2003 ANNUAL REPORT

PDA's Mission • Advance pharmaceutical and biopharmaceutical science and technology internationally by promoting scientifically sound and practical technical information and education for industry and regulatory agencies.

PDA
An International Association For Pharmaceutical Science And Technology

www.pda.org

PDA is an individual membership association for scientists and experts who utilize manufacturing science and technology to produce pharmaceutical, biopharmaceutical and related products. We are involved with product development and production, quality assurance, quality control and regulatory affairs. The association brings together professionals from the private sector, global health authorities and academia who strongly believe:

- Good science should be the basis for everything we do professionally;
- Our work together improves the quality of medicinal products for patients around the world;
- Learning is a life-long process—the sharing of knowledge is critical in the dynamic environment in which we live and work;
- Each member plays a critical role in the advancement of pharmaceutical and biopharmaceutical science and technology;
- Good science has no geographical boundaries; and
- Together we can accomplish great things.

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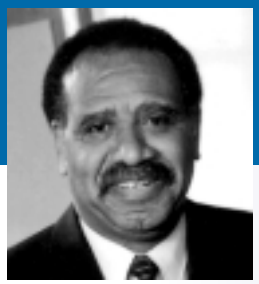


Floyd Benjamin

2003 was a year of change for PDA and for the pharmaceutical and biopharmaceutical industries as a whole. With Mr. Edmund Fry retiring as PDA's president near the end of 2002, the Association began 2003 looking for his successor. The primary concern during this search was to find the individual best suited to guide PDA during these times of change.

Before I discuss the changes taking place at PDA, I would like to reflect on Ed's exemplary service to the association. PDA selected Ed, who worked with the U.S. FDA at the time, as its president in 1992. During his tenure, PDA made great strides. Membership grew from approximately 4,500 members to 10,400. Revenues grew from approximately US$1.6 mil. to US$8.3 mil. PDA's involvement in the scientific and regulatory processes also blossomed under Ed's purview. PDA worked diligently during Ed's tenure to ensure that health authorities and industry dealt with quality control, GMP and other regulatory issues on the same technical basis. The numerous initiatives developed by PDA for this purpose have had significant positive impact on our communities.

Having worked directly with Ed on the PDA Board of Directors during the years, I can personally state that we are all indebted to him for his strong leadership and excellent managerial skills. Ed established for PDA a solid foundation on which we can continue to build a vibrant and stronger association in the years to come. PDA truly owes a debt of gratitude to Ed Fry.

In addition to Ed and his staff, I would like to give special recognition to Mr. Russell Madsen for his contributions to PDA. For many of his years at PDA, Russ guided the science and technical work performed by the association as the Vice President of Science and Technology. He worked collaboratively with PDA's scientific members and the pharmaceutical scientific communities at large. Through his tireless work, many of PDA's technical documents and papers became important standards for the entire industry. Until PDA found a replacement for Ed, Russ served as acting president. On behalf of PDA, I thank Russ for all his contributions.

Turning now to the changes, PDA was pleased to name in January 2003 Mr. Neal G. Koller as the association's new president. Neal brings to PDA the leadership skills that the association will require to meet the many challenges facing us during the coming years. To help him in this task, he has added many new and extremely talented staff members. We believe that with Neal and his strong staff, the organization is well positioned to meet the challenges facing it in the years to come.

Thanks to the hard work of the Board of Directors, PDA's professional staff and my predecessor, Mr. Robert Myers, PDA experienced financial stability during 2003. PDA saw positive results of two key decisions made prior to my term as chair, increased revenue from the PDA Training and Research Institute and from an increase in membership dues to cover the actual costs of supporting members. These contributions should continue through the coming years and will have significant impact on the financial picture. At the close of 2003, our cash position was at a very good level and we had a strong balance sheet.

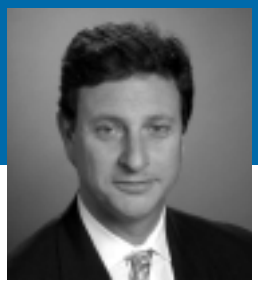
During my tenure as chair, the Board of Directors did an outstanding job rising to each challenge as it occurred. The many organizational changes faced by the Board required that we remain united and supportive of each other. During 2003, the Board had to consider the serious concerns of our members, and we worked very hard to ensure that decisions were made to the benefit of the entire association. I am proud to have served with this Board and feel that the work accomplished will serve PDA well for many years to come. I commend my fellow Board members for a job well done.

I saved the most important "thank you" for the PDA members who make us what we are. No professional association that I know of has a more committed, talented or harder working base of members. PDA's many accomplishments are the direct result of the dedication of members to PDA's Mission, Vision and Strategic Plan. Our members deserve more credit and recognition than they ever possibly could get for assuring that the quality of PDA's products are of the highest level and contribute to the development and manufacture of quality drug therapies.

Throughout this report, you will read about the many truly remarkable accomplishments made by PDA's members during 2003. PDA expanded its collaborations with health authorities around the world. Our efforts included the development and execution of a training course for the Italian Inspectorate and the first ever joint PDA/EMEA meeting last autumn. We also, for the first time, submitted science-based comments on World Health Organization guidance documents. New PDA Chapters were organized and new members added in various regions of the world. As you will see, 2003 was a productive and successful year for PDA.

Finally, as I pass the torch to Mrs. Nikki Mehringer, the new chair, I reflect on our journey over the last two years and can honestly say to the members, I have given my very best to you. I hope it has been adequate to meet the tasks at hand and it has added some lasting value to PDA.

President's Message: Neal Koller



Neal Koller

President's Message

It is with great pleasure that I report the accomplishments of PDA in 2003. My first year with PDA was characterized by many new structural and operational improvements, better positioning the association to fulfill its Strategic Plan to increase value for each member and for our community of professionals working in industry, academia and government. Each of our accomplishments in 2003 was oriented to a specific strategy of the PDA six-point Strategic Plan.

We accomplished a number of enhancements for Strategy 1: *Increase accessibility of services, education and training offerings both internationally and domestically*. Improvements in the way PDA supports its Chapters were ongoing throughout 2003. A new staff position was added, the Chapter coordinator, dedicated to work closely with and support our Chapters worldwide. We created a new system that encourages PDA Chapters to provide science-based comments on regulatory guidances and implemented a new program to help Chapters secure the involvement of health authority personnel in Chapter events.

For the individual member, PDA initiated a "Member Volunteer Program," which provides a cost-effective method for members to attend a PDA event when they volunteer some of their time at the event. To increase the value of membership, we launched a new Career Center that includes searches by job location, storage of résumés and cover letters and e-mail notifications of job matches and search agents. As the year closed, PDA offered new translations of Technical Reports in Japanese and Chinese, and a new GMP handbook in Japanese as well.

Our programs and meetings—one of the key strengths of PDA—expanded globally in 2003, with a 50% increase in the total number of meetings planned and a 50% increase in the number of meetings held outside the U.S., as well as a 75% increase in audio and web-based offerings. In addition, PDA strengthened its ability to provide valuable and cost-effective events by co-sponsoring meetings with the EMEA, the Parenteral Society, FDA and PQRI.

With respect to Strategy 2—*Build a stronger liaison with regulatory bodies*—PDA worked very hard in 2003 to expand our relationships with regulatory bodies worldwide. We met with nearly a dozen national health authorities around the world and instituted a new "deep discount government rate" for all events and publications.

PDA continued its long and productive relationship with the U.S. FDA last year, to the benefit of the entire community. PDA members worked closely with agency officials to ensure that U.S. FDA's draft guidance for aseptic processing was based on good science. The 14th annual PDA/FDA Joint Regulatory Conference remained a unique forum for the Agency, industry, academic representatives and other health authorities to interact and advance scientifically sound regulations.

