



*Connecting People, Science and Regulation®*

[www.pda.org](http://www.pda.org)

2010 ANNUAL REPORT

## ABOUT PDA

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

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### 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<sup>SM</sup> 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.



Chair, PDA  
Maik Jornitz

## MESSAGE FROM THE PDA BOARD OF DIRECTORS CHAIR

### PDA 2010: Excitement Is an Understatement, Success the Obvious

2010 was the first full year at the helm of PDA for our President Richard Johnson, and he did not wait to make an impact with his team. This team spirit and effort emphasized the importance of PDA as an exciting, driven and member-oriented organization. Being a long-time member, I am filled with enjoyment and motivation seeing how strong PDA has become. Enjoyment and motivation reflected also from the PDA team members, our volunteers and membership. Overall, the spirit of 2010 has been one of high energy, new ventures and an optimistic outlook for the future.

First of all, even with a still-soft global economy and a volcano with an unpronounceable name (but the capability to disrupt flights all over Europe), PDA still achieved its financial goals to attain a strong and solid reserve situation. This is due to proper cost management, but especially due to record-breaking attendance at conferences like the *PDA Annual Meeting*, the *PDA/FDA Joint Regulatory Conference* and the *PARENTERALS 2010 Conference*. We would like to thank our volunteers who worked tirelessly on the content of these conferences, the exhibitors and the sponsors. Without you, we would not be able to deliver high-value conferences to our membership.

Secondly, the initiated Strategic Plan was finalized under the guidance of Anders Vinther, Chair-elect. The Strategic Plan is PDA's guidance into the future, our red

line to areas of focus, and also a visible activity marker for our membership. Our 2005 Strategic Plan distinguished our focus to people, science and regulation, and our organization's identity was established: *Connecting People, Science and Regulation*®. We continue strongly with this identity and have substantially added activities and initiatives to these three pillars. Furthermore, the foundation of these three pillars was laid with business management. We believe defined financial goals and oversight structure will strengthen our organization further, and 2010 continued to solidify this foundation. PDA now is well prepared and focused for the future, and our membership will benefit from these initiatives.

Our successful Paradigm Change in Manufacturing Operations (PCMO<sup>SM</sup>) initiative has been further established. Twenty task forces are now working diligently on the topics within the categories *Lifecycle Approach*, *Quality Systems*, *Process Management* and *Quality Risk Management*. Our thanks go to the volunteers and leaders within these task forces for their time, expertise and hard work to generate another substantial source of information for our members.

On a similar note, five Technical Reports were published in 2010. The electronic versions of the *PDA Journal of Pharmaceutical Science and Technology* and Technical Reports have been very well received. The Journal's scientific papers can now be traced back 25 years, which often is of advantage when quick reference papers are needed. Our *PDA Letter* received a new look and, by popular demand, is still available in paper version. Besides the *PDA Letter*, PDA also changed its corporate identity, and our marketing department changed our looks from "old" to refreshingly new. This new design can

be seen on the website, brochures and letterhead, and it can also be seen in the attitude of PDA. We are not just looking for the same; we want to engage our membership with new ideas and activities, begun in 2010 and to be continued for the future. These ideas do not restrict themselves to new fields of manufacturing science, but also include new, upcoming industry segments and countries.

Other initiatives during 2010 included:

- The formation of the *Former Board Alumni* (Chair: Vince Anicetti) to retain long-term experiences and networks, which often were lost when a board member retired
- Revision of the PDA TRI curriculum, including the establishment of ownership of the curriculum. There are several PDA-owned TRI courses available from which our membership can choose, with more to come.
- In addition to the above-listed successful signature conferences, two new conferences were held: *PDA Vaccine Conference: Today's Challenges, Tomorrow's Opportunities* (FDA-supported) and *PDA/FDA Adventitious Viruses in Biologics: Detection and Mitigation Strategies Workshop*

I also would like to take the opportunity to thank our former board members Louise Johnson and Stefan Köhler for their time invested and welcome Lisa Skeens, Zena Kaufman and Gabriele Gori to our board.

2010 has been a busy, but an exciting, year! PDA's identity *Connecting People, Science and Regulation*® once again has been confirmed by our successful conferences, the continuous interaction with regulators and the support of our volunteers and membership. I would like to thank you for your trust and support.

## MESSAGE FROM THE PDA PRESIDENT

President, PDA  
Richard M. Johnson



### 2010 - Advancing the Science and Building for the Future

After the challenges of 2009, PDA strengthened its contributions to *Connecting People, Science and Regulation*® in 2010. Despite the continued changes in the industry and external factors that influenced our members' ability to participate in some activities (e.g., Iceland's volcanic eruption), 2010 reflected success in our key areas. One key area was the development of a revised Strategic Plan to focus our attention and resources on the priorities as defined by our volunteer leaders. From the Bethesda and Berlin offices, we had continuity of leadership and remarkable energy and innovation from the whole staff.

In 2010 PDA renewed its emphasis on member outreach. We introduced new literature and orientation programs to help members realize the full range of member benefits. We refreshed our brochures and began the transformation of our website to a more user-friendly format.

Our programs included a mix of traditional topics and new subjects of growing interest. Our 2010 *PDA Annual Meeting* in Orlando was extremely successful. The 20<sup>th</sup> annual *PDA/FDA Joint Regulatory Conference* continues to be a premier event, bringing the industry and U.S. Food and Drug Administration (FDA) together, but we also held FDA co-sponsored meetings on Supply Chain, Adventitious Virus Contamination and Vaccines. Our *Pre-filled Syringe Conference* continued to be a global signature destination, and we initiated a new *PARENTERALS 2010 Conference* in Europe. Altogether, PDA brought people, science and regulation together in more than 16 US and 24 European events, both large and small. Our chapters continued to

provide front-line interface with members throughout the world and hosted more than 50 events.

We continued expanding our world-class training through our Training and Research Institute, reaching students from around the world. Anchored by our world-class aseptic processing training, we enhanced the expertise of the industry through more than 50 different subjects at many global locations. Our offerings of in-house, intensive training to organizations allowed us to reach even more of the industry.

After publishing two Technical Reports in 2009, in 2010 we published five Technical Reports, which represented more than 7,300 free downloads by our members. PDA also co-published seven new books. Our Journal continued to expand its offerings, leveraging the move to electronic publishing while continuing its high-quality, peer-reviewed integrity.

In 2011, we have a great mix of signature conferences and new topics, including the 65th *PDA Annual Meeting* in San Antonio, the 4th *PDA/EMA Conference* in London, the 20th *PDA/FDA Joint Regulatory Conference* in Washington DC and the 8th *Pre-filled Syringe Conference* in Basel. We are also focusing on new issues at the Atypical Actives Workshop; Glass Quality; two co-sponsored conferences on Implementation of ICH Q10; and Advanced Therapies Medicinal Products.

2011 continues to be a great year to engage with PDA TRI for all your training needs. Anchored by our popular *Aseptic Processing* courses, we have more than 40 courses arranged into nine curricular areas including: Aseptic Processing, Biotech, Environmental Monitoring, Filtration, Microbiology, Quality and Regulatory Affairs, Specialized, Training and Validation.

PDA Technical Reports continue to be a major area of activity of our volunteer members, and in 2011 we are nearing the publication of several updated Technical Reports including: Technical Report No. 3 (revision), Dry Heat Sterilization; Technical Report No. 13 (revision), Environmental Monitoring; Technical Report No. 22 (revision), Process Simulation for Aseptically Filled Products; Technical Report No. 30 (revision), Parametric Release of Pharmaceutical Products and Medical Devices Terminally Sterilized by Moist Heat; and Technical Report No. 33 (revision), Evaluation, Validation and Implementation of New Microbiological Testing Methods. New Technical Reports on Analytical Methods Validation, Cleaning and Disinfection, Recommended Practices for Manual Aseptic Processes, Good Distribution Practices (GDP), and Stability Testing to Support Distribution of New Drug Products should also be published in 2011.

2011 will continue to be a challenging and rewarding year for PDA. We are focused on delivering on our Mission. This is only possible through the support of our almost 9,500 members worldwide, the more than 1,000 volunteers who served on committees, Task Forces and Planning Committees, and our hardworking, committed staff. On their behalf,

**Thank you for your continued support.**



# 2010 PDA OFFICERS AND BOARD OF DIRECTORS

## Officers



**Chair**  
**Maik Jornitz**  
*Sartorius Stedim Biotech*



**Chair-elect**  
**Anders Vinther, PhD**  
*Genentech, Inc.*



**Secretary**  
**Rebecca Devine, PhD**  
*Regulatory Consultant*



**Treasurer**  
**Harold Baseman**  
*ValSource, LLC*



**Immediate Past Chair**  
**John Shabushnig, PhD**  
*Pfizer, Inc.*

## Directors



**Véronique Davoust, PhD**  
*Pfizer, Inc.*



**Gabriele Gori**  
*Novartis Vaccines & Diagnostics*



**Lothar Hartmann, PhD**  
*F. Hoffmann-La Roche Ltd.*



**Zena Kaufman**  
*Abbott*



**Steven Mendivil**  
*Amgen, Inc.*



**Michael Sadowski**  
*Baxter Healthcare Corporation*



**Junko Sasaki**  
*Dainippon Sumitomo  
 Pharmaceuticals*



**Amy Scott-Billman**  
*GlaxoSmithKline*



**Lisa Skeens, PhD**  
*Baxter Healthcare  
 Corporation*



**Christopher J. Smalley**  
*Pfizer, Inc.*



**Laura Thoma, PharmD**  
*University of Tennessee  
 Department of  
 Pharmaceutical Sciences*



**Martin Van Trieste**  
*Amgen, Inc.*

## SCIENTIFIC AND REGULATORY AFFAIRS

The Scientific and Regulatory Affairs Department (S&RA Department) manages all of PDA's scientific, quality and regulatory activities. These activities are driven by the collective efforts of Advisory Boards, Interest Groups 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, PDA meetings and workshops, PDA Training and Research Institute (PDA TRI) courses and consensus documents. Consensus documents, such as Technical Reports, are developed by Advisory Board-approved Task Forces and provide industry with recommendations on and best practices in many pharmaceutical and biopharmaceutical topics, where little or no guidance exists. The S&RA Department also supports PDA members and the pharmaceutical and biopharmaceutical industries by reviewing and contributing to quality and regulatory guidance documents to assure that they are based on sound scientific principles.

In 2010, the S&RA Department had two full-time staff: **Richard Levy**, PhD, Senior Vice President of Scientific and Regulatory Affairs, and **Iris Rice**, Manager. There were also three part-time staff: in North America, **Bob Dana**, Senior Vice President of TRI and Quality and Regulatory Affairs, and in Europe, **Volker Eck**, PhD, Senior Director of Science and Technology, supporting European members interested in manufacturing science, and **Jim Lyda**, Senior Director of Regulatory Affairs, focusing on the European regulatory scene and contributing to the development of regulatory responses along with Bob Dana, through the Regulatory Affairs and Quality Committee (RAQC).

PDA staff was focused in 2010 on leading and supporting record-high levels of member activities in Advisory Boards, Interest Groups and Task Forces. We used online meeting tools to facilitate regular Task Force and Advisory Board activities. In 2011, we plan to upgrade InfoStrength Smart Enterprise System (S-E-S) and to implement at least one new tool to facilitate team communication and collaboration.

