PDA
An International Association For Pharmaceutical Science And Technology

2004 Annual Report

PDA'S MISSION

Advance Pharmaceutical & Biopharmaceutical Science & Technology Internationally by Promoting Scientifically Sound & Practical Technical Information & Education for Industry & Regulatory Agencies

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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.

MESSAGE
from the Chair

Chair,
PDA Board of Directors
Nikki V. Mehringer
Eli Lilly and Company

2004 was a year of challenges and opportunities for the pharmaceutical and biopharmaceutical industries, and as result, for PDA. In fact, this is a unique moment in the history of our global industry and our association. Multiple forces around the world are converging to a vision for the future shared by industry and regulatory agencies worldwide. In this vision, expectations for manufacturers are raised, efficiency and innovation are valued, continuous improvement is expected, and expertise and process understanding are required. All of this can only be accomplished through the integration of design, development, good science and quality systems in a life-cycle approach for products. Regulatory initiatives—through the International Conference on Harmonization, the U.S. FDA's "cGMPs for the 21st Century" and the EU European Medicines Agency—demonstrate the broad support for this vision among all the industry's stakeholders.

During 2004, PDA provided support and leadership to these key initiatives and others like them. Through PDA, our members have been well-informed of the changes in the environment and have had opportunities for active participation and input to these initiatives. Additionally, PDA has provided specific educational and conference activities to assist our members in the interpretation, application and implementation of new regulatory concepts and guidances as they are introduced. All of this has made for an exciting and productive 2004.

Throughout our history, PDA has been distinguished by our ability to provide the integration and practical application of science, technology, regulatory affairs and quality to the issues most important to our members and our communities. **Floyd Benjamin,** Keystone Pharmaceuticals, PDA Chair from 2002 to 2003, successfully upheld this tradition. Floyd's contributions as Chair reflected his many years of experience in active service to PDA. During his tenure, Floyd oversaw important changes both within and outside of PDA and worked tirelessly to support the best interests of the Association and its members. It was our pleasure to serve with Floyd, and it is clear that we have all benefited and learned many things from his leadership and insight.

With the close of 2004, some long-time and dedicated PDA members move on to new roles within our community. **Robert Dana,** Elkhorn Associates, Inc., and **Suzanne Levesque,** Sabex Inc. (now Sandoz, a division of Novartis), completed their service as members of the PDA Board of Directors. Bob and Suzanne's contributions to the PDA Board were significant, and we anticipate that their contributions to PDA will not end. Thank you for your considerable time and expertise. We look forward to our future work together.

Likewise, we thank **Robert Mello, PhD,** PDA's former Vice President of Education and past member of the Board, for his dedication to the mission of PDA. We look forward to continued contributions from Dr. Mello.

2004 is best described as the year of the PDA Strategic Plan. While our current six-point Strategic Plan was designed to guide us in our decision-making, we realized that it must evolve in order for PDA to continue to fulfill our Mission and move forward toward our Vision. To this end, PDA convened a new Strategic Planning Committee to assure our Plan, our principal decision-making guide, was as dynamic as the external environment and as the needs of our members. This committee met for the first time at our annual meeting in Atlanta in November 2003, established an aggressive timeline for its work, and quickly implemented several initiatives in 2004 to set the Plan in motion. To assure the new Plan is member-driven, the Strategic Planning Committee sponsored focus groups and surveys to provide data and insight into the key needs and concerns of our members. Results from the survey were studied by the Committee to understand how the association can come together and best use our resources to accomplish our goals. The data has become the foundation of our new Strategic Plan, which will be submitted to the Board for approval in 2005. This new Plan will not be a radical change in direction, but will provide more specific goals and activities to move forward. We sincerely thank the members of this committee for their thoughtful work and all the members of PDA who participated in providing answers to the surveys.

Our 2004 accomplishments were driven by a strong commitment to the current PDA Strategic Plan. We made great strides during 2004 to increase accessibility of various offerings to membership around the world. While membership held relatively steady, the total number of PDA's global chapters and affiliates grew to 24 with the addition of the India Chapter. Three new membership designations—Developing Economy, Academic and Student—made PDA more accessible to a wider array of scientific talent and greatly expanded the expertise of the membership. Furthermore, we added a dedicated audio-conference manager in 2004 who significantly increasd our operational capability to deliver timely and very cost effective science, technology and regulatory learning opportunities to our membership in the most cost-effective manner.

