2009
ANNUAL REPORT

Connecting People, Science and Regulation®

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About PDA

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

Vision

To be the foremost global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industry.

PDA Mission

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership.

PDA Mission Elements

- Promote advances in pharmaceutical and biopharmaceutical science
- Provide global forums for the scientific community, regulators and industry professionals
- Facilitate development, testing and qualification of new technologies
- Facilitate training and education on a global level
- Deliver unique hands-on training through PDA's Training and Research Institute
- Foster Career-long Learning℠ and professional development
- Enable scientific information sharing with industry peers
- Continue to be a leading and influential contributor of information for the global regulatory and harmonization processes

In addition to sponsoring educational conferences and training courses, PDA publishes the *PDA Journal of Pharmaceutical Science and Technology* and the *PDA Letter*, which focus on current industry and regulatory news. In keeping with its 60 plus-year history of promoting the growth of pharmaceutical science and technology, PDA introduced the PDA Training and Research Institute (PDA TRI) in May 1997.

History

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

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

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

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Message from the PDA Board of Directors Chair

Chair, PDA Board of Directors
John Shabushnig, PhD
Pfizer, Inc.

Looking Back and Looking Ahead...

This last year, PDA, like many organizations, was challenged by the global recession. The impact of this recession was felt especially hard in the nonprofit sector as our members reduced spending in travel and education. Careful expense management has allowed us to control costs while continuing to deliver high-value programs and services to our members. This was most apparent at our signature meetings, such as the *PDA Annual Meeting, the PDA/FDA Joint Regulatory Conference* and *PDA/EMEA Joint Conference* in 2009. The success of these meetings would not have been possible without the hard work and dedication of our staff and the support and participation of our members.

As I look ahead, I am optimistic about our future and continued contribution to the pharmaceutical and biopharmaceutical industry. I am also pleased to report a number of significant organizational changes for PDA in 2009.

After five years of outstanding service as President, Bob Myers announced his plans to retire at the beginning of the year. After an extensive search process, Richard Johnson was hired and began serving as President in September. Richard brings broad industry experience and a long history as a PDA volunteer to his new role. I know we all wish Bob well in his second retirement and I look forward to working with Richard in the years ahead.

We launched the electronic distribution of the *PDA Journal of Pharmaceutical Science and Technology* in 2009. The initial launch was quickly followed by a web-based version offering enhanced search capabilities of past issues. I would also like to welcome Dr. Govind Rao, Professor of Chemical and Biochemical Engineering at the University of Maryland, Baltimore County as the new Journal editor. We have seen an increase in the member-driven task force activities in 2009 and expect to have a full pipeline of documents in development for 2010.

The PDA Training and Research Institute (PDA TRI) continued to expand its course offerings. The two-week *Aseptic Processing Training Program* is the cornerstone of the curriculum at TRI. In addition, the faculty and staff have begun delivering custom training at company sites. This can be a cost-effective way to improve the skills of a large number of colleagues. If you have not had the opportunity to attend a course at TRI, or just visit the facility in Bethesda, I highly recommend it.

The Chapter Council has completed the PDA Chapter Handbook. This document will help guide the formation and operation of local PDA chapters. The chapters are the grassroots of our Association and continue to be the first contact with PDA for many. I am especially excited about the formation of our first student chapters. The New England and Southeast chapters have taken the lead in this new initiative.

Finally, under Maik Jornitz's leadership we have updated our Strategic Plan for 2010-2012. This plan reaffirms our commitment to People, Science and Regulation. These are the three pillars that support our Vision and Mission. They stand on a strong foundation of specific objectives, projects and programs. I am confident in our current direction. My term as Chair has come to an end, but I look forward to continued service on the Board of Directors and to the further success of our Association.

Message from the PDA President

President, PDA
Richard M. Johnson
PDA

2009 – A Year of Challenge and Transition

PDA is a member-based, volunteer-focused organization, and that was never truer than this past year. The year 2009 was challenging for the global economy and the pharmaceutical industry, and the same was true for PDA. The global economic contraction required that PDA reassess its expenditures, and focus on those activities that our members value most highly. Our members and staff answered the call, and continued to provide the expertise, effort and enthusiasm that has made PDA a leader for more than 65 years. Despite challenges, PDA continued to "connect people, science and regulation," adding value to our members and the larger pharmaceutical community.

In September 2009 I joined PDA as your President. My focus since then has been, and will continue to be, on our 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.* We also enhanced our organization by the addition of outstanding professionals to our staff, including Craig Elliott, Sr. Vice President/CFO of Finance; Adrienne Fierro, Vice President of Marketing; and David Hall, Vice President of Sales.

In 2009, PDA offered a wide variety of scientific and technical pharmaceutical and biopharmaceutical programs. In the US that translated to more than 17 conferences and workshops. We held a *PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference* in Shanghai, China. In Europe, we held 29 conferences and workshops, including the third *PDA/EMEA Joint Conference*, and a very successful meeting of *The Universe of Prefilled Syringes and Injection Devices* in Venice.

In 2009 we continued our commitment to education, offering a wide variety of courses not only at our unique facilities in Bethesda but also throughout the US and the world. Of special note were our training of the Russian Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor), three training courses in Shanghai and two courses in Israel.

After a record year for publishing Technical Reports in 2008 (six published), in 2009 there was a high level of activity replenishing the pipeline. Three technical documents were published, and the Paradigm Change in Manufacturing Operations (PCMO)[SM] project was launched, utilizing PDA's membership expertise to drive the establishment of "best practice" documents and/or training events to aid pharmaceutical manufacturers of investigational medicinal products and commercial products in implementing ICH Q8, Q9 and Q10.

We completed the transition of the *PDA Journal of Pharmaceutical Science and Technology* to a modern, electronic platform hosted by Stanford University's HighWire Press, that improves our ability to deliver our high-quality, peer-reviewed Journal efficiently and with added features to enhance the reader/researcher experience. We also completed the spinoff of *International Pharmaceutical Quality* into an independent publication.

Looking to 2010, PDA will be pursuing a number of initiatives as delineated in our updated strategic plan, which will ensure the continued strength and success of the Association.

We anticipate publishing at least six PDA Technical Reports, doubling last year's effort. And with the development of each technical report, we want to provide training and support to help members exploit the value of technical reports to the fullest.

2010 promises 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 10,000 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."**

2009 PDA Officers and Board of Directors

Officers

Chair
John Shabushnig, PhD
Pfizer, Inc.

Chair-elect
Maik Jornitz
Sartorius Stedim Biotech

Secretary
Rebecca Devine, PhD
Regulatory Consultant

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Anders Vinther, PhD
Genentech, Inc.

Immediate Past Chair
Vincent Anicetti
Genentech, Inc.

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Pfizer, Inc.

Lothar Hartmann, PhD
F. Hoffmann – La Roche, Ltd.

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Aptuit

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Steven Mendivil
Amgen, Inc.

Michael Sadowski
Baxter Healthcare Corp.

Junko Sasaki
Dainippon Sumitomo Pharma

Amy M. Scott-Billman, M.S.
GlaxoSmithKline

Christopher J. Smalley
Wyeth

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 manages all 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) training 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 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 2009, the Department had two full-time and one part-time staff members: **Richard Levy,** PhD, Senior Vice President of Scientific and Regulatory Affairs, **Iris Rice,** Executive Coordinator and **Bob Dana,** Senior Vice President of TRI and Quality and Regulatory Affairs, respectively. In Europe, **Volker Eck,** PhD, Senior Director of Science and Technology, continued to support European members interested in manufacturing science. **Jim Lyda,** Senior Director of Regulatory Affairs, continued his focus on the European regulatory scene and contributed to the development of regulatory responses through the Regulatory Affairs and Quality Committee (RAQC).

PDA staff was focused in 2009 on leading and supporting record-high levels of member activities in Advisory Boards and Task Forces. We continued to use both WebEx and PDA's knowledge management system InfoStrength to facilitate routine Task Force and Advisory Board activities. In 2010, we plan to implement at least two new tools to facilitate team communication and collaboration.

At the same time, 2009 was noteworthy for increased Task Force activities, including projects associated with the new umbrella program "Paradigm Change in Manufacturing Operations" (PCMO)℠. The goal of the PCMO program is 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. By the end of 2009, the PCMO Steering Committee had identified 20 new projects.

Science and Technology Overview

Advisory Boards

Audit Guidance Advisory Board (AGAB)

PDA established the AGAB to periodically review and approve changes to the process model and data collection tools described in PDA *Technical Report No. 32, Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations*. The AGAB also monitors auditor qualification and requalification requirements and provides oversight of the licensee of the Audit Resource Center (ARC) to ensure that the process remains current with respect to changing technology and regulatory environments; periodically analyze ARC's registration history, promotional efforts and service performance; and furnish ARC with suggestions, if any, for improvement.

In 2009, PDA consented to a one-time license reassignment from our current licensee SynTegra LLC to Intelaform, Inc., another division of Health Pathways. All of the other terms and conditions of the License Agreement remain in place, and Intelaform assumed all of the rights and obligations of the Licensee under the License Agreement. In 2010, in collaboration with Intelaform management, we expect to review the functioning of the ARC, and to prepare an updated business proposal to the Board of Directors for approval. In 2009, there was no new audit activity associated with the ARC.

Audit Guidance Advisory Board (AGAB)

Co-Chairs
Janis V. Olson, *EduQuest*
Steven D. Walker, *Merck & Co.*

Members
Richard Boeh, *Novo Nordisk Pharmaceutical Industries, Inc.*
Winnie Cappucci, *Bayer HealthCare*
Virginia L. Corbin, *Waters Corporation*
C. Wells Horton, *Procter & Gamble Pharmaceuticals*
Philip A. Lofty, *Merz Pharmaceuticals, LLC*
Peter J. Miller, *Dynamic Compliance Solutions*
Charlie Steiniger, *Sparta Systems, Inc.*
Elien Young, *Novartis Pharmaceuticals Corporation*

ARC Representatives
Debbie Dubrosky, *SynTegra Solutions, LLC*
Chris Ward, *SynTegra Solutions, LLC*
Steve Wilhelm, *SynTegra Solutions, LLC*

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

Associate/Trainer
Harvey F. Greenawalt, Jr., *IT&E International*

Scientific and Regulatory Affairs

The AGAB met three times through teleconferences, and once in person. The AGAB explored the current status and future direction of the ARC with Jeffrey Hall, Intelaform's leader, as PDA made the transition over to their management of the ARC. In 2009, the AGAB sponsored one Task Force, the Standard Audit Criteria Task Force (SACTF), which was chartered to develop and prepare a technical report for Auditing with Standard Criteria related to the Food and Drug Administration's (FDA's) Quality System approach. The AGAB also prioritized the revision of TR-32 for completion in 2011.