In Europe, PDA established closer ties with the EMEA, co-sponsoring our first joint meeting. PDA was honored by the Italian Ministry of Health when it selected the PDA Training and Research Institute to create and provide a year-long Inspectorate Training Program for members of the Italian Inspectorate. PDA achieved a milestone step in our relationship with the World Health Organization by obtaining approval to comment on its guidances.

Throughout 2003, PDA and its members achieved a number of enhancements in advancing Strategy 3: *Continually improve the relevance and quality of scientific information and programs offered by PDA to reach appropriate audiences*. We published eight technical books and three technical bulletins. For the first time, PDA sponsored a meeting of the Editorial Advisory Board for the *PDA Journal of Pharmaceutical Science and Technology*. Additionally, the number of people on the advisory board was increased to provide breadth of experience and improve scientific guidance and direction. A new Technical Book Editorial Board was formed in 2003 to provide scientific guidance and peer-review to this increasingly important portion of PDA science activities. PDA entered into agreements with two science editors to edit and facilitate the completion of two technical reports, improving our support to the PDA Science Advisory Board and task forces. The PDA Training and Research Institute contributed to industry's applied research by allowing new aseptic filling technology to be tested at its Baltimore facility.

President's Message

PDA completed a number of projects in 2003 to pursue Strategy 4: *Assure the financial resources are in place to support PDA's Mission to be an international influence*. Systems were implemented for finance, accounting and forecasting to assure PDA has adequate methods to monitor its businesses. To better serve the membership, the PDA Swiss bank account was activated and new bank accounts were established to allow PDA to accept multiple currencies. A new Web-based accounting system was introduced to support PDA Chapter financial activity. Most importantly, PDA effected improvements that considerably enhanced our financial footing, ensuring the association continues to be a strong organization in years to come.

PDA completed a number of new initiatives in 2003 strengthening Strategy 5: *Continue to expand and market PDA*. The PDA Board approved member petitions to start four new chapters: the France, Prague, Puerto Rico and Spain Chapters. PDA launched the new monthly *Chapter News*, added to our press-release capabilities, brought our e-mail function in-house improving capability and cost, and contracted with a new design firm to begin the improvement of what and how we communicate.

Under Strategy 6—*Improve PDA's operating structure domestically and internationally*—the PDA "Membership Services" department was reorganized to better support our members and our chapters, and as such, was renamed "Membership & Chapters." Likewise, to better serve the membership, the "Marketing and Communications" department was reorganized and renamed "Marketing Services." To support these and other structural changes, new staff members and investments were approved in the following departments: Human Resources, the PDA Training and Research Institute, Science and Technology, Programs and Meetings, Finance and Strategic Planning, Membership and Chapters, and Marketing Services.

As 2004 unfolds, PDA will remain focused on helping its membership perform better professionally and enrich their careers. We will work hard to bring the PDA community closer together. We will continue to focus on achievement of our Strategic Plan, with a special emphasis on our unique capabilities and relationships in science, technology, regulation and training.

Finally, and most importantly, I would like to recognize the hard work and extensive contributions of our members. With the continued input and collaboration of our members, we will continue to make significant contributions to the worldwide pharmaceutical and biopharmaceutical communities.

2003 Board of Directors





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Eli Lilly and Company




Over its 57-year history, PDA has earned a reputation for delivering state-of-the-art, foundational scientific and technical information to the private sector, health authority and academia professionals working in the biopharmaceutical and pharmaceutical communities. These resources provide career-long learning, helping members of the communities to perform better on the job, establish and adhere to scientifically sound regulatory policy, and advance their careers.

PDA's Science Advisory Board, Task Forces, Interest Groups and Science and Technology Department are constantly working to fulfill PDA's mission—a commitment to promoting scientifically sound and practical technical information for the pharmaceutical and biopharmaceutical industry and regulators worldwide.

PDA's 2003 science and technology contributions to the communities include:

- Publication of seven technical books;
- Release of three technical bulletins;
- Formation of PDA's first Technical Books Editorial Advisory Board;
- Reconstitution of the Editorial Advisory Board for the *PDA Journal of Pharmaceutical Science and Technology*; and
- Advancement of 16 technical report projects.

PDA Technical Books

PDA's technical books are valuable resources for the membership and the pharmaceutical and biopharmaceutical communities at large. These resources help the communities perform better on the job and advance their careers.

During 2003, the following PDA members authored technical text books for PDA:

- U.G. Barad, *The Essence of GMPS: A Concise Practitioner's Guide* and *Excellence Through Validation: A Practitioner's Guide*
- Maik Jornitz and Theodore Meltzer, *Filtration Handbook: Integrity Testing*
- Anthony Meager, *Quality and Safety of Gene Medicines: A Practical Guide*
- Jeanne Moldenhauer, *Laboratory Validation: A Practitioner's Guide*
- David Nettleton and Janet Gough, *Commercial Off-The-Shelf Software Validation for 21 CFR Part 11*
- Wayne Olson, *Rapid Analytical Microbioloty: The Chemistry and Physics of Microbial Identification*
- Mark Selby, *Supply of Chemicals in the Pharmaceutical Industry: Regulatory Guidelines and Rulings*

PDA co-published these and other technical books with Davis Harwood International Publishing, Ltd. (DHI). In 2003, a PDA Technical Books Advisory Board was established to:

- Search and review ideas and topics for books
- Search and verify the qualifications of an author for books
- Handle the peer-review of books

2003 Technical Book Advisory Board Members

Russell Madsen
PDA

Jeanne Moldenhauer, Ph.D.
Vectech Pharmaceutical Consultants, Inc.

Amy Davis
DHI

Jim Vesper
LearningPlus, Inc.

Carmen Wagner, Ph.D.
Strategic Compliance International

Siegfried Schmitt, Ph.D.
AmerSham Health

Richard Prince, Ph.D.
Richard Prince Associates

Nahid Kiani
PDA

PDA Technical Bulletins

PDA began publishing these short position papers as a quick response to issues raised during regulatory inspections around the world in 2002. These scientifically-based papers can be used to support an industry response to a regulatory concern. They address a single issue in one or two pages and consist of an issue statement, recommendation, rationale for the recommendation and references, whenever available. They are peer-reviewed by at least two experts to ensure scientific credibility. Technical Bulletins are available to all PDA members on the PDA Web site, *www.pda.org*.

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University of Illinois

Joseph Robinson, Ph.D.
University of Wisconsin

Theodore Roseman, Ph.D.
Baxter Healthcare Corporation

2003 PDA Science Advisory Board

Image supplied by Millipore Corporation

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Ignacio Tintore, Ph.D.
Tiselab. SL

Lynn D. Torbeck
Torbeck and Associates, Inc.

Glenn E. Wright
Eli Lilly and Company

Science and Technology

During 2003, PDA published three Technical Bulletins:

- Technical Bulletin No. 2003-01, *Damaged Containers in Aseptic Process Simulation Tests (Media Fills)*
- Technical Bulletin No. 2003-02, *Incubation of Intervention Units in Aseptic Process Simulation Tests (Media Fills)*
- Technical Bulletin No. 2003-03, *Freezing Microbial Samples Prior to Testing*

PDA Journal of Pharmaceutical Science and Technology Editorial Advisory Board

To better address the growing challenge of publishing scientific journals in a crowded and competitive market, PDA assembled a new Editorial Advisory Board (EAB) for the *PDA Journal of Pharmaceutical Science and Technology*. Chaired by Journal Editor Lee Kirsch, Ph.D., Professor, The University of Iowa, the EAB met at the 2003 PDA Annual Meeting in Atlanta, Georgia, to establish a strategy for the Journal in 2004.

