2011 ANNUAL REPORT

PDA®

Parenteral Drug Association

Connecting People, Science and Regulation®

www.pda.org

About PDA

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

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 a 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-plus-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 and Research Institute in Bethesda, Md., 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 and biopharmaceutical 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, bulletins and responses to regulatory initiatives, PDA and its members influence the future course of pharmaceutical and biopharmaceutical product technology.

With more than 9,500 individual members worldwide, PDA draws its strength from the technical expertise of its membership. Conferences, meetings and open forums bring together pharmaceutical manufacturers, suppliers, users, academics and regulatory officials to discuss issues of mutual interest. These exchanges of technical knowledge and expertise assist the advancement of pharmaceutical science and technology in the interest of public health.

Message from the PDA Board of Directors Chair

PDA 2011: CONTINUING TO EXCEL AND BUILDING SUSTAINABILITY

Maik Jornitz, Chair, *PDA*

2011 followed 2010 in its foot-steps regarding the previous year's success. After a year of consolidation and organization in 2010, 2011 became a year of focus for long term sustainability. The first step to sustainability was the accomplishment of the strategic plan, reaching out to 2015. The plan is guidance for the Board of Directors, active volunteers and employees of PDA to plan their activities in accordance to the determined goals. It creates focus and a step by step approach to enhance current member services, but also to provide these services to new members and upcoming regions like China and India. Moreover, besides People, Science and Regulation, the pillars of our organization, Business Management, the foundation, was added to the strategic plan. We realized that we needed to include this focus to truly become a sustainable organization, which can also invest in its membership and services.

Enhancement included a new web site design, which makes it easy and exciting to navigate the PDA web site. It creates a platform to gain information and contacts, as well as an outlet for our chapters and their activities. PDA also launched weekly *Newsbrief*, which members can subscribe to and gain easy access to current information, updates and trends to the pharmaceutical industry, suppliers and regulators. Another initiative was to focus on quality instead of quantity; therefore we consolidated our TRI training courses and conferences to be able to achieve the best possible service and content for our membership. This has been recognized by the membership, as our TRI courses have been even more successful than in the past. PDA added signature conferences within the US and Europe, which were already well visited but received additional appreciation with record attendees numbers. PDA is well known for these conferences like *PDA/EMA Conference*, *Prefilled Syringe* and *Visual Inspection*. Newer topics like *Glass Quality, Single-use Technology* and *Implementation of ICH Q10* were added to the conference portfolio. To accomplish all these tasks, PDA implemented a new governance system and portfolio steering committee. The former Board member alumni had its first meetings and will support current activities with their experience. PDA also is proud to have over 1,000 active volunteers within program committees, task forces, interest groups and advisory boards. The lifeline of any nonprofit organization is volunteers and we are very grateful to have such a strong base of active volunteers. *Our thanks belongs to their tireless support*.

I would like to express my sincere gratitude to Laura Thoma, Veronique Davoust and Lothar Hartmann, our former Board members, for their time invested and welcome Jette Christensen, Sue Schniepp and Glenn Wright to the Board of Directors.

All activities of 2011 have further solidified PDA as an organization to support its membership with science and technology training, information and guidance. PDA's identity *Connecting People, Science and Regulation*® was once more evident in 2011. The strive to support its membership by being an interface and connection has been very visible in a multitude of activities. Having said this, these activities can only happen with your support.

I would like to thank you for your trust and support.

Message from the PDA President

Richard M. Johnson, President, *PDA*

I am pleased to report that 2011 was a very successful year for your association. With the help of countless member-volunteers and your hardworking staff, PDA delivered outstanding conferences and training, enhanced member benefits, and continued development of industry-leading technical reports and regulatory comments. All of this activity was guided by your input, and the PDA 2010-2015 Strategic Plan (published Jan. 2011 PDA News Letter). I would like to highlight a few elements of the plan for this year:

Focus 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
- 2011 Process Simulation for Aseptically Filled Products
- Risk Mitigation of Tribromoanisole (TBA)/Trichloroanisole (TCA) Taints and Odors: A Pharmaceutical Industry Survey

Continued strong Signature meetings, such as:

- 65th PDA Annual Meeting in San Antonio
- 4th PDA/EMA Joint conference in London
- 20th Annual PDA/FDA Joint Regulatory Conference, in Washington
- 6th Microbiology Conference in Bethesda
- 8th Pre-filled Syringe Conference in Basel
- And others

Explore newer topics to help our community meet new challenges, including:

- 1st Glass Quality Conference
- Single Use System Workshop
- Analytical Methods Validation Workshop
- Advanced Therapies Conference
- Enhancing 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.
- Improving our interaction and support for chapters, including one new Chapter in Missouri Valley.
- Expanding our Global Impact by reaching out to emerging markets, including: reduced membership rates for emerging markets.
- Working 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.
- Managing your Association's resources to assure our continued capability to deliver the value you have come to expect.

Yes, it will be a busy year, but 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.

This is *your* association. We would love to hear from you.

2011 PDA Officers and Board of Directors

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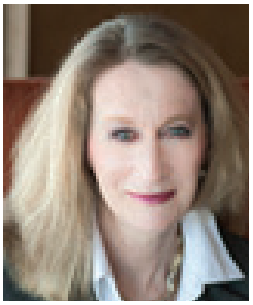

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Scientific and Regulatory Affairs

The Scientific and Regulatory Affairs Department (SᾶRA Department) manages all of PDA's scientific, quality and regulatory activities. These activities are driven by the collective efforts of Advisory Boards, Interest Groups and Task Forces. Each working group is made up of member volunteers who collectively review current trends and develop deliverables to address industry challenges. Deliverables may include strategic and tactical plans, concepts for PDA meetings and workshops, PDA Training and Research Institute (PDA TRI) courses, industry surveys, position papers and consensus documents. Consensus documents, such as Technical Reports, are developed by Advisory Board approved Task Forces and provide industry with recommendations and best practices on many pharmaceutical and biopharmaceutical topics. The SᾶRA 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 2011, the SᾶRA 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 and **Iris Rice**, Support Manager. There were also three part-time staff: in North America, **Robert Dana**, Senior Vice President of Quality and Regulatory Affairs; **Vince Anicetti**, PDA Fellow and in Europe, **James Lyda**, Senior Director of Regulatory Affairs, focusing on the European regulatory scene and contributing to the development of regulatory responses along with Robert Dana, through the Regulatory Affairs and Quality Advisory Board (RAQAB).

The SᾶRA staff was focused in 2011 on leading and supporting ever increasing levels of member activities on Advisory Boards, Interest Groups and Task Forces. To help meet those needs, a project manager was added in fourth quarter, as well as the appointment of Vince Anicetti as the first PDA Fellow. In this new role, Vince provides strategic input into the scientific, quality and regulatory activities of PDA, including multiple PDA Advisory Boards. Vince also participates in and provides guidance to selected PDA Task Forces, works with PDA's Interest Groups, participates in program planning committees and education activities and provides technical and regulatory input and support to internal PDA departments as needed.

In 2011, the first projects in the PDA Paradigm Change in Manufacturing Operations℠ (PCMO) initiative began to reach closure, including "*Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations*," "*Application of Phase-Appropriate Quality Systems and CGMP to the Development of Therapeutic Protein Drug Substance (or API)*" and "*Utilization of Statistical Methods for Production and Business Processes*." PCMO projects are expected to facilitate knowledge transfer among the experts from industry, universities and regulators as well as experts from the respective ICH Expert Working Groups and Implementation Working Groups.

PDA sponsored several industry surveys in 2011, including a survey examining pharmaceutical glass quality and another evaluating the business case for quality. The results of both surveys were presented at the PDA/FDA Glass Quality Conference and the Pharmaceutical Quality System (ICH Q10) Conference respectively, and will be published in 2012.

The Department, along with members from related Interest Groups and Task Forces, contributed expertise and guidance in the development of several new PDA Workshops, including the PDA/FDA Adventitious Agents and Novel Cell Substrates, Analytical Methods Development & Validation, Atypical Actives , Combination Products, and Single Use Systems Workshops.

As part of a PDA wide project to strengthen our governance process, PDA developed the following Standard Operating Procedures (SOP):

- Activities of PDA Technical Advisory Boards; Incorporating Quality by Design
- PDA Guide for Authors: Task Force and Technical Reports

The former documents describe the membership, organization, activities and responsibilities of the PDA Technical Advisory Boards and defines the mechanisms required to initiate and approve Advisory Board and Advisory Board Task Force activities while the latter document is a guide for the actual process of drafting the final Technical Report draft document (e.g., task force chairs, subgroup of members, project managers, etc.). These two new SOP's became effective January 2011.

SCIENCE

BIOTECHNOLOGY ADVISORY BOARD

The Biotechnology Advisory Board (BioAB) establishes the strategic direction and provides oversight for PDA's biopharmaceutical scientific and technical activities through the development of guidelines, technical reports, technical bulletins and recommendations of other activities such as conferences or training courses. The BioAB, through its partner Advisory Board (Regulatory Affairs and Quality Advisory Board), interacts with regulatory authorities by participating in the development of consensus responses to regulatory drafts, final guidance and directives.

In 2011, 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 also managed the progress of PDA Task Forces, including Analytical Methods Development, Analytical Methods Validation, two new Cell Substrate related task forces, GMPs for IDPs; two projects focused on Mycoplasma, Single-Use-Systems and Vaccines. The BioAB was instrumental in managing the approval process for two PDA Technical Reports published in 2010.

Scientific and Regulatory Affairs

In 2011, the BioAB approved the following three ballots:

- Ballot No. 42: *Gene and Cell-Based Therapies Task Force Proposal*
- Ballot No. 43: *Analytical Method Validation and Transfer for Biotechnology Products (Technical Report)*
- Ballot No. 44: *Application of Phase-Appropriate CGMP and Quality Systems to the Development of Protein Bulk Drug Substance (or API)*

Ballot 42 is important because Gene and Cell-Based Therapies (GCBTs) represent a change of paradigm for 21st century healthcare. These therapies involve the manipulation of genes and cells as pharmaceutical products, and although the basic science has been around for about 40 years and, significant advances have been made during the last 20 years so that the field is now starting to come of age. These types of pharmaceutical products have a strong science base, but will require careful nurturing, characterized by effective interactions between manufacturers and regulators. PDA is very well-placed to encourage the kind of working environment which will bring these components together.

Biotechnology Advisory Board (BioAB)

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Co-Chair
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Michael E. Wiebe, PhD, *Quantum Consulting, LLC*
Hannelore Willkommen, PhD, *RBS Consulting*
Wendy Zwolenski-Lambert, *Abbott Laboratories*

PDA Staff Liaisons

Richard Levy, PhD, Scientific and Regulatory Affairs, *PDA*
James C. Lyda, Regulatory Affairs, *PDA*
Iris Rice, Manager, Scientific and Regulatory Affairs, *PDA*

SCIENTIFIC ADVISORY BOARD

The Scientific Advisory Board (SAB) establishes the strategic direction and provides oversight for PDA's scientific and technical activities through the development of guidelines, technical reports, technical bulletins and recommendations of other activities such as surveys, conferences and training courses. The SAB, through its partner Advisory Board (Regulatory Affairs and Quality Advisory Board), interacts with regulatory authorities by participating in the development of responses to regulatory draft guidance and final guidance and directives.