Biotechnology Advisory Board (BioAB)

To complement the Science Advisory Board (SAB) and to further focus PDA's scientific efforts on biotechnology, the BioAB has the responsibility for identifying biotechnology issues of interest to PDA members globally. Once an issue is identified, the BioAB either forms a task force to study and prepare written comments, or hands the issue off to the RAQC or SAB for action. The BioAB also serves to complement the activities of PDA's SAB and RAQC by, for example, providing insight into regulatory documents and technical reports related to biopharmaceuticals.

The BioAB was proactive in the identification of scientific/technical/regulatory issues affecting biotech products, with a focus on those scientific/technical areas in biotech that are still rapidly evolving. The BioAB also managed the progress of task forces, including Analytical Methods Development, Analytical Methods Validation, Cleaning and Disinfection of Biotech Products, Cell Substrates, Combination Products, GMPs for IDPs, four projects on *Mycoplasma*, Single-Use-Systems and Vaccines. Two of the teams, Cell Substrates and Combination Products, organized and sponsored two PDA workshops in 2009.

In 2009, the BioAB approved the following nine ballots:

- Ballot No. 28: *Technical Report No. 15: Validation of Tangential Flow Filtration in Biopharmaceutical Applications*
- Ballot No. 29: FDA Draft Guidance for Industry, *Process Validation: General Principles and Practice*
- Ballot No. 30: EDQM, *European Pharmacopeia,* Proposed revision to General Chapter XXXX:2031 "*Monoclonal Antibodies for Human Use*"
- Ballot No. 31: EDQM Proposed Revisions to Chapter 2.6.16. *Test for Extraneous Agents in Biological Products*, and Chapter 5.2.3. *Cell Substrates for the Production of Biological Products*
- Ballot No. 32: EMEA Note for Guidance on *Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (Revision 4)*
- Ballot No. 33: Draft Guidance for Industry and FDA Staff: *Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products*
- Ballot No. 34: Nomination of Stephen Notarnicola, Ph.D. as co-Chair to PDA's Biotechnology Advisory Board
- Ballot No. 35: PDA Comments on WHO *Recommendations for the Evaluation of Animal Cell Cultures as Substrates for the Manufacture of Biological Medicinal Products and for the Characterization of Cell Banks*
- Ballot No. 36: Technical Report No. 47: *Preparation of Virus Spikes Used for Virus Clearance Studies*

Biotechnology Advisory Board (BioAB)

Co-Chairs
Jeffrey C. Baker, PhD, *MedImmune*
Norbert Hentschel, *Boehringer Ingelheim Pharma*

Members
S. Robert Adamson, *Wyeth Biopharma*
Kurt A. Brorson, PhD, *US FDA, CDER*
Christopher M. Bussineau, PhD, *BioVascular, Inc.*
Anita Derks, *F. Hoffman-La Roche Ltd.*
Rebecca A. Devine, PhD, *Regulatory Consultant*
John Geigert, PhD, *Biopharmaceutical Quality Solutions*
Brian D. Kelley, *Genentech, Inc.*
Peter F. Levy, *PL Consulting*
Rohin Mhatre, PhD, *Biogen Idec*
Annemarie Möritz, PhD, *Novartis Pharma AG*
Jill 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, Pharm. D., *NDA Regulatory Service AB*
Robert Sitrin, PhD, *Merck Research Labs*
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*

Scientific Advisory Board (SAB)

The SAB focuses on PDA's scientific efforts in pharmaceutical science and technology, and has the responsibility for identifying and prioritizing issues and trends of interest to PDA members globally. Once an issue is prioritized for action, the SAB either forms a task force to study and prepare written comments or best practices, or in the case of draft regulatory guidances, hands the issue off to the RAQC for action.

The SAB manages the progress of their approved task forces including, but not limited to, several on sterilization such as revisions to TR No. 30: *Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat* and TR No. 3: *Validation of Dry Heat Processes Used for Sterilization and Depyrogenation* as well as new technical reports on Moist Heat Sterilizer Systems and Steam in Place. All of these Technical Reports will be companion documents to TR No. 1, which was revised in 2007.

Scientific and Regulatory Affairs

In the area of pharmaceutical microbiology: revisions of TR No. 13: *Fundamentals of an Environmental Monitoring Program*, and TR No. 33: *Evaluation, Validation and Implementation of New Microbiological Testing Methods* are in progress, as well as projects on Endotoxins, Blow-Fill–Seal Operations (with the BFSI Operators Society) and Microbial Data Deviations.

Another noteworthy task force is updating TR No, 43, focusing on the Classification of Non-Conformances in Ampoules, Syringes and Injector Devices. The SAB also has oversight over the Pharmaceutical Cold Chain Interest Group, which is very active and has 10 Task Forces developing Good Distribution Practices (GDPs) documents for the Pharmaceutical Supply Chain, as well as yearly PDA Cold Chain meetings held in the US and Europe.

In 2009, the SAB approved the following 15 ballots:

- Ballot No. 147: Technical Report No. XX: *Biological Indicators for Sporicidal Vapor Phase Decontamination Processes: Specification, Manufacture, Control and Use*
- Ballot No. 148: FDA Draft Guidance for Industry, *Process Validation: General Principles and Practice*
- Ballot No. 149: Nomination of Jean-Luc Clavelin to the PDA Science Advisory Board
- Ballot No. 150: Technical Report No. 22: *Process Simulation for Aseptically Filled Products (revised 2009)*
- Ballot No. 151: New Task Force Proposal on Pre-filled Syringe User Expectations
- Ballot No. 152: Technical Report No. 46: *Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End-User*
- Ballot No. 153: New Task Force Proposal on Evaluation and Control of Aseptic Processes
- Ballot No. 154: Nomination of Joyce Bloomfield to the PDA Science Advisory Board
- Ballot No. 155: Appointment of Scott Bozzone as Leader of the PDA Process Validation Interest Group
- Ballot No. 156: Technical Report No. 48: *Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance*
- Ballot No. 157: The Re-ballot of Technical Report No. 46: *Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End-User*
- Ballot No. 158: PDA Technology Transfer Interest Group Survey: *Intra-Company Technology Transfers*
- Ballot No. 159: Appointment of Jeffrey Hartman as co-Chair of the PDA Quality Risk Management Interest Group
- Ballot No. 160: Technical Report No. 30 (2009 Revision): *Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat*
- Ballot No. 161: Technical Report No. 3 (2009 Revision): *Validation of Dry Heat Processes Used for Depyrogenation and Sterilization*

Scientific Advisory Board (SAB)

Co-Chairs

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

Members

Raphael Bar, *BR Consulting*
Joyce Bloomfield, *Merck & Co., Inc.*
Jean-Luc Clavelin, *Lilly France S.A.S.*
Roger Dabbah, PhD
Don E. Elinski, *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.*
Karl L. Hofmann, *Bristol-Myers Squibb*
Lisa A. Hornback, *Hornback Consulting*
Michael Long, *KMP International Associates*
Russell E. Madsen, *The Williamsburg Group, LLC*
Jeanne E. Moldenhauer, PhD, *Excellent Pharma Consulting*
Ken H. Muhvich, PhD, *Micro-Reliance, LLC*
John G. Shabushnig, PhD, *Pfizer, Inc*
Christopher J. Smalley, PhD, *Wyeth Pharmaceuticals*
Lynn Torbeck, *Torbeck and Associates, Inc.*
Brenda W. Uratani, PhD, *CDER, US FDA*

PDA Staff Liaisons

Richard Levy, PhD, Scientific and Regulatory Affairs, *PDA*
Volker Eck, PhD, Science and Technology, *PDA Europe*

Scientific and Regulatory Affairs

Interest Groups

PDA's Interest Groups continued to flourish in 2009. Interest Groups met in person at both the PDA 2009 Annual Meeting and the *2009 PDA/FDA Joint Regulatory Conference*, and there were 12 Interest Group meetings at each. It is also noteworthy that there were two face-to-face Interest Group Leadership Meetings at which PDA staff worked with Interest Group leaders to identify and discuss challenges facing Interest Groups. A "laundry list" of challenges was created and actions to address these challenges were proposed. Initial steps were taken by PDA staff to address some of the concerns in 2009, while other action items were expected to be addressed in 2010.

Quality and Regulatory Affairs Overview

The year 2009 was a busy one for PDA's Regulatory Affairs and Quality Committee (RAQC). The Committee continued their work to monitor the global regulatory landscape and ensure PDA's positions on these proposals were communicated to the appropriate regulatory authorities in a clear and timely manner. PDA's positions, in the form of comments on the regulatory proposals, were prepared by various RAQC Task Forces, all led by and composed of member volunteers with an interest and knowledge of the specific subjects involved. In addition to these ballots on regulatory proposals, RAQC also approved Ballot No. 74 which authorized the formation of a Supply Chain Management Interest Group and Ballot No. 75 which approved standard operating procedures for commenting on regulatory documents.