PDA Technical Reports and Task Forces

One of the most substantial contributions PDA members have made to the communities over the years has been the publication of the PDA technical reports. In total, PDA has published 36 technical reports on a wide variety of subjects relating to pharmaceutical production, validation and quality assurance.

Throughout 2003, the SAB, members and the PDA Science and Technology Department devoted a significant amount of time to 16 separate technical report projects, three of which involve updates and revisions to existing technical reports. The technical report projects reached various stages in 2003, ranging from initial proposal to final review. Thanks to the hard work of the technical report Task Forces and the member volunteers during 2003, PDA anticipates publishing several technical reports in 2004.

The Audit Repository Center (ARC)

By the end of 2003—ARC's fourth year of operation—over 65 pharmaceutical, biotechnology and medical device companies used ARC's services to obtain PDA Technical Report #32 supplier audit data.

2003 was another successful year for ARC as 14 companies subscribed to ARC's computer audit service for the very first time. Another 25 companies renewed their subscriptions.

ARC added new audits to its audit library for eight companies, including Waters Corporation, Agilent Technologies, Documentum, Rational Software and GE Kaye instruments. Serena Software and IBM joined the repository as "participating suppliers" (paying for and providing their audits as opposed to being audited by a customer) and Sparta Systems and Applied Biosystems renewed for two more years as participating suppliers.

Interest Groups are a unique and valuable PDA resource. PDA members form these groups, which meet every year at major PDA events like the annual meeting and the PDA/FDA Joint Regulatory Conference, to discuss specific topics of special interest. Interest Groups represent an excellent opportunity for members to exchange new ideas and network. They also represent a great way for members to start engaging themselves in PDA. Interest Group Leaders often become members of Task Forces, the PDA Regulatory Affairs and Quality Committee and the PDA Science Advisory Board. Most members of the PDA Board of Directors traditionally first became involved via PDA Interest Groups.

The 2003 PDA Interest Groups and Leaders

Biotechnology
Frank Matarrese
Chiron Corporation

Computer Systems
Barbara L. Meserve
The Hollis Group, Inc.

Contract Manufacturing
Thomas E. Handel
Meridian Medical Technologies, Inc.

Drug-Device Delivery Systems
Raymond A. Pritchard
Alkermes, Inc.

Filtration
Jack Cole
Jack Cole Associates LLC

GMP Purchasing
Nancy M. Kochevar
Amgen Inc.

Inspection Trends/Regulatory Affairs
Robert L. Dana
Elkhorn Associates, Inc.

Isolation Technology
Dimitri P. Wirchansky
Jacobs Engineering Group, Inc.

Lyophilization
Edward H. Trappler
Lyophilization Technology, Inc.

Microbiology/Environmental Monitoring
Jeanne E. Moldenhauer, Ph.D.
Vectech Pharmaceutical Consultants, Inc.

Ophthalmics
Chris Danford
Alcon Laboratories, Inc.

Packaging Science
Edward J. Smith, Ph.D.
Wyeth Pharmaceuticals

Pharmaceutical Water
Theodore H. Meltzer, Ph.D.
Capitola Consulting Co.

Production and Engineering
Frank Bing
Abbott Laboratories

Quality Assurance/Quality Control
Don E. Elinski
Eli Lilly and Company

Solid Dosage Forms
Pedro J. Jimenez, Ph.D.
Eli Lilly and Company

Stability
Rafik H. Bishara, Ph.D
Eli Lilly and Company

Sterilization/Aseptic Processing
James P. Agalloco
Agalloco & Associates

Training
Thomas W. Wilkin, Ed.D.
Schering-Plough Corporation

Vaccines
Frank S. Kohn, Ph.D.
FSK Associate

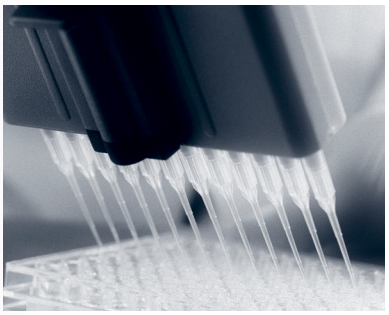
Validation
Bohdan M. Ferenc
Qualification Services

Visual Inspection of Parenterals
John G. Shabushnig, Ph.D.
Pfizer Inc.

2003 was a busy year for the PDA Regulatory Affairs and Quality Committee (RAQC) and the PDA Quality and Regulatory Affairs Department as healthcare authorities worldwide—particularly in the U.S. and Europe—looked to advance regulatory harmonization and to implement new and better approaches to pharmaceutical and biopharmaceutical regulations and quality control.

A major component of PDA's regulatory affairs and quality-related work is dedicated to scientifically analyzing regulatory policies and guidances and submitting written opinions, or comments, to the health authorities. Health authorities rely on science-based, objective commentary from stakeholders to ensure policies and guidances are based on sound scientific principles and are not redundant, burdensome or unnecessary.

In 2003, PDA was actively involved in a number of policy initiatives of the U.S. Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA) and the World Health Organization (WHO).



U.S. FDA

Over the course of 2003, FDA released a number of policy guidances and initiatives related to pharmaceutical and biopharmaceutical manufacturing and quality control. In September alone, the Agency published one final and four draft guidances. PDA provided science-based comments on the following guidances, proposed rules and FDA queries:

- "Guidance for Industry: Comparability Protocols—Chemistry, Manufacturing and Controls Information"
- "Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application"
- "Draft Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing"
- "Draft Guidance for Industry: PAT—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance"
- "Draft Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing and Controls Information"
- Proposed Bar Code Rule
- FDA query regarding its Reporting Biological Deviations in Manufacturing rule.

PDA members played an influential role in the development of the FDA draft guidance on aseptic processing. The PDA Aseptic Processing Task Force, formed in 2001, published a "Points to Consider for Aseptic Processing" as a supplement to the March/April 2003 *PDA Journal of Pharmaceutical Science and Technology*. Next, as a founding member of the Product Quality Research Institute (PQRI), PDA supported the formation of a PQRI working group to address specified key questions relating to the FDA preliminary concept paper called, "Sterile Drug Products Produced by Aseptic Processing." Members of the PDA Task Force provided the leadership and the core members for the PQRI working group, which published its final report in March 2003. When the FDA published its "Draft Guidance for Sterile Drug Products Produced by Aseptic Processing" in September 2003, the PDA Task Force evaluated the entire document independently and submitted 31 pages of comments to the FDA in November 2003.

The following PDA members and staff participated in the Aseptic Processing Task Force and PQRI working group.

Chair: Glenn Wright
Eli Lilly and Company

James Agalloco
Agalloco & Associates

James Akers, Ph.D.
Akers, Kennedy & Associates

Diane Alexander
U.S. FDA

Barbara Bassler, Ph.D.
Bridge Associates International

Susan Bruederle
U.S. FDA

Don Burstyn, Ph.D.
Alkermes, Inc.

Roger Dabbah, Ph.D.
U.S. Pharmacopeia

Roger Deschenes
AstraZeneca

William Frieben, Ph.D.
Pfizer Inc.

Richard Friedman
U.S. FDA

John Grazal
AstraZeneca

Klaus Haberer, Ph.D.
Compliance Advice & Services

Nigel Halls, Ph.D.
GlaxoSmithKline, ret.

Karl Hofmann
Bristol-Myers Squibb Company

David Hussong, Ph.D.
U.S. FDA

Richard Johnson
Abbott Laboratories

Kunio Kawamura, Ph.D.
Otsuka Pharma. Co., Ltd.

