PDA[SM]

Parenteral Drug Association

Connecting People, Science and Regulation[SM]

2005 ANNUAL REPORT

www.pda.org

2005

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.

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

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MESSAGE FROM THE CHAIR

Chair
Nikki V. Mehringer
Eli Lilly and Company

I have been honored to serve as Chair of PDA for the last two years. My tenure as Chair coincided with the development of a number of exciting opportunities and challenges for the pharmaceutical and biopharmaceutical industries, and also for PDA. Members of industry and regulatory agencies across the globe have diligently worked together to develop a new vision of manufacturing excellence for the 21st Century, to develop and enable the implementation of innovative technologies, and to better understand the realities and needs of the global marketplace. We at PDA have risen to meet the multitude of challenges these forces have created. Our programming, training courses and publications have never been better. Now, as I join the long and distinguished list of Past Chairs, I'd like to reflect on some of the highlights of my time as PDA's Chair.

No area of PDA activity is more important to the membership than the strong scientific contributions our members make to the industry. In 2005, four member-volunteer task forces saw the tactile result of their hard work with the publication of PDA Technical Reports on cold chain management, sterilizing filtration of gases, virus filtration and validation of protein manufacture. Other task forces projects concluded with Board of Director approval and will publish in 2006, including a technical report on post-approval changes for sterile solutions.

During my time as Chair, the PDA Board of Directors undertook a major initiative to engage members in developing the strategy, and the supporting goals and actions, for the Association over the next three years. The process began with a comprehensive "members' needs" survey. A committee of members representing the varied interests and backgrounds of the PDA membership developed a revised Strategic Plan. The return to our traditional identity—the Parenteral Drug Association—resulted from this process. In addition, PDA adopted a revised Mission (page 1) and Vision (page 3) to more accurately reflect our activities and the contributions of our members. All of these changes will keep PDA committed to meeting member needs now and in the future within the framework of our dynamic industry.

Increasing opportunities for membership participation and leadership has been a primary focus of the Board of Directors over the last two years. In 2005, three new PDA Advisory Boards began functioning—the Biopharmaceutical Advisory Board, the Training and Research Institute Advisory Board and the Programs Advisory Board. These three groups join the Science Advisory Board and the Regulatory Affairs and Quality Committee to form the top tier of membership input, just below the Board of Directors. Members of these committees provide direction to PDA's professional staff and recommendations to the Board of Directors that shape PDA's activities. In addition, the structure supporting PDA Interest Groups was strengthened with the formation of an Interest Group Steering Committee. We also formed a Membership Editorial Committee for the *PDA Letter*, which is working with PDA staff to generate membership contributions to the publication.

PDA's role in *Connecting People, Science and Regulation*℠ is another valued service we provide our members. Our tradition of working with regulatory authorities began in the 1960's and has only grown stronger through the decades. I am pleased that PDA and the European Medicines Agency (EMEA) reached agreement in 2005 for the first PDA/EMEA Joint Conference, scheduled for October 2006. The efforts to create this event reflect: PDA's efforts to enhance the value of membership to our European colleagues; the recognition PDA's members receive worldwide as leaders in the industry; and the importance of having a forum to gather and share ideas.

In the United States, the PDA/FDA Joint Regulatory Conference was again the best example of PDA providing a platform for dialogue with regulatory agencies. This conference has become the most anticipated annual regulatory meeting in the industry, and I'm proud to have presided over the two best attended to date, with 2005's record attendance of over 1200 professionals (for the conference, exhibits and TRI courses) surpassing 2004's record of more than 1000.

PDA also continued its program to help health authorities prepare their inspectorates for the challenges of the 21st Century. In 2005, PDA provided training to 44 representatives of the Kazakhstan Ministry of Health and National Center for Assessment of Drugs, Items for Medical Purposes and Medical Equipment.

As I leave the position of Chair, I'd like to thank the members of PDA for giving me the opportunity to serve as Chair and for continually volunteering to lead and participate in the task forces, committees and programs that create the work that distinguishes PDA. I'd also like to express my thanks and admiration to the members of the Board of Directors who have worked with great thoughtfulness and dedication to the mission of PDA. Finally, I'd like to thank our fine professional staff for their constant support and willingness to go above and beyond to deliver high quality products and services for the members. I am confident the Parenteral Drug Association is poised for continued success as we find new and exciting ways to connect people, science and regulation.

MESSAGE FROM THE PRESIDENT

President
Robert Myers
PDA

Before I discuss PDA's 2005 accomplishments, I would like to thank Nikki Mehringer for her dedicated service to our Association as PDA's Chair during the past two years. During her term from 2004 to 2005, there was significant progress in many areas, especially in renewing our focus on pharmaceutical science, technology and education. The development of a new Strategic Plan with several new and significant initiatives provides a roadmap for PDA's future. Returning to the original emphasis on Parenteral Drug Association and the new vision developed by PDA's Strategic Planning Committee has been extremely helpful in clarifying our identity and stating the purpose of our organization.

In 2005 we increased our delivery of goods and services and grew by 24%. This allowed PDA to achieve its 2005 budget and make the planned contributions to our reserves. Our plans for 2006 call for another 24% growth. Most of this will be in Europe where we have established a more significant presence with a new Senior Vice President of PDA Europe, Georg Roessling, PhD. Jim Lyda also joined our European team in 2005 and the Board of Directors has approved a significant investment in Europe to build our presence there. We expect the PDA/EMEA Joint Conference, our first, to be held in October 2006 to become an annual event of significant importance to the European pharmaceutical community. As we are growing, we are becoming more global by building stronger programs outside North America.

One other activity in 2005 that signifies our global significance was the training of 44 members of the Kazakhstan Inspectorate. This training is planned to bring the level of expertise in Kazakhstan to a level where they may establish their own regulatory agency. Gail Sherman, Vice President of Education/Director of TRI, led the effort, and it is a credit to the global reputation of the PDA that we were selected to conduct this important three-year program of training. A significant challenge was a requirement to conduct the entire program in Russian. It was a great success based on the feedback from the participants and their desire to continue the training.

Organizationally, we significantly strengthened our senior leadership with the addition of Rich Levy, PhD, as Senior Vice President Scientific and Regulatory Affairs. He is an outstanding scientist and has many years of experience in PDA, including several years on the PDA Board and as an officer of our organization. Another longtime member and former board member, Bob Dana, reports to Dr. Levy as our new Vice President of Quality and Regulatory Affairs. These two gentlemen bring enormous credibility to our staff and have made our organization much more effective in only the first few months of service. They have increased our support of PDA's technical publications with four new technical reports and eight new books co-published with Davis International Publishing. In 2006 they will continue this effort and also focus on servicing our Chapters.

PDA is working to increase the value of membership and implementing a new initiative to support the Chapters. This will be a focus for 2006. Our Chapters are an important aspect of the PDA experience and there will be increased attention from our central office in Bethesda. We also established career placement activity for our members. We introduced live and virtual career fairs and are building on this successful initiative in 2006. We expect this to grow and become a fixture of our Annual Meeting and the PDA/FDA Joint Regulatory Conference.