These positions were balloted by the RAQC and included the following:

- Ballot No. 67: FDA Draft Guidance for Industry, *Process Validation: General Principles and Practice*
- Ballot No. 68: EDQM, *European Pharmacopeia, Proposed revision to General Chapter XXXX:2031 Monoclonal Antibodies for Human Use*
- Ballot No. 69: Proposed Revisions to Chapter 2.6.16. *Test for Extraneous Agents in Biological Products, and Chapter 5.2.3. Cell Substrates for the Production of Biological Products*
- Ballot No. 70: FDA Draft Guidance for Industry, *Good Importer Practices*
- Ballot No. 71: FDA Draft Guidance for Industry, *Standards for Securing the Drug Supply Chain*
- Ballot No. 72: EMEA Concept Paper on the Implementation of ICH Q10 into the EU GMP
- Ballot No. 73: Concept Paper on the Revision of the EU Guideline on Good Distribution Practice (GDP)
- Ballot No. 74: PDA New Interest Group Proposal: Supply Chain Management
- Ballot No. 75: RAQC Document Commenting Process – Standard Operating Procedures (SOP)
- Ballot No. 76: EMEA Note for Guidance on *Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (Revision 4)*

Interest Groups and Leaders

Biopharmaceutical Sciences

Biotechnology: Jill A. Myers, PhD, *BioPro Consulting, Inc.* and **Hannelore Willkommen,** PhD, *RBS Consulting*

Lyophilization: Edward H. Trappler, *Lyophilization Technology* and **Harald Stahl,** PhD, *GEA Pharma Systems*

Vaccines: Frank S. Kohn, PhD, *FSK Associates, Inc.*

Laboratory and Medical Sciences

Pharmaceutical Cold Chain: Rafik H. Bishara, PhD, *Eli Lilly and Company (ret.)* and **Erik van Asselt,** *Merck, Sharp and Dohme*

Microbiology/Environmental Monitoring: Jeanne E. Moldenhauer, PhD, *Excellent Pharma Consulting* and **Phillipe Gomez,** *Sartorius AG*

Visual Inspection of Parenterals: John G. Shabushnig, PhD, *Pfizer, Inc.* and **Markus Lankers,** PhD, *Rap. ID GmbH*

Manufacturing Sciences

Facilities and Engineering: Christopher J. Smalley, PhD, *Wyeth* and **Phillipe Gomez,** *Sartorius AG*

Filtration: Russell E. Madsen, *The Williamsburg Group* and **Michael Rook,** *Global Consepts EURL*

Pharmaceutical Water Systems: Theodore Meltzer, PhD, *Capitola Consulting Company*

Prefilled Syringes: Thomas Schoenknecht, PhD, *Amgen, Inc*

Sterile Processing: Richard M. Johnson, *RMJ Consulting*

Pharmaceutical Development

Clinical Trial Materials: Vince L. Mathews, *Eli Lilly and Company*

Combination Products: Michael A. Gross, PhD, *Chimera Consulting*

Packaging Science: Edward Smith, PhD, *Packaging Science Resources*

Process Validation: Mark P. Roache, *Bayer* and **Scott Bozzone,** PhD, *Pfizer, Inc.*

Quality Risk Management: Michael Long, *KMP International Associates*

Technology Transfer: Andrea Morelli, *Kedrion,* **Volker Eck,** PhD, *PDA Europe* and **Zdenka Mrvova,** *Zentiva*

Quality Systems and Regulatory Affairs

Regulatory Affairs: Amy Giertych, *Baxter Healthcare Corporation* and **Barbara Jentges,** PhD, *PhACT GmbH*

Inspection Trends: Robert Dana, *PDA* and **Dr. –Ing Stephan Rönninger,** *F. Hoffman-LaRoche Ltd.*

Quality Systems: Anders Vinther, PhD, *Genentech* and **Lothar Hartmann,** PhD, *F. Hoffman-LaRoche, Ltd.*

Scientific and Regulatory Affairs

- Ballot No. 77: Draft Guidance for Industry and FDA Staff: *Technical Considerations for Pen, Jet and Related Injectors Intended for Use with Drugs and Biological Products*
- Ballot No. 78: *Using an Interactive Voice Response System or Interactive Web Response Technology to Manage Investigational Medicinal Product Retest Dates in Lieu of Placing Retest Dates on Labels* (a White Paper)
- Ballot No. 79: New PDA Interest Group Proposal, Supply Chain Management
- Ballot No. 80: PDA Comments to the EMEA Guidance, *Use of Near Infrared Spectroscopy (NIRS) by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations*
- Ballot No. 81: PDA Comments on WHO *Recommendations for the Evaluation of Animal Cell Cultures as Substrates for the Manufacture of Biological Medicinal Products and for the Characterization of Cell Banks*
- Ballot No. 82: Regulatory and Quality Control Committee Handbook
- Ballot No. 83-1: FDA's Proposed Rule, *Postmarketing Safety Reporting for Combination Products*

Of particular note in 2009 was the response to FDA's Draft Guidance for Industry *Process Validation: Principles and Practice*. This draft guidance elicited a broad response from PDA members who expressed themselves in more than 400 individual comments to the Task Force developing the Association's position. While PDA's official comments indicated recognition that the draft guidance was a good document that would advance the new quality paradigm consistent with a science and risk-based approach, the comments focused on six aspects of the draft guidance about which the Association was concerned. These included: wording and terminology; commercial distribution; viral/impurity clearance; concurrent release; scope and legacy systems; and collectively qualification, documentation, organization and regulatory impact. PDA articulated the belief that current industry practices were already adequate in these areas and further regulatory input was not required.

In an unprecedented approach, PDA made all 400-plus comments received by the Task Force available to FDA for their awareness and consideration as they move toward a final Guidance on this subject, while recognizing that these individual comments did not reflect an official PDA position.

In addition, RAQC was busy developing and implementing documents aimed at strengthening its governance process. The procedure for assessing regulatory proposals, and developing and approving regulatory comments was formalized with the approval and implementation of an appropriate Standard Operating Procedure. In addition, to strengthen the operation of the Committee, a Handbook was developed, approved and implemented. This Handbook was intended to facilitate the orientation and integration of new members onto the Committee.

With respect to RAQC membership, six new members joined RAQC in 2009. They were **Jeff Broadfoot, Alan Burns, Robert Caunce, John Finkbohner, Siegfried Schmitt** and **Hongyan Xie**. These additions further strengthened the global perspective of RAQC.

Regulatory Affairs and Quality Committee (RAQC)

Co-Chairs
Steven Mendivil, *Amgen, Inc.*
Dr. –Ing Stephan Rönninger, *F. Hoffmann-LaRoche Ltd.*

Asia-Pacific Regional Leader
Michihisa Inokuma, PhD, *Towayakuhin*

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

Members
Ruhi Ahmed, PhD, *BioMarin Pharmaceuticals, Inc.*
Jeffrey R. Broadfoot, *Cangene Corporation*
Allan C. Burns, *Sartorius Stedim Biotech*
Robert B. Caunce, *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 Pharma*
Siegfreid Schmitt, PhD, *PAREXEL Consulting*
Susan Schniepp, *Antisoma*
Janeen Skutnik, *Pfizer, Inc.*
Michael VanDerWerf, *GlaxoSmithKline Biologicals*
Hongyan Xie, *Qilu Pharmaceuticals Co., Ltd.*
Barbara B. Zinck, *Zinck Consulting*

PDA Staff Liaisons
Robert Dana, Quality and Regulatory Affairs, *PDA*
James Lyda, Regulatory Affairs, *PDA Europe*

Scientific and Regulatory Affairs

Publications 2009

PDA Journal of Pharmaceutical Science and Technology

Science publishing at PDA took a great leap forward in 2009 with the transition of the *PDA Journal of Pharmaceutical Science and Technology* and the PDA Technical Reports to electronic products.

The *PDA Journal of Pharmaceutical Science and Technology* made the leap into Internet distribution when PDA partnered with HighWire Press—a division of Stanford University—to create a new, modern online experience for the readers. The new website—http://journal.pda.org—is loaded with value-added features that enhance the member experience.

Members will derive the most value from the advanced search and discovery tools available on the new website. The site also allows members to choose how they read or print articles—either as HTML pages or as PDFs. Members also can sign up for topic alerts and electronic table of contents and RSS feeds, which will keep the most interested readers well-informed and well-engaged with the *PDA Journal*.

A unique feature of the HighWire Press site is its "Toll Free Reference Linking," in which a reader who subscribes (either individually or through an institution) to one journal can click through to a referenced article in another participating HighWire journal and read the full text of that article, regardless of whether that reader has subscription rights to the referenced journal.

Another tool PDA feels members will enjoy is PowerPoint slide creator—a one-click way to convert images and figures in the articles into fully cited PowerPoint slides.

PDA members automatically receive free access to the current volume year and the previous year as part of their membership fee. Access to the archives, which currently go back to 1998, can be achieved on a pay-per-article basis or by purchasing unlimited access annually. The archives will be expanded, eventually, to include all years of the *PDA Journal*.

A new editorial team was put in place for the PDA Journal in 2009. Following the departure of former Editor **Lee Kirsch**, PhD, in 2008, PDA launched an extensive search to find the right person to take over the editorial operations of the *PDA Journal.* In the interim period, PDA Senior Vice President **Richard Levy,** PhD, served as the Acting Editor, and Assistant Editor **Salil Desai** (who worked with Dr. Kirsch) stayed on as Assistant Editor.

Govind Rao, PhD

In July 2009, the search for the new Editor was competed, and, following months of intense screening of many qualified applicants, Professor **Govind Rao,** PhD, *University of Maryland, Baltimore County (UMBC)* was named the new Editor, the seventh in the *PDA Journal*'s long history.

Dr. Rao appointed three, highly qualified Associate Editors to assist him:

Antonio Moreira, PhD, is Vice Provost for Academic Affairs and Professor of Chemical and Biochemical Engineering at UMBC since 1997.

Dr. Kurt Brorson is a staff scientist in FDA's Center for Drug Evaluation and Research (CDER), Division of Monoclonal Antibodies, Office of Biotechnology Products. Brorson received a BA in biology from the University of Chicago (Chicago, Ill.) in 1984 and PhD in molecular biology from the California Institute of Technology (Pasadena, Calif.) in 1990.

Dr. Anurag S. Rathore is a consultant with Biotech CMC Issues. He is also on the faculty at the Department of Chemical Engineering, Indian Institute of Technology, Delhi, India. His previous roles included management positions at Amgen Inc., Thousand Oaks, Calif., and Pharmacia Corp., St. Louis, Mo. He has a PhD in Chemical Engineering from Yale University.

The new Assistant Editor is **Mia Ricci**, a publishing professional with a background in journalism. She attended the City University of New York and graduated Cum Laude with a Bachelor of Arts degree in Journalism and a Certificate in Publishing.

Scientific and Regulatory Affairs

Technical Reports

In 2009, PDA technical reports were removed from under the *PDA Journal* umbrella. This decision was based on a number of factors, foremost of which was the fact that the technical reports are produced through a peer review process entirely separate from that used to referee the Journal. The latter undergoes an academic review common to most scientific and other kinds of academic journals and is overseen by the Journal Editor. The technical reports, on the other hand, 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 2009, PDA published the following three reports, bringing the number of active technical reports in PDA's library to 46:

- PDA Technical Report No. 46: *Last Mile, Guidance for Good Distribution Practices for Pharmaceutical Products to the End User*
- PDA Technical Report No. 15 (2009 Revision): *Validation of Tangential Flow Filtration in Biopharmaceutical Applications*
- White Paper – "Using an Interactive Voice Response System or Interactive Web Response Technology to Manage Investigational Medicinal Product Retest Dates in lieu of Placing Retest"

PDA Letter

The *PDA Letter* continued to inform members of the latest industry trends and Association news in 2009.

The Editorial Staff introduced new regular content to the Letter in 2009, which will carry over into 2010. The first was the "Tools for Success," a series of articles that focus on various career-enhancing topics. This was launched in response to the worsening economic conditions as an effort to help members during trying times.