In 2011, the SAB approved the following 13 ballots:

- Ballot No. 173: Good Guidance Distribution Practices for the Pharmaceutical Supply Chain
- Ballot No. 174: *Guidance for Industry: Stability Testing to Support Distribution of New Drug Products (Technical Report)*
- Ballot No. 175: TBA Task Force Benchmarking Survey
- Ballot No. 176: PDA 2011 Glass Quality Survey
- Ballot No. 177: Appointment of Tor Gråberg to the PDA Scientific Advisory Board
- Ballot No. 178: Pharmaceutical Container Closure Development Survey
- Ballot No. 179: Technical Report No. 22 (revised), *Process Simulation for Aseptically Filled Products*
- Ballot No. 180: PDA Bioburden and Biofilm Management Task Force Proposal
- Ballot No. 181: Appointment of William Collentro as Co-Leader of the PDA Pharmaceutical Water Systems Interest Group Leader
- Ballot No. 182: Appointment of Chuck Reed as Leader of the PDA Blow-Fill-Seal Interest Group
- Ballot No. 183: *Utilization of Statistical Methods for Production and Business Processes (PCMO Technical Report)*
- Ballot No. 184: *Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations (PCMO Technical Report)*
- Ballot No. 185: FDA Draft Guidance for Industry; Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET)

Highlights of SAB's role in PDA's 2011 success include:

The SAB was instrumental in managing the development, approval, and publication of two PDA Technical Reports in 2011.

In 2011, the SAB continued to manage a large portfolio of Task Forces with revisions of existing PDA Technical Reports and emerging projects from the PDA Pharmaceutical Cold Chain Interest Group (PCCIG). Several task forces managed by the SAB reached final draft stage in 2011 and are anticipated to complete their work in 2012 including the revision of TR 3 – Dry Heat Sterilization, TR 30 – Parametric Release and TR 39 – Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment, as well as several new Technical reports such as Steam-in Place, TBA Taints and Odors, and the Guidance for Temperature-Controlled Medicinal Products.

Scientific and Regulatory Affairs

Scientific Advisory Board (SAB)

Co-Chairs

Harold S. Baseman, *ValSource, LLC*
Jens H. Eilertsen, PhD, *Novo Nordisk A/S*

Members

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Christopher J. Smalley, PhD, *Merck & Co., Inc.*
Brenda W. Uratani, PhD, *US FDA, CDER*
Glenn E. Wright, *Eli Lilly and Company*

PDA Staff Liaisons

Richard Levy, PhD, Scientific and Regulatory Affairs, *PDA*
Iris Rice, Manager, Scientific and Regulatory Affairs, *PDA*

REGULATORY AFFAIRS

REGULATORY AFFAIRS AND QUALITY ADVISORY BOARD

The year 2011 was a busy year for PDA's Regulatory Affairs and Quality Advisory Board (RAQAB). Along with SAB and BioAB, RAQAB completes the top tier of three advisory boards that serve as the umbrella volunteer organizations capturing all of PDA's science and regulatory affairs activities, including the alignment of the various interest groups.

RAQAB is responsible for monitoring global regulatory activities and ensuring that the views of PDA's members on proposed regulatory rules or requirements are communicated in a timely manner to the appropriate authorities in a clear, concise and professional manner. PDA's positions are developed by volunteer-led task forces composed of members with expertise in the subject matter being considered and supported by the PDA staff. The consensus technical comments prepared by these task forces are reviewed and approved by both RAQAB and the PDA Board of Directors.

In 2011 RAQAB members submitted the following official comments with regulators and other ballots:

- Ballot No. 97: PDA Comments on EU Revisions to GMP Chapter 5: *Production*
- Ballot No. 98: PDA Comments on EU Revisions to GMP Chapter 7: *Outsourced Activities*
- Ballot No. 99: PDA Comments on FDA's "Periodic Review of Existing Regulations; Retrospective Review" under E.O. 13563
- Ballot No. 100: PDA Comments on EMA BWP *Concept paper on the need for a guideline on process validation of medicinal products containing biotechnology derived proteins as active substance*
- Ballot No. 101: PDA Comments on ICH Q11; *Development and Manufacture of Drug Substances*
- Ballot No. 102: PDA Comments on FDA Amendments to Sterility Test Requirements for Biologic Products
- Ballot No. 103: *Application of Phase-Appropriate CGMP and Quality Systems to the Development of Protein Bulk Drug Substance (or API), (PCMO Technical Report)*
- Ballot No. 104: *Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations (PCMO Technical Report)*
- Ballot No. 105: PDA Comments on *EC Guidelines on Good Distribution Practice of Medicinal Products for Human Use*
- Ballot No. 106: PDA Comments on CDER Draft Guidance for Industry; *Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs*

Highlights of the RAQAB's role in 2011 include:

Expanded role and function: In 2011, RAQAB assumed an expanded role in PDA's governance by assuming the oversight of a number of PDA Interest Groups (IG). These include the Clinical Trial Materials IG, Inspection Trends IG, Quality Risk Management IG, Quality Systems IG, Regulatory Affairs IG and the Supply Chain Management IG. This expanded role allows the Association to better leverage the activities of each IG.

PCMO Technical Reports – Review and Approval: The RAQAB began to review technical guidance prepared by PDA volunteer members in the form of the reports prepared under the auspices of the project for "Paradigm Change in Manufacturing Operations" (PCMO). Prior to PCMO, RAQAB was limited to review and approval of regulatory commentary of consultation to FDA, EMA and other authorities. Review of the PCMO series of technical reports from a subject-matter-expert perspective, gives RAQAB the same leverage and added value as BioAB and SAB - Member service through reliable and pragmatic technical guidance.

Support of Global Regulatory Conferences: RAQAB members were intimately involved in two valuable conferences held by PDA in 2011 – the 20th Annual PDA/FDA Joint Regulatory Conference held in Washington, DC, in September 2011, and the 4th PDA/EMA Conference, held in London, in May 2011. RAQAB members helped develop many of the topics at both conferences, and served as speakers in several sessions.

Scientific and Regulatory Affairs

RAQAB Reflects PDA's International Reach: The 2011 RAQAB was chaired for the first time by a volunteer member based in Europe. Dr-Ing Stephan Roenninger, F. Hoffmann-La Roche, Basel, served as RAQAB Chair during 2011, one of the most active years in RAQAB history. Including the ballots described in this section, and other expansions of RAQAB noted above, Roenninger brought a new level of organization and efficiency to the AB, including the issuance of a new "RAQAB Handbook" which helps calibrate and define the activities of the AB, and the responsibilities of its members.

Regulatory Affairs and Quality Committee

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Dr. –Ing Stephan Rönninger, *F. Hoffmann-La Roche, Ltd.*

Co-Chair
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Canada Regional Leader
Jeffrey R. Broadfoot, *Cangene Corporation*

United States Regional Leader
Alan C. Burns, *Sartorius Stedim Biotech*

Australia Regional Leader
Robert B. Caunce, *Hospira*

Asia Pacific Regional Leader
Junko Sasaki, *Dainippon Sumitomo Pharmaceuticals*

Members

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Don E. Elinski, *Lachman Consultant Services, Inc.*
John D. Finkbohner, PhD, *MedImmune*
Amy Giertych, *Baxter Healthcare Corporation*
Karen Ginsbury, *PCI Pharmaceutical Consulting Israel Ltd.*
Barbara Jentges, *PhACT GmbH*
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Steven Mendivil, *Amgen, Inc.*
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Siegfried Schmitt, PhD, *PAREXEL Consulting*
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Jacqueline Veivia-Panter, *Abbott Laboratories*
Hongyan Xie, *Qilu Pharmaceuticals Co., Ltd.*
Barbara B. Zinck, *Zinck Consulting*

PDA Staff Liaisons and Support
Robert Dana, Quality and Regulatory Affairs, *PDA*
James Lyda, Regulatory Affairs, *PDA Europe*
Iris Rice, Scientific and Regulatory Affairs, *PDA*

INTEREST GROUPS

In 2011, the Science and Technology Department was more proactive in engaging our Interest Groups, providing asstance to enhance collaboration and sharing knowledge and best practices in forums and venues outside of the two PDA signature conferences.

Interest Groups were most active at signature PDA meetings, and Interest Group Leaders met during the PDA Annual Meeting as well as the PDA/FDA Joint Regulatory Conference to identify and discuss challenges facing Interest Groups and to collaborate on how to resolve those challenges. Action items that were established as milestones which were resolved in 2011.

In 2011, 12 of PDA's Interest Groups met during the *PDA 2011 Annual Meeting* and the 2011 *PDA/FDA Joint Regulatory Conference*.

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. **Emily Hough**, 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 other products, including The History of PDA: 65 Years of Connecting People, Science and Regulation.

ELECTRONIC *PDA JOURNAL OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY*

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Scientific and Regulatory Affairs

E-Letters and Online Submission Management Introduced

Peer reviewed publication is an important component of scientific progress. This journal, like many of its sister publications, has a rigorous peer review procedure. An initial selection of submitted articles is made by the editorial team to decide which ones merit further consideration. The selected papers are then peer-reviewed by two to three experts in the field. Typically, most manuscripts come back with extensive suggestions for revision and improvement, and once these are done the manuscript is then accepted for publication.

Individual Journal article sales: **616 in 2011** compared to 336 in 2010.

However, there are occasions where we have fielded questions about a paper's methodology after it is published. In the past, there has been no ready mechanism to readily incorporate reader feedback. So, in 2011 we introduced E-Letters, which allows readers to post comments to the articles they read. The intent is to move our unique niche of regulatory science forward faster. This back and forth exchange is what makes scientific meetings interesting and interactive. Our hope is to capture that same richness of experience and dialog alongside papers that appear in the journal. We do know that several hundred downloads of articles appearing in the journal take place—what we don't know is what people think of the papers and what sorts of questions or discussions the papers spark. In particular, our association and the journal are at the interface of science and regulation, and facilitating this interaction should allow for a robust and archived discussion to develop.

We were also delighted to announce our all-electronic workflow. For a better part of a year, the editorial team worked with HighWire Press to introduce a new e-submission tool (**http://submitjournal.pda.org**). The publication itself is all electronic, and it was logical to implement a process where the submission and review of manuscripts also follow suit. This all electronic workflow means faster processing time at the *Journal*, which is important as we strive to reduce the time from submission to decision.

The electronic workflow should further streamline the journey from submission to electronic publishing and make the entire process all the more convenient for authors and reviewers.