At the beginning of 2010, PDA became very active in the implementation of the new projects identified in the PDA Paradigm Change in Manufacturing Operations (PCMO<sup>SM</sup>) initiative. In 2011, PDA will continue to drive the establishment of "best practice" documents and/or training events to assist pharmaceutical manufacturers of investigational medicinal products (IMPs) and commercial products in implementing the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on Pharmaceutical Development (ICH Q8, Q11), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Systems (ICH Q10). 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. Several PCMO PDA Technical Report publications are anticipated in 2011.

The S&RA Department was pleased to host a unique intern in 2010—**Hee-Young "Hailey" Park** of the Korea Food & Drug Administration. Hailey interned at PDA as part of her Long-Term Fellowship Program for Overseas Study, sponsored by the Government of Korea. Besides meeting regularly with Richard Levy, Senior Vice President, Scientific and Regulatory Affairs, and routinely filing reports with her Agency throughout the year, Hailey contributed a regular essay to the *PDA Letter* about different aspects of the Korean regulatory system.

### 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 Boards (Regulatory Affairs and Quality Advisory Board and Scientific Advisory Board), interacts with regulatory authorities by participating in the development of consensus responses to regulatory drafts, final guidances and directives.

In 2010, 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, Cleaning and Disinfection of Biotech Products, Cell Substrates, Combination Products, GMPs for IDPs; and four projects on Mycoplasma, Single-Use-Systems and Vaccines. Two of the teams, Cell Substrates and the Filtration sub-group of the Mycoplasma Task Force, organized and sponsored two PDA workshops in 2010. The BioAB was instrumental in managing the approval process for two PDA Technical Reports published in 2010.

## SCIENTIFIC AND REGULATORY AFFAIRS

In 2010, the BioAB approved the following five ballots:

- Ballot No. 37: *Viral Contamination during Drug Manufacture: Detection, Response and Prevention Task Force Proposal*
- Ballot No. 38: *Emerging Methods for the Detection of Viral Contamination Task Force Proposal*
- Ballot No. 39: *PDA Technical Report No. 49: Points to Consider for Biotechnology Cleaning Validation*
- Ballot No. 40: *PDA Technical Report No. 50: Alternative Methods for Mycoplasma Testing*
- Ballot No. 41: *EU GMP Annex 2: Manufacture of Biological Medical Substances and Products for Human Use*

### 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 Boards (Regulatory Affairs and Quality Advisory Board and Biotechnology Advisory Board), interacts with regulatory authorities by participating in the development of responses to regulatory draft guidance and final guidance and directives.

The SAB was instrumental in managing the approval process for the publication of two PDA Technical Reports in 2010. In 2011, the SAB will continue to manage Task Forces with revisions of existing PDA Technical Reports and emerging projects from the PDA Pharmaceutical Cold Chain Interest Group (PCCIG). Several publications that are managed by the SAB are anticipated in 2011.

In 2010, the SAB approved the following 11 ballots:

- Ballot No. 162: Nomination of Ken H. Muhvich, PhD, as the PDA Sterile Processing/Parenteral Drug Manufacturing Interest Group Leader
- Ballot No. 163: Nomination of Edward Tidswell, PhD, as the PDA Sterile Processing/Parenteral Drug Manufacturing Interest Group co-Leader
- Ballot No. 164: Post-Aseptic Fill Lethal Treatments Task Force Proposal
- Ballot No. 165: Technical Report on *Steam in Place*
- Ballot No. 166: Appointment of Stefan Köhler to the PDA Scientific Advisory Board
- Ballot No. 167: Technical Report No. 22 (revised): *Process Simulation for Aseptically Filled Products*

### Biotechnology Advisory Board (BioAB)

#### Co-Chairs

**Jeffrey C. Baker**, PhD, formerly of MedImmune  
**Norbert Hentschel**, Boehringer Ingelheim Pharma

#### Members

**S. Robert Adamson**, Wyeth Biopharma  
**Kurt A. Brorson**, PhD, US FDA, CDER  
**Christopher M. Bussineau**, PhD, ONELAMBDA, Inc.  
**Anita Derks**, F. Hoffman-La Roche Ltd.  
**Rebecca A. Devine**, PhD, Regulatory Consultant  
**John Geigert**, PhD, Biopharmaceutical Quality Solutions  
**Peter F. Levy**, PL Consulting, LLC  
**Annemarie Möritz**, PhD, Novartis Pharma AG  
**Jill A. Myers**, PhD, BioPro Consulting, Inc.  
**Barbara J. Potts**, PhD, Genentech, Inc.  
**Anurag S. Rathore**, PhD, Indian Institute of Technology, Delhi  
**Amy M. Scott-Billman**, GlaxoSmithKline  
**Karin Sewerin**, PharmD, NDA Regulatory Service AB  
**Robert Sitrin**, PhD, Merck Research Labs  
**Gail Sofer**, Sofeware Associates  
**Søren Thuesen Pedersen**, Novo Nordisk A/S  
**Michael VanDerWerf**, GlaxoSmithKline Biologicals (RAQC Liaison)  
**Hannelore Willkommen**, PhD, RBS Consulting

#### PDA Staff Liaisons

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

### Scientific Advisory Board (SAB)

#### Co-Chairs

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

#### Members

**Raphael (Raphy) Bar**, PhD, BR Consulting  
**Joyce E. Bloomfield**, Merck & Co., Inc.  
**Jean-Luc Clavelin**, Lilly France S.A.S.  
**Walter De Matteo**, Institut Biochimique SA (IBSA)  
**Phil DeSantis**, Merck & Co., Inc.  
**Don E. Elinski**, RPh, Lachman Consultant Services, Inc.  
**Kristen D. Evans**, Amgen, Inc.  
**Klaus Haberer**, PhD, Compliance Advice and Services in Microbiology, GmbH  
**Lothar Hartmann**, PhD, F. Hoffmann-La Roche Ltd.  
**Maik W. Jornitz**, Sartorius Stedim North America Inc.  
**Stefan Köhler**, AstraZeneca, Sweden Operations  
**Joachim Leube**, PhD, formerly of QA Kogenate Europe  
**Michael Long**, formerly of KMP International Associates  
**Russell E. Madsen**, The Williamsburg Group, LLC  
**Grace E. McNally**, US FDA, CDER  
**Jeanne E. Moldenhauer**, PhD, Excellent Pharma Consulting  
**Ken H. Muhvich**, PhD, Micro-Reliance, LLC  
**John G. Shabushnig**, PhD, Pfizer, Inc.  
**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  
**Georg Roessling**, PhD, PDA Europe gGmbH

## SCIENTIFIC AND REGULATORY AFFAIRS

- Ballot No. 168: PDA Blow-Fill-Seal Interest Group Proposal
- Ballot No. 169: Technical Report No. 51: *Biological Indicators for Sporicidal Vapor Decontamination Processes: Specification, Manufacture, Control and Use*
- Ballot No. 170: Technical Report No. 13 (revised): *Fundamentals of an Environmental Monitoring Program*
- Ballot No. 171: PDA Task Force Proposal in the matter of TBP (2, 4, 6-tribomophenal) Fungicidal and/or Flame Retardant Treatment on Lumber Products
- Ballot No. 172: PDA Task Force Proposal in the matter of Technical Report No. 32, *Auditing Computer Systems*

### Regulatory Affairs and Quality Committee

#### Co-Chairs

Steven Mendivil, *Amgen, Inc.*  
Dr. -Ing Stephan Rönninger,  
*F. Hoffmann-La Roche, Ltd.*

#### Asia-Pacific Regional Leader

Michihisa Inokuma, PhD, *Towayakuhin*

#### North America Regional Leader

John K. Towns, PhD, *Eli Lilly and Company*

#### Members

Ruhi Ahmed, PhD, *BioMarin Pharmaceuticals, Inc.*

Jeffrey R. Broadfoot, *Cangene Corporation*

Alan C. Burns, *Sartorius Stedim Biotech*

Robert B. Counce, *Hospira*

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

John D. Finkbohner, PhD, *MedImmune*

Amy Giertych, *Baxter Healthcare Corporation*

Karen Ginsbury, *PCI Pharmaceutical*

*Consulting Israel Ltd.*

Louise Johnson, *Aptuit*

Brian Matthews, PhD, *Alcon Laboratories, (UK), Ltd.*

Junko Sasaki, *Dainippon Sumitomo*

*Pharmaceuticals*

Siegfried Schmitt, PhD, *PAREXEL Consulting*

Susan Schniepp, *Oso Pharmaceuticals*

Janeen Skutnik, *Pfizer, Inc.*

Michael VanDerWerf, *GlaxoSmithKline Biologicals*

Hongyan Xie, *Qilu Pharmaceuticals Co., Ltd.*

Barbara B. Zinck, *Zinck Consulting*

#### PDA Staff Liaison and Support

Robert Dana, Quality and Regulatory Affairs, *PDA*

James Lyda, Regulatory Affairs, *PDA Europe*

Iris Rice, Scientific and Regulatory Affairs, *PDA*

### Regulatory Affairs and Quality Committee

The year 2010 was an even busier year for PDA's Regulatory Affairs and Quality Committee (RAQC). Along with SAB and BioAB (both previously described), RAQC 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.

RAQC 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 RAQC and the PDA Board of Directors. In 2010 PDA members submitted the following official comments with the regulators (listed by the RAQC ballots number):

- Ballot No. 85: FDA Proposed Rule affecting 21 CFR Part 4, Current Good Manufacturing Practice Requirements for Combination Products
- Ballot No. 86: FDA Draft Guidance for Industry, *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products*
- Ballot No. 87: EU Draft Guidance, *Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File and Content of a Site Master File*
- Ballot No. 88: FDA Transparency Task Force
- Ballot No. 89: EU Guidelines to Good Manufacturing Practice, Chapter 1, *Quality Management System*
- Ballot No. 90: EU Guidelines to Good Manufacturing Practice, Chapter 2, *Personnel*
- Ballot No. 91: EU GMP Annex 2, *Manufacture of Biological Medical Substances and Products for Human Use*
- Ballot No. 92: EMA, *Guideline on the Requirements for Quality Documentation, Qualification of Biological IMP for Clinical Trials*
- Ballot No. 93: World Health Organization, *Good Practices for Pharmaceutical Microbiology Laboratories*
- Ballot No. 94: FDA Draft Guidance for Industry, *CMC Post-approval Manufacturing Changes Reportable in Annual Reports*



## SCIENTIFIC AND REGULATORY AFFAIRS

RAQC also approved ballots related to creation of task forces to initiate/develop projects aimed at adding value to PDA's portfolio, including:

- Ballot No. 95: PDA Task Force Proposal: *Sterile Manufacturing Gap Analysis*
- Ballot No. 96: PDA Task Force Proposal: Technical Report No. 32, *Auditing Computer Systems*

As the PDA Committee most directly involved with the Inspection Trends/Regulatory Affairs Interest Group, the Regulatory Affairs and Quality Committee (RAQC) also approved Ballot 84 authorizing the split of that Interest Group into two, with **Amy Giertych** being named the North American leader of the new Regulatory Affairs Interest Group and **Bob Dana** continuing as North American leader of the Inspection Trends Interest Group. **Barbara Jentges** remains head of the European Regulatory Affairs Interest Group.