The second was a series highlighting the winners of PDA various Honor Awards, given at the Annual Meeting each year. This series was launched to accompany the "Volunteer Spotlight" as a way to further recognize PDA's highly active volunteers.

Finally, a series of articles on Green Manufacturing was introduced in the Science & Technology Snapshot. These articles focus on various ways pharmaceutical companies are changing their practices and processes to reduce their "carbon footprint."

2009 *PDA Letter* Editorial Committee

Michael Awe, *American Pharmaceutical Partners*
Harold Baseman, *ValSource, LLC*
Vinod Gupta, PhD, *Organon USA, Inc.*
Elizabeth Martinez, *Terra Farma, S.A.*
Kristina Nordhoff, *Genentech*
Susan Schniepp, *Antisoma*
Scott Sutton, PhD, *Vectech Pharmaceutical Consultants*
Anita Whiteford, *Pennsylvania College of Technology*

PDA Staff Liaisons
Walter Morris, *Director of Publications*
Emily Hough, *Writer/Editor*

Scientific and Regulatory Affairs

PDA 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 the book development, review and publication process is managed by Amy Davis of DHI.

In 2009, PDA adopted the following measures to proactively manage the cost of goods of the PDA/DHI books:

- By moving the books from offset print to digital print, PDA was able to reduce printing costs and in return PDA was able to maintain book prices in 2009. This measure has also shortened the production lead time.
- By negotiating with a courier agent to handle the international shipments, we have reduced our international shipping and handling cost 5% from 2008.
- By offering customers an additional 10% discount when pre-ordering the new books in 2009 (a new member benefit), we have reduced the need for overstocks.
- With the introduction of electronic version (through conversion of the old soft-cover books and chapter booklets to PDF format) in addition to hard-copy version, we have reduced book reprinting costs, while still providing hard-cover books on demand.
- The availability of electronic versions of the books reduces the need to maintain large warehouse inventory, and customers can get the information more expediently.

The following PDA members authored or were editors of PDA/DHI books in 2009:

- **Jack Lysfjord,** *Practical Aseptic Processing: Fill and Finish, Volume I & II*
- **Theodore H. Meltzer,** PhD and **Maik W. Jornitz,** *Anatomy of a Pharmaceutical Filtration Differential Pressures, Flow Rates, Filter Areas, Throughputs and Filter Sizing*
- **Anthony M. Cundell,** PhD and **Anthony J. Fontana Jr.,** PhD, *Water Activity Applications in the Pharmaceutical Industry*
- **Jeanne Moldenhauer,** PhD, *Environmental Monitoring: A Comprehensive Handbook, Volume 3*

Annually, PDA presents an award for the best editor/author of PDA/DHI co-published books as selected by the PDA community. The 2009 PDA/DHI Distinguished Editor/Author Award recipients are:

- **Jack Lysfjord**
- **Theodore H. Meltzer,** PhD and **Maik W. Jornitz**

In 2009 the top five best-selling PDA/DHI books were:

- *Practical Aseptic Processing: Fill and Finish,* Volume I and II, edited by Jack Lysfjord
- *Environmental Monitoring: A Comprehensive Handbook,* Volume 3 edited by **Jeanne Moldenhauer,** PhD
- *Microbiology in Pharmaceutical Manufacturing,* Second Edition, Revised and Expanded, Volume I and II, edited by **Richard Prince,** PhD
- *Anatomy of a Pharmaceutical Filtration: Differential Pressures, Flow Rates, Filter Areas, Throughputs and Filter Sizing,* by **Theodore H. Meltzer,** PhD and **Maik W. Jornitz**
- *Biological Indicators for Sterilization Processes,* edited by **Margarita Gomez,** PhD and **Jeanne Moldenhauer,** PhD

Technical Books Advisory Board

Chair
Amy Davis, *Davis Healthcare International Publishing*

Members
Jack Lysfjord, *Lysfjord Consulting, LLC*
James Vesper, *LearningPlus, Inc.*
Jeanne Moldenhauer, *Excellent Pharma Consulting*
Maik Jornitz, *Sartorius Stedim Biotech*
Michael J. Miller, *Microbiology Consultants, LLC*
Russell Madsen, *The Williamsburg Group, LLC*
Scott Sutton, *Microbiology Network, Inc.*
Siegfried Schmitt, *PAREXEL Consulting*

PDA Staff Liaisons
Janny Chua, Product Operations Manager, *PDA*
Richard Levy, PhD, Scientific and Regulatory Affairs, *PDA*

PDA Training and Research Institute

The PDA Training and Research Institute (PDA TRI) strives to establish innovative education, training and applied research opportunities in pharmaceutical and biopharmaceutical sciences and associated supporting technologies.

The year 2009 was a challenging one for TRI. We faced and overcame both the impact of personnel changes and a declining economy that adversely affected registrations for our courses, both at the TRI facility and at our remote course locations.

To address the impact of the reduced registrations, we developed an aggressive campaign to promote the value and benefit of our customized in-house training programs. In addition, we developed partnerships and programs to offer our training in such diverse areas as Moscow, Shanghai and Tel Aviv.

Working with Eli Lilly Vostok S.A., Purdue University and the Russian Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor), PDA TRI conducted training in Moscow to improve Roszdravnadzor's employees' knowledge of Current Good Manufacturing Practices (CGMPs), advance Russian manufacturing pharmaceutical technology and quality control and provide information on regulations in pharmaceutical operations and inspections in different countries. We provided training to 35–40 students on *Process Validation, Quality Risk Management in Aseptic Processing (Technical Report No. 44), Validation of Moist Heat Sterilization Processes (Technical Report No. 1)* and *Auditing Skills and Techniques*. Purdue University staff also presented courses focused on general GMPs and solid oral dosage forms. Thanks to the hard work of the PDA staff and some outside help, along with a dedicated and tireless interpreter, the entire training program was presented in Russian.

In Shanghai, TRI conducted three training courses in conjunction with the *PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference*. We trained approximately 70 students in *Process Validation, Validation of Moist Heat Sterilization Processes* and *Sterilizing Filtration of Liquids (Technical Report 26)*.

Our third venture outside the US borders was to Tel Aviv, where we partnered with the PDA Israel Chapter to present courses on *Process Validation and Quality Risk Management in Aseptic Processing (Technical Report 44)* to 35 students.

As an added bonus to the course participants and PDA, 23 of the students became new PDA members at the time of the training.

Recognizing that economic conditions made travel to our courses more difficult for prospective students, we focused heavily on our ability to customize our courses and bring them to individual company sites. This proved to be an effective strategy; one which was supported by PDA staff, PDA Board members and several of our faculty. We conducted four different, hands-on training programs for Hospira at their facility in McPherson, KS in 2009, training more than 75 employees there. We followed that up with in-house training programs for other companies as well, and trained almost 75 more students as part of these additional in-house offerings. Both laboratory and lecture training was provided.

TRI focuses on *Career-long Learning*SM and provides practical, hands-on training that the students can apply immediately when they return to their jobs. To ensure our courses remain relevant, we continually evaluate our curriculum and update it with new courses as appropriate. In 2009, we offered 22 such new courses, 4 of which were laboratory courses *(Autoclave Operations, Biosystems Fundamentals: Fermentation and Cell Culture Workshop, Sterile Filtration in the Biopharmaceutical Industry* and *Contamination Control)*.

The 18 new lecture courses offered were:

- *Cleanroom Design, Contamination Control and Environmental Monitoring for Controlled Environments*
- *Developing a Robust Supplier Management Process*
- *Development and Implementation of Qualification and Validation Programs: A Risk and Science-Based Approach*
- *Documenting and Conducting Out of Specification Investigations*
- *Effective Investigations and Corrective Actions*
- *Environmental Monitoring*
- *Fundamentals of Biopharmaceutical Microbiology*
- *Global Harmonized Drug GMPs; Closer Than You Think*
- *GMPs for Manufacturers of Sterile and/or Biotechnology Products*
- *Integration of Risk Management into Quality Systems*
- *Introduction to HACCP and Other Risk-Based Systems as Applied to Aseptic Pharmaceutical Manufacturing*
- *Principles of Effective Quality Audits*
- *Process Validation for Pharmaceuticals: Current and Future Trends*
- *Quality by Design for Biopharmaceuticals: Concepts and Implementation*
- *Role of the Quality Professional in the 21st Century*
- *Solving Strategic Quality, Regulatory and Technical Issues During the Development of Prefilled Syringes, Autoinjectors and Injection Pens*
- *The Quality System: Implementation, Evaluation and Management of Processes*
- *Validation of Microbiological Test Methods*

PDA Training and Research Institute

The flagship course at TRI continues to be our ten-day *Aseptic Processing Training Program*. This course, taught by more than 20 subject matter expert instructors, was held five times in 2009 and all five sessions sold out. The course takes advantage of the unique capabilities of the TRI facility and its clean room which mimics a commercial clean room, but is in a training environment that promotes hands-on learning of aseptic processing techniques in a neutral setting without jeopardizing company clean rooms or commercial products. In addition to this course and the four new courses mentioned above, several other laboratory courses were held in our Bethesda, Md. facility in 2009.

We continued to offer lecture courses as part of PDA's signature and focused conferences as well. In 2009, we established a new record for participation in our *PDA/FDA Joint Regulatory Conference* course series, training more than 170 students in conjunction with the conference. We also had more than 30 students at our *Global Regulations and Standards: Influence on Cold Chain Distribution Practices: Development and Testing of Cold Chain Packaging and Transport Systems* course in Bethesda, held immediately following the *2009 PDA Cold Chain Management Conference*. TRI courses were also held in conjunction with the *2009 PDA Annual Meeting* and the *4th Annual Global Conference on Pharmaceutical Microbiology*.

In addition to the courses held following our conferences, we offered training course series around the US in New Brunswick, N.J.; St. Louis, Mo.; San Diego and San Francisco, Calif.; and Silver Spring, Md.

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 2009 Annual Report. Our heartfelt thanks go out to them all. It is through their efforts that we achieved the successes we had in 2009.

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 TRI.