SPECIAL ISSUE: Proceedings of the PDA/FDA Adventitious Viruses in Biologics: Detection and Mitigation Strategies Workshop in Bethesda, MD, USA; December 1–3, 2010—36 articles—were published in the Nov/Dec 2011 PDA Journal of Pharmaceutical Science and Technology (Vol. 65 Is. 6).

The December 2010 workshop was organized by the PDA and FDA in response to recent viral contamination events to encourage modernization in industry with respect to viral detection and control measures for enhancing product safety. Such a strategy would further assure continued use of vaccines for public health and avoid costly interruptions in the manufacture of medically necessary biological drugs and the associated shortages that affect seriously ill patients.

Online Archives Expanded

2011 saw a major expansion of content available on the electronically *PDA Journal of Pharmaceutical Science and Technology:* 18 years of additional content (volumes 34-51; 1980-1997) were loaded in April.

PDA Journal articles were previously available electronically on the *PDA Journal* archives disc product however, they were not digitalized PDFs and were not compatible with the HighWire platform. As a result, the Publications team began working with a vendor in India that came up with a novel solution for making the files "indexable" on the HighWire platform. This project began in October 2010, and by April 2011, the files had been converted, tested multiple times and posted online. Soon after, the PDA Membership Department began selling 1 year licenses for access to all the archived content; a product that was purchased by over 100 members during the year.

In addition, PubMed and Medline began re-indexing the electronic *PDA Journal of Pharmaceutical Science and Technology* again in April 2011.

Article Sales

The combination of the new archive content, the restoration of PubMed/Medline indexing, and the continued high quality of content provided by the Journal editors resulted in a record year for individual article sales: 616 in 2011 compared to 336 in 2010.

Usage Statistics

In 2011, average monthly site usage was extremely strong with the home page viewed 5,831 timers per month, the current Table of Contents page viewed 1,132 times per month, and archive Table of Contents viewed over 3,000 times per month.

The aggregate number of article abstracts accessed in 2011 (all abstracts read by all individuals) was 350,000; the aggregate number of articles in PDF format accessed was 38,000; and the aggregate number of full HTML versions of articles accessed was 6,900. Over 25,000 searches for content were conducted on the site in 2011 (this counts only searches conducted on journal.pda.org, not those done on other sites that direct traffic to the Journal).

Overall, the website received 66,503 unique visitors in 2011 and the average number of pages accessed per visit was 3.25 and the average duration per visit was 2.5 minutes. By the end of 2011, there were over 7,000 individuals signed up for Table of Contents Alerts.

Institutional Subscriptions

130 institutions subscribed to the online Journal in 2011.

Sponsors

Sartorius Stedim Biotech and Veltek Associates, Inc. continued to support the Journal by placing banner ads on the home page throughout 2011.

Scientific and Regulatory Affairs

PDA LETTER

A New Look Up Front

In 2011, PDA decided to give the *PDA Letter* a new look on the cover by removing the front page feature article. This move only confirmed the direction the Letter had been going in for several years; that is away from the newsletter format and towards a magazine style. To help the internal team with artwork decisions, several members of the PDA Letter Editorial Committee have formed a subgroup to comment on cover and internal designs. They are indicated below with asterisks.

Member Submissions

PDA members contributed a record 14 feature-length articles to the *PDA Letter* in 2011, 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:

- "Protective Packaging Choices Challenge Packaging Engineers" by Emilio Frattaruolo *(January)*
- "The Power of Knowledge"by Thomas Peither *(March)*
- "Multi-Pronged Strategy Needed to Combat Counterfeiters" by Martin VanTrieste *(May)*
- "IPEC Contributions Mitigate Risk in Excipient Supply Chain" by Juanita Garofalo *(May)*
- "Implementing Regulatory Intelligence – An Organizational Program Management Approach" by Winston Brown *(June)*
- "The Value of Plant Isolates in Pharma Quality" by David Myatt and Charlotte Morgan *(July/August)*
- "Delamination Propensity of Pharmaceutical Glass Containers by Accelerated Testing with Different Extraction Media" by Emanuel Guadagnino and Daniele Zuccato *(July/August)*
- "Root Cause an Elusive End for Micro Investigations" by Randy Hutt *(July/August)*
- "Reduce Your Deviations: Implement a Quality Near Hit Program" by John Parrish *(September)*
- "IV/IM Micro Quality: Whose Responsibility is it?" by Cheryl Moser *(September)*
- "PDA Israel Chapter Calls for Additional Work on Q11" by Karen Ginsbury *(October)*
- "Evaluating the Use of RFID in the Pharmaceutical Industry" by Ashley Goldberg *(October)*
- "PDA/FDA Serves as Platform for Agency to Announce Initiatives, Industry to Comment" by Anastasia Lolas *(November/December)*
- "Reasons for Missing the Mark of First Cycle Approvals" by Bob Darius *(November/December)*

2011 PDA Letter Editorial Committee

Chair
Walter Morris, Managing Editor, *PDA*

Vice Chair
Karen Ginsbury, *PCI Pharmaceutical Consulting*

Kamaal Anas, *International AIDS Vaccine Initiative*
Vince Anicetti,* *Genentech*
Harold Baseman, *ValSource*
Winston Brown, *Baxter*
José Caraballo,* *Amgen*
Doris Conrad, *Conrad Consulting*
Robert Darius,* *GlaxoSmithKline*
Miriam Estrano, *Medtronic*
Martha Folmsbee,* *Pall*
Georgiann Keyport, *Canopy Medical*
Anastasia Lolas, *U.S. FDA*
Matt Schmidt, *Merck & Co.*
Susan Schniepp,* *OSO BioPharmaceuticals Manufacturing*
Janeen Skutnik-Wilkinson, *Pfizer*
Sandra Zoghbi-Gay,* *bioMérieux*

* PDA Letter Editorial Committe (PLEC) Art Subcommittee

PDA Staff
Emily Hough, Writer/Editor, *PDA*
Katja Yount, Publications Design Specialist, *PDA*

PDA TECHNICAL REPORTS

PDA published two new and one revised technical report in 2011, extending the collection to 53. They are:

- *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 2011 Process Simulation for Aseptically Filled Products*

PDA SURVEY

In 2011 PDA published a new product, the PDA Survey. The first PDA Survey to be published supported PDA Technical Report No. 55 and was titled:

Risk Mitigation of Tribromoanisole (TBA)/Trichloroanisole (TCA) Taints and Odors: A Pharmaceutical Industry Survey (single user digital version)

Plans are in place to publish more benchmarking surveys, either as standalone documents or in support of technical reports and/or PDA conferences and workshops. In 2012, PDA will work on surveys on glass quality and the cost of quality control.

Scientific and Regulatory Affairs

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. PDA manages the daily retail operations and sales activities 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 2011:

James L. Vesper, *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry*, Fourth Edition, Revised & Expanded

Dr. Siegfried Schmidt, *Quality by Design: Putting Theory into Practice*

Jeanne Moldenhauer, PhD, *Environmental Monitoring: A Comprehensive Handbook*, Volume 5

Karen Zink McCullough, *The Bacterial Endotoxin Test: A Practical Guide*

Jeanne Moldenhauer, PhD, *Thermal Validation in Moist Heat Sterilization*

Jeanne Moldenhauer, PhD, *Rapid Sterility Testing*

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 2011 PDA/DHI Distinguished Editor/Author Award recipient was:

- **Dr. Siegfried Schmidt**

In 2011 the top five best-selling PDA/DHI books were:

- Quality by Design: Putting Theory into Practice, edited by **Dr. Siegfried Schmitt**
- The Bacterial Endotoxin Test: A Practical Guide, edited by **Karin Zink McCullough**
- GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition, Revised & Expanded, by **James L. Vesper**
- Environmental Monitoring: A Comprehensive Handbook, Volume V, edited by **Jeanne Moldenhauer, PhD**
- Practical Aseptic Processing: Fill and Finish, Volume I and II, edited by **Jack Lysfjord**

Technical Book Committee

Chair

Walter Morris, Director of Publishing, *PDA*

Vice Chair

Amy Davis, *Davis Healthcare International Publishing*

Members

Joyce Bloomfield, *Merck & Co., Inc.*

Norbert Hentschel, *Boehringer Ingelheim Pharma GmbH & Co. KG*

Jack Lysfjord, *Lysfjord Consulting, LLC*

Russell Madsen, *The Williamsburg Group, LLC*

Michael J. Miller, *Microbiology Consultants, LLC*

Jeanne Moldenhauer, *Excellent Pharma Consulting*

Siegfried Schmitt, *PAREXEL Consulting*

Steven Mendivil, *Amgen, Inc.*

Stephan Rönninger, *F. Hoffman-La Roche Ltd.*

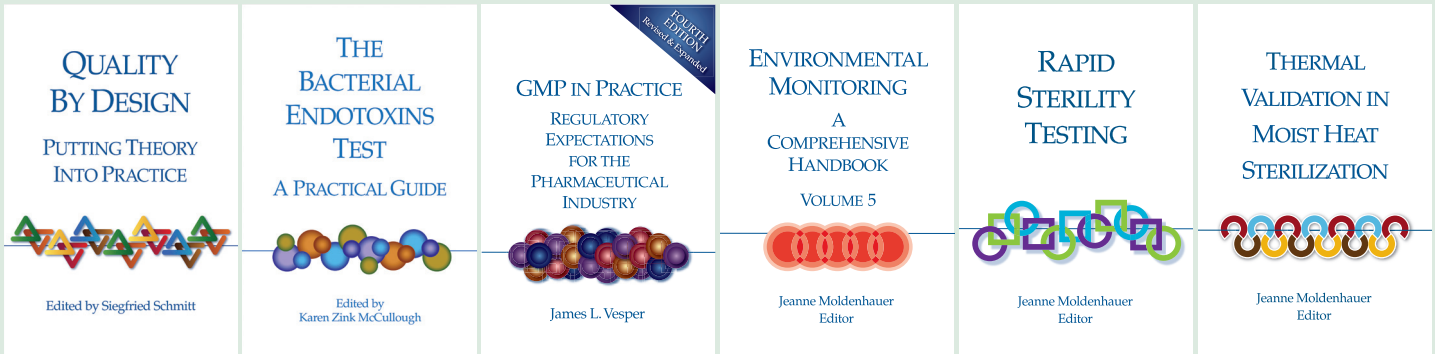
Scott Sutton, *Microbiology Network, Inc.*

James Vesper, *LearningPlus, Inc.*

PDA Staff Liasons

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), established in 1997, provides innovative hands-on education, training and applied research opportunities in pharmaceutical and biopharmaceutical sciences and associated supporting technologies. We offer courses at our training facility in Bethesda, Md., as well as in conjunction with major North American PDA Conferences, and in select regional locations around the US.

We focus on *Career-Long Learning* and 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, 2011 was a very successful year for TRI and PDA's education programs.