A number of changes to the RAQC membership took place in 2010, including the end of terms for three long-serving members in July: (1) Former Chair and Immediate Past Chair, **Zena Kaufman**, (2) Japan Regional Leader, **Michihisa Inokuma** and (3) North American Regional Leader, **John Towns**. RAQC Chair **Steve Mendivil** transitioned to Past Chair and still serves on the committee. Co-Chair **Stephan Rönninger** assumed the responsibilities of RAQC Chair, and **Sue Schniepp** moved up to Co-Chair and also was named the Pharmacopoeial Liaison member. Other new Committee assignments were **Alan Burns** (North American Leader), **Shin-Ichiro Mohri** (Japan representative), **Junko Sasaki** (Japan Regional Leader) and **Janeen Skutnik** (Emerging Regions Leader). **Jackie Vevia-Panter**, Abbott Laboratories, joined the RAQC to complete the roster changes.

During 2010, PDA headquarters hosted **Hee-Young "Hailey" Park**, an employee of the Korean FDA. Hailey spent 12 months working with PDA in the Science and Regulatory Affairs department, learning how FDA and other regulatory authorities operate. Hailey, who became popular as a PDA "staff" member, has been missed since she returned to Korea in December 2010, after completion of her assignment.

As part of a PDA-wide project to strengthen our governance process, RAQC revised the following Standard Operating Procedures:

- Activities of Advisory Boards Incorporating Quality by Design
- Regulatory Commenting Procedure

In addition, a revised handbook designed to familiarize new Committee members was also approved in 2010. This handbook and the two governance SOPs became effective January 2011.

### Interest Groups

Interest Groups were proactive in 2010 with the appointment of Christopher Smalley as PDA's Interest Group Leaders Liaison. Interest Group Leaders met during the two PDA signature meetings to identify and discuss challenges facing Interest Groups, and to collaborate on how to resolve those challenges. Action items that were established as milestones with "due diligence" are expected to be resolved in 2011.

In 2010, 12 of PDA's Interest Groups met during the *PDA 2010 Annual Meeting* and the *2010 PDA/FDA Joint Regulatory Conference*. The Blow/Fill/ Group was established in 2010, and four new PDA members assumed leadership of two Interest Groups by the close of 2010.

In 2011, the Science and Technology Department will seek to become more proactive in engaging our Interest Groups to collaborate and share knowledge and best practices in forums and venues outside of the two PDA signature conferences.

## SCIENTIFIC AND REGULATORY AFFAIRS



### 2010 PDA Letter Editorial Committee

**Kamaal Anas**, *International AIDS Vaccine Initiative*  
**Michael Awe**, *APP Pharmaceuticals*  
**Harold Baseman**, *ValSource, LLC*  
**Miriam Estrano**, *Medtronic*  
**Karen Ginsbury**, *PCI Pharmaceutical Consulting*  
**Georgiann Keyport**, *Canopy Medical*  
**Kristina Nordhoff**, *Genentech, Inc.*, a Member of the Roche Group  
**Matt Schmidt**, *Merck & Co., Inc.*  
**Susan Schniepp**, *OSO BioPharmaceuticals Manufacturing, LLC*  
**Anita Whiteford**, *Pennsylvania College of Technology*  
**Sandra Zoghbi-Gay**, *bioMérieux sa*

### PDA Staff

**Walter Morris**, Director of Publications, PDA  
**Emily Hough**, Writer/Editor, PDA  
**Katya Yount**, Publications Design Specialist  
**Richard V. Levy**, Senior Vice President, Scientific and Regulatory Affairs, PDA

By the end of 2010, three members were added to PDA's Editorial Committee furthering the diversity and technical experience of the group.

## Publications 2010

### PDA Letter

In 2010, the Publications Department had three full-time staff members: **Walter Morris**, Publications Director, **Emily Hough**, Writer and Editor and **Katya Yount**, Publications Design Specialist.

PDA members contributed a record 11 feature-length articles to the *PDA Letter* in 2010, 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.

In addition, a series of reports on European regulatory developments from volunteer **Barbara Jentges** ran in 2010 along with a series called "Hailey's Comments," by **Hailey (HeeYoung) Park**, a PDA Intern from the Korean FDA, about the history and future of Korea's drug laws and GMP regulations.

### Feature-length articles submitted by members and published in 2010:

- "Current Regulation Harmonization Process within the EU"  
by Barbara Jentges (*January*)
- "Present and Future of European GMP/GDP Update from the Dec. Interested Parties Briefing Meeting"  
by Martyn Becker, Stephan Rönninger and Tesh Patel (*February*)
- "PDA WCC Hosts FDA Speaker at Dinner Meeting"  
by Kristina Nordhoff (*March*)
- "Ongoing Collaboration Between European Medicines Agency/U.S. FDA Regarding Orphan Drugs"  
by Barbara Jentges (*May*)
- "The Status of Current Good Distribution Practice Regulations in Israel"  
by Rachel Karpel (*June*)
- "Design Specification – Missing Link to Knowledge Management"  
by Carol DeSain (*July/August*)
- "Acting Right Can Facilitate Good Regulatory Inspections"  
by Sue Schniepp and Karen Ginsbury (**September**)
- "Arm Yourself with Knowledge for Your First Inspection"  
by Melissa Smith and Lorraine Murphy (*September*)
- "Rapid Deployment Tips to Prepare for an Inspection Quickly"  
by John Avellant (*September*)
- "Moving Towards eCTD Submissions"  
by Barbara Jentges (*September*)
- "Challenges in Aseptic Processing of Sterile Biologics"  
by Miriam Estrano (*October*)

## SCIENTIFIC AND REGULATORY AFFAIRS

### *PDA Journal of Pharmaceutical Science and Technology*

#### Letter from the Editor

2010 was a time of transition and change as the *PDA Journal of Pharmaceutical Science and Technology* cleared the backlog of papers in the pipeline from the previous editorial team. However, even in this period several exciting changes occurred—the most obvious being the introduction of an all-electronic format. The Journal is slowly but surely coming into alignment with the overarching mission of PDA of connecting people, science and regulation. To continue to foster this dialog, a new vehicle will be an electronic letters (eletters) section that will allow readers to comment on papers and for the authors (or anyone else) to respond and continue the dialog. Our review and submission process will also be all electronic through Benchpress. This process was initiated last year and is on track to launch over the summer. Its implementation will allow authors to submit papers electronically and the entire review process will also be electronic. We anticipate faster turnaround times as a result, and this final step completes the transition of our Journal to an entirely web-based workflow from submission through to publication. In the next sections, we provide you some examples of the other changes that we have implemented.

#### Summary of Published Editorials

Our new format provides a forum for various issues and points of view to be highlighted. Editorials are written either by our editors or by special invited guest editors. Unsolicited suggestions for editorials are welcome. Here is a list that illustrates the diversity of topics and people who wrote them:

#### List of Published Editorials

**January/February 2010:** “Advancing Biotechnology Innovation Depends on the Right Public Policies” (*Guest editorial by James C. Greenwood*)

**March/April 2010:** “PAT and the Future of Biotechnology” (*Kurt Brorson*)

**May/June 2010:** “Happy Birthday, ICH!” (*Antonio Moreira*)

**July/August 2010:** “Biosimilars” (*Anurag Rathore*)

**September/October 2010:** “Cell Substrates: PDA Journal Special Issue” (*Govind Rao*)

**November/December 2010:** “Implementation of Quality by Design (QbD) for Biopharmaceutical Products” (*Anurag Rathore*)

**January/February 2011:** “Future of Consensus Standards in Biotechnology” (*Chris Watts and Kurt Brorson*)

**March/April 2011:** “Author Redux: An Opportunity for Our Readers” (*Govind Rao*)

#### Special Issues

Another initiative that we have launched is to use the Journal as a vehicle to rapidly capture presentations at conferences and make them available to our broader membership because not everyone is able to attend a specialty conference. Proceedings are managed separately from our regular submission and review process and are guided by the conference organizers. They collect and edit the material and are responsible for working with the authors to maintain the Journal’s standards. An example is our recent special Cell

#### Journal Editorial Staff

##### Editor:

Govind Rao, PhD

##### Associate Editors:

Kurt Brorson, PhD

Antonio Moreira, PhD

Anurag Rathore, PhD

##### Assistant Editor:

Mia Ricci

##### PDA Staff

Walter Morris, Director of Publications, PDA

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

### Manuscript Statistics for 2010

- Manuscripts submitted: **147**
- Manuscripts accepted: **31**
- Manuscripts rejected: **63**
- Papers published: **72**

## SCIENTIFIC AND REGULATORY AFFAIRS

Substrate Issue (Vol. 64, No. 5). **Michael Wiebe** and **Kathryn King**, along with support from **Mia Ricci**, **Richard Levy** and **Walter Morris**, contributed to publish this 20-paper issue (double our normal content) in a very short period of time. We are gratified by the response as this issue has proven to be very popular. We are exploring other similar special issues and conference proceedings. One that will come out later this year will be based on the *PDA/FDA Adventitious Viruses in Biologics: Detection and Mitigation Strategies Workshop*.

### Cell Substrate Issue (September/October 2010) List of Articles

“Cell Substrates: PDA Journal Special Issue”  
(Editorial by Govind Rao)

“Introduction: PDA Cell Substrate Workshop Proceedings” (Kathryn King, Michael Wiebe and on behalf of the Cell Substrate Task Force)

“Animal Cell Substrates: Back to the Future”  
(John Petricciani)

“Lentiviral Vector-Mediated Genetic Modification of Cell Substrates for the Manufacture of Proteins and Other Biologics” (Lajos Baranyi, Andre Roy, Heather D. Embree and Boro Dropulic)

“Application of Lentiviral Vectors for Development of Production Cell Lines and Safety Testing of Lentiviral-Derived Cells or Products” (Cherylene Plewa)

“Experiences with HEK293: A Human Cell Line”  
(Michael Rubino)

“Safety Testing and Use of Insect Cells for Recombinant Protein Production”  
(Penny L. Post)

“Testing Considerations for Novel Cell Substrates: A Regulatory Perspective”  
(Arifa S. Khan)

“Gamma-Irradiation of Serum for the Inactivation of Adventitious Contaminants”  
(Gay Gauvin and Raymond Nims)

“Viral Risk Mitigation for Mammalian Cell Culture Media” (Bob Weaver and Scott Rosenthal)

“Raw Materials Case Histories”  
(Michael Rubino)

“TSE Case Studies Associated with Japanese and Other Regulatory Authorities—Talk Transcript” (Barbara J. Potts)

“Regulatory Considerations for Raw Materials Used in Biological Products”  
(Arifa S. Khan)

“Rapid Molecular Assays for Microbial Contaminant Monitoring in the Bioprocess Industry” (Rangarajan Sampath, Lawrence B. Blyn and David J. Ecker)

“Root Cause Investigation of Unusual Results Experienced during Master Cell Bank (MCB) Testing and Characterization”  
(Dayue Chen and Christopher C. Hatfield)

“Apparent Virus Contamination in Biopharmaceutical Product at Centocor”  
(Linda C. Hendricks, Jarrat Jordan, Tong-Yuan Yang, Paul Driesprong, Gert Jan Haan, Mareike Viebahn, Thomas Mikosch, Henri Van Drunen and Anthony S. Lubiniecki)

“Adventitious Viruses Detected in Biopharmaceutical Bulk Harvest Samples over a 10 Year Period” (Andrew Kerr and Raymond Nims)

“Regulatory Expectations of Validation/Qualification of Adventitious Virus Assays”  
(S. A. Baylis and J. Blmel)

“Synthesis Session Summary”  
(Kathryn King, Michael Wiebe and on behalf of the Cell Substrate Task Force)

### Usage Statistics

In its first full year, the electronic *PDA Journal of Pharmaceutical Science and Technology* (the E-Journal) experienced steady traffic from members and nonmembers, with monthly average traffic at 3,000 (measured by individual IP addresses). More than 6,000 individuals had subscribed to electronic Table of Contents Alerts by the end of 2010 and 84 institutions had signed up for subscriptions. In addition, PDA enjoyed support from advertisers to help with the cost of the E-Journal, with two vendors sponsoring the homepage throughout 2010: Sartorius Stedim and Veltek.