TRI Supporting Companies, 2009

Alcan Packaging
Aramark
Atlantic Technical Systems
Becton Dickinson
Biolog
BioMerieux
Cardinal Health
Charter Medical
Cole Parmer
Corning
DuPont
Eisai Machinery U.S.A., Inc.
EMD Chemicals, Inc.
Fedegari Technologies, Inc.
General Econopak
Hach Ultra Analytics, Inc.
Hardy Diagnostics
Hitech Instruments, Inc.
ITW Texwipe
Kimberly Clark
Millipore
Pall Life Sciences
Particle Measuring Systems
PML Microbiologics
Raven BioLabs
Remel
Sartorius Stedim Biotech
Seidenader
ThermoFisher Scientific
Veltek Associates, Inc.
West Pharmaceutical

PDA Training and Research Institute

2009 Faculty

Mike Anisfeld, *Globepharm Consulting, Inc.*
Eddie Balance, *Eisai, Inc.*
Raphael Bar, *BR Consulting*
Harold Baseman, *ValSource, LLC.*
Rafik H. Bishara
Scott Bozzone, *Pfizer, Inc.*
John Brecker, *Fleet Laboratories*
Carolyn Briguglio, *Genzyme*
Vivian Bringslimark, *HPIS Consulting*
Jose Bruno-Barceno, *North Carolina State University*
Sean Byrd, *FDA*
David Chesney, *PAREXEL Consulting*
Harolyn M. Clow, *Lancaster Laboratories, Inc.*
William Collentro, *Consultant*
Andrew Collentro, *Water Consulting Specialists, Inc.*
Mark Compo, *Veltek Associates, Inc.*
Nate Conover, *Pathwise, Inc.*
James Cooper, *Endotoxin Consulting Services*
Dave Crance, *Particle Measuring Systems, Inc.*
Cheryl Custard, *Sanofi Pasteur*
Bob Dana, *PDA*
Anne Marie Dixon, *Cleanroom Management Associates, Inc.*
David Doleski, *FDA*
Kris Evans, *Amgen*
J. Kirby Farrington, *JFK Microbiology Consultants*
Bob Ferer, *The Ferer Group, Inc.*
Barry Friedman, *Consultant*
Wayne Garafola, *Sartorius-Stedim Biotech*
Karen Ginsbury, *PCI Ltd.*
Daniel Gold, *D. H. Gold Associates Inc.*
Tricia Griffiths, *Millipore*
Michael Gross, *Chimera Consulting*
Joseph Habarta, *J. Habarta Consulting*
Klaus Haberer, *Advice and Services in Microbiology GmbH*
Colleen Hagofsky, *Merck*
Tibor Hlobik, *West Pharmaceutical Services, Inc.*
Lisa Hornback, *Hornback Consulting, LLC.*
Sylvia Isaacson, *Millipore*
Maik Jornitz, *Sartorius Stedim Biotech*
Patty Kiang, *Kiang Consultant Services*
Bob Kieffer, *RGK Consulting*
Frank Kohn, *FSK Associates, Inc.*
Markus Lankers, *Rap-ID*
David Lansky, *Lansky Consulting, LLC*
Destin LeBlanc, *Cleaning Validation Technologies*
Samuel Lebowitz, *Electrol Specialties Company*
Ronald Leversee, *Baxter*
George Levinson, *Compliance Software Solutions Corp.*
John Ludwig, *Pfizer Global Biologics*
Larry Mager, *Pathwise, Inc.*
Jerold Martin, *Pall Corporation*
David Matsuhiro, *Cleanroom Compliance*
Theodore Meltzer, *Consultant*
Greg Meyer, *Compliance Media*
Marion Michaelis, *FDA*
Jeanne Moldenhauer, *Excellent Pharma Consulting*
Charles Montague, *Scienta Solutions*
Miguel Montalvo, *Expert Validation Consulting*
Petra Motzkau, *Sartorius-Stedim Biotech*
Wenzel Nowak, *Groninger*
Martin Orlowski, *Bioquell, Inc.*
Matthew Ostrowski, *Pfizer, Inc.*
Diane Paskiet, *West Analytical Services*
Maurice Phelan, *Millipore Corporation*
Dave Porter, *Vectech Pharmaceutical Consultants, Inc.*
Tom Pringle, *Pharmaceutical and Biomedical Temperature Controlled Transport Packaging*
Anurag Rathore, *Department of Chemical Engineering, Indian Institute of Technology*
Thomas Reidy, *Syntonix*
Mike Sadowski, *Baxter Healthcare*
Dale Seiberling, *Electrol Specialties Company*
John Shabushnig, *Pfizer, Inc.*
Destry Sillivan, *FDA*
Alan K. Smith, *Cognater Bioservices, Inc.*
Ed Smith, *Packaging Science Resources*
Gail Sofer, *Sofeware Associates*
Todd Spencer, *Biomerieux*
Ernest Stadler, *Consultant*
Scott Sutton, *The Microbiology Network*
Patrick Swann, *FDA, OBP, OPS, CDER*
Ron Tetzlaff, *PAREXEL Consulting*
Judith Torres, *Eli Lilly and Company*
Mark Trotter, *Trotter Biotech Solutions*
Ed Trappler, *Lyophilization Technology*
Barbara van der Schalie, *SAIC-Frederick, Inc.*
Art Vellutato, Jr., *Veltek Associates, Inc.*
Gang Wang, PhD., *FDA*
Tom Weaver, *Weaver Consulting, LLC.*

Programs, Meetings & Web Seminars

In 2009, PDA offered an unprecedented number of successful educational, scientific, and technical pharmaceutical and biopharmaceutical programs. This was due to the commitment of 200 volunteers who served on the PDA Program Planning Committees and who were keenly aware of the importance of face-to-face communication and networking.

The formula for planning 17 conferences and workshops in 2009 is based on feedback received from the membership, along with suggestions focused on topics that correlate to the PDA Vision and Mission statements.

2009 Web Seminars

To complement the face-to-face networking experience, PDA provides the opportunity for the pharmaceutical and biopharmaceutical professional to communicate, share documents, make presentations, demonstrate products and services, collaborate, reduce travel cost and increase productivity through web conferencing. The Web Seminar innovative technology combined with quality educational content is considered a valuable tool with no limitations.

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 and available for users' reference at their convenience.

A listing of the 2009 PDA Conferences and Web Seminars is included in this section.

PDA Program Advisory Board

2009 PDA Conferences and Workshops

Sterilization Technology Today and Tomorrow
March 2 – 3 | San Francisco, Calif.

Workshop on FDA's New Guidance on Process Validation
March 4 | San Francisco, Calif.

2009 PDA Pharmaceutical Cold Chain Management Conference
March 23 – 24 | Bethesda, Md.

2009 PDA Workshop: Cleanrooms Technology and Contamination Control
April 19 | Las Vegas, Nev.

PDA 2009 Annual Meeting
April 20 – 22 | Las Vegas, Nev.

Workshop on FDA's New Guidance on Process Validation
April 23 | Las Vegas, Nev.

Sterilization Technology Today and Tomorrow
May 14 – 15 | New Brunswick, N.J.

Workshop on FDA's New Guidance on Process Validation
June 8 – 9 | Chicago, Ill.

2009 PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference
June 15 – 17 | Shanghai, China

Cell Substrate Workshop
July 29 – 30 | Bethesda, Md.

2009 PDA/FDA Joint Regulatory Conference
September 14 – 16 | Washington, DC

Assessing Risks of Changing Sterile Drug Manufacturing Sites Workshop
September 16 | Washington, DC

Combination Products Workshop
September 16 – 17 | Washington, DC

PDA's 4th Annual Global Conference on Pharmaceutical Microbiology
October 5 – 7 | Bethesda, Md.

2009 Visual Inspections Conference
October 19 – 21 | Bethesda, Md.

Workshop on FDA's New Guidance on Process Validation
October 26 – 28 | Bethesda, Md.

Sterilization Technology Today and Tomorrow
November 18 – 19 | San Juan, Puerto Rico

Workshop on FDA's New Guidance on Process Validation
November 20 | San Juan, Puerto, Rico

Programs, Meetings & Web Seminars

PDA 2009 Web Seminars

Quality Oversight of Electronic Data & Computerized Systems: Current Perspectives for US FDA Compliance
Monica J. Cahilly, *President, Green Mountain Quality Assurance, LLC*

Passing a Team Biologics Inspection
Ann Marie Montemurro, Lead CSO, Biologics, *ORA, ORO, FDA*

Quality System Framework Approach to Risk Management: A Case Study in Computerized System Validation
James Huang, PhD, Quality Assurance and Regulatory Compliance, *Almac Clinical Technologies*

The Pen is Mightier than the EDC – Alternate
Dave Nettleton and Doug Patterson, FDA Compliance Specialists, *FDA*

How Do I Implement QbD?
Dr. Siegfried Schmitt, Principal Consultant, *PAREXEL Consulting*

Securing Your Supply Chain
Karen Ginsbury, President, *PCI Pharmaceutical Consulting Israel Ltd.*

Process Analytical Technology for the Automation of Quality Assurance and Control
Sandy Weinberg, PhD, *Health Care Management*

On Line, Real-Time Monitoring for Microbiological Contamination in Pharmaceutical Waters using MALS Technology
John Adams, Chief of Sensor Products, *JMAR Technologies*

Paperless Validation – Bridging IT and Compliance~A Case Study
Nagesh Nama, *ValiMation, Inc.*

Excel Spreadsheets – Step By Step Instructions for Compliance
Dave Nettleton, FDA Compliance Specialist, *Computer System Validation*

Molecular Methods for the Modern Microbiology Laboratory: Microbial Detection using Real-Time PCR
Olga Petrauskene, PhD, *Life Technologies*

Patient Care and "Last Mile" Distribution of Medicinal Products
James Soucey, Director of Clinical Services, *Wal-Mart Specialty Pharmacy*

Cold Chain Management – International Shipping Lane Compliance
Arminda Montero, Distribution QA Program Manager, *Abbott Laboratories*

Process Analytical Technology – Case Study
Linus Mockus, Senior Research Scientist School of Chemical Engineering, *Purdue University*

Disinfectants and Sporicides to Address Mold and Bacterial Endospore Outbreaks
Jim Polarine, Technical Service Specialist, *Steris Corporation*

Optimization of Part Washer Productivity
Marcel Dion, Senior Product Marketing Manager, *Steris*

Fragment Analysis and Whole Genome Sequencing
Elena Bolchacova, *Life Technologies*

Single-use Membrane Chromatography: Novel Applications and Regulatory Guidelines
Dave Zhou, Associate Product Manager, *Sartorius Stedim Biotech*

Application of Process Analytical Technologies (PAT) for Effective Cleaning Validation Risk Management
Keith Bader, Director of Technical and Quality Services, *JM Hyde Consulting, Inc.*

Thermal Validation: Matching the Tool to the Task for Both Accuracy and Efficiency
Kevin Bull, CEO, *Veriteq Instruments*

Efficiency Improvements in the Purification of Protein-Based Therapeutics Using Highly Specific Design Affinity Ligands
Johan Hamminga, Director QA & RA, *BAC BV*

New Technologies to Meet Temperature Challenges During Storage and Transportation
Jean Bedard, *Alternative Technologies Pharma Inc.*