Finally, I would like to thank the PDA Board and all the volunteers and members for the strong support in my first few months in 2005. We had a successful year and have a new infrastructure in place to build on in 2006. It is obvious that we in the Parenteral Drug Association have a huge opportunity to contribute in many ways to the improved quality of pharmaceutical manufacturing, quality control and compliance with the various regulations. We have the ability and an obligation to capitalize on that opportunity.

PDA VISION

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

2005 PDA OFFICERS AND BOARD OF DIRECTORS

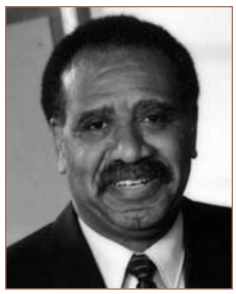
OFFICERS

Chair
Nikki V. Mehringer
Eli Lilly and Company

Chair-elect
Richard V. Levy, PhD
PAREXEL Consulting

Secretary
Stephanie R.Gray
GlaxoSmithKline, ret.

Treasurer
Georg L. Roessling, PhD
Schering AG



Immediate Past Chair
Floyd Benjamin
Keystone Pharmaceuticals, Inc.

DIRECTORS

Jennie Allewell
Wyeth Research

Vincent R. Anicetti
Genentech, Inc.

Rebecca A. Devine, PhD
Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals Corporation

Yoshihito Hashimoto
Chiyoda Corporation

Maik W. Jornitz
Sartorius Corporation

Tim R. Marten, PhD
AstraZeneca

John G. Shabushnig, PhD
Pfizer Inc

Eric Sheinin, PhD
United States Pharmacopeia

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Laura Thoma, PharmD
University of Tennessee
College of Pharmacy

Anders Vinther, PhD
CMC Biopharmaceuticals A/S

SCIENTIFIC AND REGULATORY AFFAIRS

2005 was a year of accomplishment and challenge for PDA's science activities. The challenges, posed by the departure of key staff, were heavily outweighed by our many accomplishments. None was more significant than the merger of PDA's science and regulatory departments into one cohesive organization, under the leadership of PDA's new Vice President for Scientific and Regulatory Affairs. PDA also successfully published four new technical reports, launched a new membership advisory board, co-published eight new technical books, enhanced the value and effectiveness of the Interest Groups, and inaugurated the new *PDA Journal of Pharmaceutical Science and Technology* Student Programs.

The New Scientific and Regulatory Affairs Department

With the departure of former Science and Technology Vice President George Robertson, PhD (rejoined industry) and Quality and Regulatory Affairs Vice President Vicki Dedrick (retired), PDA made the decision to merge the two departments, reflecting the interconnectedness of our science and regulatory activities. Longtime PDA member and former board member and chair-elect Richard Levy, PhD, was chosen to head this new Scientific and Regulatory Affairs Department as the PDA Senior Vice President. Another long-time member and former board member, Bob Dana, was selected to report to Dr. Levy as PDA's new Vice President of Quality and Regulatory Affairs. With this new leadership structure in place, the newly created department will be better positioned to help PDA members continue to disseminate valuable technical information to the industry and review and comment on relevant regulatory guidances and regulations.

Technical Reports

No PDA product defines the Association as well as our technical reports. Technical reports are produced by volunteer task forces which work under the auspices of the PDA Science Advisory Board (SAB) and the new Biotechnology Advisory Board (BioAB). Once an advisory board adopts a technical report, the PDA Board of Directors decides whether it should be published, revised or abandoned. This 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 2005, PDA published the following four technical reports as supplements to the *PDA Journal of Pharmaceutical Science and Technology*, increasing the number of active technical reports in PDA's library to 38:

- TR No. 39: *Cold Chain Guidance for Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment*
- TR No. 40: *Sterilizing Filtration of Gases*
- TR No. 41: *Virus Filtration*
- TR No. 42: *Process Validation Protein Manufacturing*

SAB ROSTER

Co-Chairs

Richard Johnson
Abbott Laboratories

Martin VanTrieste
Amgen

Members

Michael J. Akers, PhD
Baxter Pharmaceutical Solutions LLC

Harold Baseman
Valsource, LLP

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Volker Eck, PhD
Nerviano Medical Science S.r.L.

Jens H. Eilersen, PhD
Novo Nordisk A/S

Don E. Elinski
Lachman Consultant Services, Inc.

Gordon J. Farquharson
Bovis Lend Lease Pharmaceuticals

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

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

Karl L. Hofmann
Bristol-Myers Squibb

Jeanne E. Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

John G. Shabushnig, PhD
Pfizer Inc

Gail Sofer
GE Healthcare

Lynn D. Torbeck
Torbeck and Associates, Inc.

Brenda W. Uratani, PhD
CDER, U.S. FDA

PDA Staff Liaisons

Richard V. Levy, PhD
Scientific and Regulatory Affairs

Robert L. Dana
Regulatory Affairs

SCIENTIFIC AND REGULATORY AFFAIRS 2005

In addition, the PDA Board of Directors approved Technical Report No. 38: *Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation* in 2005; it will be published by the end of first quarter 2006. Furthermore, the SAB approved the formation of eight new task forces in 2005:

- Virus Preparation Standardization Task Force
- Virus Spike Task Force
- Technical Report #22 Revision Task Force
- Risk Management Task Force
- Process Validation Task Force
- Depth Filter Task Force
- Biotechnology Bioburden Survey Task Force
- Glass Defects Task Force

Biotechnology Advisory Board

To complement the SAB and to further focus PDA's scientific efforts on biotechnology, PDA created the Biotechnology Advisory Board (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 refers the issue to the Regulatory Affairs and Quality Control Committee (RAQC) or SAB for action.

The BioAB is intended to be 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 rapidly evolving. The BioAB also serves to support the activities of PDA's SAB and Regulatory Affairs and Quality Committee (RAQC) by, for example, providing insight into regulatory documents and technical reports related to biopharmaceuticals. In 2005, BioAB initiated an expert review of TR#42, which had previously been approved by the SAB.

Technical Books

PDA members contributed a wealth of knowledge to the industry in 2005 with the publication of eight technical books, as part of PDA's growing library of books co-published with Davis Healthcare International Publishing. The following PDA members authored or were editors of PDA/DHI books in 2005:

- Michael J. Miller, PhD, *Encyclopedia of Rapid Microbiological Methods, Volume I*
- Jeanne Moldenhauer, PhD, *Environmental Monitoring, Volume I and Volume II*
- Theodore H. Meltzer, PhD and Maik W. Jornitz, *Filtration Handbook: Air And Gas*
- Brian R. Matthews, PhD, *Pharmaceutical Excipients: A Manufacturer's Handbook*
- Michael Jahnke, PhD, *Quality Assurance Workbook for Pharmaceutical Manufacturers*
- Mark Gibson, PhD, *Technology Transfer: An International Good Practice Guide for Pharmaceutical and Allied Industries*
- Siegfried Schmitt, *The Manager`s Validation Handbook: Strategic Tools For Applying Six Sigma To Validation Compliance*

BIOAB ROSTER

Co-Chairs
Gail Sofer
GE Healthcare

John Geigert, PhD
BioPharmaceutical Quality Solutions

Members
Kurt A. Brorson, PhD
CDER, U.S. FDA

Christopher M. Bussineau, PhD
Cambrex Bio Science

Norbert Hentschel
Boehringer Ingelheim Pharma

James G. Kenimer, PhD
Biologics Consulting Group

Peter F. Levy
Altus Pharmaceuticals

Annemarie Moëritz, PhD
Novartis Pharma AG

Barbara J. Potts, PhD
Genentech, Inc.