Besides a number of minor tweaks and revision to the website, the PDA Director of Publishing initiated a number of projects in 2010 to improve the E-Journal. By March, Google Analytics was implemented to increase the tools available for tracking usage. By end of year, projects were underway to expand the archive section of the E-Journal by 18 volume years and to implement an online submission and review tool to streamline the submission/review process. Both projects will come to fruition by mid-2011.



## SCIENTIFIC AND REGULATORY AFFAIRS

### Technical Reports

New in 2010, PDA Technical Reports go through a different kind of peer review, beginning with the groups of experts, which PDA calls Task Forces, who draft the documents. They are also reviewed and critiqued by PDA Advisory Boards and the PDA Board of Directors.

In recent years, PDA injected a “global review” into the process. This includes offering a draft of the Technical Report for public scrutiny, requesting certain regulatory authorities to comment on the draft, and, in some cases, holding PDA workshops to elicit feedback. This entire process is managed by PDA staff.

In light of the rapidly changing nature of scientific information exchange, specifically the shift to electronic publishing, PDA made the decision to go electronic. Scientific journals like the *PDA Journal of Pharmaceutical Science and Technology* require mass visibility and access to make them relevant and successful, thus the move to publish the Journal electronically in partnership with HighWire Press.

PDA Technical Reports, while equally as scientific and/or technical as peer-reviewed articles, represent major original works created by teams of PDA members, often taking two or more years to produce. Technical Reports are very valuable intellectual properties of members, and ownership of them is a special privilege granted only to our members. In PDA's final analysis, the new HighWire website did not offer the kind of security needed to protect Technical Reports from illegal distribution.

In 2010, PDA published the following five reports, bringing the number of Technical Reports in PDA's library to 51:

- PDA Technical Report No. 51: *Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use*
- PDA Technical Report No. 50: *Alternative Methods for Mycoplasma Testing*
- PDA Technical Report No. 49: *Points to Consider for Biotechnology Cleaning Validation*
- PDA Technical Report No. 48: *Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance*
- PDA Technical Report No. 47: *Preparation of Virus Spikes Used for Virus Clearance Studies*

In the first quarter of 2010, PDA published *PDA Technical Series: Filtration — A Compilation of Technical Reports on Filtration*. Over the years, PDA expert task forces have developed several Technical Reports on various aspects of filtration. Now all five of them are available in one easy-to-use, hardbound volume. This volume is a convenient and powerful reference for individuals working with filtration processes for water and virus removal, and is an invaluable guide for navigating the scientific and regulatory aspects of filtration.

### Technical Books

PDA, in partnership with Davis Healthcare International Publishing, Inc. (DHI), publishes books written on topics relevant to our membership. Authors are subject matter experts in the area, and all books are reviewed by several other experts prior to publication. **Janny Chua**, Product Operations Manager, manages the daily retail operations and sales activities for PDA, while Amy Davis of DHI manages the book development, review and publication process.

In 2010, PDA took steps to better integrate the technical books program with PDA's science and regulatory programs by adding representatives of the Scientific Advisory Board, the Biotechnology Advisory Board and Regulatory Affairs and Quality Committee to the Technical Book Advisory Board.

## SCIENTIFIC AND REGULATORY AFFAIRS

### Technical Books Advisory Board

#### Chair

**Amy Davis**, *Davis Healthcare International Publishing*

#### Members

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

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

**Maik Jornitz**, *Sartorius Stedim Biotech*

**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 Liaisons

**Janny Chua**, *Product Operations Manager, PDA*

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

**Walt Morris**, *Director of Publishing, PDA*

The following PDA members authored or were editors of PDA/DHI books in 2010:

- **Paul L. Pluta**, PhD, *Cleaning and Cleaning Validation, Volume 1*
- **Destin A. LeBlanc**, *Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 2*
- **Jeanne Moldenhauer**, PhD, *Environmental Monitoring: A Comprehensive Handbook, Volume 4*
- **Scott Sutton**, PhD, *Laboratory Design: Establishing the Facility and Management Structure*
- **Jeanne Moldenhauer**, PhD, *Recent Warning Letters Review for Preparation of an Aseptic Processing Inspection*
- **Jeanne Moldenhauer**, PhD, *Recent Warning Letters Review for Preparation of a Non-Sterile Processing Inspection, Volume 2*
- **Lynn Torbeck**, *Validation by Design®: The Statistical Handbook for Pharmaceutical Process Validation*

Annually, PDA presents an award for the best editor/author of PDA/DHI co-published books as selected by the PDA community. The 2010 PDA/DHI Distinguished Editor/Author Award recipient is:

- **Jeanne Moldenhauer**, PhD

In 2010 the top five best-selling PDA/DHI books were:

- *Validation by Design®: The Statistical Handbook for Pharmaceutical Process Validation*, by **Lynn Torbeck**
- *Environmental Monitoring: A Comprehensive Handbook, Volume 4*, edited by **Jeanne Moldenhauer**, PhD
- *Recent Warning Letters Review for Preparation of an Aseptic Processing Inspection*, by **Jeanne Moldenhauer**, PhD
- *Practical Aseptic Processing: Fill and Finish, Volume I and II*, edited by **Jack Lysfjord**
- *Cleaning and Cleaning Validation, Volume 1*, edited by **Paul L. Pluta**, PhD

PRACTICAL  
ASEPTIC  
PROCESSING  
FILL AND FINISH



VOLUME 2  
Edited by  
Jack Lysfjord

PRACTICAL  
ASEPTIC  
PROCESSING  
FILL AND FINISH



VOLUME 1  
Edited by  
Jack Lysfjord

CLEANING  
AND  
CLEANING  
VALIDATION  
VOLUME 1



Paul L. Pluta  
Editor

ENVIRONMENTAL  
MONITORING  
A  
COMPREHENSIVE  
HANDBOOK  
VOLUME 4



Jeanne Moldenhauer  
Editor

RECENT  
WARNING LETTERS  
REVIEW FOR  
PREPARATION OF AN  
ASEPTIC PROCESSING  
INSPECTION



Jeanne Moldenhauer

VALIDATION  
BY  
DESIGN®  
THE STATISTICAL  
HANDBOOK FOR  
PHARMACEUTICAL  
PROCESS VALIDATION



Lynn Torbeck

## PDA TRAINING AND RESEARCH INSTITUTE (PDA TRI)

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.

At our Bethesda facility, we provide lecture courses, as well as training programs featuring classroom lectures accompanied by hands-on laboratory training. In 2010, we provided three new and/or updated laboratory-based courses: *Choosing the "Right" Microbial Identification Program for Your Biopharmaceutical/Pharmaceutical Quality Control Laboratory*, *Developing an Environmental Monitoring Program*, and *Environmental Mycology Identification*.

Our flagship course remains the ten-day *Aseptic Processing Training Program*. This course, which consists of two one-week sessions approximately a month apart, was held five times again in 2010 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.

A number of other laboratory courses were also held in our Bethesda training center. In addition to our core courses, in 2010, PDA TRI worked with FDA scientists and investigators to develop and present hands on-laboratory training in analytical and microbiological technologies to 50 FDA laboratory staff from around the country.



## PDA TRAINING AND RESEARCH INSTITUTE (PDA TRI)

### TRI Supporting Companies, 2010

- Alcan Packaging
- Aramark
- Atlantic Technical Systems
- Becton Dickinson
- Biolog
- BioMerieux
- Cardinal Health
- Cole Parmer
- Corning
- Dupont
- EMD
- General Econopak
- Hach Ultra
- Hardy Diagnostics
- ITW Texwipe
- Kimberly Clark
- Millipore
- Particle Measuring Systems
- Raven BioLabs
- Sartorius Stedim Biotech
- Veltek Associates, Inc.
- West Pharmaceutical



While our laboratory-based training is a key part of the PDA TRI learning experience, it is complemented by our more traditional classroom-based lecture courses. As with our laboratory courses, we constantly update our lecture curricula to reflect the needs of the students and the trends in our industry. In 2010, we presented 14 new lecture courses. These new courses were:

- A Former FDA Investigator's Perspective on Conducting Effective Deviation Investigations, Root Cause Investigations, and Corrective and Preventive Actions
- A Risk-Based Approach to Technology Transfer
- Applying Lean to Aseptic Processes
- Bioprocess Validation
- Isolators: From Concept Through Qualification
- Principles of Microbiological Containment
- Rapid Microbiological Methods: Overview of Technologies, Validation Strategies, Regulatory Opportunities and Return on Investment
- Risk Mitigation Solutions: The Response to Risk Assessment
- Syringes and Elastomers: Understanding the Effects on Quality and Demonstrating the Production Process, Influences and Needs
- Technical Development of Prefilled Syringes, Autoinjectors and Injection Pens
- Uses of Bioassay for Vaccine Development and Product Control: Practical and Statistical Considerations
- Vaccines 101
- Validation of Microbiological Test Methods
- Virus Clearance

We conducted training courses in conjunction with major PDA Conferences as well, including:

- 2010 *PDA Annual Meeting*, Orlando, FL
- 2010 *PDA Pharmaceutical Cold Chain Management Conference*, Bethesda, MD
- 2010 *PDA Vaccine Conference*, Bethesda, MD
- 2010 *PDA/FDA Joint Regulatory Conference*, Washington, DC
- 2010 *PDA Biennial Training Conference*, Baltimore, MD
- *The Universe of Prefilled Syringes and Injection Devices*, Las Vegas, NV
- *PDA's 5<sup>th</sup> Annual Conference on Pharmaceutical Microbiology*, Bethesda, MD
- 2010 *Pharmaceutical Freeze Drying Workshop*, San Diego, CA

These lecture courses also enjoyed some significant successes in 2010. For example, our training center classroom was filled to capacity, overflowing with the 33 students and two instructors at our Cold Chain course, while our two courses held in conjunction with the Pre-filled Syringe Conference enrolled 118 students!

In addition, we held course series in Boston, Denver (held in cooperation with the PDA Mountain States Chapter), New Brunswick and San Diego. Responding to the feedback provided by our students, 2010 marked the last year we plan to offer these stand-alone series, as they don't seem to meet the needs of our student base as well as some of our other venues.



## PDA TRAINING AND RESEARCH INSTITUTE (PDA TRI)

The third leg of our training programs continued to be the provision of customized in-house training to various clients. Our ability to customize and deliver in-house training is yet another example of how we serve the needs of our industry by providing unique hands-on training our students can bring home and apply immediately on the job. In 2010, we offered both laboratory- and lecture-based courses to almost 100 students at their own company facilities.