A Novel Approach to Cleaning Validation for Biopharmaceutical Processes
Adam Mott, Director, Quality Control, *Lonza Biologics*

Impact of Tubing Material on the Failure of Product-Specific Bubble Points of Sterilizing-Grade Filters
Brian Meye, Research Fellow, *Merck & Co., Inc.*

Validation Master Plan for a New Aseptic Filling Technology
Françoise Delhalle, Responsible Pharmacist, QA/QC Director, *Aseptic Technologies*

Molecular Methods for the Modern Microbiology Laboratory: Microbial Identification by Targeted DNA Sequencing
Elena Bolchakova, *Life Technologies*

Molecular Methods for the Modern Microbiology Laboratory: Whole Genome Sequencing Methods for Microbial Characterization
Paolo Vatta & Craig Cummings, *Life Technologies*

Optimal Cold Chain Management through North American Distribution Networks
Jean Bedard, CEO, *Alternative Technologies Pharma Inc*

Sharps Injury Prevention–Update on the European Landscape
William Dierick, Business Development Manager, *Global Pharmaceutical Solutions*

Qualification of Antifoam Sterile Filtration for a Biopharmaceutical Fermentation Process
Niels Guldager, Senior Process Engineer, *NNE A/S*

Clinical Trials: Responsible Parties and Shared Responsibilities, Sponsor Vs CRO
Andrea Zobel, Director Clinical Logistics Services Europe, *PAREXEL International GmbH*

Container Closure Systems and Products Lifecycle
Mihaela Simianu, Research Advisor, Manufacturing Science and Technology, *Eli Lilly and Company*

Programs, Meetings & Web Seminars

Exhibitions

PDA exhibitions provide PDA Members and conference attendees the opportunity to find new resources, tools and innovative technologies to help them become more proficient in their jobs. These events also encourage extensive networking to enable information exchange amongst global regulatory authorities, industry professionals and academia.

PDA offered exhibitions during its two signature meetings in 2009: the PDA 2009 Annual Meeting and the *2009 PDA/FDA Joint Regulatory Conference*. With more than 100 exhibitors, the *PDA Annual Meeting* continues to be our largest exhibition. Although not as large in attendance as PDA's signature meetings, the focused conferences, including *PDA's 4th Annual Global Conference on Pharmaceutical Microbiology, PDA Cold Chain Conference* and *PDA Visual Inspection Conference,* were just as appealing to exhibitors and sponsors.

PDA exhibitions continue to support conferences and our professional community with the most up-to-date, commercially available products and services. PDA would like to thank the 2009 Exhibit Committee for their dedication and efforts in planning successful and valuable exhibitions this year.

PDA Exhibit Advisory Committee

Committee Chair
Patricia Stancati, *Sartorius Group North America*

Exhibitor Representatives
James Bruce, *Applied Biosystems*
Steve Delity, *Rapid Micro Biosystems*
Carol Dellicicchi, *Pall Corporation*
Parsa Famili, *Novatek International*
Mark Fields, *Drumbeat Dimensions*
Marc Glogovsky, *EMD Chemicals, Inc.*
Christine Hilbert, *Remel Inc.*
Kevin McLean, *SGD Glass*
Lawrence Pepper, *Genesis Machinery Products*
Peter Pratt, *Bioscience International*
Debora Rothwell, *ITW Texwipe*
David Shelep, *Accugenix, Inc.*
Jaspreet Sidhu, *Molecular Epidemiology Inc.*
Art Vellutato, Jr., *Veltek Associates, Inc.*
Brent Watkins, *Veltek Associates, Inc.*
Pascal Yvon, *AES Chemunex, Inc.*

PDA Board of Directors and Staff Liaisons
Harold Baseman, *ValSource*
David Hall, *PDA*

Membership and Chapters

2009 Membership Accomplishments

Strengthening Volunteer Focus

In an effort to recognize and reward PDA volunteers and to expand membership participation, in 2009 PDA continued to publish Volunteer Spotlights and has highlighted 45 volunteers to date in the *PDA Letter*. The Volunteer Spotlights in each issue of the *PDA Letter* was created to recognize and reward PDA volunteers. Each issue highlights two volunteers who have substantially contributed to the PDA community. To further highlight volunteers, PDA introduced its first PDA Volunteer Spotlight Movie to members at the *2009 Annual Meeting* Volunteer Luncheon.

Improving Member Benefits

PDA partnered with HighWire Press, a division of Stanford University Libraries, to create a new website dedicated to the *PDA Journal*. This website gives PDA members powerful research capabilities which include "Most read" and "Most cited" listings. In addition, PDA now offers an "Unlimited Journal Archive Access" and "Pay-Per-View - Journal Access" products which allow members to have immediate access to more than ten years of PDA research. These new features will ensure that the *PDA Journal* becomes an even more useful tool for PDA members and subscribers. In 2010, the PDA Membership Department plans to host "Virtual Membership" orientations to educate members on all the benefits they have available to them.

Increasing Membership Recruitment

In 2009 PDA introduced a two-year membership renewal option which has proved to be successful as we have more than 500 members who took advantage of this offer. Due to its success, PDA plans to continue offering this discounted membership option in 2010.

Improving Guidance and Support for Chapter Volunteers

The PDA Membership Team, in partnership with the Chapter Council, introduced the PDA Chapter Handbook, which was approved by the PDA Board of Directors in 2009. The Handbook is provided as a reference for chapter volunteers and includes policies and procedures relevant to running a chapter as well as tips and suggestions for maximizing chapters' success.

Membership and Chapters

PDA Global Chapters and Leaders

ASIA-PACIFIC

Australia Chapter
President: Robert Caunce, *Hospira*
President-elect: Ano Xidias, *PharmOut*
Treasurer: Greg Jordan, *ICS Analytics*
Secretary: Malcolm Tipping, *Synertec*

Japan Chapter
President: Katsuhide Terada, PhD, *Toho University*
Vice President: Shigeo Kojima, PhD, *Pharmaceuticals and Medical Devices Agency*
Treasurer: Yukio Hiyama, PhD, *National Institute of Health Sciences*
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.*

EUROPE

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

Ireland Chapter
President: Coleman Casey, PhD, *University College Cork*
Treasurer: Joan Fitzgerald, *Allergan*
Secretary: Paul A. Louge, *Elan Corporation*

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

Italy Chapter
President: Stefano Maccio, *CTP Technologie di Processo*
President-elect: Claudia Nardini, PhD, *Kedrion Spa*
Treasurer: Dr. Joachim Leube, *Bayer Healthcare Manufacturing S.r.l.*
Secretary: Barbara Sambucco, PhD, *Bristol Myers Squibb*

United Kingdom Chapter
President: Siegfried Schmitt, *PAREXEL Consulting*
Treasurer: John Moys, *Sartorius Stedim Biotech*

NORTH AMERICA

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

Capital Area Chapter
President: Allen Burgenson, *Lonza*
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*
Secretary: Stephen S. Trombetta, *Veltek Associates, Inc.*

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

Midwest Chapter
Acting President: Peter Noverini, *Baxter*
Secretary: Matthew Anderson, *Hospira, Inc.*
Treasurer: Kurt Puterbaugh, *Vetter*

Mountain States Chapter
President: Robert Buchholz, *Global Quality Alliance, LLC*
President-elect: Patricia Brown, *Agilent Technologies*
Treasurer: Nikolas Burlew, *REGULUS Pharmaceutical Consulting*

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: Manuel Melendez, *Amgen, Inc.*
Treasurer: Frederick Fontanez, *GlaxoSmithKline*
Secretary: Gloria Martinez, *Amgen, Inc.*

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 2009—**Georg Roessling**'s fourth year as head of PDA Europe—change, growth and member service continued with fresh 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; **Frederike Mohme (Graeper),** Event Manager; **Astrid Guenther,** Marketing Manager; **Katharina Keisers-Engstfeld,** Event Manager; and **Dirk Stelling,** Manager, Finance and Controlling. **Ailyn Kandora,** Event Manager, joined us in September 2009.

The Place

In 2009 PDA Europe celebrated its third year in permanent office space in the Glienicke (Nordbahn) suburb of Berlin, Germany. The "green" building has ample room for expansion of staff.

Volunteers and Members

In 2009 PDA is pleased to report approximately 2,100 members in Europe and about 2,260 members when Israel is included. This represents a steady increase in membership for the past three years. The top ten countries for membership are shown below (data as of November 30, 2009):

Germany	345
Switzerland	239
UK	232
France	190
Italy	184
Denmark	180
Israel	163
Belgium	143
Sweden	142
Ireland	128

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 to all.

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 from 2009 include:

- **PDA/EMEA Joint Conference:** Building on the successful *2006 PDA/EMEA Joint Conference* in London, and the *2008 PDA/EMEA Joint Conference,* Budapest, the *2009 PDA/EMEA Joint Conference* was held in Berlin, October 13-14. This conference covered three topical areas including Supply Chain Quality; Impact of ICH Q8, Q9 and Q10; and Manufacturing & GMP. The conference was co-chaired by **Katrin Nodop,** with support from **David Cockburn,** both of the EMEA Inspections Sector. The other co-chairs were **Veronique Davoust** and **Regine Leo**. Inspectors on the planning committee included **Vjaceslavs Krauklis,** *State Agency of Medicines, Latvia;* **Karl-Heinz Menges,** *Regierunspraesidium Darmstadt, Germany*; **Annie Rietveld,** *Health Care Inspectorate, the Netherlands*; and **Ian Thrussell,** *MHRA, UK.*
- **Interested Parties Meetings:** PDA was well-represented at the annual EMEA Inspections Sector's Interested Parties Meeting on December 2, 2009, where the latest GMP and inspection issues were discussed in detail. Attending for PDA were **Stephan Roenninger,** *F. Hoffmann LaRoche*; **Martyn Becker,** *MB Associates*; and **Tesh Patel,** *Astellas Pharma Europe*. A report on the meeting was prepared and sent to all PDA members.
- **EMEA/Biologics Working Party:** In mid-2008, a PDA delegation was invited to the EMEA/Biologics Working Party (BWP) to discuss the PDA commentary on the revised EMEA Guideline on the Production and Quality Control of Monoclonal Antibodies. This effort led to a series of scientific interactions with the BWP, and a series of workshops on the manufacture of monoclonal antibodies, the most recent in June 2009 in Munich. This workshop has become an annual event, with the 2010 workshop scheduled in Berlin in June.