Lee Kirsch, Ph.D.
University of Iowa

Carol Lampe
Baxter Healthcare Corporation

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John Lindsay
Aseptic Solutions, Inc.

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Leonard Mestrandrea, Ph.D.
Pfizer Inc.

Karl Minor
Eli Lilly and Company

Kenneth Muhvich, Ph.D.
Micro-Reliance LLC

Terry Munson
KMI/PAREXEL

Rainer Newman
Johnson & Johnson

Jean Olsen
GlaxoSmithKline

Carolyn Renshaw
U.S. FDA

Robert Sausville
U.S. FDA

Neal Sweeney, Ph.D.
U.S. FDA

Ian Symonds
GlaxoSmithKline

Laura Thoma, Ph.D.
University of Tennessee

Brenda Uratani, Ph.D.
U.S. FDA

Martin Van Trieste
Abbott Laboratories

Richard Wood, Ph.D.
Pfizer Inc.

Jeff Yuen
Jeff Yuen and Associates

Throughout 2003, PDA's RAQC, members and staff closely followed the progress of the FDA quality initiative—"A Risk-Based Approach to Pharmaceutical Current Good Manufacturing Practices (cGMP) for the 21st Century." FDA senior staff appeared at the 2003 PDA/FDA Joint Regulatory Conference in September to provide updates on many elements of the initiative and Center for Drug Evaluation and Research (CDER) Acting-Director Steven Galson, Ph.D., provided an end-of-year progress report on the initiative at the 2003 PDA Annual Meeting.

The PDA RAQC nominated PDA member Gerry Migliaccio (Pfizer Inc.) to fill the newly created industry representative seat (non-voting) on FDA's Advisory Committee for Pharmaceutical Science; FDA chose him for the seat.

EMEA

PDA strengthened its relationship with the EU's EMEA during 2003. In autumn, PDA and the EMEA jointly sponsored a public conference on virus safety—the first time the two organizations teamed up in this way. Also during 2003, PDA was one of a select group of pharmaceutical associations chosen to participate in the EMEA's "GMP Inspectors Group: Interested Parties Meeting."

Moreover, PDA's RAQC moved very quickly to address the many compliance issues that arose following the revision of the European Commission Good Manufacturing Practices Guide to Annex 1, "Manufacture of Sterile Medicinal Products." On July 30, 2003, PDA held a one-day workshop to discuss the changes, PDA comments and the results of a meeting in London on the revisions. RAQC also submitted science-based comments to the EMEA regarding GMP Annex II note for guidance on "Process Validation, Non-standard Processes."

World Health Organization

2003 marked the first time PDA was officially approved to comment on World Health Organization draft guidances and policies. PDA's RAQC commented on the following WHO guidances:

- WHO Sampling Guideline
- WHO Validation

Regulatory Affairs and Quality

2003 RAQC

Chair: Suzanne Levesque
Sabex, Inc.

Jennie Allewell
Cell Therapeutics, Inc.
(RAQC Asian-Pacific Regional Liaison)

Vincent Anicetti
Genentech, Inc.

Donald Bake, Ph.D.
Fujisawa Healthcare, Inc.

Stephen Bellis
AstraZeneca

Robert L. Dana
Elkhorn Associates, Inc.

Rebecca A. Devine, Ph.D.
Consultant

Don E. Elinski
Eli Lilly and Company

Michael A. Gross, Ph.D.
Aventis Behring

Hiltrud Horn, Ph.D.
Horn Pharmaceutical Consultants

Richard M. Johnson
Abbott Laboratories

James C. Lyda
KMI/PAREXEL LLC

Russell Madsen
PDA

Gautam Maitra
PDA

Steven R. Mendivil
Amgen Inc.

David J. Miner, Ph.D.
Eli Lilly and Company

Toshiaki Nishihata, Ph.D.
Santen Pharm Co. Ltd.

Amy M. Scott-Billman
GlaxoSmithKline

Lisa M. Skeens, Ph.D.
Baxter Healthcare Corporation
(RAQC North American Regional Liaison)

Anders Vinther, Ph.D.
CMC Biopharmaceuticals A/S
(RAQC European Regional Liaison)

Career-long learning is the core of PDA's mission and the PDA Training and Research Institute continues to provide the most valuable hands-on training available in the community. With the number of training options growing each year, the PDA Training and Research Institute offers one of the only nonprofit production and laboratory facilities dedicated to instruction of pharmaceutical and biopharmaceutical professionals. In its sixth year, the Institute expanded its offerings, served more students and provided valuable services to industry and regulators alike.

Inspectorate Training

The "Regulatory Compliance School for the Italian Pharmaceutical Inspectorate" sponsored by the PDA Training and Research Institute was a valuable service for the entire community. The PDA Training and Research Institute administered the program for the Italian Ministry of Healh and the Instituto Superiore di Sanita. The school offered six training modules for a majority of the Italian inspectors. We thank PDA member Carmen M. Wagner, Ph.D., (Strategic Compliance International Inc.) for her hard work as Director of the Regulatory Compliance School for the Italian Inspectorate. PDA also thanks Dr. Jörg Neuhaus from the German Inspectorate for teaching many of the training courses. Dr. Neuhaus' hard work and dedication earned him PDA's 2003 James P. Agalloco Award, given to the PDA member who exemplifies excellence in education.

Laboratory Course Training

The PDA Training and Research Institute continued its extremely popular Aseptic Processing course, which utilizes the only aseptic processing facility of its kind dedicated to this important training for pharmaceutical and biopharmaceutical manufacturers. The two-week, two-part course was held four times in 2003 and helped over 80 community professionals learn how to effectively work in an aseptic processing environment within the boundaries of regulatory expectations. This course provides unparalleled value to PDA members and the pharmaceutical and biopharmaceutical communities.

An additional eleven laboratory courses were held at the PDA Training and Research Institute facility in 2003 with over 120 people benefiting from the learning experience. These courses addressed:

- Cleaning Validation
- Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance
- Ensuring Measurement Integrity in the Validation of Thermal Processes
- Environmental Mycology Identification Workshop
- Fundamentals of D, F and Z Value Analysis

Lecture Course Training

PDA's Training and Research Institute provides lecture courses at its facility and at various locations around the world, including at company locations. In 2003, 60 lecture courses were conducted worldwide for approximately 1,459 participants in the following cities:

Atlanta, Georgia	Prague, Czech Republic
Baltimore, Maryland	San Diego, California
Boston, Massachussetts	San Francisco, California
Charleston, South Carolina	Washington, D.C.