Our efforts to build a stronger liaison with regulatory authorities greatly benefited the membership. No PDA accomplishment was more exemplary of these strong relationships than the 2004 PDA/FDA Joint Regulatory Conference. The membership responded by attending in record numbers—over 900 participants met for the conference, exhibits and TRI courses. The PDA Regulatory Affairs and Quality Committee (RAQC) made a record 15 submissions of science based comments and recommendations to regulatory authorities around the world. The World Health Organization (WHO) requested PDA commentary on a draft guidance for sampling of pharmaceuticals and related materials. In addition, PDA strengthened or established liaison relationships with health authorities thoughout Europe, including the EMEA, as well as authorities in Jordan, Japan, Singapore, Canada and Taiwan.

MESSAGE
from the Chair

PDA appointed regional editors for the *PDA Journal of Pharmaceutical Science and Technology* in China, India and Thailand and launched two new student programs, the Student Research Symposium and the Student Fellowship Grant program, to promote submissions of cutting-edge scientific papers.

In a time of constant change, PDA staff and members sought to assure the financial resources needed to support PDA's mission. For 2004 this proved to be challenging. Attendance at our conferences during the first half of 2004 was considerably lower than usual. Both members and staff responded with dedication and vigor resulting in a conference and training course schedule for the second half of 2004 which was simply terrific. In 2004, we further built on the structural and system improvements made in 2003 for financial, accounting and forecasting systems to better track our services. We appointed a new outside auditor and established a member Audit Committee. The valuable work performed in 2004 will go a long way toward focusing our efforts to strengthen our financial position in 2005 and beyond.

PDA increased its ability to serve European members and the European Community as a whole by expanding staff and office capability in Brussels. This made it easier, more convenient and less costly for European members to interact with PDA.

Moving forward, PDA is assembling three new member-based advisory boards to help us further hone the quality of our scientific and educational activities: the Biopharmaceutical Advisory Board, the PDA Training and Research Institute Advisory Board and the Programs Advisory Board. Working together with the established Science Advisory Board and the Regulatory Affairs and Quality Committee, these important groups will direct our activities. PDA Interest Groups have been restructured into five sections to better incorporate them into our committee structure: Quality Assurance and Regulatory Affairs, Laboratory and Microbiology, Pharmaceutical Development, Biopharmaceutical Sciences, and Manufacturing Sciences. Interest Groups now include seven European branches which enhances networking opportunities for our members.

As the new year begins, our task is to build and enhance upon an impressive body of work. To this end, we will work to assure the integration and balance of our key scientific, technical, regulatory and quality disciplines, realizing that the credibility of our regulatory comment submissions is grounded in the soundness of our science. We will work to strengthen the member-based, data-based Strategic Plan that will guide our decision making for the future.

PDA members have much to look forward to in 2005. We are determined to continue providing the community with the best *Career-long Learning*™ technical resources, programs and courses. We encourage members to participate in surveys and other programs; we need your input, support, and cooperation to continuously improve our offerings and ensure the success of the exciting opportunities ahead of us.

We have full confidence in the continued success of PDA, based on the strength of our members, our Board and our staff. Our opportunities are plentiful. Working with our fine PDA staff and our members worldwide, we are energized to meet the opportunities and challenges we face together.

PDA's international activities continue to reach pharmaceutical and biopharmaceutical professionals around the world, including those in Russia, Mexico, Singapore (pictured on cover), Germany (Frankfurt pictured on cover), Taiwan, Australia and Jordan.

2004 PDA
Board of Directors

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Eli Lilly and Company

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Richard V. Levy, PhD
PAREXEL Consulting

Secretary
Stephanie R. Gray
GlaxoSmithKline, ret.

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Georg L. Roessling, PhD
Schering AG

Immediate Past Chair
Floyd Benjamin
Keystone Pharmaceuticals, Inc.

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Jennie Allewell
Wyeth Research

Vincent R. Anicetti
Genentech, Inc.

Robert L. Dana
Elkhorn Associates, Inc.

Rebecca A. Devine, PhD
Consultant

Kathleen S. Greene
Novartis Pharmaceuticals Corporation

Yoshihito Hashimoto
Chiyoda Corporation

Maik W. Jornitz
Sartorius Corporation

Suzanne Levesque
Sabex, Inc.