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 2010 PDA Annual Report. Our heartfelt thanks go out to them all. It is through their efforts that we achieved the successes we had in 2010.

**And finally, a word of thanks to our loyal, hard-working staff and last, but by no means least, our students. Without them there would be no PDA TRI!**

### 2010 Faculty

**Mike Akers**, *Baxter BioPharma Solutions*

**Mike Anisfeld**, *GlobePharm Consulting, Inc.*

**Eddie Ballance**, *Eisai, Inc.*

**Harold Baseman**, *ValSource, LLC*

**Rafik Bishara**

**John Brecker**, *Fleet Laboratories*

**Carolyn Briguglio**, *Genzyme*

**Jose Bruno-Barceno**, *North Carolina State University*

**Sean Byrd**, *FDA*

**Steve Chenal**, *Bioquell, Inc.*

**James Cooper**, *Endotoxin Consulting Services*

**Dave Crance**, *Particle Measuring Systems, Inc*

**Cheryl Custard**, *Sanofi Pasteur*

**Bob Dana**, *PDA*

**William Deckert**, *Alliance Engineering*

**Trevor Deeks**, *Emergent Biosolutions*

**Anne Marie Dixon**, *Cleanroom Management Associates Inc.*

**William Egan**, *PharmaNet Consulting*

**J. Kirby Farrington**, *Auburn University*

**Bob Ferer**, *The Ferer Group, Inc.*

**Dave Ferrazza**, *Millipore*

**Barry Friedman**, *Consultant*

**John Geigert**, *BioPharmaceutical Quality Solutions*

**Michael Gills**, *West Pharmaceuticals*

**Daniel H. Gold**, *D.H.Gold Associates, Inc.*

**Tricia Griffiths**, *Millipore*

**Joseph Habarta**, *J. Habarta Consulting*

**Lisa Hornback**, *Hornback Consulting, LLC*

**Tim Joyce**, *Compliance Software Solutions Corp.*

**J. Scott Kemp**, *JSK Consulting Services*

**Patty Kiang**, *Kiang Consulting Services*

**Bob Kieffer**, *RGK Consulting*

**Frank Kohn**, *FSK Associates, Inc.*

**David Lansky**, *Lansky Consulting, LLC*

**Destin LeBlanc**, *Cleaning Validation Technologies*

**Samuel Lebowitz**, *Electrol Specialties Company*

**Elaine Lehecka Pratt**, *Lehecka Pratt Associates, Inc.*

**Ronald Leversee**, *Baxter*

**George Levinson**, *Compliance Software Solutions Corp.*

**Mike Long**, *KPM, International Associates*

**John Ludwig**, *Pfizer Global Biologics*

**David Matsuhira**, *Cleanroom Compliance*

**Randa Melham**, *FDA*

**Marion Michaelis**, *FDA*

**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*

**Martin Orłowski**, *Bioquell, Inc.*

**Matthew Ostrowski**, *Pfizer*

**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*

**Tim Schofield**, *GlaxoSmithKline*

**Dale Seiberling**, *Electrol Specialties Company*

**John Shabushnig**, *Pfizer*

**Destry Sillivan**, *FDA*

**Peter Smith**, *PAREXEL Consulting*

**Ernest Stadler**, *Consultant*

**Patrick Swann**, *FDA*

**Edward Trappler**, *Lyophilization Technology*

**Mark Trotter**, *Trotter Biotech Solutions*

**Nicole Trude**, *FDA*

**Barbara van der Schalie**, *SAIC-Frederick, Inc.*

**Art Vellutato, Jr.**, *Velte Associates, Inc.*

**Nancy Waites**, *FDA*

**Adam Warner**, *Bioquell, Inc.*

**Randy Wilkins**, *Millipore*

**Jeff Yuen**, *Jeff Yuen and Associates, Inc.*

## PROGRAMS, MEETINGS AND WEB SEMINARS

### 2010 Program Chairs

James Agalloco, *Agalloco and Associates, Inc.*  
 Barbara Allen, PhD, *Eli Lilly S.A.*  
 Dr. Jeffrey C. Baker, *Medimmune*  
 Rafik H. Bishara, PhD  
 Harold Baseman, *ValSource, LLP*  
 Edward S. Balkovic, PhD, *Genzyme Corporation*  
 Rey Chern, PhD, *Merck & Co. Inc.*  
 Rebecca Devine, *Regulatory Consultant*  
 Lynne Ensor, PhD, *FDA*  
 Patricia Hughes, *FDA*  
 Arifa Khan, *FDA*  
 Dr. Michael A. Long, *KPM Int. Assoc.*  
 Brigitte Reutter-Haerle, *Vetter Pharma International*  
 Diane Paskiet, *West Pharmaceuticals*  
 Amy Scott-Billman, *GlaxoSmithKline*  
 Susan Schniepp, *OSO BioPharmaceuticals*  
 Edward H. Trappier, *Lyophilization Technology, Inc.*  
 Mike Wiebe, *Quantum Consulting, LLC*  
 Joyce S. Winters, *Lachman Consulting, Inc.*  
 Edwin Rivera-Martinez, *PAREXEL*  
 Brigitte Reutter-Haerle, *Vetter Pharma International*

In 2010, PDA conferences exceeded expectations with a strategic mix of tried-and-true and new Career-long Learning<sup>SM</sup> educational, scientific and technical pharmaceutical and biopharmaceutical programs.

The continued success of these 16 programs offered is largely due to our volunteers who serve on the program planning committees and lend their knowledge and expertise to the development of these unique programs. The success formula is: Volunteer Experts x Hours + Planning = Success. In addition, the feedback that is provided from our global membership continues to address the PDA Mission and Vision to be the foremost global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industry.

### 2010 Web Seminars

The innovative technology of Web Seminars is another unique opportunity to provide quality educational training and is considered a valuable tool with no limitations. Since 2002, PDA has offered the pharmaceutical and biopharmaceutical professional the chance to communicate, share documents, make presentations, demonstrate products and services, collaborate, reduce travel cost and increase productivity through Web conferencing. Web Seminars, combined with quality educational content, continue to complement the face-to-face networking experience.

In addition, PDA has a vast library of On-Demand Web Seminars. These recordings of previous Web Seminars and select conference sessions are posted on-line at [www.pda.org](http://www.pda.org) and are available for users' reference at their convenience.

### 2010 PDA Conferences and Workshops

2010 PDA Annual Meeting  
 March 15-19, 2010, Orlando, FL

Lean Manufacturing Workshop  
 March 17, 2010, Orlando, FL

2010 Pharmaceutical Cold Chain Management Conference  
 April 12-13, 2010, Bethesda, MD

2010 PDA/FDA Pharmaceutical Supply Chain Workshop  
 April 26-28, 2010, Bethesda, MD

2010 PDA/FDA Vaccine Conference  
 May 17-19, 2010, Bethesda, MD

2010 PDA Pre-filled Syringe IG Workshop  
 June 21-22, 2010, Carlsbad, CA

2010 PDA/FDA Joint Regulatory Conference  
 September 13-15, 2010, Washington, DC

2010 PDA Extractables and Leachables Workshop  
 September 15-16, 2010, Washington, DC

2010 ICH Quality Implementation Working Group (Q-IWG) Integrated Implementation Training Workshops for ICH Q8, Q9 and Q10  
 October 6-8, 2010, Bethesda, MD

2010 PDA Biennial Training Conference  
 October 11-13, 2010, Baltimore, MD

2010 Universe of Pre-filled Syringe and Injection Devices  
 October 18-19, 2010, Las Vegas, NV

PDA's 5<sup>th</sup> Annual Global Conference on Pharmaceutical Microbiology  
 October 25-27, 2010, Washington, DC

2010 PDA Workshop on Aseptic Processing: Issues and Approaches  
 November 15-16, 2010, Bethesda, MD

PDA 2010 Pharmaceutical Freeze Drying Workshop  
 November 17-18, 2010, San Diego, CA

2010 PDA/FDA Adventitious Viruses in Biologics: Detection and Mitigation Strategies Workshop  
 December 1-3, 2010, Bethesda, MD

2010 PDA Technical Report Workshop: Moist Heat Sterilizer Systems, Steam in Place and Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat  
 December 6-7, 2010, Chicago, IL

# PROGRAMS, MEETINGS AND WEB SEMINARS

## 2010 PDA Web Seminars

**Pharmaceutical Water Mythology**  
**Teri Soli**, PhD, President  
 and Principal Consultant,  
 Technical Support, *Soli Pharma  
 Solutions, Inc.*  
 February 23, 2010

**Development and Validation of an  
 Integrity Test Method for a Sterile  
 Connection Device: Correlation  
 of Integrity Test Limits to Loss of  
 Integrity of Devices**  
**Gael Peron**, Product Manager,  
 Fluid Management Technologies,  
*Sartorius Stedim Biotech S.A*  
 March 2, 2010

**Environmental Monitoring  
 in Isolators**  
**Jim Akers**, PhD, President,  
*Akers Kennedy & Associates*  
 March 9, 2010

**Single Use Disposable  
 Technologies**  
**Mark Trotter**, Consultant,  
*Trotter Biotech Solutions*  
 March 22, 2010

**Intrinsic Foreign Particulate  
 Matter Identification and  
 Application of ISO 16232  
 Cleanliness Testing Procedures  
 and Qualified Equipment to  
 Control and Minimize Foreign  
 Particulate Matter in Parenterals  
 down to 1µm**  
**Oliver Valet**, Co-founder, *rap-ID  
 Particle Systems GmbH*  
 March 31, 2010

**Process Validation Excellence –  
 It's as Simple as 1,2,3**  
**Peter Watler**, CTO, *Hyde  
 Engineering + Consulting*  
 April 13, 2010

**Bioreactor Process Monitoring  
 for Early Detection of Mollicutes  
 Utilizing a Novel Sample  
 Preparation Technology Coupled  
 with Real-Time Transcription-  
 Mediated Amplification**  
**Wayne Miller**, Field Marketing  
 Manager, *Millipore*  
 April 15, 2010

**Adopting ICH Q10 to Achieve  
 Competitive Compliance**  
**Siegfried Schmitt**, PhD,  
 Consultant, *PAREXEL*  
 April 21, 2010

**High Efficiency Single Use Mixing  
 Systems for Biopharmaceutical  
 Applications**  
**Nicolas Voute**, Global Product  
 Manager, Fluid Management  
 Technologies, *Sartorius Stedim  
 Biotech S.A.*  
 April 29, 2010

**Fundamentals of Lyophilization  
 in Syringes**  
**Shawn Kinney**, PhD, President  
 & CEO, *Hyaluron Contract  
 Manufacturing (HCM)*  
 May 4, 2010

**Fermentation Cell Culture  
 Technologies**  
**Mark Trotter**, Consultant,  
*Trotter Biotech Solutions*  
 May 11, 2010

**Integration of an ISO  
 13485:2003 Quality System  
 into an Existing QSR Facility**  
**Deborah Ford**, Regional  
 Manager, *QPharma, Inc.*  
 May 18, 2010

**In-line E-Beam Tunnels in  
 the Medical Device and  
 Pharmaceutical Industries**  
**Philippe Fontcuberta**, Managing  
 Director, *Getinge Linac  
 Technologies S.A.S*  
 May 27, 2010

**Supplier Qualification:  
 Auditing/Products and Services**  
**Eric Berg**, Director, Supplier  
 Quality, *Amgen, Inc.*  
 June 10, 2010