Courses offered were:

- A Practical Approach to Aseptic Processing and Contamination Control
- Achieving cGMP Compliance during Development of a Biotechnology Product
- Active Pharmaceutical Ingredients: Manufacture & Validation
- Analytical Problem Solving for CAPA Systems
- Annual Product Reviews: How to Comply with FDA & ICH Requirements
- Aseptic Processing Validation – Trends & Issues
- Assay Validation
- Assessing Packaging and Processing Extractables/Leachables
- Auditing Techniques for cGMP Compliance
- Basic Concepts in Cleaning and Cleaning Validation
- Beyond the GMP/ISO Basics – Practical Strategies for Everyday Compliance
- Bioassay Development & Validation
- Biopharmaceutical QA/QC for Senior Management
- cGMP & Compliance
- Change Control & Documentation
- Cleanroom Management
- Computer-Related Systems Validation
- Conducting Compliant Deviation Investigations for Pharmaceutical Industry
- Designing, Monitoring and Validation of Pharmaceutical Manufacturing Ventilation
- Environmental Monitoring in Pharmaceutical Manufacturing
- Everything You Wanted to Know About Environmental Monitoring, but were Afraid to Ask
- Failures/Deviations and Change Control
- GMP for Investigational Medicinal Products – Draft GMP Annex 13 and the European Clinical Trials Directive
- GMP Fundamentals
- GMP Training Manager Workshop
- Good Documentation Practices in the Pharmaceutical Industry
- Improving Sterile Drug Submissions to the FDA

- Knowledge & Skills of the Successful QA/QC Manger in the Pharmaceutical Industry
- Managing in a GMP Environment
- Maximizing SOPs – An Untapped Resource of Training
- Parenteral Packaging: Rubber, Glass, Plastic and Metal Seals
- Pharmaceutical Water Systems: A Practical Approach
- Preparing for a FDA Pre-Approval Inspection
- Sterile Pharmaceutical Dosage Forms: Basic Priniciples
- Tablet Formulation
- Validation of Sterilization Processes
- Validation: An Introduction
- Z1.4 Attribute Inspection Sampling in a cGMP Environment

Courses taught at company sites in 2003 were:

- PDA Computer Products Supplier Auditing Process Model: Auditor Training (March, July and September/October)
- Compliance Auditing of Cleanrooms and Controlled Environments (August)
- cGMP Trainers Qualification Program (August)
- PDA/BFS Joint Workshop on Blow/Fill/Seal Processing (September)

Applied Research

The PDA Training and Research Institute also lends its facility to firms who wish to test new analytical tools and manufacturing equipment. In 2003, faculty and staff were contracted for testing a new filling system developed by MedInstill Technologies. Results were presented at PDA's 2004 SciTech Summit and Annual Meeting in March in Orlando, Florida.

Image supplied by Pall Corporation

PDA Training and Research Institute 2003 Contributors

Atlantic Technical Systems	service calibrations
Becton Dickinson Microbiologics Systems	microbiology supplies
Bershire Corporation	supplies
bioMerieux, Inc.	supplies, equipment
Bioscience International	equipment
Biotest Diagnostics Corp.	service
Cardinal Health	supplies
Charter Medical, Inc.	supplies
Cole-Parmer	supplies
Contec, Inc.	supplies
Corning	supplies
DeconLabs	supplies
DuPont Tyvek	supplies
EMD Chemicals	supplies, equipment
GEKaye Instruments, Inc.	equipment, service
General Econopak, Inc.	supplies
Glove Pharma	supplies
Kimberly-Clark	supplies
Larson Mardon Wheaton	vials
Lyophilization Technology	services
Micronova Manufacturing, Inc.	supplies
Millipore Corporation	supplies
National Instruments Co.	services
Particle Measuring Systems	equipment, service
Perfex Corporation	supplies
R2s	services
Raven Biologicals Lab	supplies
Remel	supplies
Sartorius Corporation	equipment, service
Shott Glass	vials
Sievers Instruments, Inc.	services
Steris Corporation	services
Ultra Analytics	services
Veltek Associates, Inc.	supplies
West Pharmaceutical Services	supplies

PDA Training and Research Laboratory and Lecture Course Faculty

James Agalloco
Agalloco & Associates

Michael Akers, Ph.D.
Baxter Pharmaceutical Solutions

John Brecker
Decon Laboratories Inc.

Göran Bringert
GE Kaye, Inc.

Carolyn Broughton, Ph.D.
Genentech, Inc.

Tisha Butts
The Atlas Group

Rod Chu
MDS Nordian Inc.

A. Samuel Clark
KMI/PAREXEL

Nate Conover
PathWise, Inc.

James Cooper, Ph.D.
Endotoxin Consulting Services

Cheryl A. Custard
Aventis Pasteur SA

Anne Marie Dixon
Cleanroom Management Associates, Inc.

Gayle Dolecek, Ph.D.
AAC Consulting Group, Inc.

Jayne Dovin
GlaxoSmithKline

J. Kirby Farrington, Ph.D.
Eli Lilly and Company

Hubert Fleming, Ph.D.
Black Diamond Group

Renee Galkin
R.B. Galkin and Associates

David Gallup, Ph.D.
Training & Communications Group, Inc.

John Geigert, Ph.D.
Biopharmaceutical Quality Systems

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

Joseph Habarta, Ph.D.
J. Harbarta Consulting

Mark Hallworth
Particle Measuring Systems, Inc.

Peter Holman
Genentech, Inc.

Ruey-Ching Hwang, Ph.D.
Pharmacia Corporation

Sylvia Isaacson
Millipore Corporation

Patty Kiang, Ph.D.
Schering-Plough Corporation

Robert Kieffer, Ph.D.
RGK Consulting

David Lansky, Ph.D.
Lansky Consulting, LLC.

Destin LeBlanc
Cleaning Validation Technologies

Geoge Levinson
Compliance Software Solutions

John Lindsay
Aseptic Solutions, Inc.

Robert Livingston
Arion Water, Inc.

Sandra Lowery
Quality Systems Consulting, Inc.

John Ludwig, Ph.D.
Pfizer Inc.

Dave Manley
Biomeiux Industry

Jeffrey Masten
Genentech, Inc.

David Matsuhiro
Cleanroom Compliance, Inc.

Robert J. Mello, Ph.D.
PDA

Theodore Meltzer, Ph.D.
Capitaola Consulting Co.

Steven Messick
Genentech, Inc

Jeanne Moldenhauer, Ph.D.
Vectech Pharma. Consultants, Inc.

Kenneth Muhvich, Ph.D.
Micro-Reliance, LLC.

Alan Newberry MRSC
KMI/PAREXEL

Diane Paskiet
Monarch Analytical Laboratories, Inc.

Gilbert Paul
Arion Water, Inc.

Velumani Pillai
Pfizer Inc.

Elaine Lehecka-Pratt
Lehecka Pratt Associates, Inc.

Maureen Reagan
Quality Systems Consulting, Inc.

Thomas Reidy
Shire Biologics, Inc.

Rick Rogers
Consultant

Richard Sands
RTS Training Services

Dale Seiberling
Electrol Specialties Company

Anne Shandy
Aseptic Solutions, Inc.

John Shirtz
American Pharmaceutical Partners, Inc.

Alan Smith, Ph.D.
Pharmaceutical Quality & Technology Consultant

Edward Smith, Ph.D.
Wyeth Pharmaceuticals

Jenny Stevens
Merck & Co., Inc.

Ronald Tetzlaff, Ph.D.
KMI/PAREXEL

Lynn Torbeck
Torbeck and Associates, Inc.

Edward Trappler
Lyophilization Technology, Inc.

Art Vellutato, Jr.
Veltek Associates, Inc.

James Vesper
LearningPlus, Inc.

Jon Voss
Genzyme Corporation

Charles Waite
Process Design Consultants, Inc.

Richard Wood, Ph.D.
Pfizer Inc.

PDA is respected globally for providing unparalleled education, training and research in pharmaceutical and biopharmaceutical science and technologies. In 2003, PDA offered an unprecedented number and variety of career-long learning educational, scientific, and technical programs. Without the tireless efforts of the members who volunteer to serve on PDA's program planning committees, these meetings could not have come to fruition. PDA extends its gratitude to these individuals for their input and vision in arranging a successful year of meetings.

The following meetings were held in 2003:

2003 PDA International Congress, Courses and Exhibition
February • Prague, Czech Republic
Back to the Future—Ahead to the Past
Program Planning Committee Chair: Trevor Deeks, Fluor Limited, UK

2003 PDA Spring Conference, Courses and Exhibition
March • San Diego, California
Bridging the Gap between Science and Compliance
Co-Chairs: Rhona M. O'Leary, Ph.D., Genentech, Inc., and Robert C. Branning, Genetech, Inc.

