actively involved with various professional and trade organizations, including United States Pharmacopeia (USP), Pharmaceutical Quality Research Institute (PQRI),

Pharmaceutical Research and Manufacturers of America (PhRMA), and AdvaMed, and he is a member of the Board of Directors of the Parenteral Drug Associations (PDA). He is the founder and first Chairman of Rx-360 and is currently on their Board of Directors. Rx-360 is a nonprofit international supply chain organization that will enhance patient safety by increasing the security and quality of all parts of the supply chain. PharmaVoice in 2012 named Mr. VanTrieste as one of the 100 most inspiring people in the pharmaceutical industry and called him "a man with a mission." Included in Mr. VanTrieste's extensive volunteer history with PDA, he served on the PDA Board of Directors from 2007-2012.

PDA Europe Service Appreciation Award

Chosen by the PDA Europe Senior Staff. This award is given in recognition of special acts, contributions, or service that have contributed to the success and strength of PDA Europe.

STEPHAN RÖNNINGER, PhD Stephan Rönninger is the Head External Affairs Europe, International Quality of Amgen. He provides leadership, support and representation to external activities impacting Amgen's operations functions. He works with associations in the EU, Japan and emerging markets with a focus on Russia and Turkey. He is responsible for advocacy in various external organizations and provides assessment and communication to Amgen. Mr. Rönninger holds a PhD and engineering degree in organic chemistry. After his postdoctoral studies he worked for Roche 1992-2013 starting in an API manufacturing site with responsibilities for laboratory, project management, as a production manager, in Quality Assurance and Quality Management. In 2003, he changed to Global Quality where he was responsible for global quality systems. He represents his company in trade associations (e.g. EFPIA) and the European industry at ICH working groups such as Q9-EWG, Q-IWG, Q7-IWG. He serves on the PDA Board of Directors, Chairs the Regulatory Affairs and Quality Advisory Board (RAQAB), the PDA-Europe Inspections Trends Interest Group and co-chairs several international conferences. He is one of the founders and co-chair of the Paradigm Change in Manufacturing Operations (PCMO) project.

PDA President's Award

WANDA NEAL

Wanda Neal is PDA Senior Vice President of Programs and Meetings. Chosen by the PDA President, this award recognizes a PDA staff member, other than Senior Staff, whose exemplary performance has contributed to PDA's success during the previous year.



2012 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 Fourth 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 7% from \$14.7 million in 2011 to \$15.7 million in 2012. Revenue was driven by strong growth in our Programs and Meetings as well as our customized in-house training offered from our Training and Research Institute.

Achieving Long-Term Strategic Business Goals

As outlined in the strategic plan, PDA is committed to rebuilding the financial reserves while also investing in new capital projects. PDA's unrestricted net assets grew 39% from \$4.0 million in 2011 to \$5.6 million in 2012. PDA's cash and investments increased from \$5.9 million in 2011 to \$7.5 million in 2012 — a 26% 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.

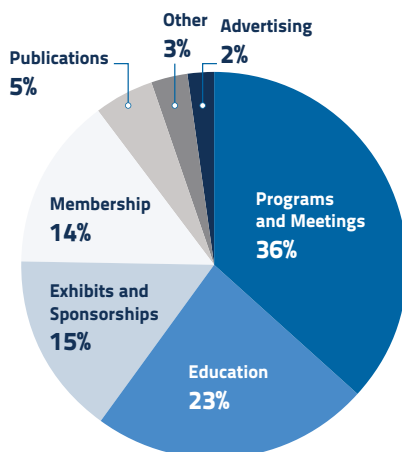
2012 Annual Report Financial Summary

	2012	2011
Total Revenues	\$ 15,731,233	\$ 14,696,079
Total Expenses¹	\$ 14,149,531	\$ 12,824,490
Net Income Surplus (Deficit)²	\$ 1,581,702	\$ 1,871,589
Net Assets at beginning of year	\$ 4,010,926	\$ 3,135,623
Net Assets at end of year	\$ 5,592,628	\$ 4,010,926
Net Asset ratio (Net Assets/Annual Expenses)	40%	31%

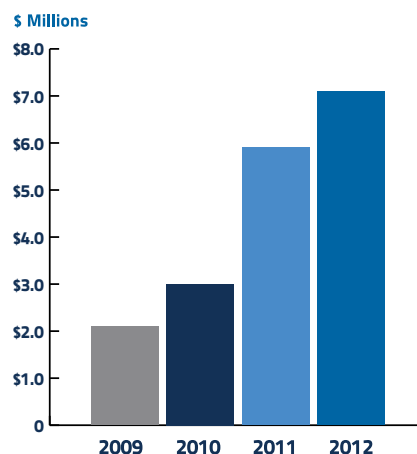
¹ Foreign currency translation adjustments account for a decrease of \$14,671 in 2012 expenses and an increase of \$83,775 in 2011 expenses. See Note F of the 2012 audited financial statements for additional detail.

² 2011 net income excludes a onetime write-off of \$996,286 for the abandonment of an IT software project. See Note D of the 2011 audited financial statements for additional detail.

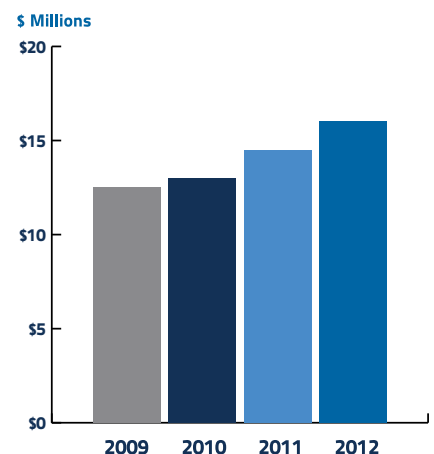
2012 Revenue Sources



Cash & Investments



Revenue



2012 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



PRESIDENT
Richard M. Johnson

Directors



Ursula Busse
Novartis



Ian Elvins



Gabriele Gori
*Novartis Vaccines and
Diagnostics*



John Finkbohner
MedImmune



Gabriele Gori
*Novartis Vaccines and
Diagnostics*



Zena Kaufman
Hospira, Inc.



Stephan Roenninger



Michael Sadowski
Baxter Healthcare



Junko Sasaki
Dainippon Sumitomo



Sue Schniepp
Allergy Laboratories, Inc.



Lisa Skeens, PhD
Hospira, Inc.



Christopher Smalley, PhD
Merck & Co.



Martin Van Trieste
Amgen, Inc.



Glenn Wright
Eli Lilly

2012 PDA Staff

Executive Office

Richard M. Johnson, President
Brianne Dornbush, Senior Administrative Assistant

Scientific and Regulatory Affairs

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