**Analytical Method Transfer  
 Strategies for a Contract  
 Manufacturing Organization**  
**Barbara Berglund**, Manager, QC,  
*Hollister-Stier Laboratories*  
 June 22, 2010

**Development and Validation  
 of an Integrity Test Method for  
 Large Volume 3D Bag Chambers**  
**Nicolas Voute**, Global Product  
 Manager, Fluid Management  
 Technologies, *Sartorius Stedim  
 Biotech S.A.*  
 July 6, 2010

**Protecting the Global Supply  
 Chain through an Effective  
 Audit Program**  
**Gerard Pearce**, Executive Vice  
 President, *SQA Services, Inc.*  
 July 8, 2010

**Application of a Risk-Based  
 Approach to Optimize a Rapid  
 Mycoplasma Test for Cell Therapy  
 and Tissue-Engineered Products**  
**John Duguid**, Staff Scientist,  
*Genzyme*  
 July 15, 2010

**Scale-up of Filters for Sterilizing  
 Filtration of Liquids**  
**Sal Giglia**, Principal Applications  
 Engineer, *Millipore*  
 August 19, 2010

**Risk Management:  
 A Way of Thinking and Its  
 Practical Applications**  
**Robert Kieffer**, PhD, President,  
*RGK Consulting*  
 August 26, 2010

**Current Perspectives  
 in Biofilms Growth**  
**Paul Sturman**, Coordinator,  
 Industrial Development,  
*Montana State University*  
 September 14, 2010

**Batch Definition and Logistic  
 Systems for the Supply of  
 Primary Packaging Materials  
 made of Tubular Glass**  
**Alfred Breunig**, Director  
 Technical Customer Support,  
*MGlas AG*  
 September 21, 2010

**Security by Design, Modernizing  
 Controlled Substance Tracking**  
**Avery Edwards**, Senior  
 Consultant, *Clarkston Consulting*  
 September 22, 2010

**Myths and Realities in Validating  
 Pharmaceutical, Biotechnology,  
 and Medical Device Facilities**  
**Jeffrey Gassman**, PhD, President,  
*ValidationPlus, Inc.*  
 September 28, 2010

**Heavy Metals Testing: An  
 Analytical Review of the Current  
 Status and the Impact on the  
 Manufacture of Drug Products**  
**Daniel Zuccarello**, Manager,  
*Intertek USA, Inc. d/b/a QTI*  
 October 5, 2010

**Review by Exception –  
 Implementing MES and  
 Maintaining Compliance**  
**Marc Puich**, VP, MES Program  
 Management, *Werum America*  
 November 4, 2010

**How To Use Part 11 To Add Value  
 To Your Work (For More Than Gap  
 Analysis And Remediation)**  
**Jeffrey Gassman**, PhD, President,  
*ValidationPlus, Inc.*  
 November 9, 2010

**Use of a Laser-Scatter Triggering  
 Mechanism for the Imaging  
 of Sub-Visible Particles in  
 Parenterals**  
**Lew Brown**, Director, Marketing,  
*Fluid Imaging Technologies, Inc.*  
 December 9, 2010

**Determination of Trace Levels of  
 Silicone in Pre-filled Syringes and  
 Container Closure Systems**  
**Daniel Zuccarello**, Manager,  
*Intertek USA, Inc. d/b/a QTI*  
 December 16, 2010

## MEMBERSHIP AND CHAPTERS

### Strengthening Volunteer Focus

In an effort to recognize and reward PDA volunteers and to expand membership participation, in 2010 PDA continued to publish Volunteer Spotlights in the *PDA Letter* and has highlighted 61 volunteers to date. Each issue highlights one or two volunteers who have substantially contributed to the PDA community. To further educate members on volunteer opportunities, we hosted our first webinar, "Virtual Volunteer Orientation" hosted by past chair, **John Shabushnig**. PDA will host quarterly webinars in 2011 and introduce a Virtual New Member Orientation as well.

### Improving Member Benefits and Services

In 2010, in an effort to improve membership services, PDA developed a communication plan. Deliverables included a PDA New Member Benefits Guide, Non-Member Recruitment Brochure and Anniversary Membership Pins. To improve member services, PDA staff received in-house customer service training. To measure the success of our communication plan, PDA launched a year-end Membership Satisfaction Survey. The Membership Committee will use this as a platform in 2011 to develop strategies to improve member benefits/services.

### Increasing Membership Recruitment

In 2010 PDA leveraged the chapters to conduct various road shows in the US and Asia. In this road show a PDA representative would highlight new PDA member benefits and services available to them. This gave members and non-members the opportunity to learn more about PDA and the advantages membership provides. In 2011 we will continue this initiative globally in line with the strategic plan.

### Improving Guidance and Support for Chapter Volunteers

PDA introduced harmonization checklists to PDA Chapters in order to facilitate communication concerning PDA's expectations for following the rules and policies set forth in the Chapter By-Laws and the Chapter Handbook. This discussion led to positive dialogue and a proposal for a Chapter Points Program to incentivize and reward improvements in these areas.

PDA stepped up its commitment to support the activities carried out by chapters, encouraging every chapter to take advantage of services such as event registration support, badge printing and bulk email distribution support through MagnetMail. An increasing number of chapters have taken the opportunity to pass these time-consuming logistical tasks on to PDA where possible, allowing volunteers to focus their efforts more efficiently at the local level.

In the summer of 2010 the PDA Board of Directors approved the Charter of the PDA Missouri Valley Chapter. The chapter is the twelfth in North America and will serve PDA members in the FDA Kansas City District area including the states of Iowa, Kansas, Missouri and Nebraska.





## MEMBERSHIP AND CHAPTERS

## PDA Global Chapters and Leaders

## ASIA-PACIFIC

## Australia Chapter

**President:** Ano Xidias, PharmOut  
**Treasurer:** Paul Kerr, SeerPharma  
**Secretary:** Anna Corke, Genera Biosystems

## Japan Chapter

**President:** Katsuhide Terada, PhD, Toho University  
**President-elect:** Shigeo Kojima, PhD, Pharmaceuticals and Medical Devices Agency  
**Treasurer:** Yukio Hiyama, PhD, National Institute of Health Sciences  
**Secretary:** Yoshiaki Hara, Sartorius Stedim Japan KK

## 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, Taiwan PDA

## EUROPE

## France Chapter

**President:** Philippe Gomez, Sartorius Stedim  
**Treasurer:** Jean-Luc Clavelin, Eli Lilly and Company

## Ireland Chapter

**President:** Colman Casey, PhD, University College Cork  
**President-elect:** Brendan Cahill, Pfizer Biotechnology Ireland  
**Treasurer:** Joan Fitzgerald, Allergan  
**Secretary:** Paul A. Louge, Elan Corporation

## Israel Chapter

**President:** Mordechai Izhar, PhD, Ludan  
**President-elect:** Rina Yamin, Alcobra Ltd.  
**Treasurer:** Karin Baer, PhD, Teva Kfar Saba  
**Secretary:** Karen S. Ginsbury, PCI Pharmaceutical Consulting Israel

## Italy Chapter

**President:** Stefano Maccio, CTP Technologie di Processo  
**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:** Michael Baker, Pharma Quality Consulting, Ltd.

## NORTH AMERICA

## Canada Chapter

**President (Acting):** Patrick Bronsard, SNC Lavalin  
**President-elect:** Sabrina Ullah, SNC-Lavalin Pharma Inc.  
**Secretary:** Antonella Maggio, Generex Biotechnology

## Capital Area Chapter

**President:** Allen Burgenson, Lonza  
**Treasurer:** Barry Friedman, PhD, Cambrex Corporation  
**Secretary:** Stephen Rochelle, Rochelle & Associates

## Delaware Valley Chapter

**President:** Arthur Vellutato, Jr., Veltek Associates, Inc.  
**Treasurer:** Marlene Raschiatore, Wyeth

## Metro Chapter

**President:** Robert Johnson, GlaxoSmithKline  
**Treasurer:** Lisa Burns, Church & Dwight  
**Secretary:** Lara Soltis, ITW Texwipe

## Midwest Chapter

**President:** Peter Noverini, Baxter  
**President-elect:** Jeanne Moldenhauer, Excellent Pharma Consulting  
**Treasurer:** Ken Paddock, Baxter Healthcare  
**Secretary:** Beth Kirschenheiter, Hospira

## Missouri Valley Chapter

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

## 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:** Gerald Boudreault, Drug Development Resources Inc.  
**President-elect:** Russell Morrison, Commissioning Agents, Inc.  
**Treasurer:** Maryellen Brown, Pall Life Sciences  
**Secretary:** Sarvang Mishra, Shire

## Puerto Rico Chapter

**President:** Jose Cotto, Amgen, Inc.  
**President-elect:** Melba Clavell, Pfizer  
**Treasurer:** Yaritza Martinez  
**Secretary:** Ruth Toledo, Amgen

## Southeast Chapter

**President:** Michele Creech, Talecris Biotherapeutics  
**President-elect:** Beth Meinig, Integrated Compliance Consulting  
**Treasurer:** Bruce Craven, Vantage Consulting Group  
**Secretary:** Shelley Preslar, Hyde Engineering + Consulting, Inc.

## Southern California Chapter

**President:** Saeed Tafreshi, Intelitec Corporation  
**Treasurer:** William Nichols, Parexel International

## West Coast Chapter

**President:** Elizabeth Leininger, PhD, Elizabeth Leininger Consulting  
**Treasurer:** Michael Place, Bayer Healthcare  
**Secretary:** Kristina Nordhoff, Genentech, Inc.

## PDA EUROPE

### The Staff

During 2010, Georg Roessling's fifth year as head of PDA Europe, change, growth and member service continued with renewed vigor. The professional staff began the year with **Georg Roessling**, Senior Vice President; **James Lyda**, Regulatory Affairs; **Volker Eck**, Science and Technology; **Antje Petzholdt**, Administration and Membership; **Ailyn Kandora**, Event and Program Manager; **Nadine Gold**, Marketing Manager; **Katharina Keisers-Engstfeld**, Exhibition & Sponsorship Manager; and **Dirk Stelling**, Finance Control.

### Volunteers and Members

For 2010 PDA Europe reports approximately 2,250 members for Europe and the Middle East, about the same as last year. The top 11 countries for membership are (data as of December 2010):

Germany	400
Switzerland	249
UK	204
France	181
Denmark	169
Israel	166
Italy	155
Ireland	148
Belgium	144
Netherlands	114
Sweden	105

### The Place

In 2010 PDA Europe celebrated its fourth year in permanent office space in the Glienicke (Nordbahn) suburb of Berlin. This 'green' building has ample room for expansion of the staff.

### Regulatory Affairs and Relations

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

### European Medicines Agency

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

- In 2010, planning was started for the 4<sup>th</sup> *PDA/EMA Joint Conference* to be held in London in early May 2011. Building on the successful 2006 Joint Conference in London, the 2008 Joint Conference in Budapest and the 2009 Joint Conference in Berlin, the 2011 Conference will be held at London's Heathrow Airport in May. The conference will be co-Chaired by **Riccardo Luigetti**, EMA, and **Lothar Hartmann**, F. Hoffmann-La Roche.
- Interested Parties Meetings: PDA was well represented at the annual EMEA Inspection Sector's Interested Parties Meeting on September 14, 2010, by **Siegfried Schmitt**, Parexel International, and **Brian Matthews**, Regulatory Health Care Consulting. The latest GMP and inspection issues were discussed in detail, and PDA made a presentation on the PCMO<sup>SM</sup> Risk-Based Auditing Technical Report.
- Training on ICH Q8, Q9 and Q10: At the request of the ICH Quality - Implementation Working

Group (Q-IWG), PDA was the lead organizer for the training workshop held in Tallinn, Estonia, June 2-4, 2010. More than 200 industry and regulatory experts convened to learn how best to implement the new ICH guidances. We enjoyed this historic city and the northern 'White Nights' where it never became dark.