Anurag S. Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Robert J. Seely, PhD
RMC Pharmaceutical Solutions

RAQC Liaison
Rebecca A. Devine, PhD
Regulatory Consultant

PDA Staff Liaisons
Richard V. Levy, PhD
Scientific and Regulatory Affairs

Robert L. Dana
Regulatory Affairs

James C. Lyda
Europe Operations

SCIENTIFIC AND REGULATORY AFFAIRS

PDA is grateful for the dedication of the Technical Book Advisory Board, which once again helped PDA target authors who could contribute valuable books to the PDA/DHI library. The Technical Book Advisory Board's 2005 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.

Interest Groups

The PDA Board of Directors approved the reorganization of PDA's Interest Groups in 2005. The new structure ensures that the Interest Groups represent PDA's strategic plan and maximize member benefits by improving networking and technical information flow and providing relevant program topics for our meetings. The reorganization also formalizes for the first time membership in Interest Groups and provides additional support to them via improved electronic communication. In addition, new Interest Groups were created, others were combined and a limited number were deactivated.

Now, PDA Interest Groups are grouped into five subject-related sections, aligning them for improved effectiveness, increased synergies and additional opportunity for Interest Group members to play a more active role in Task Forces (for a full listing, turn to page 9). The five sections are:

- Quality Systems and Regulatory Affairs
- Laboratory and Microbiological Sciences
- Pharmaceutical Development
- Biotechnological Sciences
- Manufacturing Sciences

PDA Journal of Pharmaceutical Science and Technology 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 three applicants selected in 2005 were: Shankar Seetharaman, University of Brighton, for "Investigation of Parameters in the Preparation of Tc-99m MAG3;" Murali Krishna Divi, University of Tennessee, for "Stealth Liposome Formulation of a Novel Anticancer Agent for Glioma Treatment;" and Ramakrishna Nallamouth, University of Tennessee, for "Targeted Liposomal Formulation Development for a Novel Antivascular Drug, Combrestatin A4."

The **Predoctoral Fellowship Program** provides selected candidates with a stipend to assist them in their research. Three $10,000 stipends were awarded in 2005 to: Stuart Cantor, University of Maryland, Baltimore, for research of design and characterization of a unique compacted multiparticulate system for modified release; William Riodan, University of Wisconsin, for research of virus-ligand interactions in adsorptive membrane separation processes; and Madhushree Gokhale, University of Iowa, for research of the kinetics and mechanism of the reaction of kynurenine with D-glucose in aqueous solutions.

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 and 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, Dean of the China Pharmaceutical University; and Sompol Prakongpan, PhD, Pharmacy Dean of 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 are: Michael Akers, PhD, Baxter Pharmaceutical Solutions; Frederick J. Carleton, retired; 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.

SCIENTIFIC AND REGULATORY AFFAIRS 2005

Regulatory Affairs and Quality

In 2005, PDA and our member-volunteer Regulatory Affairs and Quality Committee (RAQC) worked on establishing closer ties with a number of standards-setting organizations and regulatory authorities, including the European Medicines Agency (EMEA), the U.S. FDA, the Product Quality Research Institute and the U.S. Pharmacopeia. In addition, PDA continued to follow developments in the International Conference on Harmonisation and comment on draft guidelines.

PDA submitted official written comments to the following regulatory and compendial documents in 2005:

- Proposed changes to USP General Chapter <1> Injections (Pharmacopeial Forum 31 (5) September/October 2005)
- ICH Q9 — Quality Risk Management, August 2005
- ICH Q8: Draft Consensus Guideline Pharmaceutical Development, November 2004

PDA/EMEA Joint Conference

PDA entered into negotiations with the EMEA in 2005 to develop a joint conference. By the autumn, an agreement was reached and preparations for the first ever PDA/EMEA Joint Conference were underway. PDA looks forward to presenting the conference to the membership in October 2006!

REGULATORY AFFAIRS AND QUALITY COMMITTEE (RAQC)

Chair
Amy M. Scott-Billman
GlaxoSmithKline

Asian Regional Leader
Jennie Allewell
Wyeth Research

Members
Stephen J. Bellis
IVAX Pharmaceuticals UK Ltd.

Rebecca A. Devine, PhD
Regulatory Consultant

Don E. Elinski
Lachman Consultant Services Inc.

Roland Guenther
Novartis Pharma AG

Hiltrud Horn
Horn Pharmaceutical Consultants

Zena G. Kaufman
Abbott Laboratories

Brian R. Matthews, PhD
Alcon Labs (UK) Ltd.

Steven Mendivil
Amgen, Inc

Toshiaki Nishihata
Santen Pharmaceutical Co. Ltd

Joyce R. Ramsbotham
Solvay Pharmaceuticals

Stefano Salmieri
Farmabios, SPA

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

John K. Towns, PhD
Eli Lilly and Company

Barbara B. Zinck
Cambrex Corporation

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

PDA Journal Editor
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University of Iowa

