2006
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. As a nonprofit organization, we are committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of our more than 10,000 members worldwide.

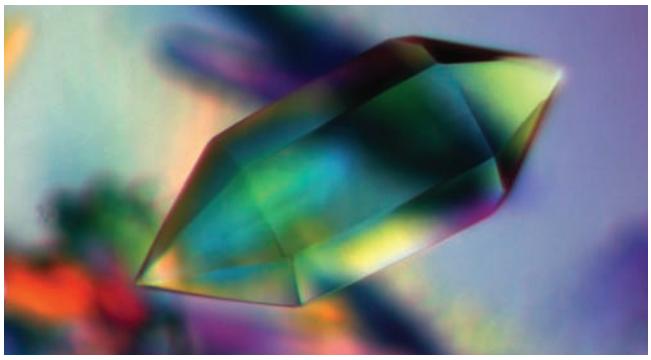
Mission

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*SM 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

2006 PDA/FDA Joint Regulatory Conference



Kineret, IL-1 Ra protein crystal, photo courtesy of Amgen

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Message from the Chair

Chair, PDA Board of Directors
Vincent Anicetti
Genentech, Inc.

2006 was PDA's 60th anniversary, a great accomplishment for any organization. PDA began its anniversary celebration in 2006 at our Annual Meeting in Anaheim, California in April. The celebration continued throughout the year at our *PDA/FDA Joint Regulatory Conference* in Washington, D.C. in September and the first-ever *PDA/EMEA Joint Conference* in London, England in October.

Anniversaries are also a time to reflect, and PDA did that in 2006 with a series of articles on past leaders in the *PDA Letter*. In addition, we also paid homage to the strong scientific contributions our members have made to the industry by recognizing six Outstanding PDA Scientists of the first 60 years. They are: **Kenneth Avis, DSc**, for parenteral manufacturing; **Irving Pflug, PhD**, for heat sterilization; **Theodore Meltzer, PhD,** for membrane separation; **Julius Knapp** for particulate inspection; and the team **Bengt Ljungqvist, PhD** and **Berit Reinmuller, PhD**, for contamination control. Their collective work represents the best examples of scientific and technological innovation and advancement driven by PDA members.

It's a pleasure to tell you of the progress PDA has made on two of the key goals that the Board of Directors outlined at the beginning of 2006. While PDA's purpose is science and education, it is also important that we are a successful, nonprofit business. Managing our finances to maintain a sustainable nonprofit business is a necessary foundation for our ability to advance pharmaceutical science.

One of the goals we established for 2006 was to increase our operating reserves as an organization. PDA does not exist to make money; we are a nonprofit organization. However, it is good sense to operate in the black most of the time and to have a safety net for the times you don't. Operating reserves are that safety net, and most nonprofits are advised to carry six to nine months of reserves for a rainy day. We are currently at five months of reserves and are working diligently towards building to the six to nine month level through the development of solid business plans. I'd like to thank the hard work of PDA President **Bob Myers** and the entire PDA staff in working towards achieving this goal. It's extremely important to the organization for two reasons. First, if you are constantly thinking about the bottom line, you will not look very far into the future. Second, it allows us to take some risks with programs that have great scientific content but may not draw a large audience. I want PDA to be able to pursue its activities based on science and need, not simply the bottom line.

A second goal we set forth in 2006 was the establishment of strong European organization and scientific strategy. Thanks to the efforts of PDA Senior Vice President, **Georg Roessling, PhD**, his staff and the European chapters, we have made tremendous progress in the past year. PDA co-sponsored its first meeting with the European Medicines Agency (EMEA) last year, and we expect to host more than 20 scientific meetings in 2007, with at least one in each of our European chapters. Why the emphasis on Europe? Pharmaceutical development and manufacturing are increasingly subject to regional regulatory requirements and inspectorates. To be effective in providing science-based education and guidance to both industry and regulators, PDA must address policy and practice on a global basis. I hope to use the PDA Europe model for establishing stronger PDA programs and presence in other parts of the globe.

In my final year as chairman of PDA, I have asked the Board of Directors to focus on one additional goal. It is to strengthen our chapter system. As a PDA member who started in the West Coast Chapter and who served as its president, I strongly believe our chapter system is an incredible resource to PDA and its members. While our chapter system is certainly not broken, I believe we can increase our support activities for chapters and fully realize their potential to help our many members who are on limited travel budgets and seeking local networks.

Through the hard work and dedication of many volunteers and staff, PDA has led the advancement of parenteral drugs for more than 60 years. I am sure you are all as proud as I am of the contributions PDA has made to patient safety and educating the professionals who help ensure it. Hopefully the progress we have made in building our organization the past two years will help, in part, to ensure that PDA remains a leader in the advancement of parenteral science for the next 60 years.

Message from the President

President, PDA
Robert Myers
PDA

PDA had another very successful year in 2006, our 60th! The volume of our products and services to the membership increased by 16% compared to the previous year. Over the last two years, our volume has grown by 47%. Next year, our goal is an additional 8% increase in products and services, resulting in over 60% combined growth over 2004 as a base.

This growth means PDA is providing programs, courses, publications and other products and services our members require in order to improve their skills, increase their knowledge and advance their careers. Much of our growth in 2006 came in Europe, where our new staff, led by **Georg Roessling,** met the challenge of providing a valuable line-up of programs throughout the year. The crowning achievement of the year in Europe was the fantastic *PDA/EMEA Joint Conference*—the first of what we anticipate will become an annual event. Over 400 industry professionals turned out in London for courses, exhibits and the conference. Georg and his team, **Jim Lyda** and **Volker Eck,** deserve all the credit for expanding the association's influence and relevance throughout Europe.

In the United States, the annual meeting in Anaheim and the *PDA/FDA Joint Regulatory Conference* in Washington were the largest of many successful meetings and courses. In October, nearly 500 professionals visited Bethesda, Md., to attend PDA's *Universe of Pre-filled Syringes and Injection Devices Forum*—the third and largest conference on this topic we have sponsored to date. Our volunteer members and sponsors provided the resources we needed to provide high-quality programming, with **Wanda Neal-Ballard** (Programs and Meetings) and **Nahid Kiani** (Sales) being responsible for the excellent venues, networking activities and exhibits that accompanied these meetings. The PDA Training and Research Institute (TRI) had another successful year, as well.

Our plan for 2007 includes significantly more programs, meetings and educational opportunities. While many of these events might not be as large as those in 2006 in terms of total attendance, we will have 30 meetings globally, versus 17 in 2006. Many more conferences will be offered in Europe to better serve our growing membership there. Early next year, we will make announcements regarding a number of new programs, so keep checking the *PDA Letter*, the *Connector* and the website.

Throughout 2006, we worked hard to enhance our sterilization and technical report program. Sterilization is one of PDA's core strengths, and Technical Report No. 1: *Validation of Moist Heat Sterilization* is one of the association's most well-known and practical technical publications. The process of revising this nearly 30-year-old document has been a long one, and one of the goals I assigned to Senior Vice President of Scientific and Regulatory Affairs **Rich Levy, PhD,** was to expedite this process and have a new version out in 2007. We made significant progress on the document in 2006 and conducted a number of public outreach sessions to garner a wide breadth of stakeholder input, including that from regulators in Europe and the United States. We published two technical reports in 2006—six since January 2005. We anticipate publishing four or more technical reports in 2007 on practical and relevant topics.

Another exciting initiative approved by the PDA Board in 2006 was the consolidation of TRI and the PDA headquarters in Bethesda. The first stage of the consolidation took place in August, when we moved the headquarters from 3 Metro Center to Bethesda Towers. Plans were developed to build a state-of-the-art training lab, cleanroom and lecture area on the first floor of our new location. We were delighted to work with Vectech Pharmaceutical Consultants, Inc., in designing the facility, as well as other companies, like Fedegari SPA, who pledged support in the form of equipment and supplies. Others will no doubt donate in 2007. We expect the new TRI facility to open in August 2007.

All of these developments made PDA's 60th year special. We worked hard this year to recognize our proud past and those contributors who have helped PDA grow over the years. The excellent feedback we received from the members throughout the year helps us plan for the future needs of our community.

I am looking forward to next year and beyond!

2006 PDA Officers and Board of Directors

Officers

Chair
Vincent Anicetti
Genentech, Inc.