At our Bethesda facility, we provided lecture courses, as well as training programs featuring classroom lectures accompanied by hands-on laboratory training. In 2011, we provided 16 laboratory courses; two of which were new and/or updated laboratory-based courses. *Quality Systems for Aseptic Processing* was developed in response to suggestions from the graduates of our flagship *Aseptic Processing Training Program*. The Quality Systems course is presented by **David Matsuhiro** and **Harold Baseman**, the lead instructors from the *Aseptic Processing Training Program*, as well as some of the other instructors from that program. The 2011 course was a sellout, and we anticipate this course becoming a standard in our curriculum for the next several years. The other new laboratory course we offered in 2011 was *Filters and Filtration in the Biopharmaceutical Industry – Advanced Course*. This course was one of two focusing on filtration technologies, with a lecture-based basic course on filtration technologies rounding out this subject.

As mentioned above, our ten-day *Aseptic Processing Training Program* remains our flagship course. This course, which consists of two one-week sessions approximately a month apart, was held five times in 2011 and was sold out each time. The course, which is taught by more than 20 subject-matter expert instructors, provides the students with an opportunity to participate in the didactic learning experience of the classroom complemented by more than 50 hours of hands-on learning in our clean room and laboratories, where they apply their classroom-acquired knowledge in a small-scale aseptic filling environment. The opportunity to apply their new knowledge in a risk-free setting that mimics a commercial clean room, without jeopardizing company clean rooms or commercial products, continues to provide our students with a learning opportunity not found elsewhere in the biopharmaceutical/pharmaceutical industry.

In addition to our laboratory-based courses, we provided 35 traditional classroom-based lecture courses. Reflecting our commitment to continually review and upgrade our curriculum, these included the following ten new courses:

- *Steam Sterilizers – Getting it Right from the Beginning*
- *DoE Basics for Validation by Design*
- *Technical Report 43: Identification and Classification of Non-Conformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing*
- *Selection and Utilization of Glass Containers in Pharmaceutical Manufacturing*
- *Economical Design of Lyophilization Experiments Workshop*
- *Validation of Lyophilization*
- *Practical Applications of Risk Management*
- *Environmental Control and Monitoring for Regulatory Compliance*
- *Filters and Filtration in the Biopharmaceutical Industry – Basics Course*
- *Quality and Compliance Management for Virtual Companies*

These lecture courses were held at the TRI facility and at the following PDA Conferences:

- 2011 *PDA Pharmaceutical Cold Chain Management Conference;* Bethesda, MD
- 2011 *PDA Annual Meeting;* San Antonio, TX
- 2011 *PDA/FDA Glass Quality Conference*; Arlington, VA
- 2011 *PDA/FDA Supply Chain Conference*; Bethesda, MD
- 2011 *PDA/FDA Joint Regulatory Conference*; Washington, DC
- *PDA's 6th Annual Global Conference on Pharmaceutical Microbiology*; Bethesda, MD

We also offered the laboratory-based course *An Introduction to Visual Inspection* in conjunction with the 2011 *PDA Visual Inspection Conference* in Bethesda.

In addition to the above U.S. offerings, in 2011 we brought TRI courses to Israel and China. Two courses were provided in Israel; in February, 20 students participated in *Microbiology Update* taught by **Jeanne Moldenhauer**, and in November, more than 40 students took part in *Applied Statistics in Process Validation and Ongoing Product/Process Performance Monitoring,* taught by **Jason Orloff**. Two courses were also offered in China; **Harold Baseman** and **Bob Dana** presented training on PDA **Technical Report No. 22** (Process Simulation Testing for Aseptically Filled Products) and **Technical Report No. 28** (Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals) to approximately 80 participants in Beijing and Shanghai.

PDA Training and Research Institute

We continued our customized in-house training programs in 2011 as well. These allow us to deliver courses tailored specifically for the needs of the various clients we serve. Over 200 students participated in these programs in 2011.

None of our training courses would have been possible without the support of those companies that lent or donated supplies and equipment used in the conduct of the courses and the efforts of our dedicated faculty members who took time away from their normal routines to serve as instructors for our courses. A complete list of these donors and volunteers accompanies this section of the 2011 PDA Annual Report. It is through their efforts that we achieved the successes we had in 2011.

TRI Supporting Companies 2011

ARAMARK

ATLANTIC TECHNICAL SYSTEMS

BECTON DICKINSON

BIOLOG

BIOMERIEUX

CARDINAL HEALTH

COLE PARMER

EMD MILLIPORE

GENERAL ECONOPAK

HACH ULTRA

HARDY DIAGNOSTICS

ITW TEXWIPE

KIMBERLY CLARK

NILFISK

PARTICLE MEASURING SYSTEMS

SARTORIUS STEDIM BIOTECH

STEVANATO GROUP

THERMOFISHER SCIENTIFIC

VELTEK ASSOCIATES, INC.

WEST PHARMACEUTICAL

2011 FACULTY

Carolyn Adams, *Genzyme*
Mike Anisfeld, *Globepharm Consulting, Inc.*
Roger Asselta, *Genesis Technical Advisors*
Harold Baseman, *ValSource, LLC*
Barbara Berglund, *Jubilant HollisterStier*
Karen Bossert, *Lyophilization Technology Inc.*
Rafik Bishara, *Pharmaceutical Cold Chain Interest Group (PCCIG)*
Qiao Bobo, *FDA*
Scott Bozzone, *Pfizer*
John Brecker, *Fleet Laboratories*
Sean Byrd, *FDA*
David Chesney, *PAREXEL Consulting*
William Collentro, *Concordia ValSource, LLC*
Anne Conners, *EMDMillipoe*
Nathan Conover, *PathWise Inc.*
James Cooper, *Endotoxin Consulting Services*
Ruth Cordoba-Rodriguez, *FDA*
Dave Crance, *Particle Measuring Systems, Inc*
Cheryl Custard, *Sanofi Pasteur*
Bob Dana, *PDA*
Nicholas DeBello, *Wheaton Industries Inc.*
Grace Deneke, *FDA*
Anne Marie Dixon, *Cleanroom Management Associates Inc.*
Donald Ertel, *FDA*
Dave Ferrazza, *EMD Millipore*
Barry Friedman, *Consultant*
Wayne Garafola, *Sartorius Stedim Biotech*
John Geigert, *BioPharmaceutical Quality Solutions*
Daniel H. Gold, *D.H.Gold Associates, Inc.*
Tricia Griffiths, *EMD Millipore*
Michael Gross, *Biologics Consulting Group*
William Harclerode, *Forest Labs*
Tibor Hlobik, *West Pharmaceutical, Inc.*
Matt Hofacre, *STERIS Life Sciences*
Lisa Hornback, *Hornback Consulting, LLC*
Richard Johnson, *PDA*
Maik Jornitz, *Sartorius Stedim Biotech*
Bob Kieffer, *RGK Consulting*
Frank Kohn, *FSK Associates, Inc.*
Markus Lankers, *Rap-ID*
Destin LeBlanc, *Cleaning Validation Technologies*
Samuel Lebowitz, *Electrol Specialties Company*
Ronald Leversee, *Perrigo*
George Levinson, *Compliance Software Solutions Corp.*
John Ludwig, *Pfizer Global Biologics*
David Matsuhiro, *Cleanroom Compliance*
Edwin Melendex, *PAREXEL*
Randa Melham, *FDA*
Kimberly Miller, *West Pharmaceutical Services*
Mike Miller, *Microbiology Consultants, LLC*
Charles Montague, *Scienta Solutions*
Antonio Moreira, *University of Maryland, Baltimore County*
Wenzel Novak, *Groninger and Co. GmbH*
Martha O'Lone, *FDA*
Jason Orloff, *PharmStat*
Martin Orlowski, *Bioquell, Inc.*
Matthew Ostrowski, *Pfizer*
Lori Peters, *FDA*
Tom Pringle, *Pharmaceutical and Biomedical Temperature-Controlled Transport Packaging*
Anurag Rathore, *Indian Institute of Technology*
Thomas Reidy, *Syntonix*
Paul Ricciatti, *CIBA Vision Sterile Manufacturing*
Peter Schofield, *Walker Barrier Systems*
Dale Seiberling, *Electrol Specialties Company*
John Shabushnig, *Pfizer*
Destry Sillivan, *FDA*
Chris Smalley, *Pfizer*
Edward Smith, *Packaging Science Resources*
Patrick Swann, *FDA*
Edward Trappler, *Lyophilization Technology*
Mark Trotter, *Trotter Biotech Solutions*
Deborah Trout, *FDA*
Nicole Trudel, *FDA*
Barbara van der Schalie, *SAIC-Frederick, Inc.*
Art Vellutato, Jr., *Veltek Associates, Inc.*
Nancy Waites, *FDA*
Brent Watkins, *Veltek Associates, Inc.*
Randy Wilkins, *Millipore*

Programs, Meetings & Registration Services

2011 produced another record year for PDA in the Programs and Meetings Department utilizing the same strategy of combining the mix of tried and true scientific, technical pharmaceutical and biopharmaceutical programs for career long learning.

The Programs, Meetings and Registration Services Department manages all aspects of program planning, including logistics associated with the events, timeline management and registration with the collective support of fourteen Program Planning Committees that represent one hundred and seventy-five committee representatives from the regulatory and scientific industry.

In 2011, the department had six full-time and one part-time staff member who all played a role in the planning and execution of the 2011 events. Many aspects and details are required to plan an event and teamwork is the key ingredient in meeting deliverable deadlines. If you have served on a planning committee, you know that there is no shortage of "T's" to cross and "I's" to dot. The staff members: **Wanda Neal**, CMP, Senior Vice President, Programs and Registration Services, **Tanya Allen**, Coordinator, Programs and Meetings, **Jason Brown**, Senior Manager, Programs and Meetings, **Patresa Day**, Manager, Registration and Customer Accounts, **Leon Lewis**, Senior Manager, Programs and Meetings, **Melissa Pazornik**, Coordinator, Programs and Meetings and **Andrea Viera**, Senior Coordinator, Programs and Registration Services represent the four areas of the department (Program, Speaker, Registration and Logistics).

In 2011, it was clear that companies still had a watchful eye on business expenses by limiting the number of individuals to travel to attend an event as travel budgets were being cut. So to meet the demand and needs of the industry, PDA added conference recordings to our tried and true events.