PDA Staff Liaisons
Robert L. Dana
VP, Quality & Regulatory Affairs

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

Robert B. Myers
PDA President

James C. Lyda
Acting Director, European Operations

SCIENTIFIC AND REGULATORY AFFAIRS

2005

IGs and Leaders

North American Interest Groups

Section Leader	Frank Kohn, PhD *FSK Associates*	David Hussong, PhD *U.S. FDA*	Don Elinski *Lachman Consultants*	Sandeep Nema, PhD *Pfizer Inc.*	Robert Dana *PDA*
Section Title	Biopharmaceutical Sciences	Laboratory and Microbiological Sciences	Manufacturing Sciences	Pharmaceutical Development	Quality Systems and Regulatory Affairs
Related IGs and Group Leaders	**Biotechnology** Frank Matarrese *Frank Mataresse GxP Consulting* E-mail: frank_matarrese@alamedanet.net **Lyophilization** Edward H. Trappler *Lyophilization Technology* E-mail: etrappler@lyo-t.com **Vaccines** Frank S. Kohn, PhD *FSK Associate Inc.* E-mail: fsk@iowatelecom.net	**Analytical Labs/Stability** Rafik H. Bishara, PhD *Eli Lilly & Company (ret.)* E-mail: rafikbishara2@yahoo.com **Microbiology/ Environmental Monitoring** Jeanne E. Moldenhauer, PhD *Vectech Pharm. Consultants, Inc.* E-mail: jeannemoldenhauer@yahoo.com **Visual Inspection of Parenterals** John G. Shabushnig, PhD Pfizer Inc. E-mail: john.g.shabushnig@pfizer.com	**Facilities and Engineering** Don Elinski *Lachman Consultant Services, Inc.* Email: d.elinski@lachmanconsultants.com **Filtration** Russ Madsen *The Williamsburg Group, LLC* E-mail: madsen@thewilliamsburggroup.com **Pharmaceutical Water Systems** Theodore H. Meltzer, PhD *Capitola Consulting Co.* E-mail: theodorehmeltzer@hotmail.com **Sterile Processing** Richard Johnson *Fort Dodge Animal Health* E-mail: johnson4@fdah.com	**Clinical Trial Materials** Mr. Vince Mathews *Eli Lilly & Company* E-mail: vlm@lilly.com **Combination Products** Michael Gross *QLT Inc.* E-mail: mgross@qltinc.com **Packaging Science** Edward J. Smith, PhD *Wyeth Pharmaceuticals* E-mail: smithej@wyeth.com **Process Validation** Harold Baseman *ValSource, LLP* E-mail: halbaseman@adelphia.net	**Inspection Trends/ Regulatory Affairs** Robert L. Dana *PDA* E-mail: dana@pda.org **Quality Systems** David Mayorga *Global Quality Alliance, LLC* E-mail: david@gqaconsulting.com

European Interest Groups

IGs and Leaders *(as of December 2005)*					
	Biotech Roland Güenther *Novartis Pharma AG* E-mail: roland.guenther@pharma.novartis.com	**Visual Inspection of Parenterals** Markus Lankers, PhD *Rap.ID GmbH* E-mail: markus.lankers@rap-id.com	**Production and Engineering** Philippe Gomez *Sartorius SA* Email: Philippe.gomez@sartorius.com **Filtration** Roger Seiler *Sartorius SA* Email: roger.seiler@sartorius.com **Prefilled Syringes** Thomas Schoenknecht, PhD *Bünder Glas GmBH* Email: tschoenknecht@gerresheimer.com	**Combination Products** Alexandra Schlicker, PhD *F. Hoffman La Roche AG* E-mail: alexandra.schlicker@roche.com Georgios Imanidis, PhD *University of Basel, Pharamceutical Technology* E-mail: georgios.imanidis@unibas.ch	**Nanotechnology** D. F. Chowdhury *Aphton BioPharma* E-mail: Fazc@aol.com **Technology Transfer** Volker Eck, PhD *Nerviano Medical Science S.r.l* E-mail: Volker.eck@nervianoms.com Zdenka Mrvova *Zentiva* E-mail: mrvova@leciva.cz

2005 PDA TRAINING AND RESEARCH INSTITUTE

The PDA Training and Research Institute (PDA TRI) strives to establish unprecedented worldwide education, training and applied research in pharmaceutical sciences and associated technologies. In 2005, we reached new heights.

Close to 900 registrants were trained in our laboratory and lecture courses in both the United States and abroad. The PDA/FDA Joint Regulatory Conference course series attendance broke all TRI lecture course records with 160 participants in eight courses.

In conjunction with Purdue University, PDA TRI provided training for 44 staff members from the Kazakhstan Ministry of Health and the National Center for the Assessment of Drugs, Items for Medical Purposes and Medical Equipment. PDA TRI instructors and PDA staff conducted two weeks of GMP training in areas including: aseptic processing; basic microbiology; FDA and EU regulatory and compliance issues; biotechnology manufacturing; training; and document and records control. All training materials and instruction, via simultaneous translation, were presented in Russian.

PDA TRI signed a memorandum of agreement with the University of Maryland Biotechnology Institute to provide training to students wishing to enter the pharmaceutical and biotech industry. This endeavor gives us the opportunity to provide the local industry the expertise most needed when recruiting for positions within their companies.

The TRI Advisory Board (TRIAB) was activated and established subcommittees for e-learning and standards and certification.

Our focus on *Career-long Learning*℠ serves as a precedent for PDA TRI to continually evaluate the curriculum and update and add courses to provide the most current information in both our laboratory and lecture courses.

Laboratory Course Training

PDA TRI distinguishes itself with its hands-on laboratory training. Our popular ten-day "Aseptic Processing Training Program" ran four times this year, selling out the last two sessions. The "Practical Aspects of Aseptic Processing" course was conducted twice in Basel, Switzerland, selling out the second session.

State-of-the-art environmental monitoring software and equipment were installed at TRI, which served as a great resource for our "Aseptic Processing," "Environmental Monitoring Database and Trending Technologies," and "Pharmaceutical and Biopharmaceutical Microbiology 101" courses. A new four-day laboratory course was added: Pharmaceutical and Biopharmaceutical Microbiology 101 and was fully attended.

Other laboratory courses run at the TRI facility included:

- Advanced Environmental Mycology
- Cleaning Validation
- Developing and Validating Cleaning and Disinfection Programs for Controlled Environments
- Environmental Mycology Identification Workshop
- Fundamentals of D, F and z Value Analysis
- Validating a Steam Sterilizer

Lecture Course Training

PDA TRI provided lecture-based training in its facility in Baltimore, Maryland and also traveled to the following U.S. cities: Princeton, New Jersey; San Antonio, Texas; and San Francisco, California. Course series were also run in conjunction with PDA's 2005 PDA Annual Meeting in Chicago, Illinois, and the PDA/FDA Joint Regulatory Conference in Washington, D.C. For the first time, TRI conducted a course series in Basel, Switzerland that was not associated with a major conference or meeting event.

New lecture courses offered at TRI included: "Biotechnology: Overview of Principles, Tools, Processes and Products" and "Fundamentals of Pharmaceutical Filtrations and Filters." Additionally, ten new lecture courses were provided in the Lecture Course Series.

Other lecture courses run at the TRI facility included:

- Basic Skills for the Training Professional
- Computer Products Supplier Auditing Model: Auditor Training
- Sterile Pharmaceutical Dosage Forms: Basic Principles

Thank You

The PDA Training and Research Institute extends a sincere thank you to those companies that lent or donated high-quality supplies and equipment to PDA TRI (see page 11 for a complete list of 2005 contributors). We also extend our appreciation to the expert faculty who participated in our program (see page 12). Your support helps us achieve our goals.