Chair-elect
John Shabushnig, PhD
Pfizer Inc

Secretary
Lisa Skeens, PhD
Baxter Healthcare Corporation

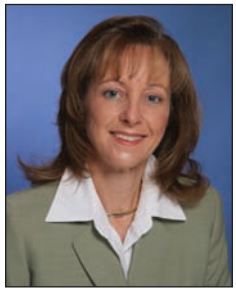
Treasurer
Maik Jornitz
Sartorius Corporation

Immediate Past Chair
Nikki Mehringer
Eli Lilly and Company

Directors

Jennie Allewell
Wyeth Research

Stephen Bellis
IVAX Pharmaceuticals UK



Rebecca Devine, PhD
Regulatory Consultant

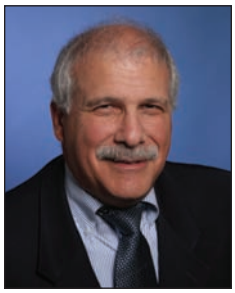
Kathleen Greene
Novartis Pharmaceuticals Corporation

Yoshihito Hashimoto
Chiyoda Corporation

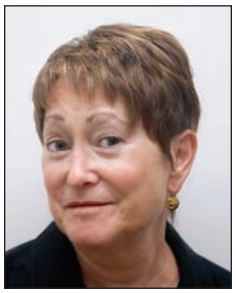
Tim Marten, DPhil
AstraZeneca

Steven Mendivil
Amgen

Amy Scott-Billman
GlaxoSmithKline



Eric Sheinin, PhD
United States Pharmacopeia



Gail Sofer
GE Healthcare

Laura Thoma, PharmD
University of Tennessee College of Pharmacy

Anders Vinther, PhD
CMC Biopharmaceuticals A/S

Scientific and Regulatory Affairs

This year was one of renewal and revitalization for PDA's scientific and regulatory activities. The benefits of adding two key staff in 2005 and the merger of PDA's science and regulatory departments into one cohesive organization under the leadership of **Rich Levy, PhD,** Senior Vice President of Scientific and Regulatory Affairs and **Bob Dana,** Vice President of Quality and Regulatory Affairs, were recognizable in the increasing level of member activities supported by the Department in 2006. The addition of professional resources for project management and technical writing and editing began the process of reinvigorating many of the existing task force teams, and in so doing, accelerated the progress for those task forces. So, 2007 promises to be a noteworthy year for task force deliverables, including meetings and Technical Reports.

In Europe, the addition of **Volker Eck, PhD,** Senior Director of Science and Technology, ensured that manufacturing science in Europe receives additional attention. **Jim Lyda,** Senior Director of Regulatory Affairs, who joined PDA in 2005, continued his focus on the European regulatory scene and contributed to the development of regulatory responses through the Regulatory Affairs Quality Committee (RAQC). The additional presence of PDA staff in Europe has the added value of serving our European membership locally.

To further strengthen the scientific, technological and regulatory content of the *PDA Letter,* the *PDA Letter* staff was linked directly to the Science and Regulatory Affairs staff by reporting into **Rich Levy**.

Science and Technology Overview

Meetings, Conferences and Workshops

One of the main activities of the Science and Regulatory Department is to support the design, development and execution of PDA programs, conferences and workshops. Each of the senior members of the department spent significant time in 2006 representing PDA on the planning committees for each meeting.

2006 was a notable year, as we renewed the PDA Microbiology Meeting, last held in 2001 (*PDA Spring Conference on Modern Pharmaceutical Microbiology*). The goal now is to hold a meeting on this critical science annually.

In addition, PDA hosted a series of four data-gathering/outreach conferences in North America and Europe on the revision of PDA Technical Monograph No. 1, *Validation of Moist Heat Sterilization*. Europe hosted three of the conferences which were held in London, England; Cork, Ireland; and Pavia, Italy. The meetings in Europe ensured European input into the revision of PDA's most critical technical report, which will be published in 2007.

Publications

Technical Reports

No product defines PDA as well as our technical reports. Technical reports are produced by task forces which work under the auspices of the PDA Science Advisory Board (SAB), the Biotechnology Advisory Board (BioAB) and the Audit Guidance Advisory Board (AGAB - formerly Industry Advisory Board). Once an advisory board adopts a technical report, the PDA Board of Directors decides whether it should be published, revised or abandoned. A rigorous PDA peer-review system ensures that PDA technical reports meet the highest scientific standards and are of maximum value to the membership and the industry at large.

In 2006, PDA published the following two technical reports as supplements to the *PDA Journal of Pharmaceutical Science and Technology*, bringing the number of active technical reports in PDA's library to 38:

- TR No. 38: *Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation*
- TR No. 28: *Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals (2006 Revision)*

Of note is the effort which was undertaken to revise PDA's flagship Technical Monograph No. 1 on Moist Heat Sterilization published in 1978. After considerable efforts by many PDA members over an extended period of time, and the production of an all inclusive draft document, the Technical Report Team's scope statement was revised and narrowed by the PDA Board of Directors. A smaller team was engaged to complete the revision. Under the leadership of Rich Levy, considerable progress was made in 2006, including the introduction of an open review process, which included feedback sessions in the United States and Europe, as well as the development of a web-based review tool to enable PDA members to participate in the review process. The result was a new draft and plans for the disposition of material developed by the original task force.

Technical Books

The following PDA members authored or were editors of PDA/Davis Healthcare International Publishing (DHI) books in 2006:

- **Destin LeBlanc,** *Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing*
- **Bengt Ljungqvist** and **Berit Reinmuller,** *Practical Safety Ventilation in Pharmaceutical and Biotech Cleanrooms*
- **Theodore Meltzer, PhD** and **Maik Jornitz,** *Pharmaceutical Filtration: The Management of Organism Removal*
- **Orlando Lopez,** *Computer Infrastructure Qualification for FDA Regulated Industries*

Scientific and Regulatory Affairs

- **Michael Miller,** *Encyclopedia of Rapid Microbiological Methods, Volumes I, II and III*
- **David Nettleton** and **Janet Gough,** *Risk-Based Software Validation: Ten Easy Steps*
- **Susan Schniepp,** *Understanding the United States Pharmacopeia and National Formulary: Demystifying the Standard Setting Process*
- **David Stokes,** *Successfully Validating ERP Systems (and other large, configurable applications)*
- **James Vesper,** *Risk Assessment and Risk Management in the Pharmaceutical Industry, Clear and Simple*

PDA is grateful for the dedication of the Technical Advisory Board, which once again helped PDA target authors who could contribute valuable books to the PDA/DHI library.

The Technical Advisory Board's 2006 members were: **Russell Madsen,** *The Williamsburg Group LLC*; **Jeanne Moldenhauer, PhD,** *Vectech Pharmaceutical Consultants, Inc.*; **Amy Davis,** *Davis Healthcare International Publishing*; **James Vesper,** *LearningPlus, Inc.*; **Carmen Wagner, PhD,** *Strategic Compliance International*; **Siegfried Schmitt, PhD,** *Amersham Health*; **Richard Prince, PhD,** *Richard Prince Associates*; and **Nahid Kiani,** *PDA*.

PDA Journal of Pharmaceutical Science and Technology

PDA recognizes **Lee Kirsch, PhD,** for continuing to provide the membership a scientific journal of the highest quality. In addition, Dr. Kirsch was aided by three regional editors: **Amarjit Singh, PhD,** *Sun Pharmaceuticals Ltd.,* Mumbai, India; **Qineng Ping, PhD,** *China Pharmaceutical University;* and **Sompol Prakongpan, PhD,** *Mahidol University,* Thailand.

PDA also is grateful for the efforts of the Editorial Advisory Board for the *Journal* in 2005, chaired by Dr. Kirsch. Its members include: **Michael Akers, PhD,** *Baxter Pharmaceutical Solutions*; **Frederick Carleton** (ret.); **Patrick DeLuca, PhD,** *University of Kentucky*; **Barry Garfinkle, PhD,** *Merck & Co., Inc.*; **Michael Groves, PhD,** *University of Illinois*; **Joseph Robinson, PhD,** *University of Wisconsin*; and **Theodore Roseman, PhD,** *Baxter Healthcare Corporation*.

Task Forces

The primary focus of Science and Technology in 2006 was the revitalization of the PDA Task Force process. A concerted effort was made to reengage existing Task Forces which had been inactive, and to provide professional project management and technical editing assistance to those Task Forces in need of such assistance. To provide further direction to scientific activities, a Standard Operating Procedure was written for both the Science Advisory Board (SAB) and Biotechnology Advisory Board (BioAB), and is expected to be implemented early in 2007. Efforts to create a *PDA Guide to Authors of Technical Report*s were initiated in 2006, and the guide is expected to be introduced in the third quarter of 2007.

Furthermore, PDA staff, working with the SAB, BioAB and RAQC, generated new ideas and concepts for additional task forces and their associated deliverables.

Advisory Boards

Audit Guidance Advisory Board (AGAB–formerly IAB)

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* (TR-32). The AGAB also monitors auditor qualification and requalification requirements and provides oversight of the SynTegra, LLC Audit Resource Center (ARC) to ensure that: the process remains current with respect to changing technology and regulatory environments; to periodically analyze ARC's registration history, promotional efforts; and to service performance, and furnish ARC with suggestions, if any, for improvement.

The AGAB met six times through teleconferences and had one face-to-face meeting at PDA headquarters in 2006. During the meetings, they reviewed the activities of the ARC, worked on revising their charter and procedures, and determined that the TR-32 model could be used as a model to conduct other types of audits.