## PDA EUROPE

## 2010 PDA Regulatory Consultation Europe

In 2010, PDA members and volunteers in Europe and around the globe helped prepare regulatory consultation on the following European proposed guidance. All comments can be found on the PDA Web site, [www.pda.org](http://www.pda.org).

- EMA/draft GMP guidance: Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File and Content of a Site Master File
- EMA/Guidelines to Good Manufacturing Practice: Chapter 1, Quality Management System
- EMA/Guidelines to Good Manufacturing Practice: Chapter 2, Personnel
- EMA/Guidelines to Good Manufacturing Practice: Annex 2, Manufacture of Biological Medical Substances and Products for Human Use
- EMA/CMC: Guideline on the Requirements for Quality Documentation, Qualification of Biological IMP for Clinical Trials

## 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 more 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 2011.
- PDA continued to build on its 2008 commentary on the revised EMEA Guideline on the Production and Quality Control of Monoclonal Antibodies, with our third MAB workshop held in Berlin in June 2010. There was agreement moving ahead for the fourth workshop to be held in Basel, June 7-8, 2010.
- Another PDA Working Group is putting together a draft Technical Report on Endotoxins, planned for 2011.

## 2010 Conferences and Workshops Europe

**Investigational Medicinal Products** January 26–27, Paris, France  
**Small Batch Production** February 23–24, Berlin, Germany  
**Technical Report – Media Fills** February 25, Berlin, Germany  
**Microbiology Methods** February 23–24, Berlin, Germany  
**Endotoxins** March 2–3, Milan, Italy  
**Stoppers & Elastomers** March 24–25, Cologne, Germany  
**Siliconisation** March 18, Cologne, Germany  
**Filtration** April 13–14, Berlin, Germany  
**Bio-Films** April 20–21, Frankfurt, Germany  
**Container Closure Systems + Annex 1** April 27–28, Berlin, Germany  
**Flexible Immediate Containers** May 5–6, Berlin, Germany  
**Cleanrooms/RABS/Isolators** June 8–9, Basel, Switzerland  
**Aseptic Technologies** June 10–11 Basel, Switzerland  
**Advanced Therapies** June 15, Berlin, Germany  
**Vaccines** June 16, Berlin, Germany  
**Monoclonal Antibodies** June 17–18, Berlin, Germany  
**Lean Manufacturing** September 20–21, Dublin, Ireland  
**Freeze Drying** September 27–28, Vienna, Austria  
**Cold Chain** October 5–8, Berlin, Germany  
**Visual Inspection** October 5–8, Berlin, Germany  
**Parenteral Conference** October 26–28, Berlin, Germany  
**Analytic Method Validation** November 11–12, Vienna, Austria  
**Contract Manufacturing** November 30 – December 1, Amsterdam, The Netherlands  
**Modern Biopharmaceutical Manufacturing** December 7–8, Paris, France

## Interest Group Meetings

**Technology Transfer** March 25, Frankfurt, Germany  
**Pre-filled Syringes** April 15, Berlin, Germany  
**Visual Inspection** April 22, Frankfurt, Germany

## 2010 Training Courses Europe

- Investigational Medicinal Product Dossier
- Clinical Trial Formulation Development
- Container & Closure Development
- Container Closure Systems & Alternatives to the Dye Test
- An Introduction to Visual Inspection of Parenterals
- Good Cold Chain Management
- Development of a Freeze Drying Process
- Contract Manufacturing/Quality Agreements

## 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.

**Leon D. Lewis** started working at PDA in February 2009 as an Assistant Manager of Programs and Web Seminars. Combining his previous experiences in program development, project management and meeting coordination, Leon has made numerous major strides at PDA. Over the course of his career at PDA, he has maintained an excellent record of being dependably prepared to handle increasing responsibilities and recently became Manager of Programs and Web Seminars. Leon also oversees several PDA signature events such as the Annual Microbiology Conference and the PDA/FDA Pharmaceutical Supply Chain Workshop, along with numerous focus meetings.

**Dirk Stelling** was born in Berlin in 1974. After studying general business management at the Technical University of Berlin, he started working for Ernst & Young as an audit assistant. After almost seven and a half years, he left Ernst & Young to start working for PDA Europe. Here he is responsible for accounting, controlling and several other administrative duties. In addition to this, he is mainly responsible for the development of PDA Europe's website.

### Service Appreciation Award

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

**Raphael (Raphy) Bar, PhD**, is a pharmaceutical consultant for the pharmaceutical and biopharmaceutical industries. He provides consulting services on pharmaceutical development and analytical support for building a CMC package, all related to investigational, new and generic drugs as well as medical devices and combination products. He is receiving this award because of the exemplary performance he has contributed as President of the Israel Chapter of PDA.

**Gerard Boudreault** is President and founder of Drug Development Resources, Inc. (DDRES.COM). DDR provides hands-on, results-driven CMC consulting services to industry. Prior to founding DDR in 2001, he spent 12 years at Biogen in manufacturing, operations and CMO quality management and then Transkaryotic Therapies, where he was responsible for all outsourced manufacturing. Boudreault is a longtime member of PDA and past President of the New England Chapter.

**Colman J. Casey, PhD**, is director for research and industrial liaison, College of Medicine and Health, University College Cork. Prior to that he spent seven years as General Manager of Schering-Plough (Brinny) biotech manufacturing company in Ireland; ten years in line management in a pharmaceutical manufacturing environment; and seven years in enzyme production for the food industry. Casey founded the PDA Ireland Chapter in 2006 and served as President for the last two years. The PDA Ireland Chapter currently has 147 members.

**Michele F. Creech** is a Quality Operations Manager at Talecris Biotherapeutics in Clayton, North Carolina, with almost 20 years of Quality experience in the pharmaceutical industry. In addition to being a long-standing PDA member, Creech has obtained ASQ certification as a Certified Quality Auditor and as a Certified Quality Manager. She served as the PDA-Southeast Chapter Vice President, Chapter President and currently remains active as Chapter Past-President. During her tenure, the PDA-SE Chapter team was proud to launch a local Student Chapter and implement an annual Student Scholarship Awards Program.

**Véronique D. Davoust, PhD**, has over 20 years' experience in the pharmaceutical industry, both in Regulatory Affairs and Manufacturing, for Pfizer Inc. In her current position she is responsible for the monitoring and analysis of European emerging regulations and guidelines, especially focusing on Good Manufacturing/Distribution Practices and registration of the Quality section of Marketing Authorization dossier throughout the product life cycle. She has served on planning committees for the *PDA/EMA Joint Conference* since its creation in 2006, and was a member of the previous PDA Board of Directors.

**Lothar Hartmann, PhD**, 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/CEPIC. 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 past member of 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.



## HONOR AWARDS

**Manuel Melendez** has over 30 years of experience working in the Health Care and Biopharmaceutical fields, most of them in leadership positions as Director, Site Quality Head, ED Plant Manager and ED Quality for major healthcare and biopharmaceutical firms. During his tenure in the healthcare and biotechnology industries, Melendez has played an important role in the development of systems to ensure production plants run in a continued state of compliance. He has also served the professional community as a member of Puerto Rico Medical Technologists College, American Society for Microbiologists (ASM), American Society for Clinical Pathologists (ASCP) and PDA where he was President of the Puerto Rico Chapter for three years.

**Lara A. Soltis** is a Sales Manager for Texwipe. She manages the US Mid-Atlantic territory for Cleanroom consumables: wipers, pre-wetted wipers, sterile alcohol, stationery, etc. She is Secretary of the PDA Metro Chapter (and Immediate Past President). Ms. Soltis has an MBA from Fairleigh Dickinson University and BS in Biology from The College of New Jersey. Ms. Soltis began her career as a QA Environmental Monitoring Microbiologist at J&J, she wrote SOPs, validation procedures and FDA submissions. She was previously Product Manager at Biotest where she oversaw the EM product line of Air Samplers, Particle Counters and culture media.

**Laura A. Thoma**, Pharm.D. received her Pharm.D. from the University of Tennessee where she is currently Professor of Pharmaceutical Sciences and Director of the Parenteral Medications Laboratories at the University of Tennessee College of Pharmacy. As an involved PDA member for over 20 years, she has been active in the organization, through her contribution to numerous programs, planning committees, task forces, advisory boards and the PDA Board of Directors.

### 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.

*Root Cause Analysis of Tungsten-Induced Protein Aggregation in Pre-filled Syringes*, Jan./Feb. 2010, 64:11-19

**Janice M. Davis, PhD**, is Senior Director of Protein Structure at WildRose Analytica.

**Erwin Freund, PhD**, is Scientific Executive Director of Advanced Sciences & Engineering at Amgen.

**Yijia Jiang, PhD**, is Scientific Director in the Formulation and Analytical Resources Department at Amgen.

**Wei Liu, PhD**, is Senior Engineer in the Biologics Manufacturing Science and Technology group at Genentech.

**Anthony Mire-Sluis, PhD**, is Executive Director of Global Product Quality and Quality Sciences at Amgen.

**Linda Narhi** is Scientific Executive Director in the Formulation and Analytical Resources group in the Research and Development department at Amgen.

**Yasser Nashed-Samuel, PhD**, is Principal Scientist at Amgen.

**Robert Swift** is Senior Principal Engineer in Primary Container Engineering at Amgen.

**Gianpiero Torraca, MS**, is Senior Scientist in the Department of Formulation and Analytical Resources at Amgen.

**Aylin Vance** is Senior Associate Scientist in Department of Formulation and Analytical Resources at Amgen.

**Zai-Qing Wen, PhD**, is Principal Scientist in the Department of Formulation and Analytical Resources at Amgen.





## HONOR AWARDS

### 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.

**Jeanne Moldenhauer** is the Vice President of Excellent Pharma Consulting. She is receiving this award for *Environmental Monitoring: A Comprehensive Handbook, Volume 4*, *Recent Warning Letters Review for Preparation of an Aseptic Processing Inspection, Volume 1* and *Recent Warning Letters Review for Preparation for a Non-Sterile Processing Inspection, Volume 2*.

### 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.

**Stephan W. Brown, PhD**, has been an enthusiastic and tireless supporter of PDA since joining. His expertise lies in microbiology, cell products and vaccines. He joined the planning committee for the first *Biopharmaceutical Manufacturing and Development* conference in Europe in 2007. He continued on the PDA committee, planning for follow-up conferences in 2008/9/10, and helped plan the *Modern Biopharmaceutical Manufacturing* conference in Paris, December 2010. During this period Brown was active in PDA's technical projects through the PDA Europe Biotech Interest Group, where he managed the ongoing facilities design subgroup. His efforts have helped make PDA recognized in Europe in the areas of biologics, biotechnology and advanced therapies. In late 2010 Brown was invited to join the PDA Biotechnology Advisory Board (BioAB), and has already proposed setting up an advanced therapies interest group for PDA.