2005

PDA TRAINING AND RESEARCH INSTITUTE

PDA SUPPORTERS

Alcan Packaging Inc. ..... Supplies
Ascotec ..... Equipment
Atlantic Technical Systems ..... Service
Becton Dickinson ..... Supplies
Biolog ..... Supplies, Service
BioMerieux ..... Supplies, Service
Bioscience International ..... Equipment
Biotest ..... Service
Cardinal Health ..... Supplies
Charter Medical ..... Supplies
Cole-Parmer ..... Supplies
Contec ..... Supplies
Decon Labs ..... Supplies
EMD Chemicals ..... Supplies
GE Ionics ..... Supplies, Service
GE Kaye ..... Service
General Econopak ..... Supplies
Hach Ultra Analytics ..... Service
ITW Texwipe ..... Supplies
Kimberly-Clark ..... Supplies
Lyophilization Technologies, Inc. ..... Service
Mesa Labs, Inc. ..... Equipment
Microbiologics ..... Supplies
Millipore ..... Supplies
Novatek ..... Equipment (Software)
PALL Life Sciences ..... Supplies
PAREXEL ..... Equipment
Particle Measuring Systems ..... Service
PDA Central European Chapter ..... Equipment, Service
Perfex ..... Supplies
Prudential Cleanroom Services ..... Supplies
R2S ..... Service
Raven Bio Labs ..... Supplies
Remel ..... Supplies
Sartorius ..... Supplies, Equipment, Service
Steris ..... Supplies
Steritool ..... Supplies
Synbiosis ..... Equipment
Veltek Associates Inc. ..... Supplies, Equipment, Service
West Pharmaceutical Services ..... Supplies

PDA TRAINING AND RESEARCH INSTITUTE

2005 FACULTY

Lecture Training

K.A. Ajit-Simh ..... Shiba Associates
Michael J. Akers, PhD ..... Baxter
Harold Baseman ..... ValSource, LLC
Trevor Deeks, PhD ..... Skanska Pharmaceutical Group
Anne Marie Dixon ..... Cleanroom Management Associates, Inc.
J. Kirby Farrington, PhD ..... Eli Lilly and Company
Hubert Fleming, PhD ..... O'Brien and Gere
Renee B. Galkin ..... RB Galkin and Associates
David Gallup, EdD ..... Training and Communications Group, Inc.
John Geigert, PhD ..... BioPharmaceutical Quality Solutions
Daniel H. Gold, PhD ..... D.H. Gold Associates, Inc.
Joe Habarta ..... J. Habarta Consulting
Klaus Haberer ..... Compliance Advice and Services in Microbiology GmbH
Maik W. Jornitz ..... Sartorius Corporation
Johannes Kramer, PhD ..... PHAST
David Lansky, PhD ..... Lansky Consulting, LLC
Max Lazar ..... FDA Regulatory Compliance Consulting
Destin A. LeBlanc ..... Cleaning Validation Technologies
Elaine Lehecka Pratt ..... Lehecka Pratt Associates, Inc.
John Ludwig, PhD ..... Pfizer, Inc.
Mitchell Manning ..... Mitchell W. Manning, Consultant
Frank Matarrese ..... Frank Matarrese GxP Consultant
David Matsuhiro ..... Cleanroom Compliance, Inc.
Theodore Meltzer, PhD ..... Capitola Consultancy
Karen Mills ..... East Shore Associates
Alan Minsk ..... Arnall Golden Gregory
Antonio R. Moreira, PhD ..... SPI USA, Inc.
Kenneth Muhvich, PhD ..... Micro-Reliance
Clifford Nilsen ..... Nilsen Consulting
Jeffrey Priem ..... Molecular Insight Pharmaceuticals
Harald Rettig ..... Biovista LLC
Rick Rogers ..... Consultant
Steve Stachelski ..... PAREXEL Consulting
Ronald F. Tetzlaff, PhD ..... PAREXEL Consulting
Lynn Torbeck ..... Torbeck and Associates, Inc.
James Vesper ..... LearningPlus, Inc.
Charles Waite ..... ProDesCon
Tom Weaver ..... Weaver Consulting, LLC
Jeffrey Yuen ..... Jeff Yuen and Associates

Inspectorate Training

Diane Alexander ..... FDA
Eddie Ballance ..... Eisai, Inc.
Kurt Brorson ..... FDA
Colman Casey ..... University College Cork
David Chesney ..... PAREXEL Consulting
Robert Dana ..... PDA
Suze Fry ..... The Taormina Group
Elena Gonikberg ..... USP
Joseph Kutza ..... FDA
Richard Levy ..... PDA
John Lindsay ..... Aseptic Solutions, Inc.
David Matsuhiro ..... Cleanroom Compliance, Inc.
Bob Myers ..... PDA
Brian Neely ..... Don Hill and Associates
Horatio Pappa ..... USP
David Porter ..... USP
Catherine Sheehan ..... USP
Gail Sherman ..... PDA
Barbara van der Schalie ..... MedImmune, Inc.
Leonard Wilson ..... FDA
Robert Yetter ..... FDA

Lab Faculty

Naomi Baer ..... Millipore
Chris Bartlett ..... Biolog, Inc.
Dawn Block ..... Wyeth
Carolyn Broughton ..... Genentech
John Brecker ..... Decon Labs
Anthony Cannon ..... Lyophilization Technolgy, Inc.
Jim Cooper ..... Endotoxin Consulting Services
David Crance ..... Particle Measuring Systems
Cheryl Custard ..... Sanofi Pasteur
Fred Devries ..... PAREXEL, Inc.
Jayne Dovin ..... Pfizer
Donald Drew ..... PAREXEL, Inc.
Mike Finger ..... Tunnell Consulting
Grace Gardner ..... Aseptic Solutions, Inc.
Peter Holman ..... Genentech
Mark Hallworth ..... Particle Measuring Systems
Sylvia Isaacson ..... Millipore
Peter Koger ..... Veltek Associates, Inc.
Destin LeBlanc ..... Cleaning Validation Technologies
George Levinson ..... Compliance Software Solutions, Corp.
John Lindsay ..... Aseptic Solutions, Inc.
Sandra Lowery ..... Quality Systems Consulting, Inc.
Jason Mangler ..... GE Ionics
David Manley ..... Biomerieux
David Matsuhiro ..... Cleanroom Compliance
Steve Messick ..... Genentech
Jeanne Moldenhauer ..... Vectech Pharmaceutical Consultants, Inc.
Russ Nyberg ..... Raven Biological Labs, Inc.
Robert O'Brian ..... Consultant
Maureen Reagan Mueller ..... Quality Systems Consulting, Inc.
Tom Reidy ..... Syntonix
John Schlottig ..... K. John Schlottig Consulting
John Shirtz ..... Baxter
Dale Seiberling ..... Electrol Specialties
Edward Trappler ..... Lyophilization Technolgy, Inc.
Art Vellutato ..... Veltek Associates, Inc.
Veronique VonBuynder ..... Genzyme Flanders
Jonathan Yourkin ..... GE Ionics

2005 PROGRAMS AND MEETINGS

In 2005 PDA implemented its new strategic goal of complementing its three primary events (the International Congress, the Annual Meeting and the PDA/FDA Joint Regulatory Conference) with a line-up of single topic meetings. Each of these meetings focused on a "hot" topic deemed of particular interest to PDA's membership and the pharmaceutical and biopharmaceutical communities. This new approach was met with resounding success, exceeding budgeted attendance for all the meetings combined.