ICH Q7A Training Workshops
August • San Francisco, California

2003 PDA/FDA Joint Regulatory Conference, Courses and Exhibition
September • Washington, D.C.
Navigating Current GMPs: Catch the Compliance Wave
Chair: Frank F. Settineri, Chiron Corporation

2003 PDA/EMEA European Virus Safety Forum
September/October • Langen, Germany

2003 Taormina Conference and Exhibition
October • Taormina, Sicily, Italy
Managing for Quality in a Cost-Focused Environment
Chair: Antonio Giannetto, S.I.F.I. SpA

2003 PDA Annual Meeting, Courses and Exhibition
November • Atlanta, Georgia
Chair: Shelley A. Abrams, Eli Lilly and Company

Audio Conferences

In 2003 PDA began to offer audio conferences to better serve our members' needs. The following audio conferences were offered in 2003:

- FDA's Aseptic Processing Concept Paper
- Emerging Rapid Microbial Methods Technology
- Quality Contracts from Both Sides of the Table
- How to Build an Effective CAPA Program

Exhibitions

PDA continued to host successful product and service exhibitions during 2003. In 2003, exhibitions were held in conjunction with the International Congress, the Spring Conference, the PDA/FDA Joint Regulatory Conference, the Taormina Conference and the Annual Meeting. PDA wishes to thank all of our exhibitors in 2003 and especially our "platinum" exhibitors.

PDA thanks the Exhibit Advisory Committee for all their time and hard work helping us plan successful and valuable exhibitions.

Exhibit Advisory Committee

Chair: Thomas Handel
Meridian Medical Technologies, Inc.

Richard Levy, Ph.D.
KMI/PAREXEL

Howard Drake
Saint Gobain Desjonquers Pharmaceutical Division

Carol Dellicicchi
Pall Corporation

Carol Julich
Biotest Diagnostic Corporation

Jerry Kirkpatrick
Hach Ultra Analytics

Kevin O'Brien
Alliance Medical Products, Inc.

Melissa Rossi
Associates of Cape Cod

Georgia Tsaganos
American Pharmaceutical Partners, Inc.

Art Vellutato, Jr.
Veltek Associates Inc.

Nahid Kiani
PDA

Wanda O. Neal
PDA

The PDA Membership Community is comprised of more than 10,000 individual members representing regulatory agencies, academia and industry, who are leaders in pharmaceutical and biopharmaceutical science and technology.

Together, we are dedicated to encouraging excellence and innovation in pharmaceutical and biopharmaceutical science and technology, expanding the body of scientific work that serves as the foundation for our communities, and linking good science with good manufacturing and good quality control with good regulatory practices.

In 2003, PDA was proud to add several new benefits, better enabling members to …

- Easily access the latest scientific and regulatory advances
- Learn from global experts through conferences, training programs, scientific publications and resources available only from PDA
- Participate in a diverse network of over 10,000 dedicated individuals who share their knowledge and expertise, answering specific questions and offering solutions to the challenges faced on the job
- Discover new opportunities
- Grow professionally and have fun!

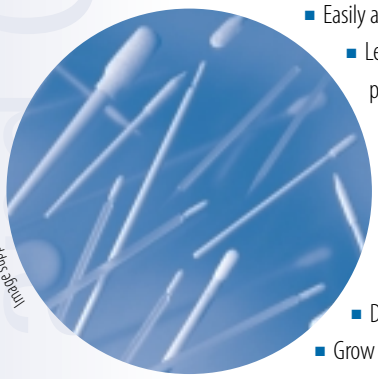


Image supplied by ITW Texwipe

New member benefits introduced in 2003 include …

- **Online PDA Publications E-store:** Provides members with an interactive one-stop shop for pharmaceutical and biopharmaceutical science, technology and regulatory publications and *Career-long Learning* resources
- **Online Career Center:** Offers user-friendly job searches, the ability to store and maintain résumés and cover letters, and utilize "search agents" for e-mail notification of job matches
- **PDA Chapter Regulatory Comments Program:** Enables PDA Chapters to conveniently provide science-based input directly to PDA on regulatory guidances and documents from health authorities from around the world
- **Member Volunteer Program:** Provides a cost-effective way for members to participate in PDA events for which they provide volunteer assistance
- **New PDA Chapters – France, Prague, Puerto Rico and Spain:** Provides members with a local structure to better meet their needs
- **PDA Chapter News:** A monthly electronic publication focused on PDA Chapter accomplishments, events, leadership, and the latest local PDA news
- **Memberships and Chapters Department:** Created to improve support and services to PDA members and the Chapters
- **Marketing Services Department:** Created to increase and improve communications to the membership
- **Chapter Coordinator Position:** Established to work closely with and support PDA Chapters worldwide
- **Senior Editor Position:** Established to bring an increased professional contribution to the *PDA Letter* and media publications
- **PDA Press Releases Program:** Established to better communicate PDA activities to the PDA communities and media worldwide

2003 PDA Chapters

Asia Pacific

Australia Chapter
Area Served: Australia
President: **Ken Dibble**
Millipore Australia

Japan Chapter
Area Served: Japan
President: **Katsutoshi Mise, Ph.D.**
Ministry of Health, Labour and Welfare

Korea Chapter
Area Served: South Korea
President: **Woo-Hyun Paik, Ph.D.**
Boryung Pharm. Co. Ltd.

Southeast Asia Chapter
Areas Served: ASEAN nations (including Brunei, Darussalam, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam, Laos, Myanmar and Cambodia)
President: **Kanneganti Prasad, Ph.D.**
Wyeth Pharmaceuticals Pte. Ltd.

Taiwan Chapter
Area Served: Taiwan
President: **Shin-Yi Hsu, Ph.D.**
Otsuka Pharmaceutical Co., Ltd.

Europe

Central Europe Chapter
Areas Served: Germany, Switzerland and Austria
President: **Erich Sturzenegger, Ph.D.**
Novartis AG

France Chapter
Area Served: France
President: **Jean Louis Saubion, Ph.D.**
UFCH

Italy Chapter
Area Served: Italy
President: **Vincenzo Baselli**
Pall Italia

Prague Chapter
Areas Served: Czech Republic, Hungary, Poland, Slovenia, Slovakia, and Croatia
President: **Zdenka Mrvova**
Zentiva