**Ursula Busse, PhD, MBA**, is Head of Project Office, Global BiopharmOps at Novartis in Basel, Switzerland. Prior to joining Novartis in 2006, Busse worked for 11 years in small biotech startup companies in Québec City, Canada, starting in R&D and project management, and moving to positions with increasing responsibility in QA and Regulatory Affairs. Busse has been a longtime member of PDA and has volunteered in different areas such as the PDA Canadian chapter, the PDA Annual Meeting Committee since 2006, and the PCMO<sup>SM</sup> initiative. She is also actively supporting PDA Europe, namely as program committee member of the monoclonal antibody workshop which she is chairing this year.

**Lee E. Kirsch, PhD**, is a Professor of Pharmaceutics and Chemical and Biochemical Engineering at The University of Iowa. He was an industrial scientist and group leader in the Pharmaceutical Product Development Division in Lilly Research Laboratories for 12 years before joining the faculty at The University of Iowa in 1995. Shortly after embarking on his academic career, Kirsch received a major research grant from PDA to conduct basic research in sterile product package integrity. This effort resulted in a series of six research papers in the *PDA Journal of Pharmaceutical Science and Technology*, the Fred Simon Award for the best manuscript in 1997, and numerous presentations, short courses and task force activities on container closure integrity quality assurance. Kirsch was the editor of the *PDA Journal* from 2000 to 2008 and served on numerous PDA, PQRI and USP committees. He has been a faculty member for the PDA Training and Research Institute.

**David K. Matsuhiro** is the Principal for Cleanroom Compliance, Inc. He has worked as a consultant for Aseptic Solutions and KMI Systems, specializing in water, environmental systems and aseptic processing. He has also worked for Genentech, Inc., in a variety of environmental control positions. Matsuhiro is a member of several professional associations, including PDA, the American Society of Microbiology and the International Society of Pharmaceutical Engineers. At PDA he is the lead instructor for the aseptic processing course, literally hundreds of hours per year.

**Kevin D. Trupp** is the Manager of Sterilization Engineering at Hospira. He has more than 30 years of pharmaceutical engineering experience and has global responsibility for the selection and application of sterilization technology for aseptic and terminally sterilized drugs and devices. Trupp has made numerous contributions to PDA including the generation/updating of PDA Technical Reports (TR-1, TR-30, SIP) and has done a significant amount of PDA training (webinars, workshops and conferences) for industry and regulators.

## HONOR AWARDS

### 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.

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

### 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.

**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.

### 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.

**Robert L. Dana** is Senior Vice President, Regulatory Affairs and Training and Research Institute for the Parenteral Drug Association. He is currently responsible for the planning, operation and administration of PDA's educational programs, as well as the identification and pursuit of global regulatory affairs opportunities for PDA. He is a former Director of PDA and is a member of the University of Connecticut Pharmacy School Advisory Board, and the University of Connecticut Pharmacy School Alumni Association Board of Directors.

### 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.

**Nikki V. Mehringer** is Senior Director of Quality for Global Medical Affairs, Regulatory, and Safety at Eli Lilly and Company. Mehringer is a longtime member of PDA and has volunteered in a number of roles including Chair of the *PDA/FDA Joint Conference*, Chair of the Quality Interest Group and member of the Regulatory Affairs/Quality Committee. She served on the PDA Board of Directors for 11 years, during which time she served as Treasurer, as Chair of the Board in 2004 - 2005, and as Chair of the Strategic Planning Committee. Mehringer received the Frederick J. Carleton Award in recognition of her contributions to the PDA Board of Directors in 2008.

## 2010 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.

### Focusing on the Bottom Line

PDA successfully managed costs in 2010 by investing resources in the activities its member's value most highly. Total global expenses grew 3% in 2010 from \$11.9 million in 2009 to \$12.3 million. As a result of strong revenue growth and focused cost management, net income grew from \$686,548 in 2009 to \$901,432 in 2010 — a 31% year-over-year increase.

### Strong Financial Performance Continues in 2010

Continuing on the financial success of 2009, PDA delivered solid top and bottom-line growth in 2010. Global revenue grew 5% in 2010 from \$12.6 million in 2009 to \$13.2 million in 2010. PDA brought a strong slate of high-valued programs to our members in 2010 driving global program and meeting revenues up from \$6.2 million in 2009 to \$7.5 million in 2010 — a 20% increase.\*

### Achieving Long-Range Strategic Business Goals — PDA Reserves Increase 42%

As outlined in its strategic plan, PDA is committed to rebuilding the financial reserves to their target level. PDA's unrestricted net assets increased 38% from \$2.4 million in 2009 to \$3.3 million in 2010. Equally if not more important, PDA's cash and investments grew from \$2.1 million in 2009 to \$3.0 million in 2010 — a 42% increase.

The following is a summary of the financial statements incorporated in the annual audit issued by the certified public accounting firm of Tate & Tryon for the year ending December 31, 2010. The full audit report is available upon request from PDA headquarters in Bethesda, Maryland.

\* Global program and meetings revenue includes registrations fees, exhibitor fees and event sponsorships.

### 2010 Annual Report Financial Summary

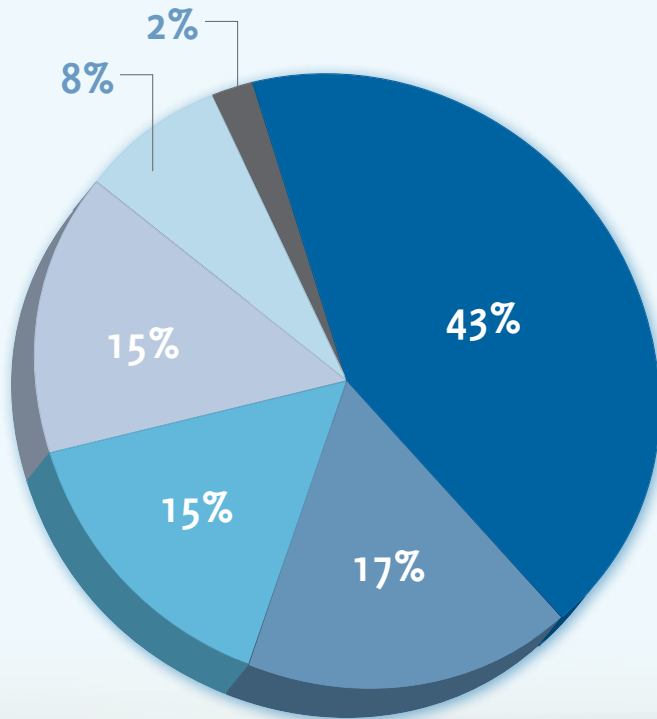
	2010	2009
<b>Total Revenues<sup>1</sup></b>	\$13,166,309	\$12,571,985
<b>Total Expenses<sup>2</sup></b>	\$12,264,877	\$11,885,437
<b>Net Income Surplus (Deficit)</b>	\$901,432	\$686,548
<b>Increase (Decrease) in Net Assets</b>	\$901,432	\$686,548
<b>Net Assets at beginning of year</b>	\$2,397,045	\$1,710,497
<b>Net Assets at end of year</b>	\$3,298,477	\$2,397,045
<b>Net Asset ratio (Net Assets / Annual Expenses)</b>	27%	20%

<sup>1</sup> 2009 revenue and expense includes \$158,037 of in-kind contributions which were excluded from revenue and expenses reported in the 2009 annual report.

<sup>2</sup> Total expense includes the foreign currency translation adjustment of \$11,870 in 2010 and \$7,315 in 2009. This is considered a non-operating expense item.

## 2010 FINANCIAL REPORT

2010 Revenue Sources



- Programs & Meetings 43%
- Membership & Chapters 17%
- Education 15%
- Exhibits & Sponsorships 15%
- Publications 8%
- Advertising 2%





## 2011 PDA OFFICERS AND BOARD OF DIRECTORS

### Officers



**Chair**  
**Maik Jornitz**  
*Sartorius Stedim Biotech*



**Chair-elect**  
**Anders Vinther, PhD**  
*Genentech, Inc.*



**Secretary**  
**Rebecca Devine, PhD**  
*Regulatory Consultant*



**Treasurer**  
**Harold Baseman**  
*ValSource, LLC*



**Immediate Past Chair**  
**John Shabushnig, PhD**  
*Pfizer, Inc.*

### Directors



**Jette Christensen**  
*Novo Nordisk*



**Gabriele Gori**  
*Novartis Vaccines & Diagnostics*



**Zena Kaufman**  
*Abbott*



**Steven Mendivil**  
*Amgen*



**Michael Sadowski**  
*Baxter Healthcare*



**Junko Sasaki**  
*Dainippon Sumitomo*



**Sue Schniepp**  
*OSO BioPharmaceuticals*



**Amy Scott-Billman**  
*GlaxoSmithKline*



**Lisa Skeens, PhD**  
*Baxter Healthcare Corporation*



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



**Martin Van Trieste**  
*Amgen, Inc.*



**Glenn Wright**  
*Eli Lilly*



## 2010 PDA STAFF

### Executive Office

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

### Regulatory Affairs Department

**Richard V. Levy**, PhD, Senior Vice President,  
 Scientific and Regulatory Affairs  
**Robert L. Dana**, Senior Vice President,  
 Regulatory Affairs and Training and Research Institute  
**Iris D. Rice**, Manager, Scientific & Regulatory Affairs

### Office of Science and Technology

**Richard V. Levy**, PhD, Senior Vice President,  
 Scientific and Regulatory Affairs  
**Iris D. Rice**, Manager, Scientific & Regulatory Affairs  
**Walter Morris**, Director, Publishing  
**Emily Hough**, Writer/Editor  
**Katja Yount**, Publication Design Specialist

### Membership Services

**Hassana Howe**, Manager, Membership Services and Chapters  
**Trevor Swan**, Senior Assistant Manager, Membership  
 Services and Chapters  
**Katie Ruiz**, Receptionist

### Sales

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

### PDA Training and Research Institute

**Robert L. Dana**, Senior Vice President, Regulatory Affairs and  
 Training and Research Institute  
**Stephanie Ko**, Senior Manager, Lecture Education  
**James Wamsley**, Senior Manager, Laboratory Education

### Marketing Services

**Adrienne Fierro**, Vice President, Marketing Services  
**Julia Zimmerman**, Manager, Marketing Services  
**Annie Gavett**, Marketing Coordinator  
**Faramarz Kolivand**, Webmaster

### Programs and Registration Services

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

### Administration

**Craig Elliott**, Senior Vice President, CFO  
**Michelle Lax**, Controller  
**Ana Vallenias**, Accounts Payable Analyst  
**Shanna Morgan**, Accounts Receivables Specialist  
**Feng Chen**, Senior Manager, Information Technology  
**Frank Wang**, IT Specialist  
**Bob Collier**, Database Administrator  
**Janny Chua**, Manager, Publications

### PDA Europe

**Georg Roessling**, PhD, Senior Vice President  
**James Lyda**, Senior Director, Regulatory Affairs  
**Nadine Gold**, Marketing Manager  
**Katharina Keisers-Engstfeld**, Exhibition & Sponsoring Manager  
**Ailyn Kandora**, Event & Program Manager  
**Antje Petzholdt**, Assistant, Administration and Membership  
**Dirk Stelling**, Manager, Finance and Controlling



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