PDA Europe

Pharmaceutical Inspection Cooperation Scheme (PIC/S)

It is also a priority for PDA to strengthen our relationship with PIC/S as it grows in geographic size and influence in defining global GMP. In November 2008, PDA conducted, in association with PIC/S, a workshop in Geneva for regulators and industry entitled, "Manufacture of Sterile Medicinal Products; EU/PICS revised GMP Annex 1, New and Possible Uses of Quality Risk Management." The three major goals of the workshop, in priority, were:

- To build a safe and constructive platform for technical discussions between inspectors and industry
- To better interpret and implement the latest revision of EU/PICS revised GMP Annex 1
- To explore the potential uses of QRM in the manufacture of sterile medicines

Registration totalled 96 including 42 inspectors from 26 different countries. Workshop evaluations showed strong value of the workshop for both the industry and regulators, with future collaboration planned for 2010. The PIC/S members of the planning team were:

Leadership & Direction

Jacques Morénas, *Chairman PIC/S & AFSSAPS, France*
Tor Gråberg, *First Deputy Chairman PIC/S & Medical Products Agency, Sweden*

Topic Leaders for Case Studies

Stan O'Neill & Paul Sexton, *Irish Medicines Board*
Lina Ertle, *AFSSAPS, France*
Paul Hargreaves, *MHRA, UK*

Regulatory Commentary/Consultation for 2009

In 2009, PDA members and volunteers helped prepare regulatory comments on the following European and international proposed guidance:

EDQM/European Pharmacopeia

- Pharmeuropa Vol. 21, No.1, January 2009, proposed revisions to Chapter XXXX:2031, "Monoclonal Antibodies for Human Use." PDA comments submitted March 31, 2009.
- Pharmeuropa Vol. 21, No. 1, January 2009, proposed revisions to Chapter 2.6.16, "Test for extraneous agents in biological products," and Chapter 5.2.3, "Cell substrates for the production of biological products." PDA comments submitted March 31, 2009.

European Medicines Agency

- "EU Guidelines to GMP, Draft Annex 13, Manufacture of Investigational Medicinal Products," (11 April 2008). PDA comments submitted January 29, 2009.
- "Guideline on the Use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations, draft" (Doc. Ref. EMEA/CHMP/CVMP/QWP/17760/2009 Rev 1, 16 February 2009). PDA comments submitted August 31, 2009.
- "Concept Paper on Revision of the EU Guideline on Good Distribution Practice (GDP)"; doc EMEA/INS/GMP/42223/2009; 2 March 2009. PDA comments submitted May 27, 2009.
- "Concept Paper on the Implementation of ICH Q10; doc EMEA/INS/GMP/ 34212/2009; 11 March 2009." PDA comments submitted May 27, 2009.
- "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products" (Doc. Ref. EMEA/410/01 – Rev. 4, 21 February 2008). PDA comments submitted June 30, 2009.

Science and Technology Highlights

- The year started with a theme that had a major impact on the European pharmaceutical industry in 2008—EU GMP Annex 1. The PDA France Chapter organized a workshop on the implementation of revised Annex 1 in Lyon, France, with participation from representatives of the French Health Authority (AFSSAPS).
- PDA was once again truly connecting Science, Regulation and People when organizing a conference on Endotoxins. Sure enough, the discussion saw contributions from regulators, academia and industry around hot topics in this field including the use of advanced methods for preparing standard material as well as new testing alternatives, for example MAT.
- The Discussion Forum on the implementation of Rapid Microbiology Methods in Frankfurt, Germany, featured prominent regulators directly answering questions from the participants.
- The PDA Conference on Rapid Microbiology Methods in February 2009 demonstrated the agility of PDA in addressing the needs of its members. Proceedings of this Discussion Forum will be published so other members can share this important information.
- PDA Europe also featured a preview of EFPIA's mock documents on Quality by Design (QbD) for injectables and biotech drug substances during our Workshop on QbD. The workshop presented case studies on the complete or partial use of QbD elements and the relation of those to the ICH Guidelines of the Q8/9/10 series.

PDA Europe

Task Forces, Working Groups, Informal Meetings

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. As an example, the PDA Task Force drafting a technical report illustrating GMP needs when manufacturing Investigational Medicinal Products (clinical supplies) began its work in Europe, but now also includes members representing the US, Japan and India. The Task Force plans to issue a final draft technical report in 2010.

Another PDA Working Group is putting together a draft technical report on Endotoxins, with a draft planned for 2010. European Interest Groups, such as Filtration and Technology Transfer, met face to face to share experiences and define future areas of activity.

In this context PDA is continuing to strengthen its relationships with other science and technology organizations in Europe, such as AEFI, Spain, and R3-Nordic, Scandinavia.

Workshops and Conferences

PDA Europe organized a number of successful technical conferences and workshops in 2009.

2009 PDA Europe Conferences and Workshops

PDA Workshop on Annex 1 EU GMP Guide/Media Fills
January 14 – 15 | Lyon, France

Global Challenges for IMPs
January 28 – 29 | Rome, Italy

Rapid Microbiology Methods: Successful Implementation Strategies
February 3 – 4 | Berlin, Germany

Workshop on Disposables
March 3 – 4 | Munich, Germany

Workshop on FDA Process Validation Guidance
March 9 | Munich, Germany

PDA Europe Update on Pharmaceutical Ingredients Supply Chain
March 10 – 11 | Munich, Germany

2009 PDA Europe Conference on Endotoxins
March 17 – 18 | Paris, France

3rd Workshop on Mycoplasmas
March 24 – 26 | Berlin, Germany

Workshop on Container/Closure Systems
April 29 – 30 | Berlin, Germany

2009 Biopharmaceutical Development and Manufacturing Advanced Therapies and Vaccines
June 16 – 17 | Munich, Germany

2nd Workshop on Monoclonal Antibodies QbD: Science to Submission Approaches
June 25 – 26 | Munich, Germany

PDA Discussion Forum: Implementing Rapid Microbiology Methods
September 21 | Frankfurt, Germany

QBD by Design – Putting Principles into Practice
September 22 – 23 | Frankfurt, Germany

2009 Pharmaceutical Freeze Drying Technology
September 29 – 30 | Frankfurt, Germany

2009 Pharmaceutical Cold Chain Management
October 6 – 7 | Berlin, Germany

2009 PDA/EMEA Joint Conference
October 13 – 14 | Berlin, Germany

Workshop: The Future of Glass as Parenteral Primary Packaging
October 26 | Venice, Italy

2009 The Universe of Pre-filled Syringes & Injection Devices
October 27 – 28 | Venice, Italy

Sterilization Technologies for Pharmaceuticals
November 17 – 18 | Milan, Italy

Validation of Aseptic Processes
December 1 – 2 | Milan, Italy

2009 PDA France Chapter Workshop: Annex 1 to EU GMP Guide
Impact on Fill and Finish Practices
December 10 | Bordeaux, France

PDA Europe

2009 Training Courses – Europe

Compiling and Submitting IMPDs
January 27 | Rome, Italy

Virus Safety Assessment of IMPs
January 27 | Rome, Italy

Microbial Contamination Detected by Rapid Microbiological Methods
February 5 – 6 | Berlin, Germany

Visual Inspection
April 1 – 2 | Berlin, Germany

Freeze Drying Technology
April 1 | Frankfurt, Germany

Container Closure Development
April 28 | Berlin, Germany

Development of Biotech Products and Advanced Therapy Medicinal Products (ATMPs)
June 18 – 19 | Munich, Germany

Tangential Flow Filtration – Yield Improvement – Scale-Up
June 23 –24 | Munich, Germany

Development of a Freeze Drying Process - From Formulation to a Robust Process
October 1 – 2 | Frankfurt, Germany

Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing and Transport Systems
October 8 – 9 | Berlin, Germany

Dedicated Facilities
October 15 | Berlin, Germany

Effective Contractor and Supplier Audit
October 15 – 16 | Berlin, Germany

The Essential of GMP and GMP-Inspections, EU vs. USA
October 15 – 16 | Berlin, Germany

New EU Variations Regulation: Practical Examples
October 16 | Berlin, Germany, Germany

Development of Prefilled Syringes
October 29 – 30 | Venice, Italy

Sterilization Technologies, Today and Tomorrow
November 19 – 20 | Milan, Italy

2009 Interest Group Meetings – Europe

Visual Inspection
March 31 | Berlin, Germany

Freeze Drying Technology
April 2 | Frankfurt, Germany

Prefilled Syringes
May 27 | Berlin, Germany

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.

Feng Chen is the Senior Information Systems Manager for PDA. Feng Chen joined PDA in July 2002 as Information System Engineer and was promoted to Senior Information Systems Manager in June 2008.

Antje Petzholdt is the Office Manager for the PDA Europe office. Petzholdt has been with PDA since November 2006 at our office in Berlin. At the beginning she was involved in all activities, running meetings and helping with members and chapters. Among her duties are registration, contact with members and chapters, and initial contact to PDA Europe (telephone and mail).

Service Appreciation Award

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

Robert Buchholz is currently a Quality Auditor for Becton-Dickinson in Wilson, N.C. He is receiving this award in honor of his contributions to the PDA Mountain States Chapter, as Chapter President. Bob has been a member of the Mountain States PDA Chapter for many years and served as president the past two years. From his experience at companies such as Amgen, Somatogen, Parke-Davis and Monsanto, he has a strong background in auditing, quality assurance, protein purification, fermentation and supervision/management.

Robert Caunce is a Quality Project Manager for Hospira. He is receiving this award in honor of his contributions to the PDA Australian Chapter, as Chapter President. He has been a member of the PDA for eight years and has been on the PDA Australian committee since 2006 and been President since 2007 and now is the past president. He also is an active member of the RAQC, providing regulatory updates for the Australian region. He holds a Bachelor of Science from La Trobe University in Melbourne and is also a certified international auditor.

Louise Johnson is the Vice President of Quality for Aptuit, Inc. She is receiving this award in honor of her contributions to the PDA Board of Directors, as a Director. Louise has enjoyed a long association with PDA and is currently a member of RAQC, the Program Advisory Board and an ongoing member of the PDA/FDA planning committee. In her association with PDA, Louise served on PDA's Board of Directors, was the ex chair of the *2005 PDA/FDA* meeting and a recipient of PDA's Distinguished Service Award in 2006.

Stefan Köhler is currently working at AstraZeneca in Sweden as a director within building management and infrastructure. He is receiving this award in honor of his contributions to the PDA Board of Directors, as a Director. Stefan received his BSc degree in engineering 1987. He has spent 15 years in the pharmaceutical manufacturing field specializing in the areas of HVAC systems, cleanroom design and pharmaceutical utilities.