Tim R. Marten, PhD
Astra Zeneca

John G. Shabushnig, PhD
Pfizer Inc

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Anders Vinther, PhD
CMC Biopharmaceuticals A/S

SCIENCE AND TECHNOLOGY
Year in Review

In 2004, the PDA Science Advisory Board (SAB) voted on a number of Technical Report projects, two of which culminated in publications released during the year:

- Balloted and published: *GERM 3 (Good Electronic Records Management): Model for Systems Implementation and Evaluation*
- Balloted and published: Revision of *Technical Report #32: Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations*

Several Technical Report projects balloted during 2004 will be released during the first half of 2005, including:

- Balloted: *Technical Report 40: Sterilizing Filtration of Gases*

TR#32

Technical Report #32: Auditing of Suppliers Providing Computer Products and Services for Pharmaceutical Operations was developed by PDA in response to concerns about uncertainty, inconsistency and redundancy in the auditing process of suppliers. The report outlines a detailed six-step auditing process to be completed by qualified auditors, manufacturers and suppliers.

In association with TR#32, the PDA Industry Advisory Board (IAB) was created with the purpose of periodically reviewing and approving changes to the auditing process model and data collection tool. Additionally, the IAB monitors auditor qualifications requirements and maintains oversight of the Auditory Response Center (ARC). This group spearheaded the effort to revise TR#32.

PDA Technical Books

PDA members contributed three new technical books to our library in 2004:

- **U.G. Barad, PhD,** *Quality Assurance: A Practitioner's Guide*
- **Maik Jornitz, PhD,** and **Theodore Meltzer, PhD,** *Filtration Handbook: Liquids*
- **Bengt Ljungquvist, PhD,** and **Berit Reinmuller, PhD,** *Cleanroom Clothing Systems: People As A Contamination Source*
- **Richard Prince, PhD,** *Pharmaceutical Quality*

PDA co-publishes books with Davis Healthcare International Publishing, whose CEO, **Amy Davis,** is the recipient of the 2004 PDA Distinguished Service Award (see page 17).

PDA thanks the hard work of its Technical Advisory Board in 2003: **Russell Madsen,** The Williamsburg Group LLC; **Jeanne Moldenhauer, PhD,** Vectech Pharmaceutical Consultants, Inc.; **Amy Davis,** Davis Healthcare International Publishing; **James Vesper,** LearningPlus, Inc.; **Carmen Wagner, PhD,** Strategic Compliance International; **Siegfried Schmitt, PhD,** Amersham Health; **Richard Prince, PhD,** Richard Prince Associates; and **Nahid Kiani,** PDA.

PDA Journal of Pharmaceutical Science and Technology

In 2004, three regional editors were appointed to increase the international reach of the Journal. They are: **Amarjit Singh, PhD,** Sun Pharmaceutical Industries Ltd, Mumbai, India.; **Qineng Ping, PhD,** Dean of the China Pharmaceutical University; and **Sompol Prakongpan, PhD,** Pharmacy Dean of Mahidol University, Thailand.

PDA thanks the hard work of the Editorial Advisory Board for the Journal in 2004: **Lee Kirsch, PhD** (Chair and Journal Editor), University of Iowa; **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.

PDA SAB Surveys

Surveys conducted by SAB help the group determine the need for PDA Technical Reports, Technical Bulletins or Points to Consider. Sometimes, useful or unique survey data is published in the form of a Technical Report.

2004 SAB

CO-CHAIRS

James L. Fernandez
Fernandez and Associates

Martin VanTrieste
Bayer HealthCare

MEMBERS

Michael J. Akers, PhD
Baxter Pharmaceutical Solutions LLC

Frank Bing
Consultant

Roger Dabbah
US Pharmacopeia Convention

Volker Eck, PhD
Pharmacia Italia S.p.a.

Jens H. Eilersen, PhD
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Baxter Sterility Assurance

Gautam Maitra
PDA

Jeanne E. Moldenhauer, PhD
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Jean I. Olsen
GlaxoSmithKline

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Gail Sofer
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Lynn D. Torbeck
Torbeck and Associates, Inc.

Glenn E. Wright
Eli Lilly and Company

SCIENCE AND TECHNOLOGY
Year in Review

In 2004, the PDA survey program became Web-based, simplifying the process. The following surveys were closed in 2004:

- Visual Inspection Practices
- Environmental Control/Facility Design for Tablet and Capsule Operations

The following surveys were initiated in 2004 and remain open for a portion of 2005:

- Extractables
- Pharmaceutical Water
- AQL Glass Defects
- Terminal Sterilization

The *PDA Journal of Pharmaceutical Science and Technology* Student Programs

The *PDA Journal of Pharmaceutical Science and Technology* created three student programs designed to promote research within pharmaceutical science and technology field. The Annual Graduate Symposium invites graduate students to submit papers for presentation at the PDA Annual Meeting. The Predoctoral Fellowship Program provides selected candidates with a stipend to assist them in their research. Finally, the Student Poster Session gives an opportunity for selected students to present a poster exhibit, and in some cases, an oral presentation at a PDA or PDA Chapter conference.