Audit Guidance Advisory Board (AGAB)

Chair

Janis Olson, *EduQuest*

Members

Winnie Cappucci, *Bayer HealthCare*
Virginia Corbin, *Waters Corporation*
C. Wells Horton, *Procter & Gamble Pharmaceuticals*
Philip Lofty, *Allergan*
Catherine Luk, *3M Pharmaceuticals and Drug Delivery Systems*
Peter Miller, *Bristol-Myers Squibb*
Thomas Rudzinski, *Pfizer Inc*
Charlie Steiniger, *Sparta Systems, Inc.*
Elien Young, *Novartis Pharmaceuticals Corporation*

ARC Representatives

Tom Menighan, *SynTegra, LLC*
Debbie King, *SynTegra, LLC*

PDA Staff Liaisons

Richard Levy, PhD, *Scientific and Regulatory Affairs*
Gail Sherman, *Education*

Associate/Trainer

Charles Waite, *Process Design Consultants, Inc.*

Scientific and Regulatory Affairs

Biotechnology Advisory Board (BioAB)
To complement the SAB and to further focus PDA's scientific efforts on biotechnology, PDA created the BioAB with 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 became proactive in the identification of scientific/technical/regulatory issues affecting biotech products for which the recognition and reputation of PDA can provide a forum for discussion, with a focus on those scientific/technical areas in biotech that are still rapidly evolving. 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.

In 2006, the BioAB approved the following activities: a Bioburden Survey, a proposal to work with ASTM International to establish standards to characterize small virus filters, and PDA comments on the EMEA draft guidance on *Viral Safety Evaluation of Biotechnological Investigational Medicinal* products.

Scientific Advisory Board (SAB)
In 2006, the SAB approved the following activities and task forces: Validation of Analytical Test Methods, PDA Comments on Annex 1 (with RAQC), an Aseptic Survey, Computer Validation (Scope), Risk Management Survey, Pharmaceutical Water, Media-Fill Incubation Conditions and a Memorandum of Authorization for the *Thai Journal*.

Student Programs

In 2005, the *PDA Journal of Pharmaceutical Science and Technology* launched student programs designed to promote research within the pharmaceutical science and technology field.

The **Annual Graduate Symposium** invites graduate students to submit papers for presentation at the PDA Annual Meeting. The four applicants selected in 2006 were:

- **Saly Romero-Torres,** *Purdue University*
  Freeze-Drying Monitoring Using Non-Invasive Raman Spectroscopy
- **Cindy Hoppe,** *University of Iowa*
  Glucagon Aggregation Characterized by Field-Flow Fractionation
- **Hari Desu,** *University of Tennessee*
  Development of Integrin-Specific Targeted Flourescent Liposomes for Detection of Inflammation in Acute Lung Injury Rat Model
- **Murali Krisna Divi,** *University of Tennessee*
  Kinectics of Fluorescent Labeled Liposomes: Visualization and Quantification

Biotechnology Advisory Board (BioAB)

Co-chairs
John Geigert, PhD, *BioPharmaceutical Quality Solutions*
Gail Sofer, *GE Healthcare*

RAQC Liaison
Rebecca Devine, PhD, *Regulatory Consultant*

Members
Kurt Brorson, PhD, *US FDA*
Christopher Bussineau, PhD, *Cambrex Bio Science*
Norbert Hentschel, PhD, *Boehringer Ingelheim Corporation*
James Kenimer, PhD, *The Biologics Consulting Group*
Peter Levy, *Altus Pharmaceuticals*
Annemarie Moëritz, PhD, *Novartis Pharma AG*
Barbara Potts, PhD, *Genentech, Inc.*
Anurag Rathore, PhD, *Amgen*
Amy Scott-Billman, *GlaxoSmithKline*
Robert Seely, PhD, *RMC Pharmaceutical Solutions Incorporated*

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

Scientific Advisory Board (SAB)

Chair
Martin VanTrieste, *Bayer HealthCare*

Members
Michael Akers, PhD, *Baxter Pharmaceutical Solutions LLC*
Harold Baseman, *Valsource, LLC*
Roger Dabbah, PhD, *US Pharmacopeia*
Jens Eilersen, PhD, *Novo Nordisk A/S*
Don Elinski, *Lachman Consultant Services, Inc.*
Gordon Farquharson, *Bovis Lend Lease Pharmaceutical*
Klaus Haberer, PhD, *Compliance Advice and Services in Microbiology, GmbH*
Lothar Hartmann, PhD, *F. Hoffmann-La Roche Ltd.*
Karl Hofmann, *Bristol-Myers Squibb*
Jeanne Moldenhauer, PhD, *Vectech Pharmaceutical Consultants, Inc.*
John Shabushnig, PhD, *Pfizer Inc*
Gail Sofer, *GE Healthcare*
Lynn Torbeck, *Torbeck and Associates, Inc.*
Brenda Uratani, PhD, CDER, *US FDA*

PDA Staff Liaisons
Richard Levy, PhD, *Scientific and Regulatory Affairs*
Robert Dana, *Quality and Regulatory Affairs*
Volker Eck, PhD, *Science and Technology, PDA Europe*

Scientific and Regulatory Affairs

The **Predoctoral Fellowship Program** provides selected candidates with a stipend to assist them in their research. Five $6,000 stipends were awarded in 2006 to:

- **Janjira Intra, PhD,** *University of Iowa*
  Oral Delivery of FVIII Genes
- **Eunjung Jeon,** *University of Illinois*
  Parenteral Delivery of Peptide Drugs in Sterically Stabilized Phospholipid Micelles: Development of a Prediction Model
- **Saly Romero-Torres,** *Purdue University*
  Freeze-Drying Monitoring Using Non-Invasive Raman Spectroscopy
- **Krystyn Greco,** *University of Connecticut*
  Investigations of the Kinetics of Solution-Mediated Salt Conversion as Function of Hydrodynamics During Dissolution
- **Michael Hanson,** *University of Maryland*
  High-Throughput Bioreactor Validation and Use in Monoclonal Antibody Comparability Studies Utilizing Flobal Gene Expression Data

Additional scholarships were granted to three students from the University of Witwatersrand in Johannesburg, South Africa:

- **Diakanua Nkazi**
  Macromolecular Methotrexate Derivatives with Enhanced Therapeutic Effectiveness
- **Blessing Aderbigbe**
  Polymeric Multi-Drug Conjugages with Carcinostatic Properties
- **Hembe Mukaya**
  Polymeric Platinum Coordination Compounds in the Chemotherapy of Cancerous Diseases

PDA recognizes the work of the *Journal's* lead editor, **Lee Kirsch, PhD,** *University of Iowa,* for his efforts in 2005 to launch these student programs.

Interest Groups and Leaders

NORTH AMERICA INTEREST GROUPS

- **Biopharmaceutical Sciences**
  Biotechnology: Jill Myers, PhD, *BioPro Consulting, Inc.*
  Lyophilization: Edward Trappler, *Lyophilization Technology*
  Vaccines: Frank Kohn, PhD, *FSK Associates, Inc.*
- **Laboratory and Medical Sciences**
  Analytical Labs/Stability: Rafik Bishara, PhD, *Eli Lilly and Company (ret.)*
  Microbiology/Environmental Monitoring: Jeanne Moldenhauer, PhD, *Vectech Pharmaceutical Consultants, Inc.*
  Visual Inspection of Parenterals: John Shabushnig, PhD, *Pfizer Inc*
- **Manufacturing Sciences**
  Facilities and Engineering: Christopher Smalley, PhD, *Wyeth*
  Filtration: Russell Madsen, *The Williamsburg Group*
  Pharmaceutical Water Systems: Theodore Meltzer, PhD, *Capitola Consulting Company*
  Sterile Processing: Richard Johnson, *Fort Dodge Animal Health*
- **Pharmaceutical Development**
  Clinical Trial Materials: Vince Mathews, *Eli Lilly and Company*
  Combination Products: Michael Gross, PhD, *Chimera Consulting*
  Packaging Science: Edward Smith, PhD, *Wyeth*
  Process Validation: Harold Baseman, *ValSource, LLC*
- **Quality Systems and Regulatory Affairs**
  Inspection Trends/Regulatory Affairs: Robert Dana, *PDA*
  Quality Systems: David Mayorga, *Global Quality Assurance, LLC*

EUROPE INTEREST GROUPS

- **Biotechnology**
  Roland Guenther, PhD, *Novartis*
- **Visual Inspection of Parenterals**
  Markus Lankers, PhD, *rap.ID*
- **Facilities and Engineering**
  Phillippe Gomez, *Sartorius Corporation*
- **Filtration**
  Roger Seiler, *Sartorius Corporation*
- **Pre-filled Syringes and Injection Devices**
  Thomas Schoenknecht, *Gerresheimer*
- **Nanotechnology**
  D.F. Chowdhury, *Aphton Corporation*
- **Technology Transfer**
  Volker Eck, PhD, *PDA*
  Zdenka Mrvova, *Zentiva*

Scientific and Regulatory Affairs

Interest Groups

PDA's Interest Groups continued to be active in several areas in 2006. The linkages to the various PDA Advisory Boards provided new opportunities for Interest Group members to contribute to PDA Task Forces and Program Committees, and in Europe, Interest Groups planned and held focused meetings on subjects such as pre-filled syringes and visual inspections. Nonetheless, as 2006 drew to a close, the need to consider how the Interest Groups could continue to grow and flourish was becoming obvious, and planning for a restage of the Interest Group program began.