2011 Program Planning Committee Chairs

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

Members

Eric Berg, *Amgen, Inc.*
Rafik H. Bishara, PhD
Joyce Bloomfield, *Merck and Company*
David Cockburn, *EMA*
Richard L. Friedman, *FDA*
Amy Giertych, *Baxter Healthcare*
Michael Gross, PhD, *Biologics Consulting Group*
Lisa Hornback, *Hornback Consulting, LLC*
Arifa Khan, PhD, *FDA*
Kathryn King, PhD, *FDA*
Stephan O. Krause, *Medimmune*
Anthony Lubiniecki, *Centocor*
Morten Munk, *CMC Biologics*
Dwayne Neal, *SAIC-Frederick*
Lynne Ensor, PhD, *FDA*
Robert Repetto, *Pfizer, Inc.*
Janeen Ann Skutnik-Wilkinson, *Pfizer, Inc.*
David Schoneker, *Colorcon*
Susan Schniepp, *OSO BioPharmacueticals*
John G. Shabushnig, PhD, *Pfizer, Inc.*
Christopher Smalley, PhD, *Merck and Company*
Edward Tidswell, PhD, *Baxter Healthcare Corporation*
Edward H. Trappler, *Lyophilization Technology, Inc.*
Martin VanTrieste, *Amgen, Inc.*
Steven Wolfgang, *FDA*

2011 EVENT PHOTOS

ANNUAL MEETING

PDA/FDA

Programs, Meetings & Registration Services

2011 PDA CONFERENCES AND WORKSHOPS

PDA offered 14 programs covering a wide range of topics to suit the focus and varying interests of the regulatory and scientific industry professionals.

2011 Pharmaceutical Cold Chain Management Conference
March 1–2, 2011, Bethesda, MD

2011 PDA/FDA Atypical Actives Workshop
March 9-10, 2011, Bethesda, MD

2011 PDA Annual Meeting
April 11–13, 2011, San Antonio, TX

Process Validation Workshop
April 13-14, 2011, San Antonio, TX

2011 PDA/FDA Glass Quality Conference
May 23-26, 2011, Arlington, VA

2011 PDA/FDA Pharmaceutical Supply Chain Workshop
June 6–8, 2011, Bethesda, MD

2011 Analytical Methods Development and Validation Workshop
June 20–21, 2011, Bethesda, MD

Single Use Systems Workshop
June 22-23, 2011, Bethesda, MD

2011 PDA/FDA Joint Regulatory Conference
September 19-21, 2011, Washington, DC

2011 Combination Products Workshop
September 21-22, 2011, Washington, DC

2011 Visual Inspection Forum
October 3–4, 2011, Bethesda, MD

Pharmaceutical Quality System (ICH Q10) Conference, Co-sponsored by FDA and Supported by EMA
October 4–6, 2010, Bethesda, MD

PDA's 6th Annual Global Conference on Pharmaceutical Microbiology
October 17–19, 2011, Bethesda, MD

PDA/FDA Adventitious Agents and Novel Cell Substrates: Emerging Technologies and New Challenges
November 2-4, 2011, Rockville, MD

2011 PDA CONFERENCE RECORDINGS

Conference recordings are a distance on-line learning tool. Conference recordings in 2011 include:

- 2011 Annual Meeting:
- 2011 PDA/FDA Glass Quality Conference
- Single Use Systems Workshop
- 2011 Analytical Methods Development and Validation Workshop – The Methods Life Cycle
- 2011 PDA/FDA Joint Regulatory Conference
- 2011 Combination Products Workshop
- Pharmaceutical Quality System (ICH Q10) Conference Co-sponsored by FDA and Supported by EMA
- PDA's 6th Annual Global Conference on Pharmaceutical Microbiology
- 2011 Visual Inspection Forum
- PDA/FDA Adventitious Agents and Novel Cell Substrate Conference

2011 WEB SEMINARS

The innovative technology of Web Seminars continues to be another unique opportunity to provide quality educational training and is considered a valuable tool with no limitations. These recordings of previous Web Seminars and select conference sessions are posted on-line at www.pda.org.

What Makes a Pre-filled Syringe Usable and Ergonomic?
Anthony Andre, PhD, Founding Principal, *Interface Analysis Associates*

Water Activity Application in the Pharmaceutical Industry
Anthony M. Cundell, PhD, Director, Analytical Sciences, Microbiology, *Merck Research Laboratories*

State of Art Design of Vaccine Facilities
Niels Guldager, Senior Consultant, *NNE Pharmaplan*
Aeby Thomas, Bioprocess Consultant, Process and Facilities, *NNE Pharmaplan*

Cost-Effective Industry-Academia Partnering to Promote Manufacturing Excellence: A Case Study
Elaine Lehecka Pratt, Industry Professor, *Stevens Institute of Technology and* President, *Lehecka Pratt Associates, Inc.*

GMP Compliance and the Bacterial Endotoxins Test: Prerequisites to Testing
Karen McCullough, Principal Consultant, *MMI Associates*

GMP Compliance and the Bacterial Endotoxins Test – Workshop Two: Routine Testing
Karen McCullough, Principal Consultant, *MMI Associates*

GMP Compliance and the Bacterial Endotoxins Test – Workshop Three: GMP and Applications of BET
Karen McCullough, Principal Consultant, *MMI Associates*

Differentiation of Protein Aggregates, Silicone Oil Droplets and Air Bubbles in Formulations using Micro-Flow Imaging
Clark Merchant, Senior Optical Scientist, *Brightwell Technologies*

Preparing for an FDA Inspection – Aseptic Warning Letters
Jeanne Moldenhauer, President, *Excellent Pharma Consulting*

Preparing for a FDA Inspection by Reviewing Warning Letters – Non-Sterile Processes
Jeanne Moldenhauer, President, *Excellent Pharma Consulting*

High Efficiency Single Use Mixing Systems for Biopharmaceutical Applications
Nicolas Voute, Global Product Manager, Fluid Management Technologies, *Sartorius Stedim Biotech S.A.*

Quality by Design Putting Theory into Practice
Siegfried Schmitt, PhD, Principal Consultant, *PAREXEL Consulting*

Risk Assessment and Risk Management in the Pharmaceutical Industry
James Vesper, President, *LearningPlus, Inc.*

Development and Qualification of a Robust Cold Chain Logistics Solution for Protein Drug Products
Eric Youssef, Product Manager Associate, Fluid Management Technologies, *Sartorius Stedim Biotech*

Membership and Chapters

CONNECTING & ENGAGING MEMBERS

Our focus in 2011 was connecting and engaging members. As part of this strategy, we included PowerPoint slides on PDA membership, volunteer opportunities and chapter information at all PDA signature meetings and chapter shows. We recognized volunteers with "volunteer spotlight plaques" at the Annual Meeting. To engage members in their 1st year of membership we developed a postcard campaign to advertise all of PDA products, benefits and services. Also, for this group we introduced new letters from the membership committee chair and local chapter president to welcome new members to the community.

IMPROVING MEMBER BENEFITS AND SERVICES

PDA launched our annual Membership Satisfaction Survey to access the customer needs and level of service we provide. Our goal was a 10% response rate and we achieved a 12.4% response rate. This is a 9.4% increase compared to 2010. The new strategies that we used to increase the response rate included kiosks at signature meetings, using an iPad as an incentive and improving the content/structure of the survey. The PDA membership committee plans on analyzing this data and using it as a platform to develop strategies in 2012 to improve membership benefits and services.

On August 31st PDA introduced a new PDA member benefit called the PDA *Newsbrief* SM. The PDA *Newsbrief* is a highly informative e-news brief that delivers pharmaceutical industry news to the members every week.

In addition to the PDA *Newsbrief* and to help diversify our membership, PDA, in September, made several important changes to its membership types by expanding the availability of membership to those in developing countries, individuals who have retired from the industry and those currently seeking employment. For individuals in the developing world, the list of qualified countries where members can join under PDA's Emerging Economy membership has been expanded. Based on the World Bank's list of Developing Countries, we are now accepting people from 150 countries. Secondly, we introduced a new membership type for retired members so those with knowledge and experience can help the younger generation succeed by contributing to the PDA community. Finally, PDA is interested in helping our members who are not currently employed but who still want to remain active in our Association by creating a transitional member type.

INCREASING MEMBERSHIP OUTREACH

In 2011, PDA leveraged the chapters to conduct various road-shows in the US and Asia. In this roadshow a PDA representative highlighted new benefits and services available to PDA members. This gave members and non-members the opportunity to learn more about PDA and the advantages membership provides. In 2011, a PDA Membership Team member or other PDA staff visited more than 15 chapter meetings around the world, two tradeshows & several European meetings. The road show was presented at several International events including the following countries: Taiwan, Japan, Russia, Singapore, and Korea

IMPROVING GUIDANCE AND SUPPORT FOR CHAPTER VOLUNTEERS

A chapter incentive points program has been developed and completed on April 7th, 2011. This program was initiated at the Chapters' request and was designed to help identify, promote, and reward greater alignment between the chapters and PDA Headquarters. PDA also introduced a welcome/information packet for new chapter leaders, a financial checklist for chapter treasurers, and a PDA Chapters Marketing Toolkit to aid in promotion and member communication at the chapter level.

Membership and Chapters

PDA GLOBAL CHAPTERS AND LEADERS

ASIA-PACIFIC

Australia Chapter
President: **Ano Xidias**, *PharmOut*
President-elect: **Susan Knight**, *GlaxoSmithKline*
Treasurer: **Paul Kerr**, *SeerPharma P/L*
Secretary: **Anna Corke**, *Genera Biosystems*

Japan Chapter
President: **Katsuhide Terada**, PhD, *Toho University*
President-elect: **Takashi Sonobe**, PhD, *University of Shizuoka*
President-elect: **Shigeo Kojima**, PhD, *Pharmaceuticals and Medical Devices Agency*
Treasurer: **Yukio Hiyama**, PhD, *National Institute of Health Sciences*
Secretary: **Taiichi Mizuta**, PhD

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

Taiwan Chapter
President: **Frank Wu**, *United Biomedical Inc.*
Secretary-General: **Tuan-Tuan Su**, *PDA Taiwan Chapter*

EUROPE

France Chapter
President: **Philippe Gomez**, *Sartorius Stedim*
Treasurer: **Jean-Luc Clavelin**, *Eli Lilly and Company*
Secretary: **Sorin Haias**, *Lives International Corporation*

Ireland Chapter
President: **Coleman Casey**, PhD, *University College Cork*
President-elect: **Brendan Cahill**, *Pfizer*
Treasurer: **Joan Fitzgerald**, *Allergan*
Secretary: **Alice Redmond**, *PM Engineers & Project Managers, Cork*

Israel Chapter
President: **Mordechai Izar**, PhD, *Ludan Engineering*
President-elect: **Rina Yamin**, *Rina Yamin Pharmaceutical Consulting*
Treasurer: **Karin Baer**, PhD, *Omrix-Biopharmaceuticals, LTD*
Secretary: **Karen S. Ginsbury**, *PCI Pharmaceutical Consulting Israel*

Italy Chapter
President: **Stefano Maccio**, *CTP Technologie di Processo*
President-elect: **Antonino Giannetto**, *S.I.F.I. SPA*
Treasurer: **Dr. Joachim Leube**, *Bayer Healthcare Manufacturing S.r.l.*
Secretary: **Lucia Ceresa**, *Pall Italia*