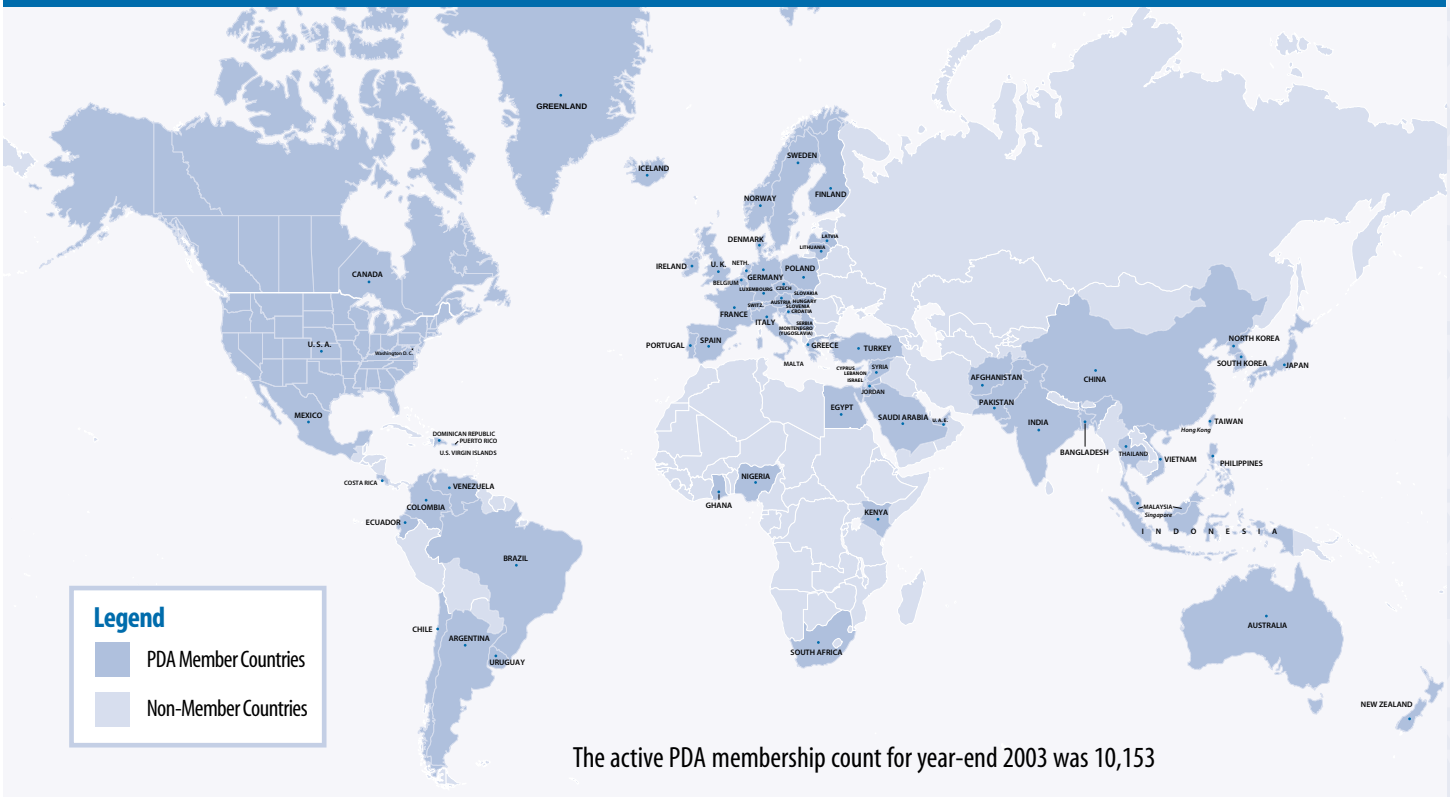
Spain Chapter
Area Served: Spain
President: **Jordi Botet, Ph.D.**
STE Compliance Services

United Kingdom and Ireland Chapter
Areas Served: UK & Ireland
President: **Frank Talbot**
FT Pharmaceutical Services

Middle East

Israel Chapter
Area Served: Israel
President: **Benny Klener**
Teva Pharmaceutical Industries Ltd.

Growing globally, active locally–the PDA membership represents 74 countries.



The active PDA membership count for year-end 2003 was 10,153

Membership and Chapters

North America

Canada Chapter
Area Served: Canada
President: **Grace Chin**
SNC-Lavalin Pharma

Capital Area Chapter
Areas Served: District of Columbia, Maryland, Virginia and West Virginia
President: **Barry Friedman, Ph.D.**
Cambrex Bio Science

Delaware Valley Chapter
Areas Served: Delaware, New Jersey and Pennsylvania
President: **Art Vellutato, Jr.**
Veltek Associates, Inc.

Metro Chapter
Areas Served: Connecticut, New Jersey and New York
President: **Frank R. Settineri**
Chiron Corporation

Midwest Chapter
Areas Served: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio and Wisconsin
President: **Amy Gotham**
BioReliance Corporation

Mountain States Chapter
Areas Served: Colorado, Idaho, Kansas, Montana, Nebraska, Oklahoma, Utah and Wyoming
President: **Paul Bilodeau**
Process Technologies, Inc.

New England Chapter
Areas Served: Connecticut, Maine, Massachusetts, Maine, New Hampshire and Rhode Island
President: **Mark A. Staples, Ph.D.**
MicroCHIPS, Inc.

Puerto Rico Chapter
Areas Served: Puerto Rico & Caribbean Basin
President: **Silma Bladuell**
Wyeth

Southeast Chapter
Areas Served: Florida, Georgia, North Carolina, South Carolina, Tennessee and Virginia
President: **Mary Carver**
Eisai Inc.

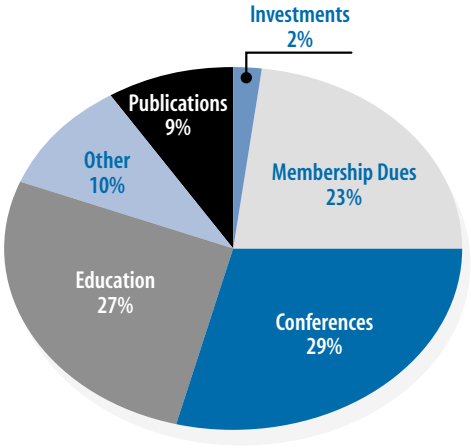
Southern California Chapter
Area Served: Southern California
President: **Kikoo Tejwani**
B. Braun Medical, Inc.

West Coast Chapter
Area Served: Northern California
President: **Randall Tedder**
IconNova

PDA is a financially independent, not-for-profit organization. The Association's primary sources of revenue are conferences, courses, publications and membership dues.

2003 was a financially challenging year for PDA. SARS and the war in Iraq adversely impacted PDA just as they negatively impacted the global economy. SARS forced cancellation of the PDA International Congress in Singapore. The Taormina Conference was postponed. The Toronto Course series was postponed and moved. The Puerto Rico Course series was postponed. The war in Iraq produced travel restrictions resulting in light attendance at PDA conferences and courses throughout the year.

PDA's 2003 Income Sources



Compensating for travel restrictions to enable the membership to participate in educational opportunities, PDA added a number of conferences and courses to bring PDA educational programs geographically closer to the membership. While 2003 revenues were well below budget, these additional conferences and courses boosted 2003 revenues to 2002 levels.

While these additional conferences and courses increased revenues (and the opportunities for the membership), they added 20% to expenses in 2003 versus 2002. PDA was successful in holding down expenses in 2003 to 89% of the 2003 budget.

Our investments, which are primarily in conservative instruments appropriate for a nonprofit association, experienced moderate capital gains of US$368,155 (compared to a loss of US$115,620 in 2002) which reflects the improving financial market which existed in 2003.

Net assets at the beginning of 2003 were 24% higher than at the beginning of 2002. During 2003, PDA's net assets decreased by US$218,670, a decrease of 5% from that recorded at the end of 2002. At the year-end 2003, our reserve ratio stood at 46.3%, which compares satisfactorily against the industry average of 47% among associations of PDA's size (according to the American Society of Association Executives *Operating Ratio Report*—10th Edition).