PDA's three major conferences, with multi-tracked learning sessions, also performed well in 2005. The year started out with the International Congress in Rome, highlighted by strong scientific content and outstanding networking events. The Annual Meeting was re-established in 2005, with healthy attendance and a well-received program. Finally, the high point of the year was the PDA/FDA Joint Regulatory Conference with record attendance of over 1200 for the conference, courses and exhibition.

Consistent with PDA's track record of bringing leading-edge science and technology information to the pharmaceutical and biopharmaceutical industry, hundreds of people took advantage of the convenience and cost-effectiveness of learning via audio conferences in 2005. Subject-matter experts presented in-depth audio conferences on a host of key areas of interest to the industry. The year culminated with a transition to a new web-based technology and a new name — Web Seminars.

PDA's presence in Europe continued to expand during 2005 with three very successful meetings. One of the series of four workshops on implementation strategies for FDA's new aseptic guidance was held in London, as was a focus meeting on nano-pharmaceuticals. And, Munich hosted the most well attended meeting in Europe in 2005, the Universe of Pre-filled Syringes in October.

2005 PDA CONFERENCES AND WORKSHOPS

Aseptic Processing Training Workshop
February 17-18 | San Francisco, California

2005 PDA International Congress, Courses and Exhibition
March 1-4 | Rome, Italy

Aseptic Processing Training Workshop
March 14-15 | Philadelphia, Pennsylvania

2005 PDA Annual Meeting
April 4-6 | Chicago, Illinois

Aseptic Processing Training Workshop
May 3-4 | London, England

Viral & TSE Safety Conference
May 16-18 | Bethesda, Maryland

Extractables/Leachables Forum
May 23-25 | Bethesda, Maryland

PDA/FDA Joint Regulatory Conference, Courses and Exhibition
September 11-14 | Washington, D.C.

Visual Inspection Forum
October 20-21 | Bethesda, Maryland

The Universe of Pre-filled Syringes
October 24-25 | Munich, Germany

Aseptic Processing Training Workshop
November 3-4 | Las Vegas, Nevada

Nano-Pharmaceutical Conference
November 10 | London, England

EXHIBITIONS

PDA's exhibitions continue to provide the community access to the products and services they need most. PDA would like to thank the Exhibit Advisory Committee for their dedication and effort in planning successful and valuable exhibitions in 2005:

Howard R. Drake
Chair
Saint Gobain Desjonqueres

Carol Dellicicchi
Pall Corporation

Douglas Hostetler
Lancaster Laboratories

Carol Julich
Biotest Diagnostic Corporation

Nahid Kiani
PDA

Lawrence Pepper
Genesis Machinery Products

Debora Rothwell
Texwipe (ITW)

Art Vellutato, Jr.
Veltek Associates

2005

PROGRAMS AND MEETINGS

2005 PDA AUDIO CONFERENCES

Managing the Change Control Process: Understanding Your Role
January 27

The Case for Multiple On-Product Anti-Counterfeiting Measures
February 15

The Impact of Recent FDA Initiatives on the Global Pharmaceutical Industry
May 5

FDA's Revised Guideline on Aseptic Processing: Essential Information on Buildings & Facilities
May 19

Update: Task Force for Virus Filter Nomenclature Standardization
May 24

ICH Draft Guidance on Pharmaceutical Development: Streamlined Quality Assurance Through "Design Space"
June 22

Microbiology for Non-Microbiologists: Essential Microbiology in Pharmaceutical Manufacturing
June 3

Extractables 101: Fundamentals of Extractables and Leachables
June 30

Optimizing Regulatory Strategy for Combination Products: From Concept to Compliance
July 19

Biotechnology: Overview of Principles, Tools, Processes and Products
July 27

Computer System Requirements – The Crucial First Step
July 28

Preparing for a Pre-Approval Inspection & Managing Risk
August 4

Exploring the Utility of Comparability Protocols in Rapid Microbiological Methods: FDA & Industry Perspectives
August 18

Change Control Revisited
September 7

Viral Safety & TSE Update – Emerging Technologies in Viral Clearance
September 29

Legal issues Surrounding FDA Inspections
October 7

Concepts for Quality Risk Management
October 13

An FDA Perspective on Quality Systems
October 20

Practical Approaches for Qualification of Product Contact Materials used During Manufacturing of Parenteral Products
October 25

Development History Reports and Technology Transfer
October 27

Process Analytical Technology: PAT Principles in Practice
November 3

Mycoplasma Contamination in TSB Derived From Plant Peptones
November 9

Factors to Consider in Reporting Manufacturing Chromatography Systems Post-Approval Changes PDA Tech Report #38
December 1

The Disconnect Between Procedures and Performance
December 2

International GMPs: Meeting US and European Requirements
December 6

2005 MEMBERSHIP AND CHAPTERS

2005 Membership Accomplishments

- **Student Scientific Programs:** New programs were established to promote applied research in areas of study relevant to the scientific foundations of pharmaceutical and biopharmaceutical product development, drug manufacturing and quality assurance technologies. These include the Annual Graduate Research Symposium, Pre-Doctoral Fellowship Program and Student Poster Sessions.
- **New Leadership Initiatives:** Several new leadership groups were formed in 2005. These included the TRI Advisory Board (TRIAB), PAT Working Group, PDA Letter Editorial Committee (PLEC), etc.
- **Enhanced PDA Branding and Mission:** PDA embraced its roots as the Parenteral Drug Association and strengthened its vision and mission behind the central purpose of the organization – *Connecting People, Science and Regulation*℠.
- **Record Number of Technical Reports Issued:** Four technical reports were printed in 2005. These included Technical Report #39: *Cold Chain Guidance for Medicinal Products*, prepared by the PDA Cold Chain Management Task Force; Technical Report #40: *Sterilizing Filtration of Gases*, prepared by the PDA Sterile Gas Filtration Committee; Technical Report # 41: *Virus Filtration, prepared by the PDA Virus Filtration Committee*; and Technical Report # 42: *Process Validation of Protein Manufacturing*, prepared by the PDA Process Validation of Protein Manufacturing Task Force. These technical reports were delivered to members with their PDA Journal.
- **New Career Fairs:** PDA hosted an in-person career fair during the Annual Meeting in Chicago and a virtual career fair online in the fall. These are expected to continue as annual events.
- **Chapter Scholarships:** The Capital Area Chapter partnered with the University of Maryland, Baltimore County, to offer scholarships to undergraduates considering a career in biotechnology or pharmaceuticals.
- **Significant Increase in Israel Chapter Membership:** The Israel Chapter welcomed 339 new members taking its total membership to 379.