Interest Groups

A reorganization of PDA Interest Groups is being spearheaded by PDA Board Member **Kathleen Greene,** Novartis Pharmaceuticals. PDA Interest Groups are being redesigned to be more interactive and productive. As part of the project, enhancements to the PDA Web site will be made to allow PDA members to more easily participate in an Interest Group and for easier communication among Interest Group participants.

International Outreach

The PDA Science and Technology Department, led by PDA Vice President **George Robertson, PhD,** worked to establish stronger relations with international organizations that could benefit the PDA community. In one case, Dr. Robertson prepared and delivered three presentations as a representative of PDA at the Biofaramceutica 2004 in Mexico City. PDA has been invited to participate in future events with the organizing committee, CEDECAN.

Additionally, Dr. Robertson was part of a delegation to Russia commissioned by the Center for Security and International Studies (CSIS), entitled "Jumpstarting Business Relations with Western Companies for Biotechnology Companies in Russia." He prepared and delivered two presentations on compliance strategies in the U.S. pharmaceutical industry, as well as participated in a U.S. expert roundtable.

Interest Groups and Leaders

ASEPTIC PROCESSING
Richard Johnson
Abbott Laboratories

BIOTECHNOLOGY
Frank Matarrese
GxP Consulting

European Branch
Roland Günther
Novartis

COMPUTER SYSTEMS
Barbara L. Meserve
Acculogix, Inc.

DRUG–DEVICE DELIVERY SYSTEMS
Raymond A. Pritchard
Consultant

European Branch
Alexander Schlicker, PhD
Hoffmann La Roche Ltd.

Georgios Imanidis, PhD
Pharmaceutical Technology

FILTRATION
Jack Cole
Jack Cole Associates

European Branch
Roger Seiler
Sartorius

INSPECTION TRENDS/ REGULATORY AFFAIRS
Robert L. Dana
Elkhorn Associates, Inc.

ISOLATION TECHNOLOGY
Dimitri P. Wirchansky
Jacobs Engineering Group, Inc.

LYOPHILIZATION
Edward H. Trappler
Lyophilization Techology

MICROBIOLOGY/ ENVIRONMENTAL MONITORING
Jeanne E. Moldenhauer, PhD
Vectech Pharma. Consulting

NANOTECHNOLOGY
European Branch
D. F. Chowdhury
Aphton Corporation

OPHTHALMICS
Chris Danford
Alcon Laboratories Inc.

PACKAGING SCIENCE
Edward J. Smith, PhD
Wyeth Pharmaceuticals

PHARMACEUTICAL WATER
Theodore H. Meltzer, PhD
Capitola Consulting Co.

PRODUCTION AND ENGINEERING
Frank Bing
Consultant

European Branch
Philippe Gomez
Sartorius SA

QUALITY ASSURANCE/ QUALITY CONTROL
Don E. Elinski
Eli Lilly & Company

STABILITY
Rafik H. Bishara, PhD
Eli Lilly & Company

TECHNOLOGY TRANSFER
European Branch
Volker Eck, PhD
Nerviano Medical Science S.r.l.

Zdenka Mrvova
Zentiva

TRAINING
Thomas W. Wilkin, EdD
University of New York

VACCINES
Frank S. Kohn, PhD
FSK Associate

VALIDATION
Bohdan M. Ferenc
Qualification Services

VISUAL INSPECTION OF PARENTERALS
John G. Shabushnig, PhD
Pfizer Inc

European Branch
Markus Lankers, PhD
APSYS GmbH

QUALITY AND REGULATORY AFFAIRS
Year in Review

2004 was a year of great contribution and accomplishment for our community with respect to PDA's Quality and Regulatory Affairs activities.

The PDA Regulatory Affairs and Quality Committee (RAQC)—comprised of member volunteers—made a record contribution of 15 submissions to global health authorities on a wide range of topics. These submissions included comments to guidances and policy announcements issued by national health authorities—the U.S. FDA, the Commission of the European Communities (CEC) and the European Medicines Agency (EMEA)—as well as the international World Health Organization (WHO). In addition, PDA sent to FDA a proposal for a new guidance covering chemistry, manufacturing and controls documentation requirements for post-approval changes to manufacturing (CMC) chromatography systems.

An International Approach

Throughout 2004, PDA worked with the following authorities toward advancing science-based approaches to regulatory harmonization and to assisting in the development and implementation of risk-based quality system approaches for continuous product improvement and reduction of regulatory burden.