Unadjusted Financial Performance

	Years ended December 31		
	2003 Actual	**2003 Budget**	**2002 Actual**
Total revenues:*	US$ 8,113,279	US$ 9,500,000	US$ 8,160,374
Total expenses:	US$ 8,700,104	US$ 9,570,000	US$ 7,232,126
Excess revenues over expenses from operations:	US$ (586,825)	US$ (70,000)	US$ 928,248
Unrealized (losses) gains on investments:	US$ 368,155	US$ 0	US$ (115,620)
Increase in net assets (reserves):	US$ (218,670)	US$ (70,000)	US$ 812,628
Net assets at beginning of year:	US$ 4,243,159	US$ 4,243,159	US$ 3,430,531
Net assets at end of year:	US$ 4,024,489	US$ 4,173,159	US$ 4,243,159
Reserve Ratio (net assets/annual expenses):	46.3%		58.7%

*Net of Bank Charges

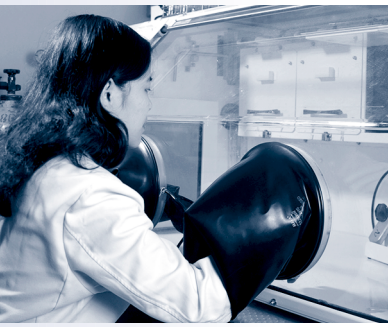
PDA Honor Awards in 2003

The following awards were bestowed at the 2003 PDA Annual Meeting.

Honorary Membership: 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, and honorary members are not eligible for other awards in the same year.

Frederick Gustafson, Abbott Laboratories (retired). Fred was a long-time member of the Regulatory Affairs Committee, where he chaired task forces that provided comments on FDA guidance and proposed regulations. He also led PDA's activities in working with FDA to propose and discuss post-approval changes for sterile products and chaired a workshop jointly sponsored by PDA and FDA on this topic.

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.



Julius Knapp, Principal, Research & Development Association. Julius has authored more than twenty papers published between 1980 and 2003 in the PDA *Journal of Pharmaceutical Science and Technology* and its predecessor, the *Journal of Parenteral Science and Technology*. In 1984, he won the PDA Journal Award for the best paper published in PDA's journal. Julius currently chairs PDA's Visual Inspection of Parenterals Task Force, which is developing PDA Technical Report No. 37, "Strategies for Effective Visual Inspection of Parenterals."

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 past or present Board members whose services on the Board are determined by his/her peers as worthy of recognition.

Henry Kwan, Ph.D., Kwan Consulting, LLC. Henry served as a Director on the PDA Board in the 1980's and 1990's. He was Chairman of the Awards Committee for 10 years and did an outstanding job of identifying and recognizing the major contributors to PDA. He is well known for his dedication and tremendous efforts in PDA related activities.

Distinguished Service Award: Given for special acts, contributions or service that has contributed to the success and strength of PDA.

Don Elinski, Validation Manager, Eli Lilly and Company, is a member of PDA's Science Advisory Board (SAB) and the Out-of-Specifications (OOS) Results Task Force, and is the leader of the QA/QC Interest Group. Don chaired PDA's Solid Dosage Process Validation Committee, out of which was produced PDA Technical Report No. 25, "Blend Uniformity Analysis: Validation and In-Process Testing." Don also served on PDA's Regulatory Affairs and Quality Committee (RAQC).

Taiichi Mizuta, Ph.D., Shionogi & Co., Ltd. Dr. Taiichi Mizuta is a founder and former president of the PDA Chapter in Japan. He also served on PDA's Board of Directors from 2000-2002. In the mid-1990's he was extremely active and helpful in setting up PDA meetings in Osaka and Tokyo, and was co-chair of several joint Chapter and U.S. PDA meetings.

Thomas Wilkins, Ed.D., Director of Technical Operations Training at Schering–Plough Corporation. Thomas has been the Chairman of the Training Interest Group since 1998. In 1996 he chaired the PDA Training Conference in McLean, Virginia, and in 2001, was the Co-Chair of the PDA International Conference in Kyoto, Japan. He has helped plan and has spoken at several other PDA conferences.

Service Appreciation Award: Given for special acts, contributions or service that has contributed to the success and strength of PDA's Exhibit Advisory Board.

Thomas Handel, Vice President – Homeland Security, Meridian Medical Technology. He has extensive experience in numerous aspects of the parenteral pharmaceutical industry, as well as a blend of business, technical and managerial skills. His technical and managerial background encompasses a variety of fields such as chemistry, microbiology, physical quality control, auditing, aseptic manufacturing, project management and business development.

James P. Agalloco Award: Presented to the PDA faculty member each year who exemplifies outstanding performance in education. Named for James P. Agalloco in honor of his work in developing the PDA education program.

Jörg Neuhaus, Ph.D., Governmental Director on Pharmacy, the German Inspectorate. Dr. Neuhaus has lectured at the University of Bonn on quality assurance. He is a frequent presenter of training courses and congresses in Europe and the United States and was a major contributor to PDA's training program in regulatory compliance for the Italian Inspectorate.

Korczynski Award: This grant recognizes the contribution made toward the development of PDA's international activities by Michael S. Korczynski, Ph.D. The grant funds travel expenses for an international guest to deliver the "Korczynski Paper" at a PDA meeting.

Anders Vinther, Ph.D., Chief Quality Officer, CMC Biotech A/S. Dr. Vinther delivered his paper at the 2004 PDA SciTech Summit. He is an RAQC member and a member of the 2004 Board of Directors.

Frederick D. Simon Award for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology* in 2003. This awards is named in honor of the late Fred Simon, a previous PDA Director of Scientific Affairs.

David Watling, Ph.D., et al, for "Theoretical Analysis of the Condensation of Hydrogen Peroxide Gas and Water Vapor as Used in Surface Decontamination."

PDA Chapter Award: This 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.

Robert Pazzano, Director of Business Development, VTS Consultants (New England Chapter),

Susan Moore, Application Specialist, Millipore Corporation. (Southeast Chapter),

Jong Hwa Oh, President, Pharmaplan Korea (Korea Chapter)

Anthony Rowland, Director at Seer Pharma (Australia Chapter).

PDA Awards

2004 Officers

Chair
Nikki V. Mehringer
Eli Lilly and Company

Chair-elect
Richard V. Levy, Ph.D.
PAREXEL Consulting

Secretary
Stephanie R. Gray
GlaxoSmithKline, ret.

Treasurer
Georg L. Roessling, Ph.D.
Schering AG

Immediate Past Chair
Floyd Benjamin
Keystone Pharmaceuticals, Inc.

2004 Leadership

Directors

Jennie Allewell
Wyeth Research

Vincent R. Anicetti
Genentech, Inc.

Robert L. Dana
Elkhorn Associates, Inc.

Rebecca A. Devine, Ph.D.
Consultant

Kathleen S. Greene
Novartis Pharmaceuticals Corporation

Yoshihito Hashimoto
Chiyoda Corporation

Maik W. Jornitz
Sartorius Corporation

Suzanne Levesque
Sabex, Inc.

Tim R. Marten, Ph.D.
AstraZeneca

John G. Shabushnig, Ph.D.
Pfizer Inc.

Lisa M. Skeens, Ph.D.
Baxter Healthcare Corporation

Anders Vinther, Ph.D.
CMC Biopharmaceuticals A/S









2004 Senior Staff

(Top row)

Neal G. Koller
President

George A. Robertson, Ph.D.
Vice President, Science and Technology

Victoria A. Dedrick
Vice President, Quality and Regulatory Affairs

Gail H. Sherman
Vice President, Education
Director, PDA Training and Research Institute

Lance K. Hoboy, CAE
Vice President, Finance and Strategic Planning

(Bottom row)

Wanda O. Neal
Director, Programs and Meetings

Nahid Kiani
Senior Sales Manager

Gautam Maitra
European Director

Matthew Clark
Director, Marketing Services
Director, Membership and Chapters

PDA Headquarters

Shelbah Adams
Executive Assistant to the President

Nancy Berlin
Manager, Audio and Web Conferences

Jason E. Brown
Meetings Coordinator

Feng Chen
IT Engineer

Janny Chua
Manager, Product Operations

KiKi Coffman
Chapter Coordinator

Nickia Gouldbourne
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