Worldwide Membership

During 2005, PDA members represented the following regions worldwide:

Africa

Egypt, Gambia, Ghana, Kenya, Nigeria, South Africa

Asia-Pacific

Afghanistan, Australia, Bangladesh, China, India, Indonesia, Japan, Malaysia, New Zealand, Pakistan, Singapore, South Korea, Taiwan, Thailand, Vietnam

Caribbean, Central & South America

Argentina, Brazil, Chile, Colombia, Costa Rica, Curacao, Dominican Republic, Panama, Uruguay, Venezuela

Europe

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

Middle East

Cyprus, Israel, Jordan, Lebanon, Saudi Arabia, Syria, Turkey, United Arab Emirates

North America

Canada, Mexico, United States

2005

MEMBERSHIP AND CHAPTERS

PDA GLOBAL CHAPTERS AND PRESIDENTS

Asia Pacific

Australia Chapter
Greg Jordan
Sigma Pharmaceuticals Pty

India Chapter
Darshan Makhey, PhD

Japan Chapter
Katsuhide Terada, PhD
Toho University

Korea Chapter
Woo-Hyun Paik, PhD
Boryung Pharmaceutical Co. Ltd.

Southeast Asia Chapter
Kanneganti P. P. Prasad, PhD
Pfizer Asia Pacific Pte Ltd

Taiwan Chapter
Shin-Yi Hsu
Otsuka Pharmaceutical Co., Ltd.

Europe

Central Europe Chapter
Erich Sturzenegger, PhD
Novartis Pharma AG

France Chapter
Jean-Louis Saubion, PhD
UFCH

Israel Chapter
Sigalit Portnoy
Taro Pharmaceutical Ind. Ltd.

Italy Chapter
Gabriele Gori
Bausch & Lomb – IOM SpA

Prague Chapter
Zdenka Mrvova
Zentiva

Spain Chapter
Jordi Botet, PhD
STE Compliance Services & QTI

United Kingdom and Ireland Chapter
Frank W. Talbot
FT Pharmaceutical Services

North America

Canada Chapter
Hein W. Wick
HWMR Ltd.

Capital Area Chapter
Barry A. Friedman, PhD
Cambrex Bio Science Baltimore, Inc.

Delaware Valley Chapter
Arthur L. Vellutato, Jr.
Veltek Associates, Inc. and Aseptic Processing, Inc.

Metro Chapter
Natale F. Manco
ECO Animal Health

Midwest Chapter
Madhu Ahluwalia
cGxP

Mountain States Chapter
Cathie Wilkerson
RTX, Inc.

New England Chapter
Myron F. Dittmer, Jr.
Hyaluron, Inc.

Puerto Rico Chapter
Silma Bladuell
Wyeth

Southeast Chapter
Lisa E. Eklund
Hospira, Inc.

Southern California Chapter
Kikoo Tejwani
B. Braun Medical Inc.

West Coast Chapter
Peter Rauenbuehler
Genentech, Inc.

2005 HONOR AWARDS

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. The award requires unanimous approval of the PDA Board of Directors.

Kunio Kawamura, PhD, Retired (formerly Otksuka). Kunio was a founder of the PDA Japan Chapter and has contributed to PDA's Japanese activity as President, Secretary and Director-at-Large for more than 15 years. He was instrumental in building PDA's relationship with the Japan National Council of Science.

Russell Madsen, The Williamsburg Group, LLC. Russ has consistently contributed and participated in various PDA committees, working groups and programs. He has always been eager to participate in any PDA related tasks or working groups.

Gordon Personeus Award

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

John Geigert, PhD, BioPharmaceutical Quality Solutions. John is a Past Board Member and has twice led the PDA annual Meeting Program Planning Committee. He has offered long-term service and is still actively involved in many PDA activities, including serving as Chair of the Biotechnology Advisory Board.

Frederick J. Carleton Award

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

Richard Levy, PhD, PDA. Rich has contributed significantly to PDA for many years. He has served on numerous task forces, subcommittees, the Science Advisory Board, program committees and as a speaker at conferences. A long-time Board Member, Rich most recently served as Chair-elect, before joining the PDA staff as Senior Vice President of Scientific and Regulatory Affairs in autumn 2005.

Michael S. Korczynski Grant

Syracuse University

This past January the PDA Community was saddened to learn of the passing of Michael S. Korczynski, PhD.

This 2005 PDA Korczynski Grant funds were donated "In Memory of Michael S. Korczynski" to Syracuse University in support the university's summer biology intern program.

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.

Louise Johnson, Vertex Pharmaceuticals. Louise served as Chair of the highly successful 2005 PDA/FDA Joint Regulatory Conference. She has been very involved with PDA's Strategic Planning initiatives and has participated in numerous program planning committees.

Michael Miller, PhD, Eli Lilly and Company. Michael was Chair of the very successful 2005 PDA Annual Meeting. He has made numerous contributions to PDA over the years, particularly with the Strategic Planning Committee, subcommittees and various program planning committees.

James Lyda, PDA. Jim played a key role in PDA's Europe activities including having led several EU program planning committees. He has been active in RAQC and contributed to numerous commentaries on EU and U.S. guidances.

Edmund Fry, Cardinal Health. Ed has served as the PDA representative to the PQRI Steering Committee and has guided the Steering Committee and the Institute for several years. He has provided invaluable views and insights and contributed tremendously to PDA and PQRI.

Martin Van Trieste, Bayer HealthCare. Martin was instrumental in PDA's leadership in aseptic technology during a time of key new guidance in this area. He was instrumental in PDA's reply to the FDA Aspetic Guidance and put together a series of programs involving involved FDA speakers. Martin served as a main speaker at these multiple one-day programs and also developed an assessment tool that participants could take back to their jobs and use.

Toshiaki Nishihata, PhD, Santen Pharmaceuticals. Toshiaki has been a Director of the Board in Japan Chapter since the chapter was established in 1991, and also PDA Board Director. He also contributed to ICH as a participant from Japanese industry and regularly contributes to PDA activities for the Annual Meetings, conferences, and various local committee activities, including KSG.

2005 HONOR AWARDS

Service Appreciation Award

Given for special acts, contributions or service that have contributed to the success and strength of PDA's Exhibit Advisory Board.

Howard Drake, Saint Gobain Desjonqueres. Howard has served as Chair of the PDA Exhibit Advisory Board for the past two years.

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.

David Matsuhiro, Cleanroom Compliance. David has been an instructor for PDA since 2000, starting with the very successful "Aseptic Processing Training Program." In 2005, David developed for PDA an in-company training program in aseptic processing and contamination control. Additionally, he developed and delivered several new courses for PDA TRI, including "Pharmaceutical Microbiology 101" and "Cleanroom Microbiology."

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.

The Award was presented to **Dennis Jenke, PhD; Molly Chacko; Tom Couch; Eric Edgcomb; Liqiong Fang; Mary Jo Garber;** and, **Steve Swanson** for "Strategy for Assessing the Leachables Impact of a Material Change Made in a Container/Closure System." All work for Baxter Healthcare Corporation.

Chapter Volunteer Award

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

Lisa Hollis McCulley, The Hollis Group, Inc. (Delaware Valley Chapter). A database specialist, Lisa helped the local Chapter address its finances/accounting systems and has been an invaluable member of the Chapter Planning Committee.