John Shabushnig, PhD, is a Senior Manager in Pfizer's Global Quality Operations. He is receiving this award in honor of his contributions to the PDA Board of Directors, as Chair from 2008-2009. John is a long-time active member of the PDA. John continues to serve on the Board of Directors, Executive Committee, Strategic Planning Committee and Science Advisory Board and as the leader of the Visual Inspection Interest Group. He also serves on the USP Parenteral Products Industrial Expert Committee (PPIEC) and the Ad hoc Committee on Visual Inspection and is a member of the American Chemical Society.

Fred 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 Fred Simon, a previous PDA Director of Scientific Affairs.

Bruce Eu, Xiaolin Cao, Aylin Vance, Fabian Vega, Robert Schultheis and Zai-Qing Wen
Distribution of Silicone Oil in Prefilled Glass Syringes Probed with Optical and Spectroscopic Methods, Mar/April 2009, 63:149-158.

Bruce Eu is a Principal Engineer in Drug Product & Device Development at Amgen Inc.

Dr. Xiaolin Cao is currently a senior scientist working in the department of formulation and analytical resources of Amgen Inc.

Aylin Vance is an Associate Scientist in Department of Formulation and Analytical Resources at Amgen Inc.

Fabian Vega works at the Instituto Technologico de Morelia, Mexcio.

Robert Schultheis is the Director of Engineering at ZebraSci, Inc.

Dr. Zai-Qing Wen is a 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.

Maik W. Jornitz is Group Vice President Marketing, Sartorius Stedim Biotech Inc. He is receiving this award as Co-Author of *Anatomy of a Pharmaceutical Filtration: Differential Pressures, Flow Rates, Filter Areas, Throughputs and Filter Sizing*.

Theodore H. Meltzer, PhD, is a consultant for Capitola Consulting. He is receiving this award as Co-Author of *Anatomy of a Pharmaceutical Filtration: Differential Pressures, Flow Rates, Filter Areas, Throughputs and Filter Sizing*.

Jack Lysfjord is Principal Consultant for Lysfjord Consulting LLC since 2007. He is receiving this award as Author of *Practical Aseptic Processing, Fill and Finish,* Volume 1 & 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.

Amy Scott-Billman is Vice President, Global Regulatory Strategy, for Immunotherapeutics in GlaxoSmithKline Biologicals. Prior to her 14 years at GSK, Billman spent 8.5 years at FDA/CBER as a reviewer, inspector, manager and policy maker. She is a long-time member of PDA and has made numerous contributions to PDA including: PDA/FDA Conference Committee Chair, PDA Vaccines Conference Committee Co-Chair; RAQC Chair, member of BioAB, TRIAC and two-term member of the Board of Directors.

Peter Rauenbuehler, PhD, is Senior Director in Corporate Quality Product Support at Genentech. He spent the past 22 years at Genentech where he is accountable for Genentech's Quality Control Laboratory Network. For the last 18 years he has been an active member of the West Coast Chapter, serving in positions of Treasurer, President and Chapter Board member. For the past several years Rauenbuehler co-chaired the PDA Chapter Council with Louis Zaczkiewicz from the New England Chapter.

Stephan Rönninger, PhD, is the 'Head of External Relations Europe/Japan' of F. Hoffmann-La Roche Ltd based in Basel, Switzerland. In PDA he acts as co-chair and the European Regional Leader in the Regulatory Affairs and Quality Committee (RAQC). He is one of the founders and steering committee member of the PDA project on Paradigm Change in Manufacturing Operations (PCMO)SM.

Jean-Louise Saubion, PhD, is currently in charge of clinical trials at the Bordeaux University Hospital (France) and teaches pharmacy law. For 30 years he has been the qualified person for a government laboratory and institute specializing in parenterals and other drugs for hospitals and private companies. He is the past president of the PDA France Chapter which he launched ten years ago. He is still active within the chapter organizing meetings in France and Europe.

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.

Barry A. Friedman, PhD, is a Consultant in the Biotechnology, Regulatory Compliance and Aseptic Processing arena. He has more than 30 years of industrial managerial experience in biopharmaceuticals and medical devices to include Quality Control, sterility assurance, microbiological/analytical validations and fermentation technology. He teaches multiple courses for TRI, focusing on environmental monitoring and microbiology, including microbiology of water.

Gordon Personeus Award

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

Susan Schniepp is the Pharmaceutical Quality Director for Antisoma. Schniepp joined PDA in 2000. She has presented at a number of PDA Meetings and participated on a number of Committees including co-Chairing the *2010 PDA/FDA Joint Regulatory Conference* Steering Committee, RAQC, Program Advisory Board, Technical Books Advisory Board and the Membership Committee. In 2007 she was the Recipient of PDA's Distinguished Author Award for the book titled Understanding the United States Pharmacopeia and the National Formulary: Demystifying the Standards-Setting Process. In 2008 Schniepp won PDA's Distinguished Service Award.

Honor Awards

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.

Vince Anicetti has been active as a leader in PDA for many years, serving first as President of his local chapter (the West Coast Chapter) and more recently as a Director and then Chair of the Board of Directors. He has long been a champion of local chapters and worked diligently to increase their visibility and importance within PDA. This has proved to be a significant benefit in connecting with our membership and developing our future leaders. During his term on the Board of Directors, Anicetti played a key role in bringing stability to our Association. He helped to refocus the organization on its core strengths of science and regulation and rebuild a strong financial foundation. These have served us well in subsequent years.

Yoshihito Hashimoto is a Senior Consultant at Chiyoda Corporation, Japan. Hashimoto has been a director of PDA for six years (since 2003). He is one of the four members who established the PDA Japan Chapter in 1991. Since then, Hashimoto has organized the Technology & Education Committee in Japan Chapter for 18 years with Dr. Morikawa from the National Institute of Public Health, and Dr. Hiyama from the National Institute of Health Sciences.

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.

Most know **Ed Fry** as the past President of PDA with service from 1991 to 2002. During his tenure PDA moved from Philadelphia to Bethesda, Md., launched the PDA Training and Research Institute and experienced a period of international growth in membership and chapters. Fry is the author of numerous papers on compliance and regulatory matters published in the *PDA Journal of Pharmaceutical Science and Technology* and elsewhere. He worked for the Food and Drug Administration for 27 years, including assignments as a Field Investigator in New York, Puerto Rico and San Francisco, and Director of Investigations in the Kansas City Region. For the last 11 years of his FDA career he was Director, Division of Manufacturing and Product Quality in the Center for Drug Evaluation and Research.

2009 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.

The Financial Recession Impacts PDA

2009 proved to be a challenging year for PDA. The economic recession which began in 2008 continued into 2009 and forced businesses to restrict travel, having a negative impact on both our conferences and training courses. The Pharmaceutical and Biotech industries, which began a period of rapid consolidation in 2000, continued earnestly in 2009 with the mergers of Pfizer and Wyeth, Merck and Schering-Plough, and Roche and Genentech. These mergers continue to put pressure on our membership as the industry consolidates and eliminates redundant positions.

PDA Staff Deflects Headwinds and Drives Impressive Financial Turnaround

In recognition of these financial challenges PDA staff engaged in the difficult task of finding ways to reduce its cost structure. By August 2009, PDA staff had executed broad cost reductions. Significant reductions were made in administrative, marketing and printing costs as well as personnel.

Despite global revenue decreasing by 13% from 2008, PDA management was successful at reducing its cost structure by 33%. This resulted in a dramatic financial turnaround from a $1.6 million net loss in 2008 to a net surplus of almost $700,000 in 2009.

PDA Financial Reserves Begin to Recover

PDA utilized much of its financial reserves in 2007 and 2008 for capital investments in the new Training and Research Institute in Bethesda, Md., a new Association Management System and launching the *International Pharmaceutical Quality (IPQ)* newsletter. These investments, combined with net income losses in 2008, significantly reduced PDA's financial reserves.

Due to the strong financial performance in 2009, PDA was able to contribute more than $686,548 to the financial reserves. PDA's primary financial goal will be to rebuild the financial reserves back to their target level.

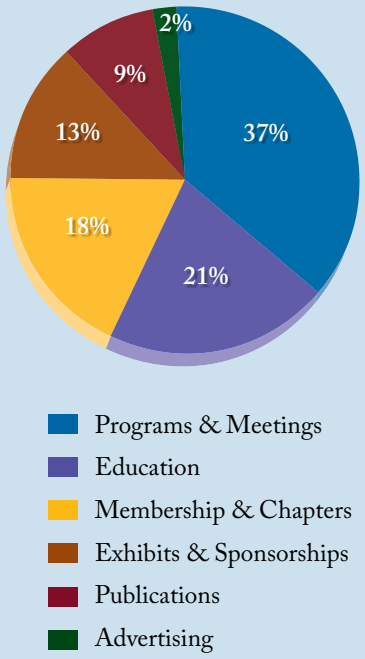
The following is a summary of the financial statements incorporated in the annual audit issued by Tate & Tryon, for the year ending December 31, 2009. The full audit report is available upon request from PDA headquarters.

2009 Annual Report Financial Summary

	2009	2008*
Total Revenues	$ 12,413,948	$ 13,987,476
Total Expenses	$ 11,727,400	$ 15,615,685
Net Revenue Surplus (Deficit)	$ 686,548	$ (1,628,209)
Increase (Decrease) in Reserves	$ 686,548	$ (1,628,209)
Reserves at beginning of year	$ 1,710,497	$ 3,338,706
Reserves at end of year	$ 2,397,045	$ 1,710,497
Reserve ratio (Reserves/Annual Expenses)	20%	11%

** For better year over year comparison, 2008 reported membership revenue includes an $855,875 one time, non-cash journal entry to correct for 2008 and prior year adjustments in deferred membership revenue. Reported unadjusted results are $1,658,760 in membership revenue; $13,131,601 total revenue; ($2,484,084) net deficit. There is no adjustment to cash reserves as this was a non-cash adjustment.*

2009 Revenue Sources



2010 PDA Officers and Board of Directors

Officers

Chair
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Iris D. Rice, Manager, Scientific & Regulatory Affairs

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Dirk Stelling, Manager, Finance and Controlling

PDA Global Headquarters
Bethesda Towers
4350 East West Highway, Suite 200
Bethesda, MD 20814
USA

Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296

PDA Europe
Adalbertstr. 9
16548 Glienicke/Berlin
Germany

Tel: +49 33056 2377-10
Fax: +49 33056 2377-77

PDA Training and Research Institute
Bethesda Towers
4350 East West Highway, Suite 150
Bethesda, MD 20814
USA

Tel: +1 (301) 656-5900 ext. 200
Fax: +1 (240) 482-1659