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

NORTH AMERICA

Canada Chapter
President: **Vagiha Hussain**, *Baxter Canada*
President-elect: **Sabrina Ullah**, *SNC-Lavalin Pharma Inc.*
Secretary: **Antonella Maggio**, *Generex Biotechnology*

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

Delaware Valley Chapter
President: **Arthur Vellutato, Jr.**, *Veltek Associates, Inc.*
President-elect: **Jason Mattis**, *GlaxoSmithKline*
Treasurer: **Marlene Raschiatore**, *Johnson & Johnson*
Secretary: **Stephen S. Trombetta**, *Veltek Associates, Inc.*

Metro Chapter
President: **Robert Johnson**, *RAJ Associates*
President-elect: **Robert Seltzer**, *GlaxoSmithKline*
Treasurer: **Lisa Burns**, *Church & Dwight*
Secretary: **Lara Soltis**, *Texwipe*

Midwest Chapter
President: **Peter Noverini**, *Baxter*
President-elect: **Jeanne Moldenhauer**, *Excellent Pharma Consulting*
Treasurer: **Kenneth Paddock**, *Baxter Healthcare*
Secretary: **Beth Kirschenheiter**, *Hospira, Inc.*

Missouri Valley Chapter
President: **Thomas Pamukcoglu**, *SAFC Biosciences*
President-elect: **Eldon Henson**, *Covidien*
Treasurer: **Keith Koehler**, *Certified Energy Labs*
Secretary: **Jeff Hargroves**, *ProPharma Group, Inc.*

Mountain States Chapter
President: **Patricia Brown**, *Agilent Technologies*
President-elect: **Suzanne Mecalo**, *Commissioning Agents, Inc.*
Treasurer: **Nikolas Burlew**, *REGULUS Pharmaceutical Consulting*
Secretary: **Karrin Hogan**, *Kelly Scientific Resources*

New England Chapter
President: **Russell Morrison**, *Protein Sciences Corporation*
President-elect: **Roland Bizanek**, PhD, *Complya Consulting Group*
Treasurer: **Mark Plucinsky**, *Shire*
Secretary: **Jonathan Morse**, *Complya Consulting Group*

Puerto Rico Chapter
President: **Jose Cotto**, *Amgen Manufacturing, Inc.*
President-elect: **Melba Clavell**, *Quantic*
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, LLC*

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, Inc.*
Treasurer: **Milan Crnogorac**, *Genentech, Inc.*
Secretary: **Beth Keij**, *Novartis Diagnostics*

PDA Europe

STAFF AND OFFICE

2011 was a year of continued growth in PDA Europe operations and member service. **Georg Roessling**, Senior Vice President, marked his sixth year as head of PDA Europe operations. Along with Dr. Roessling, the staff in 2011 included: **Ailyn Kandora**, Director Events & Exhibitions; **Antje Petzholdt**, Administration and Membership; **Nadine Gold**, Marketing Manager; **Volker Eck**, Science and Technology; **James Lyda**, Regulatory Affairs; **Creixell Espilla-Gilart**, Exhibition & Sponsorship Manager; **Dirk Stelling**, Finance Controlling; **Lu Yang**, Assistant Event Manager; **Bernd Krippner**, Program Manager; and **Ilona Frank**, Finance Support.

Volunteers and Members

For calendar year 2011, PDA Europe reports a membership total of about 2,380 members in Europe and the Middle East, which represents an increase of over 5% from last year. Germany has the largest number of members, followed by Switzerland, UK, France and Israel. Eleven of the 14 countries below showed member increases, with Switzerland showing the largest increase, followed by the UK. The major member states/countries are listed below in order of members (data as of December 2011):

GERMANY	392
SWITZERLAND	311
UK	229
FRANCE	187
ISRAEL	189
DENMARK	173
ITALY	160
BELGIUM	140
IRELAND	134
NETHERLANDS	122
SWEDEN	106
SPAIN	50
FINLAND	49
AUSTRIA	43

REGULATORY AFFAIRS–CONSULTATION AND COLLABORATION

PDA continues its tradition of supporting sound science and regulation for our membership, with a focus on positive, constructive relationships with regulators and health authorities. This is manifested in direct commentary/consultation on proposed rules and guidance documents, technical conferences and workshops, and collaborative activities of mutual benefit.

EUROPEAN MEDICINCES AGENCY (EMA) & PHARMACEUTICAL INSPECTION COOPERATION SCHEME (PIC/S)

A priority for PDA in Europe is to maintain a professional collaborative relationship with the European Medicines Agency PIC/s, the Competent Authorities of the EU Member States, and associated working groups. Highlights include for 2011:

- The 4th ***PDA/EMA Joint Conference*** was held in London in May 2011. Building on the success of the three previous conferences (2006 in London, 2008 in Budapest, and 2009 in Berlin) the 2011 Conference was held at London's Heathrow Airport, and included a record attendance in terms of participants, and in terms of speakers from the EMA and the EU Member State authorities. The conference was co-Chaired by **Riccardo Luigetti,** *EMA Inspections Sector,* and **Lothar Hartmann,** *F. Hoffmann-La Roche.*
- ***EMA GMP/GDP Interested Parties Meeting***, 23 November 2011: Again this year, PDA was well represented at the annual 'Interested Parties Meeting' in which the EMA Inspections Sector invites interested associations to participate in open discussions of GMP and related issues. In 2011 the PDA delegation was led by Dr.-Ing Stephan Roenninger, leader of the PDA RAQAB, with the delegation rounded out with Karen Ginsbury, a long-time volunteer and member of RAQAB, and Dr. Georg Roessling, PDA Europe. PDA made a presentation to the assembled group of inspectors and interested persons (estimated 75 attendees) on "Challenges with Maintenance of EU GMPs." PDA presented examples of the need for a holistic approach to the GMP revisions in the EU, and cases which needed some attention, e.g. ICH content imported into GMP; inconsistent terminology and definitions; lack of consistency between different sections; and the status of GMP Part III which includes information material which can have compliance impact.
- **GMP Training Workshop with PIC/S**
  In the autumn of 2011, PDA began working closely with the Pharmaceutical Inspection Cooperation/ Scheme (PIC/S) to conduct a training workshop on selected GMP issues to be scheduled adjacent to the PIC/S Committee Spring meeting in May 2012. A planning committee led by long-time PIC/S leader **Jacques Morénas,** AFSSAPS France, and **Stephan Roenninger**, PDA RAQAB, is planning a 1.5 day workshop for both industry and regulators in Geneva. If this project is successful, it may become an annual event.

PDA Europe

2011 PDA REGULATORY CONSULTATION EUROPE

In 2011, PDA members and volunteers in Europe and around the globe helped prepare regulatory consultation on the following European proposed guidance. The consultation task forces consisted of volunteer experts from the international membership, with leadership by members based in Europe: All comments can be found on the PDA Web site, www.pda.org.

- Revised EU GMP Chapter 5: *Production*
- Revised EU GMP Chapter 7: *Outsourced Activities*
- BWP *Concept paper on the need for a guideline on process validation of medicinal products containing biotechnology derived proteins as active substance*
- Proposed EC *Guidelines on Good Distribution Practice of Medicinal Products for Human Use*

SCIENCE AND TECHNOLOGY HIGHLIGHTS

The wealth of knowledge our members share can make a difference. This can be sensed when participating at the various Task Forces, Working Groups and other informal meetings of PDA volunteers. As PDA is a global organization, issues in Europe are frequently found to be of concern to members around the world.

- PDA Task Force continues drafting a Technical Report illustrating GMP needs when manufacturing Investigational Medicinal/Drug Products (Clinical supplies). The team began its work in Europe, but now also includes members representing the US, Japan and India. The Task Force expects a final draft Technical Report in 2012.
- PDA continued to build on its 2008 commentary on the revised EMEA Guideline on the Production and Quality Control of Monoclonal Antibodies, with our 4th MAB workshop held in Basel in June 2011, with over 100 attendees. There is agreement to move ahead for the fifth workshop to be held in Vienna, June 12-13, 2012.

2011 CONFERENCES AND WORKSHOPS – EUROPE

Clinical Trial Material
15-16 February 2011, Berlin/Germany

Workshop on PDA Technical Report No. 51
14 March 2011, Berlin/Germany

Microbiology
15-16 March 2011, Berlin/Germany

Parenteral Packaging
22-23 March 2011, Berlin/Germany

Stoppers and Elastomers
6-7 April 2011, Rennes/France

PDA/EMA Conference
3-5 May 2011, London/UK

Development and Manufacture of a Pharmaceutical Product with Benefit of QRM/ICH Q9 Methodology
5-6 May 2011, London/UK

Advanced Therapy Medicinal Products
7-8 June 2011, Helsinki/Finland

Monoclonal Antibodies
7-8 June 2011, Basel/Switzerland

Virus & TSE Safety Forum
28-30 June 2011, Barcelona/Spain
Pre-conference Workshop:
27 June 2011

Pharmaceutical Cold Chain Management
27-28 September 2011, Berlin/Germany

Pharmaceutical Freeze Drying Technology
25-26 October 2011, Barcelona/Spain

The Universe of Pre-filled Syringes and Injection Devices
8-9 November 2011, Basel/Switzerland
Pre-conference Workshop:
7 November 2011

Single-Use Systems
29-30 November 2011, Uppsala/Sweden

Modern Biopharmaceutical Technology
6-7 December 2011, Bordeaux/France

INTEREST GROUP MEETINGS

Pre-filled Syringes **24 March 2011**, Berlin/Germany
Freeze Drying **5 April 2011**, Brussels/Belgium
Visual Inspection **25 May 2011**, Berlin/Germany

TRAINING COURSES

Applying Risk Management – Manufacture of Clinical Trials Material
14 February 2011, Berlin/Germany

Microbiological Risk Management in Manufacturing Sterile Products
14 March 2011, Berlin/Germany

Rapid Microbiological Methods
17-18 March 2011, Berlin/Germany

Container Closure Development
24 March 2011, Berlin/Germany

The Expanding Role of the Quality Professional in Europe and USA
5-6 May 2011, London/UK

Good Temperature-Controlled Management Practices Training
29-30 September 2011, Berlin/Germany

ICH Q9 : Application of a Risk-Based Approach to Freeze-Drying Process
27 October 2011, Barcelona/Spain

Development of a Freeze Drying Process
27-28 October 2011, Barcelona/Spain

Quality of Glass Containers
10 November 2011, Basel/Switzerland

Development of a Pre-filled Syringe
10-11 November 2011, Basel/Switzerland

Workshop on PDA Technical Report: Single Use Technologies
8 December 2011, Bordeaux/France

Workshop on PDA Technical Report: Biotechnology Cleaning Validation
8 December 2011, Bordeaux/France

Honor Awards

PDA PRESIDENT'S AWARD

This award recognizes a PDA staff member, other than senior staff, whose exemplary performance has contributed to PDA's success during the previous year.