Quality and Regulatory Affairs Overview

The Regulatory Affairs and Quality Committee (RAQC) continued to be active in evaluating the global regulatory arena and developing PDA positions and comments on various regulatory proposals. RAQC and its member volunteer Task Forces submitted comments on the following regulatory proposals in 2006:

- Direct and Proposed Final Rules: *Current Good Manufacturing Practice Regulation and Investigational New Drugs* (US FDA)
- Draft Guidance for Industry: *INDs – Approaches to Complying with CGMP During Phase 1* (US FDA)
- GMP Annex 1: Proposals for Amendment to the Environmental Classification Table for Particles and Associated Text, Amendments to Section 42 Concerning Acceptance Criteria for Media Simulations, Amendment to Section 52 Concerning Bio-burden Monitoring and Additional Guidance in Section 88 on the Sealing of Vials. {European Commission and European Medicines Agency (EMEA)}
- *Draft Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products* (EMEA)
- Draft Guidance for Industry: *Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases.* (US FDA)
- EMEA Reflection Paper on Process Analytical Technology (PAT)

RAQC underwent a leadership change in 2006 when Amy Scott's term as RAQC Chair, from 2004 until 2006, expired. In July 2006, **Zena Kaufman** assumed the position of RAQC Chair, a role she will continue to fill until June 2008. In addition, new representatives were named as liaisons for the Asia-Pacific, Europe and North American regions.

As global regulatory thinking continued to evolve, moving to a Quality Systems approach, a new Task Force was formed under the leadership of RAQC. This Task Force was engaged in the background planning process to prepare to develop PDA comments on the expected International Conference on Harmonization (ICH) Quality Systems Guidance when it is released for general comment, most likely sometime in mid 2007.

Regulatory Affairs and Quality Control Committee (RAQC)

Chair
Zena Kaufman, *Abbott Laboratories*

Asia-Pacific Regional Leader
Michihisa Inokuma, PhD, *Denka Seiken*

Asia-Pacific Representative
Junko Sasaki, *Sumitomo Pharmaceuticals Co., Ltd.*

Europe Regional Representative
Hiltrud Horn, *Horn Pharmaceutical Consultants*

North America Representative
John Towns, PhD, *Eli Lilly and Company*

Members
Stephen J. Bellis, *CMC Biopharmaceuticals*
Rebecca Devine, PhD, *Regulatory Consultant*
Don Elinski, *Lachman Consultant Services, Inc.*
Amy Giertych, *Baxter*
Roland Guenther, *Novartis*
Louise Johnson, *Vertex Pharmaceuticals Incorporated*
Brian Matthews, PhD, *Alcon Laboratories, Inc.*
Steven Mendivil, *Amgen*
Stephan Rönninger, PhD, *F. Hoffmann-La Roche*
Stefano Salmieri, *Farmabios*
Amy Scott-Billman, *GlaxoSmithKline*
John Towns, PhD, *Eli Lilly and Company*
Barbara Zinck, *Cambrex Bio Science*

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

Rich Levy, PhD, Sr. Vice President, Scientific and Regulatory Affairs, PDA

PDA Training and Research Institute

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

In 2006, PDA TRI reached new heights in our training programs, both in the United States and abroad. The Institute increased the number of registrants trained in its laboratory and lecture courses by close to 20% over 2005. Attendance at both the *PDA/EMEA Joint Conference* courses in London, England and the *PDA Asia-Pacific Congress* courses in Tokyo, Japan surpassed expectations, with more than 100 registrants at each of these training programs.

In conjunction with Purdue University and Eli Lilly and Company, PDA TRI developed two training sessions for 40 staff members from the Kazakhstan Ministry of Health and the National Center for the Assessment of Drugs, Items for Medical Purposes and Medical Equipment. The first training program in May 2006 covered GMPs, regulatory compliance issues and laboratory procedures. The second program in October focused on medical devices and included a visit to a medical device manufacturer to learn about research, development and manufacturing of these product types. All training materials and instruction, delivered via simultaneous translation, were presented in Russian.

In April, the Board of Directors voted to consolidate PDA TRI and PDA headquarters in Bethesda, Md. Shortly thereafter, PDA staff began working with architects from Vectech Pharmaceutical Consultants, Inc. to design a state-of-the-art training facility that will simulate real-life manufacturing and testing areas in today's pharmaceutical and biopharmaceutical plants. The new facility will include a vastly updated and improved aseptic filling area, two microbiology laboratories, a biotech/Clean-in-Process (CIP) laboratory and two lecture classrooms. By the end of 2006, PDA TRI was in discussion with a number of companies for donations and support and had received a commitment from Fedegari Autoclavi SPA for a new pass-through autoclave.

Because of PDA's focus on *Career-long Learning*SM, PDA TRI continually evaluates and updates its curriculum. New courses are added to provide the most current information in both laboratory and lecture settings. The Institute takes seriously the recommendations of students and instructors when developing training programs for stakeholders in the pharmaceutical and biopharmaceutical communities.

Hands-On Laboratory Training

PDA TRI distinguishes itself with hands-on laboratory training. The Institute's popular ten-day *Aseptic Processing Training Program* ran four times in 2006, selling out each session. The *Practical Aspects of Aseptic Processing* course, based on the first week of the *Aseptic Processing Training Program,* was conducted twice in Basel, Switzerland.

State-of-the-art environmental monitoring software and equipment were installed at PDA TRI in 2006, which served as great resources for the *Aseptic Processing, Environmental Monitoring Database and Trending Technologies* and *Pharmaceutical and Biopharmaceutical Microbiology 101* courses.

New laboratory courses offered in 2006 included a three-day course, *Environmental Monitoring Database and Trending Technologies*; and a two-day course, *Cross-Flow Filtration Evaluations, Scaling and Practical Protein Purification and Separations*. The Institute conducted 15 laboratory courses in addition to our ever-popular *Aseptic Processing Training Program* during the year.

Lecture-Based Training

In 2006, PDA TRI began offering lecture courses with PDA focus meetings in addition to the association's signature meetings. The first such effort was the *Visual Inspection Conference* course in Europe, which attracted 16 students.

Lecture courses were held in conjunction with the following PDA conferences: *PDA 2006 Annual Meeting* in Anaheim, Calif.; *PDA Biennial Training Conference* in Philadelphia, Pa.; *PDA/FDA Joint Regulatory Conference* in Washington, D.C.; *PDA/EMEA Joint Conference* in London, England; and *PDA Asia-Pacific Congress* in Tokyo, Japan.

In addition to providing lecture-based training in the TRI facility in Baltimore, Md., training programs were also offered in the following cities: Lake Tahoe, Nev.; Research Triangle Park, N.C.; St. Louis, Mo.; and Boston, Mass. Staff worked closely with the PDA Chapter leadership to develop the content for many of these lecture series.

The Institute thanks those companies that lent or donated high-quality supplies and equipment (see page 11 for a complete list of 2006 contributors) and also thanks the expert faculty who spent considerable hours developing and conducting training programs (see page 12).

PDA Training and Research Institute

PDA Supporters

- **Equipment**
  Ascotec
  Becton Dickinson and Company
  bioMérieux
  Bioscience International
  Compliance Software Solutions Corporation
  Novatek, Inc.
  PAREXEL
  Sartorius Corporation
  Veltek Associates Inc.

- **Service**
  Atlantic Technical Systems
  Biolog
  bioMérieux
  Biotest
  GE Ionics
  GE Kaye
  Hach Ultra Analytics
  Lyophilization Technology, Inc.
  Mesa Laboratories, Inc.
  Particle Measuring Systems
  R2S Technologies
  Sartorius Corporation
  Vectech Pharmaceutical Consultants, Inc.
  Veltek Associates Inc.

- **Supplies**
  Alcan Packaging
  Becton Dickinson and Company
  Biolog
  bioMérieux
  Cardinal Health
  Charter Medical
  Cole-Parmer
  Contec, Inc.
  Decon Laboratories, Inc.
  EMD Chemicals
  GE Ionics
  General Econopak, Inc.
  ITW Texwipe
  Kimberly-Clark Corporation
  Millipore Corporation
  PALL Life Sciences
  Perfex Corporation
  Prudential Cleanroom Services
  Raven Labs
  Remel Inc.
  Sartorius Corporation
  Steris
  Veltek Associates Inc.
  West Pharmaceutical Services, Inc.