Thomas Quinn, The Hollis Group, Inc. (Delaware Valley Chapter). Thomas serves as a computer database specialist and was completely responsible for the redesign of the Chapter's new website in 2005.

Byong Ho Youn, PhD, Handok Pharmaceuticals Co., Ltd. (Korea Chapter). Byong-Ho has been a member of the editorial staff of the "PDA Korea Newsletter" since the PDA Korea Chapter was established in 1997. He provides instructive papers and translates foreign documents which are of value to those in the Korean pharmaceutical industry.

James Agalloco, Agalloco & Associates (Metro Chapter). Over the years, Jim has made significant, continuous and sustained contributions to the development, growth and success of PDA, the PDA Metro Chapter and to the global education and development of pharmaceutical technology.

Spyros Fetsis, Hospira (Midwest Chapter). Spyros helped the Midwest Chapter improve communication to their membership and developed the PDA Chapter's website.

Joachim Leube, PhD, Bayer Biologicals (Italy Chapter). Joachim was instrumental in the organization of several successful European conferences and has been an active and enthusiastic support to all of the Chapter's activities in the last two years.

Randall Tedder, IconNova (West Coast Chapter). Randall Tedder has been actively involved in the PDA West Coast Chapter for over 13 years, serving in several positions including Chapter Past President.

Maggie Sparhawk, Amgen (Mountain States Chapter). Maggie joined the chapter executive team in 1998 and was Chapter Treasurer 1999 until mid-2005.

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 Jornitz, Sartorius Corporation, for *Filtration Handbook: Air and Gas*

Theodore H. Meltzer, PhD, Capitola Consulting, Co., for *Filtration Handbook: Air and Gas*

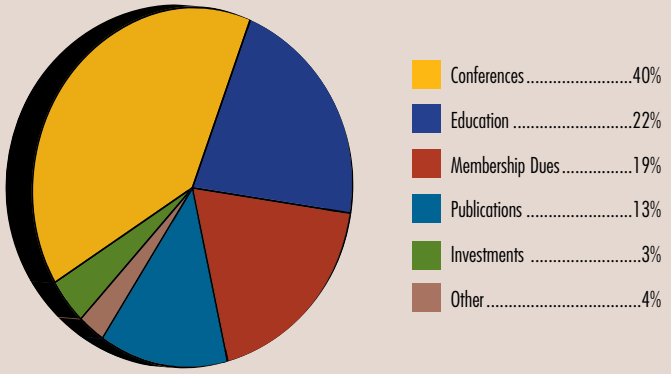
Jeanne Moldenhauer, PhD, Vectech Pharmaceutical Consultants, Inc., for *Environmental Monitoring; Volume I, Volume II* and Protocol CD

2005 FINANCIAL REPORT

PDA 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.

2005 proved to be financially successful for PDA . The association was able to exceed its planned contribution to reserves by $36,000 and its planned revenues by more than $790,000, representing a record revenue year. The primary reasons for this success stem from record attendance at the 2005 PDA/FDA Joint Regulatory Conference, a major training contract with the Kazakhstan Ministry of Health, and strong contributions from vendors to the Training and Research Institute.

2005 INCOME SOURCES



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, 2005. The full financial statements and notes are available upon request from PDA headquarters.

Our investments, which are primarily in conservative instruments appropriate for a nonprofit association, experienced capital losses of $76,007 (U.S.) as a result of climbing interest rates.

During 2005, PDA's net assets increased by $212,526, 6% on that recorded at the end of 2004. At the year-end 2005, our reserve ratio stood at 37% as compared against the industry average of 47% among associations of PDA's size.

2005 INCOME AND EXPENSES

	2005 Actual	2005 Budget	2004 Actual
Total Revenues	$ 9,863,049	$ 8,767,104	$ 7,833,119
Total Expenses	9,485,089	7,993,328	8,586,490
Excess revenues over expenses from operation	377,960	176,765	(736,378)
Unrealized gains (losses) on investments	(165,434)	–	16,993
Increase (decrease) in net reserves	212,526	176,765	(719,385)
Net reserves at beginning of year	3,305,104	3,305,104	4,024,489
Net reserves at end of year	3,517,630	3,481,869	3,305,104
Reserve ratio (net/reserves/annual expenses)	37.1%		38.5%

2006 PDA OFFICERS AND BOARD OF DIRECTORS

OFFICERS

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Genentech, Inc.

Chair-elect
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Pfizer Inc

Secretary
Lisa Skeens, PhD
Baxter Healthcare Corporation

Treasurer
Maik Jornitz
Sartorius Corporation

Immediate Past Chair
Nikki Mehringer
Eli Lilly and Company

DIRECTORS

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Wyeth Research

Stephen Bellis
IVAX Pharmaceuticals UK

Rebecca A. Devine, PhD
Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals Corporation

Yoshihito Hashimoto
Chiyoda Corporation

Tim R. 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

2006 PDA STAFF

SENIOR STAFF

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President

Gail Sherman
Vice President of Education/Director of TRI

Lance Hoboy, CAE
Vice President, Finance and Strategic Planning

Nahid Kiani
Director, Sales

Wanda Neal-Ballard
Director, Programs and Meetings

Matthew Clark
Director, Marketing Services, Membership and Chapters

Richard Levy, PhD
Senior Vice President, Scientific and Regulatory Affairs

Robert Dana
Vice President, Quality and Regulatory Affairs

Georg Roessling, PhD
Senior Vice President of PDA Europe

James Lyda
Acting Director of European Operations

STAFF

Karishma Anand
Publication Specialist

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Senior Coordinator, Programs and Meetings

Jason Brown
Senior Coordinator, Programs and Meetings

Luis Castro
Coordinator, Programs and Meetings

Feng Chen
IT Operations Technician

Janny Chua
Manager, Product Operations

Nickia Davis
Senior Customer Account Representative

Patresa Day
Customer Accounts Representative

Jennifer Fraser
Meeting Planner, Programs and Meetings

Carol Harris
Manager, Information Systems & Reporting

Valerie Heavey
Accounts Payable

Ashante Horton
Registration/Customer Service Representative

Dee Kaminsky
Associate Director, Marketing Services

Jennifer Knode
Office Manager

Megan Lahti
Education Coordinator

Dawn Marek
Assistant Manager, Marketing Services

Pete Marinovich
Manager, Production

Praneet N. Mathur, CPA
Controller

Ryan McLimans
Marketing Services Specialist

Walter Morris
Managing Editor

Jessica F. Petree
Manager, Lecture Education

Marc Povell
Manager, Membership and Chapters

Iris Rice
Coordinator, Scientific and Regulatory Affairs

Frank Sarlo
Manager, Information Technology

Angela Sugg
Manager, Sales

James Wamsley
Manager, Laboratory Education

Monica Washington, CEM
Senior Programs and Meetings Coordinator

Ludy Yo
Manager, Web Development

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USA

Tel: +1 (410) 455-5800
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PDA
Parenteral Drug Association