Ailyn Kandora is working as Director Events & Exhibitions at the PDA Europe office in Berlin/Germany. In this position, she is responsible for all PDA Europe meeting & event logistics as well as for the program management. Ailyn also leads the Exhibition & Sponsoring department. She started working with PDA in 2009 as Event and Program Manager. Before obtaining her Master's degree in Applied Media Science in 2009, she studied Event & Project Management in Sydney, Australia.

Andrea Viera joined PDA in 2006. Over the years she has directly supported the Sales, Registration and Programs & Meetings department. Her development within PDA is attributed to her background in marketing and customer service. She is recognized as a valuable staff member for positive attitude and diligence with members and staff. In addition to providing support when and wherever necessary within PDA, Andrea has taken on the responsibility of supporting and managing numerous items such as registration, sponsorship projects, on-line session evaluations and even logistics when called upon. Andrea was critical in the development of the new PDA Annual Meeting Mobile App. One of the most recent accomplishments was her involvement in the ICH Q10 conference working with the regulators and industry committee members to develop a highly successful conference.

SERVICE APPRECIATION AWARD

This award is given in recognition of special services performed on behalf of PDA.

Patricia Brown graduated from the University of Illinois, Champaign-Urbana in 1993 with a degree in Microbiology. She started her career working in the food industry in the Chicago area. In 1998 she moved to Denver, Colorado to take a job with the Food and Drug Administration, Denver District Office as a Field Investigator. Patricia specialized in the drug area doing several Drug GMP, Pre-Approval, and Bioresearch Monitoring Inspections. In 2005 she decided to make the move to industry and took a position as Quality Assurance Manager for Eyetech Pharmaceuticals in Boulder, Colorado. In her first year at the Boulder facility, the company changed hands several times till in 2006 it ended up as Agilent Technologies, Nucleic Acid Solutions Division as a contract manufacturer of oligonucleotide API. She is currently the Director of Quality. With a little stability ahead of her, Patricia decided to take a more active role in the Mountain States Chapter of PDA. In 2008 she was elected President Elect and in 2009 President for the Mountain States Chapter through 2010. When she can, Patricia still actively participates in MSPDA.

Myron Dittmer has been a member of PDA for over 25 years having held a number of offices and positions in the New England chapter including President-Elect, President, Member-at-Large, and a contributing member of the Planning Committee. He is currently in his 2nd year as co-chair of the Global PDA Chapter Council. Myron is principal consultant at MFD & Associates which provides consulting services in the areas of downstream aseptic processing, quality programs, and validation.

Jens Henrik Eilertsen, PhD – A chemical engineer by training, Jens earned his PhD from the Technical University of Denmark. In 1981 Jens joined Novo Nordisk and became a member of PDA in 1996. He joined the Science Advisory Board in 2002, serving as its co-chair 2008-2011. Jens has been active in PDA Task Forces on visual inspection and on Technical Report No. 43 on nonconformities in glass containers. In recent years he has turned his focus to quality management systems.

Norbert Hentschel´s current position is Director of global Technical QA in the Biopharma Quality Department at Boehringer Ingelheim Pharma located in Biberach, Germany. He is a chemical technician by training and has worked at Boehringer Ingelheim since 1987. He has been a PDA member since 1992. Since 2005 he has been a member of the Biotech Advisory Board, which he served as chair for two terms. As a PDA member he served as program committee member and member of different task forces.

Maik W. Jornitz is Senior Vice President Marketing at the Sartorius Stedim North America Inc.. With over 25 years of experience, Mr. Jornitz supports the biopharmaceutical industry on a global basis, focusing in validation, optimization and training in sterilizing filtration. As Immediate Past Chair of PDA, Jornitz has been part of multiple PDA task forces, committee member and conference chair. He also serves as member of the Science Advisory Board of PDA. In addition, he is member of ISPE, DIA, ASTM and multiple editorial boards. Jornitz is the author and co-author of over 100 scientific papers, 9 books, 11 book chapters and recipient of 5 book awards. He is faculty member of PDA TRI, Compliance Online and trains industry and regulatory members on a frequent basis. He holds several filter and single-use technology related patents and is the founder of Bioprocess Resources LLC. Mr. Jornitz received his M.Eng. in Bioengineering at the University of Applied Sciences in Hamburg, Germany and accomplished his PED at the IMD Business School, Lausanne, Switzerland.

Stefano Maccio has been in the World Pharmaceutical Industry for the last 35 years where he started as technical sales engineer for some of the best known Italian equipment suppliers and, in the 80s, he became Area Sales Manager for PALL Italy. In 1990, together with a friend, a chemical engineer, Stefano founded CTP Tecnologie di Processo SpA. Today CTP is the only Italian company that can fully support the technical / scientific / regulatory needs of the Pharmaceutical Industries with its integrated expertise both in Engineering and GMP Compliance. The CTP Group has now 180 employees and customers in Europe, Middle East, North Africa and South America. In the early 90s Stefano became part of the team that formed the PDA Italy Chapter, of which he was President for the last two terms.

After four years where he held this role with great satisfaction, in January 2012, he will hand over a Chapter proud of itself, with a reputation of reliability with the Italian authorities and led by a Steering Committee largely renovated.

Honor Awards

Peter Noverini is a Field Applications Scientist for Azbil BioVigilant, Inc., with expertise in developing Rapid Microbiological Methods in support of Environmental Monitoring and Sterility Assurance, specifically in the areas of validation, risk assessment, and regulatory standards. Since 1999, Peter has served on the PDA Midwest Officer Board in several roles, first as Chapter Secretary, then as President-Elect, and most recently as the Chapter President, as well as the Co-Chair of the PDA Chapter Council. He is currently a member of the Biofilm and Bioburden Management Taskforce. Peter's previous role included providing microbiological and validation support globally as part of Baxter Healthcare's Technology Resources - Sterility Assurance Organization.

Amy Scott-Billman is VP, Global Regulatory Strategy for Immunotherapeutics in GlaxoSmithKline Biologicals (GSK Bio) where she manages a global staff responsible for all regulatory activities relevant to the development and commercialization of immunotherapeutic products for cancer and chronic disorder indications. Amy is also responsible for the regulatory aspects of in-licensing opportunities and for partnership with external parties for the global development of companion in vitro diagnostics. Prior to joining regulatory affairs at GSK in 1998, Amy served in GSK's World Wide Supply Operations as a Director of Quality Assurance & Compliance; supporting various business units including R&D, Biopharmaceuticals and Pharmaceuticals. Before joining GSK in 1996, Amy served for nearly 9 years in several capacities at the Center for Biologics Evaluation and Research (CBER) at US FDA, including senior management, reviewer and inspector of biopharmaceutical manufacturing facilities. Amy has been a member of PDA for nearly 20 years and is a past 2-term Board Member. Amy received her B.S. in Microbiology from the Pennsylvania State University in and her M.S. in Biotechnology from Johns Hopkins University.

Ano Xidias is a Lead Consultant with PharmOut Pty Ltd. He joined the PDA in 1996, the PDA Australian chapter committee in 2006 and was Chapter President in 2010 and 2011. Ano has a broad knowledge of sterile pharmaceutical manufacture and quality systems for the global markets. He has worked within the pharmaceutical industry for over 20 years. His management roles have been varied from Quality Assurance, Quality control, Manufacturing, Compliance, Sterility Assurance, Product release and Process validation.

FREDERICK D. SIMON AWARD

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

RISK ANALYSIS OF STERILE PRODUCTION PLANTS: A NEW AND SIMPLE, WORKABLE APPROACH

May/June 2011, vol. 65 no. 3 217-226

Guenther Gapp, PhD, is more than 15 years head of QA/QC Microbiology within Sandoz GmbH, Austria, a big production site of Novartis. The new Sterile Risk Assessments was created 2006 together with the production department (Dr. Peter Holzknecht) to identify and reduce the microbial contamination risk of sterile products. After successful implementation within Sandoz currently an updated version will be rolled to rise the Sterility Assurance Level of all Novartis Sterile Plants

Peter Holzknecht started in 2002 within Sandoz GmbH, Austria, a production plant in the Novartis group. His first role in the company was in the Technical Competence Center, where he was responsible for technical support for customers. In 2004 he took over the leading position of the Sterile Penicillin Precipitation Plant. The new Sterile Risk Assessments, developed in 2006 together with Dr. Guenther Gapp was a good improvement to identify and reduce the microbial contamination risk of sterile products and to optimize sterile production steps.

DISTINGUISHED EDITOR/ AUTHOR AWARD

This award is presented annually for the best editor/author of PDA-DHI co-published books as selected by PDA members.

Dr. Siegfried Schmitt is Principal Consultant at PAREXEL. He is receiving this award for *Quality By Design: Putting Theory Into Practice*.

DISTINGUISHED SERVICE AWARD

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

Scott Bozzone, PhD, is a Senior Manager in Quality Systems and Technical Services-Validation for Pfizer in New Jersey. He has been at Pfizer for 25 years in Quality Operations and Research- Process Development, spending over 4 yrs in the Global Employee program. He possesses a doctorial degree in industrial pharmacy from St. Johns University. Prior to Pfizer, Scott worked at Revlon Health Care Group (Armour/USV) for several years. He is also the author or co-author of two book chapters (one in print) and an article on process validation. In his current position he is responsible for site support and guidance concentrating on cleaning and process validation, and leads Pfizer's global Validation Community of Practice.

Lothar Hartmann, PhD, is Head of Knowledge Management for the Global Quality Department of Hoffmann – La Roche. Hartmann has served as Plant Manager and in numerous functions such as Auditing, Quality Systems and External Relations, in the Global Quality Department since 1988.

He has spent nearly 10 years as Vice Chairman for the Board of APIC/CEFIC. In this function he was nominated for the ICH Q7a Expert Working Group. In this effort he received an award from FDA. Hartmann is currently a member of PDA's Scientific Advisory Board and the PDA Board of Directors. He also chairs the BioManufacturing Working Group of EBE (European Biopharmaceuticals Enterprises) and is chair of the Advisory Board of the GMP Manual. Lothar is the co-author of various documents published by CEFIC/APIC and EBE. He earned his degree in Technical Chemistry and his PhD from the Technical University of Berlin.

Honor Awards

Vince Mathews is a Quality Consultant in the Development QA organization at Eli Lilly and Company. In his current role he is involved in the establishment of corporate quality standards for the development and manufacture of investigational new drugs, provides support for an API clinical trial material manufacturing site, provides internal direction on corporate quality matters, and is active in pharmaceutical industry groups. Vince has also held QA and QC laboratory positions at a commercial API manufacturing site, and as an auditor in the corporate auditing group. Vince has a Master's degree in Analytical Chemistry from Purdue University. Vince is a member of the 2008 Joint PDA/FDA Regulatory Conference Planning Committee and is the leader of the PDA Clinical Trial Materials Interest Group.