PDA Training and Research Institute offers hands-on laboratory training

PDA Training and Research Institute

2006 Faculty

Michael Akers, PhD, *Baxter*
Diane Alexander, *US FDA*
Marina Angelozzi, *Novatek*
Naomi Baer, *Millipore Corporation*
Eddie Ballance, *Eisai Inc.*
Chris Bartlett, *Biolog*
Harold Baseman, *ValSource, LLC*
Karen Bossert, PhD, *Lyophilization Technology, Inc.*
John Brecker, *Fleet Laboratories*
Carolyn Broughton, PhD, *Genentech, Inc.*
Anthony Cannon, *Lyophilization Technology, Inc.*
Colman Casey, PhD, *University College Cork*
Bikash Chatterjee, *Pharmatech Associates, Inc.*
David Chesney, *PAREXEL*
Joanne Cochran, *JWC Associates*
Sidney Cohen, MD, PhD, *Cordis Corporation*
Andrew Collentro, *Water Consulting Specialists*
Nathan Conover, *PathWise*
Jim Cooper, PharmD, *Endotoxin Consulting Services*
David Crance, *Particle Measuring Systems*
Anthony Cundell, PhD, *Consultant*
Cheryl Custard, *Sanofi Pasteur*
John Daley, *Cordis Corporation*
Robert Dana, *PDA*
Trevor Deeks, PhD, *Emergent BioSolutions*
Rebecca Devine, PhD, *Consultant*
Anne Marie Dixon, *Cleanroom Management Associates, Inc.*
Donald Drew, *Shire*
Mark Elengold, *FDA Strategies*
Judith Eycleshymer, *Millipore Corporation*
J. Kirby Farrington, PhD, *Eli Lilly and Company*
Robert Ferer, *Vectech Pharmaceutical Consultants, Inc.*
Mike Finger, *Tunnell Consulting*
Renee Galkin, *RB Galkin and Associates*
David Gallup, EdD, *Training and Communications Group, Inc.*
Wayne Garafola, *Sartorius*
Grace Gardner, *Aseptic Solutions*
Karen Ginsbury, *PCI Pharmaceutical Consulting, Israel*
Daniel Gold, PhD, *D.H. Gold Associates, Inc.*
Jeremy Green, PhD, *Pharmatech Associates*
Joe Habarta, PhD, *J. Habarta Consulting*
Klaus Haberer, PhD, *Compliance Advice and Services in Microbiology*
J. Kyle Hendricks, *Cognate BioServices, Inc.*
Mike Herd, *Bioquell*
Peter Holman, *Genentech, Inc.*
Lisa Hornback, *Hornback Consulting*
Sylvia Isaacson, *Millipore Corporation*
Maik Jornitz, *Sartorius Corporation*
Scott Knutson, *Steris*
Peter Koger, *Veltek Associates, Inc.*
Frank Kopelson, *SuperArray Bioscience Corporation*
Mary Kremzner, PharmD, *US FDA*
David Lansky, PhD, *Lansky Consulting*
Destin LeBlanc, *Cleaning Validation Technologies*
Samuel Lebowitz, *Electrol Specialties Co.*
Elaine Lehecka Pratt, *Lehecka Pratt Associates, Inc.*
George Levinson, *Compliance Software Solutions Corporation*
Richard Levy, PhD, *PDA*
John Lindsay, *Aseptic Solutions Inc.*
Mike Long, *AstraZeneca*
John Ludwig, PhD, *Pfizer Inc*
Jason Mangler, *GE Ionics*
David Manley, *bioMérieux*
David Matsuhiro, *Cleanroom Compliance*
Paul McKim, *PAREXEL*
Theodore Meltzer, PhD, *Capitola Consulting Company*
Gregory Meyer, *Compliance Media*
Jeanne Moldenhauer, PhD, *Vectech Pharmaceutical Consultants, Inc.*
Charles Montague, *Scientia Solutions Limited*
Antonio Moreira, PhD, *SPI*
Petra Motzkau, *Sartorius Corporation*
Robert Myers, *PDA*
Russ Nyberg, *Raven Labs*
James O'Donnell, *Cordis Corporation*
Ken Peterson, *PathWise*
Tom Pringle, *SCA Packaging*
Maureen Reagan Mueller, *Quality Sytems Consulting*
Tom Reidy, *Syntonix Pharmaceuticals, Inc.*
Sally Rundquist, *Seiberling Associates*
Dale Seiberling, *Electrol Specialties Company*
Gail Sherman, *PDA*
Gregg Sherman, *PAREXEL*
John Shirtz, *Baxter*
Steve Stachelski, *PAREXEL*
Ed Sybert, *SPA USA*
Scott Sutton, PhD, *Vectech Pharmaceutical Consultants, Inc.*
Ronald Tetzlaff, PhD, *PAREXEL*
Lynn Torbeck, *Torbeck & Associates*
Ed Trappler, *Lyophilization Technology, Inc.*
Mark Trotter, *Sartorius Corporation*
Barbara van der Schalie, *SAIC*
Art Vellutato, *Veltek Associates, Inc.*
James Vesper, *LearningPlus, Inc.*
Charles Waite, *ProDesCon*
Tom Weaver, *Weaver Consulting, Inc.*
Les Weinstein, *US FDA*
Cheryl Wendel, *Cordis Corporation*
Leonard Wilson, *US FDA*
Steve Wiseman, *Amgen*
Jonathan Yourkin, *GE Ionics*
Jeffrey Yuen, *Jeff Yuen and Associates*

Programs and Meetings

Face-to-face discussion and networking continue to be the most valuable means of communication for PDA members.

In 2006, PDA complemented its two signature meetings in the United States—the *PDA Annual Meeting* and the *PDA/FDA Joint Regulatory Conference*—with more than ten focus meetings on topics of interest to the PDA membership. The success of these programs exceeded budget by 4%, and we hosted more than 6,500 conference participants. As a result of the strong demand for some of our focus meetings, programs such as PDA's 1st *Annual Global Conference on Pharmaceutical Microbiology* and *The Universe of Pre-filled Syringes and Injection Devices Forum* will now be held annually in both the United States and Europe.

The most successful US focus meeting of 2006 was *The Universe of Pre-filled Syringes and Injection Devices Forum*, held October 23-25 in Bethesda, Md., which exceeded goals for both conference participants and exhibitions.

PDA Europe meetings were also successful in 2006. The first *PDA/EMEA Joint Conference* was held in 2006 in London, England and was a success by all measures. In addition, PDA hosted six focus meetings across Europe.

2006 PDA Conferences, Forums and Workshops

PDA/USP Joint Symposium
February 7-9 | Hyderabad, India

2006 PDA Pharmaceutical Anti-Counterfeiting Forum
March 2-3 | Bethesda, Md. US

2006 PDA Pharmaceutical Cold Chain Management Conference
March 27-28 | Bethesda, Md. US

PDA 2006 Annual Meeting
April 24-28 | Anaheim, Calif. US

Workshop on Biotech Process Validation
April 26-27 | Anaheim, Calif. US

2006 PDA Biennial Training Conference
May 8-12 | Philadelphia, Pa. US

Process Understanding and the Future of Validation
May 23-24 | Barcelona, Spain

Status of Moist Heat Sterilization: Revisions to PDA Technical Report No. 1
June 7 | Cork, Ireland

Status of Moist Heat Sterilization: Revisions to PDA Technical Report No. 1
June 8 | London, England

PDA Training Workshop 2006: FDA's Aseptic Processing Final Guidance
June 19-20 | Prague, Czech Republic

Status of Moist Heat Sterilization: Revisions to PDA Technical Report No. 1
June 27 | Pavia, Italy

Status of Moist Heat Sterilization: Revisions to PDA Technical Report No. 1
July 27 | Washington, D.C. US

2006 PDA/FDA Joint Regulatory Conference
September 11-15 | Washington, D.C. US

Meeting the Aseptic Processing cGMPs in the United States and European Union
September 13 | Washington, D.C. US

2006 PDA Visual Inspection Forum
September 26-27 | Berlin, Germany

PDA European Pharmaceutical Cold Chain Management Conference: A Global Approach to Harmonization
October 5-6 | Berlin, Germany

PQRI Workshop on Excipient Testing and Control Strategies
October 10-11 | Bethesda, Md. US

2006 PDA/EMEA Joint Conference
October 12-13 | London, England

The Universe of Pre-filled Syringes and Injection Devices
October 23-25 | Bethesda, Md. US

PDA's 1st Annual Global Conference on Pharmaceutical Microbiology
October 30-November 1 | Bethesda, Md. USA

2006 PDA Asia-Pacific Congress
November 13-15 | Tokyo, Japan

Process Validation of Protein API Manufacturing
December 5-6 | Berlin, Germany

2006 ISPE/PDA Joint Workshop: Challenges of Implementing ICH Q8 and Q9 – Practical Applications
December 6-7 | Washington, D.C. US

Application of New Techniques of Sterilization for the Pharmaceutical Industry and Contaminant Removal
December 6-7 | Paris, France

Programs and Meetings

Exhibitions

Exhibitions continued to provide valuable supplemental information for many of PDA's conference attendees in 2006. The most successful exhibitions were held in conjunction with the *PDA 2006 Annual Meeting,* the *2006 PDA/FDA Joint Regulatory Conference,* the *PDA/EMEA Joint Conference* and *The Universe of Pre-filled Syringes and Injection Devices Forum*.

Our largest exhibition was at the *PDA 2006 Annual Meeting* in Anaheim, Calif., where more than 100 vendors exhibited their products and services. The success continued at the *2006 PDA/FDA Joint Regulatory Conference*, which attracted more than 60 exhibitors and numerous sponsors.

Although not as large as PDA's signature conferences, the PDA focus meetings were just as appealing to exhibitors and sponsors. One focus meeting of note was the *The Universe of Pre-filled Syringes Forum*, which debuted in the United States for the first time last year. The exhibition was a big success, with more than 30 vendors participating.

PDA exhibitions continue to provide community access to the products and services needed most. PDA would like to thank the Exhibit Advisory Committee for their dedication and effort in planning successful and valuable exhibitions in 2006.

Web Seminars

In addition to face-to-face communication and networking as valuable means of communication for pharmaceutical and biopharmaceutical professionals taking part in PDA activities, PDA offers another successful way to deliver information to its members. Cost-effective Web Seminars and live simulcasting provide an alternative method of learning for those professionals seeking information from the convenience of their home or office.

PDA Web Seminars combine technological innovation with quality educational content and exceptional member service to give members the best learning experience available online. With the help of WebEx technology, PDA is able to bring a wealth of lectures covering a wide range of topics that are specific, educational, interactive and cost-effective anywhere participants have internet access.

In addition, PDA continues to provide a vast selection of On-Demand Web Seminars. These recordings of previous Web Seminars and select conference sessions feature synched audio and presentation, including Q&A. PDA On-Demand Web Seminars allow customers to schedule learning at their convenience.

PDA Program Advisory Board

Chair

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Michael Eakins, PhD, *Eakins & Associates*
Kathleen Greene, *Novartis*
Lothar Hartmann, PhD, *F. Hoffmann-La Roche*
Louise Johnson, *Vertex Pharmaceuticals Incorporated*
Maik Jornitz, *Sartorius Corporation*
Jerold Martin, *Pall Life Science*
Michael Miller, PhD, *Eli Lilly and Company*
Jeanne Moldenhauer, PhD, *Vectech Pharmaceutical Consultants, Inc.*
Cindy Rockel, *Millipore Corporation*
Susan Schniepp, *Hospira, Inc.*
Laura Thoma, PhD, *University of Tennessee*
Joyce Winters, *Wyeth*
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PDA Staff Liaisons

Robert Dana, *Quality and Regulatory Affairs*
Richard Levy, PhD, *Scientific and Regulatory Affairs*
Wanda Neal-Ballard, *Programs and Registration Services*
Gail Sherman, *Education*

PDA Exhibit Advisory Committee

Committee Chair

Art Vellutato, *Veltek Associates, Inc.*

Exhibitor Representatives

Carol Dellicicchi, *Pall Corporation*
Mark Fields, *Drumbeat Dimensions, Inc.*
Doug Hostetler, *Lancaster Laboratories, Inc.*
Carol Julich, *Biotest*
Lawrence Pepper, *Genesis Packaging Technologies*
Steve Roon, *Advanced Analytical*
Debora Rothwell, *ITW Texwipe*
David Shelep, *Accugenix Inc.*
Patricia Stancati, *Sartorius Corporation*

Board Representative

Maik Jornitz, *Sartorius Corporation*

Programs and Meetings

PDA 2006 Web Seminars

Environmental Monitoring in Pharmaceutical Manufacturing
J. Kirby Farrington, PhD (RM/SM), Research Advisor-Microbiology and Sterility Assurance, *Eli Lilly and Company*
January 12, 2006

FDA Records Requirements and Enforcement Practices
Kevin Martin, Vice President, Business Development, *CimQuest*
January 19, 2006

Quality Agreements: A Pre-cooperative Agreement to Corroborate "What We Said and Avoid He Said – She Said"
Barbara Zinck, Senior Director, Corporate Compliance, *Cambrex Corporation*
January 26, 2006

Integrated Risk Assessment for Compendial Water Systems
William Collentro, Senior Consultant, *Water Consulting Associates*
February 9, 2006

The Role of PDA's Technical Report No. 39 in Navigating Today's Cold Chain Regulatory Climate
Rafik Bishara, PhD, Director, Quality Knowledge Mgmt./ Technical Support, *Eli Lilly and Company (ret.),* and **Bob Seevers, PhD,** Principal Regulatory Scientist, *Eli Lilly and Company*
February 14, 2006

The Change Control Challenge
Peter Smith, Principal Consultant, *PAREXEL,* and **Mark Lynch,** Senior Compliance Consultant, *PAREXEL*
February 28, 2006

Technical Training as an Integral Part of an Aseptic Operation Quality System
Eddie Ballance, Senior Manager, *Eisai*
March 9, 2006

The Future is Disposable – Benefits, Limitations and Challenges of Single-Use Technologies
Jerold Martin, Senior Vice President, Global Technology Director, *Pall Life Sciences*
March 16, 2006

CAPA Systems: Common System Failures and Measuring Performance
Frances Akelewicz, President, *Practical Solutions*
March 28, 2006

Executing Parametric Release for Moist Heat Sterilization
Tom Berger, PhD, Manager, Microbiology Pharmaceutical R&D, *Hospira, Inc.*, and **Kevin Trupp,** Engineering Manager, *Hospira, Inc.*
April 6, 2006

Applying Lean and Six Sigma in Bulk Biopharmaceutical Production
Daniel Zajac, Process Excellence Leader, *Centorcor*
April 13, 2006

A Project Manager's Perspective – Keeping the Critical Path on Track
Paul Kaladas, PhD, Senior Principal, Cell Line and Analytical Development, *Laureate Pharma, Inc.*
April 28, 2006

Streamlining Success: Supply Chain Management
Karen Ginsbury, President, *PCI Pharmaceutical Consulting Israel*
May 3, 2006

Best Practices: Process Validation of Protein Manufacturing – Technical Report No. 42
Chris Bussineau, PhD, Vice President and General Manger, *Cambrex Corporation,* and **Robert Seely, PhD,** Process Biochemist, Validation, *RMC Pharmaceutical Solutions Incorporated*
May 10, 2006

Validation of Bioreactors in a Biological Manufacturing Facility
Charles Lankford, CEO, *PharmaSys,* and **Brett Yates,** *PharmaSys*
May 17, 2006

Preventing OOS Deficiencies: Guide to OOS Regulations
Lynn Torbeck, President, *Torbeck & Associates*
May 24, 2006

Developing an Effective and Functional Operator Qualification Program on a Shoestring Budget
Diana Watson, Senior Training Associate, *Eli Lilly and Company*
June 14, 2006

Microbiology for Non-Microbiologists: Essential Microbiology in Pharmaceutical Manufacture
Suraj Baloda, PhD, Corporate Quality Manager, *Millipore*
June 28, 2006

Programs and Meetings

PDA 2006 Web Seminars (continued)

SME Trainer Certification: An Effective and Efficient Training Process Using Your Organization's Technical Resources as Certified OJT Instructors – An AstraZeneca Case Study
Rick Elmer, Senior Training Manager, *AstraZeneca*
July 13, 2006

Validation Issues with the Harmonized Microbial Limits Tests
Scott Sutton, PhD, *Vectech Pharmaceutical Consultants, Inc.*
August 10, 2006

Risk Management for FDA-Regulated Industries
Ken Peterson, *PathWise*
August 17, 2006

How to Kick-Start Your CAPA Process
Ken Peterson, *PathWise*
August 31, 2006

Effective Integration of Engineering, Construction and Validation
David Calvaresi, President, *ValSource, LLC*
September 6, 2006

Managing the Microbiological Quality of Pharmaceutical Excipients
Anthony Cundell, PhD, Director, Pharmaceutical Science, *Schering-Plough Corporation*
September 19, 2006

Design Space: DoE Basics for PAT and ICH Q8
Lynn Torbeck, President, *Torbeck & Associates*
October 4, 2006

Inspection Readiness: Cool, Calm and Collected
Kirsten Vadheim, PhD, Principal Consultant, *BioCompliance*
November 8, 2006

Developing and Validating Cleaning and Disinfection Programs for Controlled Environments
Art Vellutato, *Veltek Associates, Inc.*
November 15, 2006

Investigation of Sterility Test Failures
Scott Sutton, PhD, *Vectech Pharmaceutical Consultants, Inc.*
November 21, 2006

A Critical Evaluation of Compendial Water Systems Exhibiting the Absence of Bacteria
William Collentro, *Water Consulting Specialists, Inc.*
November 30, 2006

Disinfectant Qualification
Robert Guardino, Director, Microbiology, *AAI Pharma*
December 14, 2006

PDA also recorded sessions from *The Universe of Pre-filled Syringes and Injection Device*s (October 2006) and from the *2006 PDA/FDA Joint Regulatory Conference* (September 2006).

Membership and Chapters

2006 Membership Accomplishments

Strengthening Membership Focus

In 2006, PDA recognized the importance of strengthening the membership department. Structurally, the Sales Department was united with the Membership Department to form the Membership Services and Sales Department.

To reinforce this reorganization, PDA staffed the Membership Services and Sales Department with qualified and driven employees. In 2006, the new membership team significantly improved membership services by delivering important information, such as renewal notices and publications, in a timely manner. The membership team also improved direct communication between PDA and members with increased phone calls, emails and surveys.

Membership Database Cleanup

In 2006, the Membership Services and Sales Department made it a priority to eliminate duplicate records by implementing the membership database cleanup initiative. This project started at the end of 2006 and will continue through 2007. The goal is to increase the quality of customer service provided to PDA members by ensuring that they receive PDA communication and by eliminating duplicate information.