Edwin Rivera Martinez joined SANOFI in January 2012 as Vice President, U.S. Quality Liaison, Global Quality, where he serves as the U.S. focus point for emerging quality topics. He represents the Chief Quality Officer, Global Quality, for the quality oversight of all activities based in the U.S. and interacts with corresponding quality divisions. He will also reinforce Sanofi's presence in the various pharmaceutical quality professional associations located in the U.S. and will provide recommendations and guidance for continual improvements. Prior to joining SANOFI he served as Vice President, Technical, Strategic Compliance Services for PAREXEL Consulting from November 2010 to December 2011, where he provided CGMP and compliance services and training to clients in Puerto Rico, Europe and Asia. Previously, he served for 33 years with the U.S. Food and Drug Administration (FDA), where he advanced from Investigator in both the New Jersey and San Juan District Offices to Compliance Officer in the Office of Compliance, Center for Drug Evaluation and Research (CDER). In December, 2002 he was appointed as Branch Chief for the Manufacturing Assessment and Preapproval Compliance Branch, Division of Manufacturing and Product Quality, Office of Compliance, CDER. In June 2009, he became the Branch Chief, International Compliance Branch in CDER's Office of Compliance, where he served until the end of October 2010. Mr. Rivera Martinez has a bachelor's degree from Inter American University in Puerto Rico and received his MBA, concentration in management, from the University of Turabo, Caguas, Puerto Rico.

Michael E. Wiebe, PhD, is Founder and President of Quantum Consulting based in Redwood City, California. His consulting practice is focused on biotechnology development, biosafety, manufacturing, quality assurance and GMP compliance. He has more than 25 years of experience in the CMC aspects of biotechnology and has held positions at Genentech, BioReliance, IDEC Pharmaceuticals, Biogen Idec, Chiron, and Novartis. Earlier in his career Dr. Wiebe held positions at Duke University Medical School, Cornell University Medical College and the New York Blood Center. He received his Ph.D. in Microbiology from the University of Kansas.

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.

Wenzel Novak, PhD, was head of laboratory; in a smaller biotech-company in Munich; later located also in Leipzig and Lausanne. The basic work of this company was the development and sale of autologous skin-sheets, created out of the hair roots; which are stem cells (keratinocytes.) As head of production for presterilzed syringes in a company manufacturing plastic and glass as primary packaging he supervised the first building of the manufacturing area, buying and installation of equipment, set-up GMP-System; afterwards to organize the startup phase. While managing the project-management of presterilized syringes in the same company Dr. Novak supported internal and external projects, especially focusing on new special customer requests. Since January 2007 he is responsible, as director pharmaceutical research and development at Groninger&co.gmbh; a company developing and manufacturing filling and handling equipment for the pharmaceutical industry for identifying long term projects, adding the customer view to the knowledge base of groninger. Wenzel received his first degree from the University of Ulm; his thesis was on linear growth of hippocampal cell from the rat. As post graduate he did his dissertation in physics at the technical university in Munich. His doctoral thesis was done at the Max-Planck-Institute for Biochemistry in Martiensried near Munich on "the activity correlate signal distribution on linear grown brain-cells".

Edward H. Trappler is President of Lyophilization Technology, Inc., a contract research and development company he founded in 1992. Trappler joined the PDA in 1984 and has been actively involved in the association, participating in various committees, educational programs and presentations. He currently teaches at the PDA-TRI, heads the Lyophilization Interest Group and recently chaired the inaugural Pharmaceutical Freeze Drying Workshop in San Diego in November 2010.

GORDON PERSONEUS AWARD

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

Richard L. Friedman – Associate Director for Risk, Science, Intelligence, & Prioritization, Office of Manufacturing and Product Quality (OMPQ), CDER, FDA. Richard L. Friedman is an Associate Director in the Office of Manufacturing and Product Quality, Center for Drug Evaluation and Research (CDER), Office of Compliance, FDA. In this position, he is responsible for scientific and risk-based oversight of drug quality programs. This includes review of major regulatory action recommendations regarding inspections and manufacturing site acceptability; promoting science-based CGMP standards and expectations; assuring risk-based policy assessments and program

Honor Awards

prioritization decisions; issuing quality risk communications on emerging drug quality trends; and promoting lifecycle use of quality risk management in modern quality systems. Mr. Friedman also co-chairs two multi-center workgroups (Quality Systems Workgroup and Pharmaceutical Quality Standards Workgroup). Mr. Friedman joined FDA in 1990 and his prior positions have included New Jersey District Drug Specialist, CDER Senior Compliance Officer, Team Leader of Guidance & Policy, and Division Director. Mr. Friedman has authored several publications on topics including sterile drug, quality systems, and drug defect root causes, and was awarded the 2005 George M. Sykes Award by the Parenteral Society for outstanding journal paper. He also recently received the 2011 Kenneth Chapman Achievement Award from the Institute of Validation Technology. Mr. Friedman is an adjunct faculty member at Temple University School of Pharmacy in their QA/RA graduate program. Prior to joining FDA, Mr. Friedman worked in the toxicology research division of an innovator pharmaceutical company. Mr. Friedman received his B.S. in Biology from Montclair State University in 1989 and his M.S. in Microbiology from Georgetown University School of Medicine in May, 2001.

Stephan Rönninger, PhD, is the 'Head External Collaboration Europe / Japan / CEMA' of F. Hoffmann-La Roche Ltd based in Basel, Switzerland. This responsibility included collaboration, information management and commenting regarding Quality Management, Good Manufacturing and Distribution Practice (GMDP) topics. In the Parenteral Drug Association (PDA) he acts as chair and the European Regional Leader in the Regulatory Affairs and Quality Advisory Board (RAQAB). He is one of the founders and co-chair of the 'Paradigm Change in Manufacturing Operations' (PCMO) project. In addition he represents on behalf of Roche in the European industry association EFPIA at the 'Technical Development and Operations Committee (TDOC)". He represents EFPIA on 'foreign inspections, in the ICH Quality Implementation Working Group (Q-IWG) and on Quality Risk Management (ICH Q9). He received the FDA CDER 'Leveraging & Collaboration Award' for collaboration in developing a web-based knowledge base used for industry and regulatory briefings on ICH Q9, Quality Risk Management in 2011.

FREDERICK J. CARLETON AWARD

Presented as a tribute to lifetime contributor Fred Carleton, this award is designated for a past or present Board member whose services on the Board are determined by his or her peers as worthy of such recognition.

Kathleen Greene is the Executive Manager of the Global Quality Office for Novartis Vaccines and Diagnostics. She spent most of her career as Head of Technical Research and Development Quality Assurance at Novartis Pharmaceuticals in E. Hanover New Jersey. She has BS and MS degrees in Chemistry. Kathi has 40 years of experience in the Pharmaceutical Industry, 26 years in Analytical Development, 16 years as a Quality Assurance Site Head for Novartis Pharmaceuticals and has 3 years in Novartis Vaccines and Diagnostics. She is an active member of the PDA and currently serves on several PDA committees. She has worked with numerous government agencies and participated in many regulatory related meetings and discussions both domestically, in Europe and in China.

HONORARY MEMBERSHIP

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award is given in recognition of very long service, of a very significant nature, to PDA.

James Agalloco is President of Agalloco & Associates, a consulting firm to the pharmaceutical and biotechnology industry. He was previously employed at Bristol-Myers Squibb, Pfizer and Merck. Jim holds a BS and MS in Chemical Engineering and an MBA in Pharmaceutical Studies. He is a past PDA President and Director. He is a current member of USP's Microbiology Expert Committee. He is a member of the editorial advisory board's of Pharmaceutical Technology and Pharmaceutical Manufacturing. He serves on the scientific advisory boards of Laureate, MEDInstill, VanRX and IPS. He is a frequent author and lecturer on sterilization, aseptic processing and process validation.

2011 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 THIRD CONSECUTIVE YEAR OF FINANCIAL GROWTH

Despite the continuing economic struggles in the US and Global economies, PDA continued to deliver solid top and bottom-line growth in 2011. This is a testament to the value of the products and services PDA offers. Global revenue grew 11% from $13.2 million in 2010 to $14.7 million in 2011. Revenue was again driven by strong growth in our Programs and Meetings. Our 2011 Pre-Filled Syringe conference in Basel, Switzerland and the 20th PDA/FDA Joint Regulatory Conference in Washington, DC both saw record attendance and revenue. PDA also saw year over year revenue growth in our educational courses, exhibitors, sponsorships, adverting and publications.

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 27% from $3.3 million in 2010 to $4.2 million in 2011. Equally, if not more important, PDA's cash and investments increased from $3.0 million in 2010 to $5.9 million in 2011 — a 97% 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, 2011. The full audit report is available upon request from PDA headquarters in Bethesda, Maryland.

2011 ANNUAL REPORT FINANCIAL SUMMARY

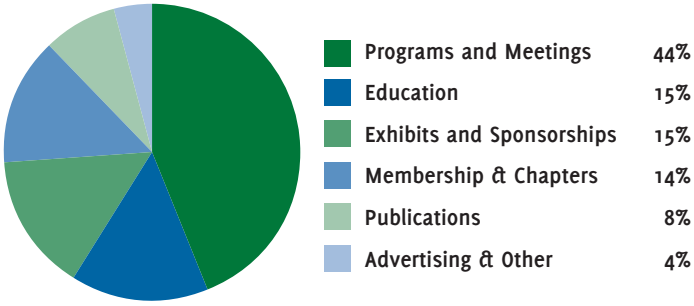
	2011	2010
Total Revenues	$14,696,079	$13,166,309
Total Expenses[1]	$12,824,490	$12,264,877
Net Income Surplus (Deficit) **from Operations**[2]	$1,871,589	$901,432
Increase (Decrease) **in Net Assets**	$875,303	$901,432
Net Assets at beginning of year	$3,298,477	$2,397,045
Net Assets at end of year	$4,173,780	$3,298,477
Net Asset ratio (Net Assets / Annual Expenses)	33%	27%

[1] *Total expense includes a foreign currency translation adjustment of $74,502 in 2011 and $11,870 in 2010. See Note F of the 2011 audited financial statements for additional detail.*
[2] *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.*

RECORD REVENUES AND COST MANAGEMENT

PDA continues to closely manage costs while also investing in new services to increase the member experience. Total global expenses grew 4.6% in 2011 from $12.3 million in 2010 to $12.8 million. As a result of strong revenue growth and focused cost management, net income from operations grew from $901,432 in 2010 to $1,871,589 in 2011 — a 108% year-over-year increase.[2]

2011 REVENUE SOURCES



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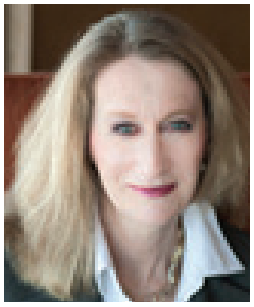

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