Global Outreach

To achieve PDA's vision of being the foremost global provider of science, technology and regulatory information and education, global participation is critical. The PDA Membership Services and Sales Department recognized this cornerstone of PDA and strived for global outreach in 2006. PDA is now represented in 71 countries in the following regions worldwide:

Africa
Egypt, Nigeria, South Africa, Tunisia, Zimbabwe

Asia-Pacific
Australia, Bangladesh, China, Hong Kong, India, Indonesia, Japan, Kazakhstan, Malaysia, New Zealand, Pakistan, Singapore, South Korea, Taiwan, Thailand, Vietnam

Caribbean, Central and South America
Argentina, Brazil, Colombia, Costa Rica, Dominican Republic, Peru, Uruguay, Venezuela

Europe
Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom

Middle East
Cyprus, Iran, Israel, Jordan, Saudi Arabia, Syria, Turkey, United Arab Emirates

North America
Canada, Mexico, Puerto Rico, United States

2006 Chapter Accomplishments

Chapter Council Co-Chairs

During the *PDA 2006 Annual Meeting*, the Chapter Council introduced new Chapter Leader positions: the Chapter Council Co-chairs. The Chapter Council Co-chairs are responsible for scheduling all Chapter Council meetings and representing all Chapter leaders when decisions need to be made quickly. In addition, this position reviews and recommends all proposed policy changes and new policies, while providing feedback from a Chapter leader standpoint. **Peter Rauenbuehler, PhD,** and **Louis Zaczkiewicz,** who were already Chapter officers, graciously agreed to co-chair the Chapter Council. This newly appointed position has a two-year term limit.

Chapter Handbook

The development of a new Chapter Handbook started in 2006, with the goal of compiling all critical documents Chapter leaders need to successfully run their respective chapters. This document will be reviewed by the PDA Board of Directors and will be available in 2007.

Europe Chapters

At the end of 2006, PDA Europe was operating with the following chapters: Central Europe, France, Ireland, Israel, Italy, Prague and the United Kingdom.

Membership and Chapters

PDA Global Chapters and Leaders

ASIA-PACIFIC

Australia Chapter
President: Anna Corke, *Medical Developments International*
President-elect: Vincent Chung, *CSL*
Treasurer: Caspar Graham, *SeerPharma*
Secretary: Malcolm Tipping, *Synertec*

India Chapter
President: Darshan Makhey, *Mayne Pharma*

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

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

Southeast Asia Chapter
President: Kanneganti Prasad, PhD, *Pfizer Inc*

Taiwan Chapter
President: Tuan-Tuan Su

EUROPE

Central Europe Chapter
President: Andreas Wenng, PhD, *Chemgineering*

France Chapter
President: Jean Louis Saubion, PhD, *UFCH-BP*
Treasurer: Jean-Luc Clavelin, *Eli Lilly and Company*

Ireland Chapter
President: Frank Hallinan, PhD, *Wyeth*
Treasurer: Joan Fitzgerald, *Allergan*

Israel Chapter
President: Sigalit Portnoy, PhD, *Taro Pharmaceutical Industries Ltd.*

Italy Chapter
President: Gabriele Gori, PhD, *Bausch & Lomb*
Treasurer: Volker Eck, PhD, *Nerviano Medical Sciences*

Prague Chapter
President: Zdenka Mrvova, *Zentiva*

United Kingdom Chapter
President: Frank Talbot, *FT Pharmaceutical Services*
Treasurer: John Moys, *Sartorius Corporation*

NORTH AMERICA

Canada Chapter
President: Patrick Bronsard, *SNC-Lavalin Pharma Inc.*
President-elect: Jacques Pilon, *RD Service/Nicram*
Treasurer: Vagiha Hussain, *SNC-Lavalin Pharma Inc.*
Secretary: Arun Malaviya, *Bimeda-MTC Animal Health*

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

Delaware Valley Chapter
President: Arthur Vellutato, *Veltek Associates, Inc.*
Treasurer: Marlene Raschiatore, *Wyeth*
Secretary: Stephen S. Trombetta, *Veltek Associates, Inc.*

Metro Chapter
President: Nate Manco, *ECO Animal Health*
President-elect: Naomi Baer, *Millipore Corporation*
Treasurer: Xiaoming Wang, *Imclone Systems Incorporated*
Secretary: Nancy Tomoney, *CSSC, Inc.*

Midwest Chapter
President: Madhu Ahluwalia, *cGxP*
President-elect: Peter Noverini, *Baxter*
Treasurer: Kurt Puterbaugh, *Vetter Pharma*
Secretary: Matthew Anderson, *Hospira, Inc.*

Mountain State Chapter
President: Sara Hendricks, *Commissioning Agents, Inc.*
Treasurer: Sheri Glaub, PhD, *Glaub Consulting Services*

New England Chapter
President: Myron Dittmer, *MFD & Associates*
President-elect: Louis Zaczkiewicz, *Hyaluron Contract Manufacturing*
Treasurer: Russell Morrison, *Commissioning Agents, Inc.*
Secretary: Melissa Smith, *MJ Quality Solutions*

Puerto Rico Chapter
President: Manuel Melendez, *Amgen*
President-elect: Evelyn Marchany, *Schering-Plough*
Treasurer: Frederick Fontanez, *GlaxoSmithKline*
Secretary: Gloria Martinez, *Amgen*

Southeast Chapter
President: Patrick Sabourin, *Clarkston Consulting*
President-elect: Michele Creech, *Talecris Biotherapeutics*
Treasurer: Bruce Craven, *BE&K Engineering of North Carolina, Inc.*
Secretary: Beth Meinig, *Integrated Compliance Consulting*

Southern California Chapter
President: Saeed Tafreshi, *Intelitec Corporation*
President-elect: Kenneth Cairns, II, *Irvine Analytical Laboratories*
Treasurer: Gregory Burnham, *Millipore Corporation*

West Coast Chapter
President: Peter Rauenbuehler, PhD, *Genentech, Inc.*
President-elect: John Ferreira, *Banziger Systems*
Treasurer: Michael Place, *Bayer*
Secretary: Kristina Nordhoff, *Genentech, Inc.*

PDA Europe

The People

Big changes and steps forward were the hallmarks of PDA's operations in Europe in 2006. The year started with the appointment of **Georg Roessling, PhD,** formerly of Schering AG, Berlin, to the position of Senior Vice President for PDA Europe. Roessling has been an active PDA volunteer and Board member for more than 15 years while with Schering and, in 1996, was one of the founders of the PDA European Chapter based in Basel, Switzerland.

By the end of 2006, the PDA staff in Europe consisted of three people in addition to Roessling: **James Lyda,** Senior Director of Regulatory Affairs; **Volker Eck, PhD,** Senior Director, Science and Technology; and **Antje Petzholdt,** Administration and Membership.

The PDA Europe team is ready to support our members in 2007 (from left): Volker Eck, Frederike Graeper, James Lyda, Astrid Guenther, Antje Petzholdt and Georg Roessling

The Place

In late 2006, PDA celebrated the founding of its first permanent office space in the Glienicke suburb of Berlin, Germany. The new office is located in a beautiful area and has ample room for future expansion of the staff.

The Impact – Regulator Relations

PDA continued its tradition of a positive, constructive relationship with regulators and health authorities in a number of ways, including direct commentary on proposed requirements and collaborative activities. Some highlights are:

Commentary on Proposed Regulatory Rules or Guidance

Sterile Products: PDA offered commentary on the draft revisions of EU-GMP Annex 1, *Sterile Medicinal Products*. The comments centered around seven critical issues: cleanroom and device classification, validation of aseptic processing, bioburden testing, capping of vials, capping in Grade A, Grade A zone monitoring and clean-up times for cleanrooms.

EMEA Reflection Paper on PAT: PDA provided its view on the EMEA Reflection Paper on PAT. The document focuses on Process Analytical Technology; however, it also includes Quality by Design, Design Space, Design of Experiments, Quality Risk Management, Process Capability and Real-Time Release. PDA offered to co-sponsor a one- or two-day workshop with EMEA in 2007, structured on the draft reflection paper. The outcome would be the next revision of the paper and more useful guidance for everyone.

Particulates in Parenterals: PDA offered comments to the European Pharmacopoeia regarding a revised monograph on particulate contamination with sub-visible particles in 100-ml preparations. Three important issues were raised: relevance to patient risk, harmonization with other pharmacopoeias and the impact on the market supply.

European Medicines Agency

A priority of the expanded staff in Europe is to build a business-like and collaborative relationship with the European authorities, especially the EMEA. Highlights from 2006 include:

PDA/EMEA Joint Conference: Culminating a year's planning, the first *PDA/EMEA Joint Conference* was held in London, England, October 12-13, 2006. With a theme of *Understanding the European Environment,* the conference was a success by all measures, demonstrating the level of interest in the European GMP situation. Informative presentations were given to a full-capacity audience, one-third of whom were from outside the European Union. The conference will be repeated in February 2008 in Budapest, Hungary, with the theme, *European GMP: Current Issues and Future Developments.*

EMEA Interested Parties Meetings: PDA participated in the EMEA Interested Parties Meetings in June 2006 (all topics) and December 2006 (Annex 1), with reports to the membership on current developments.

Pharmaceutical Inspection Cooperation Scheme (PIC/S)

PDA was one of five associations to attend the first PIC/S industry forum in Geneva, Switzerland, in November 2006. Following the forum, PDA wrote a series of articles for the *PDA Letter* highlighting the information from the forum, as well as the impact of future FDA membership in PIC/S. PDA anticipates one or more joint training opportunities with PIC/S in 2007 and/or 2008.

Workshops and Conferences

PDA Europe organized a number of successful technical conferences in 2006. See the Programs and Meetings section for a total listing.

Honor Awards

Frederick J. Carleton Award

Presented as a tribute to lifetime contributor, past President, Executive Director and Honorary Member Frederick J. Carleton, this award is designated for a past or present Board member whose services on the Board are determined by his/her peers as worthy of such recognition.

Stephanie Gray, is currently the Director of Corporate Compliance at Boston Scientific. She served as a Board member from 1998 to 2003, and was elected Secretary and served in that office and on the Executive Committee during 2004 and 2005.

Gray brought valuable and very unique experience to the PDA Board from her work in the government and in the industry, including serving as a member of the US government's negotiating team for the Mutual Recognition Agreement (MRA) with the European Union and on the ICH Expert Working Group to harmonize GMPs for active pharmaceutical ingredients, Q7A. This experience along with her thoughtful, global perspective has provided invaluable guidance to PDA and contributed to its success during her tenure and beyond.

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.

Harold Baseman is the Principal and Chief Operating Officer for ValSource, LLC. He has more than 29 years of diverse experience in the pharmaceutical, biotechnology and medical device industries. Baseman received this award for his numerous contributions to PDA during the last 25 years including participation on the PDA Science Advisory Board, Co-chair of the Risk Management for Aseptic Processing Task Force, Co-chair of Technical Report No. 22 revision team, Leader of the Process Validation Interest Group, TRI Faculty member and frequent presenter at PDA meetings.

Jerold Martin is Senior Vice President, Scientific Affairs for Pall Life Sciences and has enthusiastically participated in PDA for almost 15 years. His distinguished service at PDA includes being a contributing member of the Strategic Planning and Program Advisory Boards and numerous Annual Meeting and other Program Planning Committees. He was also Chairman of the 1999 Annual Meeting and has been a frequent speaker, Task Force and Interest Group member, and co-author of several PDA Technical Reports related to aseptic processing and filtration.

Gabriele Gori, PhD, is currently QA/QC Director of the Italian Plant of Bausch & Lomb. He is a founding member of the PDA Italy Chapter, serving two terms as Chapter Secretary and as Chapter President since 2005. His distinguished service consists of significant contributions in organizing several international conferences and other events. He has been instrumental in keeping the Italian Chapter active and has involved PDA in training the Italian Inspectorate.

James P. Agalloco Award

The James P. Agalloco Award is presented annually to the PDA 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.

Lynn Torbeck is President of Torbeck & Associates, specializing in applied statistics. He has been in the pharmaceutical industry since 1975 and is an author and editor.

Torbeck received this award for his dedication to excellence in training and support of TRI. He has been a TRI instructor for many years, providing high quality training and consistently receiving strong ratings from his students for his skill as an instructor as well as for the content of his programs.

Frederick D. Simon Award

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

Brian Meyer, PhD and **Diego Vargas**
Impact of Tubing Material on the Failure of Product-Specific Bubble Points of Sterilizing-Grade Filters, Vol. 60, No. 4, July-August 2006

Brian Meyer is a Research Fellow in the Department of Biologics and Vaccines, Pharmaceutical Research and Development at Merck Research Laboratories. He leads a group which focuses on understanding the impact of materials and processes on therapeutic proteins.

Diego Vargas is a Senior Engineer in Vaccine Technology and Engineering at Merck. He is responsible for technical support for the Pneumovax® 23 sterile formulation.

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.

Destin LeBlanc
Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing

Destin LeBlanc consults in the area of cleaning validation at Cleaning Validation Technologies. He previously worked with Steris for over 20 years, primarily in product development and technical service for cleaning and antimicrobial applications. LeBlanc is the author of two books on cleaning validation and maintains a website, which is a resource for professionals in cleaning.

Theodore Meltzer, PhD and Maik Jornitz
Filtration: The Management of Organism Removal

Theodore Meltzer is a private consultant to the pharmaceutical and semiconductor industries, dealing with fine filtration applications and with high-purity water concerns. He serves as a reviewer for the *PDA Journal of Pharmaceutical Science and Technology, Pharmaceutical Technology* and the *American Pharmaceutical Review.* Meltzer is an honorary member of PDA and heads its Pharmaceutical Water Interest Group.

Maik Jornitz is Vice President, Product Management at Sartorius. With more than 20 years of experience in separation technologies, he is co-editor and co-author of seven books, five book chapters and numerous scientific papers. He is Treasurer of PDA and editorial Board member of multiple scientific publications.

Susan Schniepp
Understanding The United States Pharmacopeia and National Formulary: Demystifying The Standard Setting Process

Susan Schniepp has more than 24 years of experience in quality assurance for both the food and pharmaceutical industries and is currently the Manager of Specifications and Test Methods for Hospira. She was Founder and Chairman of the Midwest Compendial Discussion Group and founded and co-chaired the Western Compendial Discussion Group. She has also authored several articles on compendial matters.

PDA Chapter Volunteer Award

The Chapter Volunteer Award recognizes the contributions of PDA members who are active at the Chapter level. The award is a special way to acknowledge the extra effort put forth by Chapter volunteers.

Mary Carver, Senior Manager, Microbiology, *Eisai Inc.* — Southeast Chapter

Jong-Kuk Kim, Senior Manager, *Pall Korea* — Korea Chapter

Leonard Mestrandrea, PhD, Senior Science Advisor, *Pfizer Inc* — Metro Chapter

Claudio Puglisi, Production, *S.I.F.I.* — Italy Chapter

Traute Ryan, Senior Scientist, *Merck & Co. Inc.* — Delaware Valley Chapter

Mark Staples, PhD, Vice President, Pharmaceutical Technology, *MicroCHIPS Inc.* — New England Chapter

Kikoo Tejwani, Vice President of Quality/Regulatory Compliance, *B. Braun Medical Inc.* — Southern California Chapter

Amy Twitty, Business Manager, *RMC Pharmaceutical Solutions Incorporated* — Mountain States Chapter

President's Award

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

Janny Chua is Manager, Product Operations, at PDA and is responsible for publication sales. She has always worked independently and with much enthusiasm, taking the initiative to ensure high quality delivery of PDA publications and subscription services. Chua is a hard worker and received this award for her exceptional sales performance in 2006, increasing publication sales by 35% over the previous year.

Ludy Yo is the Web Development Manager at PDA. She joined PDA in 2005 as Assistant Web Manager and was promoted to Web Development Manager in the spring of 2006. She received this award for her role in the development and design of PDA's new website, which was successfully launched in December 2006.

Maik Jornitz and Theodore Meltzer, PhD

Honor Awards Committee Chair Jennie Allewell with PDA Board of Directors Chair, Vincent Anicetti

Financial Report

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

2006 proved to be another financially successful year for PDA. The Association increased revenue over the prior year by 16%, or $1,535,000, and increased reserves by $111,159 to $4,710,496. During 2006, PDA's net assets increased by $800,000, 13% on that recorded at the end of 2005. At the end of 2006, the reserve ratio stood at 43%.

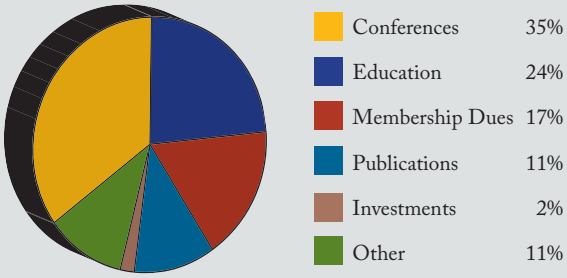
The primary drivers for this success stem from record attendance at flagship conferences, including the *PDA/FDA Joint Regulatory Conference*, the *PDA Annual Meeting*, the *PDA/EMEA Joint Conference* and *The Universe of Pre-filled Syringes and Injection Devices Forum*. In addition to popular lecture series, a demand for superior training continued most notably in the areas of aseptic processing, cleaning validation and sterilization, and pharmaceuticals and biopharmaceutical microbiology methods. Strong support from vendors for the PDA Training and Research Institute also contributed to the successful year.

The following is a summary of the financial statements incorporated in the annual audit issued by Councilor, Buchanan & Mitchell, P.C., for the year ended December 31, 2006. The full financial statements and notes are available upon request from PDA headquarters.

PDA net reserves at the end of 2006, which consist of cash, certificates of deposit and bonds, increased $111,159 verses year-end 2005. Our investments, short-term certificates of deposit and high-grade corporate bonds, are conservative and appropriate for a nonprofit association.

2006 PDA/FDA Joint Regulatory Conference

2006 Income Sources



Financial Summary

	2006 Actual	2005 Actual
Total revenues	$ 11,094,000	$ 9,559,000
Total expenses	10,966,000	9,346,474
Excess revenues over expenses from operations	128,000	212,526
Unrealized gains (losses) on investment	-	(165,434)
Increase (decrease) in net reserves	111,159	71,581
Net reserves at beginning of year	4,599,337	4,527,756
Net reserves at end of year	4,710,496	4,599,337
Reserve ratio (net/reserves/annual expenses)	43.0%	49.2%

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Robert Dana, Vice President, Quality and Regulatory Affairs

Iris Rice, Coordinator, Scientific and Regulatory Affairs

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