U.S. FDA

PDA's RAQC closely monitored the work of FDA during 2004 as it sought to complete the first phase of its 21st Century Initiative: A risk-based Approach to Pharmaceutical Good Manufacturing Practices (cGMPs) and move to phase 2 implementation. The September 20–24, 2004 PDA/FDA Joint Regulatory Conference provided PDA with an unprecedented opportunity to work with FDA to roll out the next phase of the initiative. FDA provided 23 senior staff persons from four centers to present the next steps to industry. Over 900 members of our community attended the conference, exhibit and Training and Research Institute courses. The Program Committee is to be commended for their excellent work in designing a landmark meeting for PDA.

PDA attended and reported on numerous FDA meeting and initiatives during 2004 including Science Board Meetings, Advisory Board Meetings, workshops on "Follow-on Proteins," Critical Path Initiatives, and more. Individual meetings were also held with the Agency to develop programming for PDA/FDA, training in Aseptic Processing and exploring the Pharmaceutical Analytical Technologies (PAT) initiative and PDA's potential role in training and education.

PDA strengthened its participation as a founding member of the Product Quality and Research Institute (PQRI), continuing its collaboration with other pharmaceutical and biopharmaceutical organizations and FDA to advance science-based regulation. PDA VP for Quality and Regulatory Affairs **Victoria Dedrick** and former PDA President **Edmund Fry** represented PDA in the PQRI Steering Committee. Ms. Dedrick also joined the PQRI Education, Communication and Assessment subcommittee, along with PDA Senior Editor **Walter Morris,** who also was named the volunteer editor of PQRI's newsletter. Furthermore, PDA's production team helped redesign the PQRI newsletter.

PDA also strengthened its relationship with the United States Pharmacopeia (USP). PDA senior staff met with USP in mid-2004 to discuss the structure of a agreement of mutual understanding between the two bodies. This is currently progressing toward fruition. In addition, PDA members elected USP VP for Standards Development **Eric Sheinin, PhD,** to the PDA Board of Directors. PDA Sr. Editor **Walter Morris** conducted an informative interview with USP CEO and Executive Vice President **Roger Williams,** which was published as a three-part series in the *PDA Letter*.

2004 RAQC

CHAIR
Amy Scott-Billman
GlaxoSmithKline

PAST-CHAIR
Suzanne Levesque
Sabex, Inc.

ASIAN REGIONAL LEADER
Jennie Allewell
Wyeth Research

EUROPEAN REGIONAL LEADER
Anders Vinther, PhD
CMC Biopharmaceuticals A/S

LIAISON SAB
Richard M. Johnson
Abbott Laboratories

NORTH AMERICAN REGIONAL LEADER
John K.Towns, PhD
Eli Lilly and Company

MEMBERS
Stephen Bellis
IVAX Pharmaceuticals UK Ltd.

Robert L. Dana
Elkhorn Associates, Inc.

Victoria Ann Dedrick
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Rebecca A. Devine, PhD
Regulatory Consultant

Don E. Elinski
Eli Lilly and Company

Roland K. Guenther
Novartis Pharma AG

Hiltrud Horn
Horn Pharmaceutical Consulting

Michael A. Gross
QLT, Inc.

James C. Lyda
PAREXEL Consulting

Gautam Maitra
PDA

Steven Mendivil
Amgen, Inc.

Toshiaki Nishihata
Santen Pharmaceutical Co. Ltd.

David J. Miner
Eli Lilly and Company

Joyce R. Ramsbotham
Solvay Pharmaceuticals NL

George A. Robertson, PhD
PDA

Lisa M. Skeens
Baxter Healthcare Corporation

Filippo Trionfera
Bristol Myers Squibb SpA

QUALITY AND REGULATORY AFFAIRS
Year in Review

In September, **Lisa Skeens, PhD,** VP for Global Regulatory Affairs Pharmaceuticals and Medical Devices, Baxter Healthcare Coroporation, a member of PDA's RAQC and Board of Directors, gave a presentation representing the Association at a special FDA industry/trade association meeting concerning progress with Dispute Resolution. The draft Dispute Resolution guidance was one of the many guidances that the RAQC commented on during 2004.

European Union

PDA's Quality and Regulatory function in Bethesda, supported with the aid of PDA's European Director, **Gautam Maitra,** worked to strengthen its relations in the European Union with a number of organizations. Meetings were held with the the European Medicines Agency in London, the European Department for the Quality of Medicines (the European Pharmacopoeia) in Strasbourg, France, the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Health Service in London.

PDA's RAQC contributed comments to the CEC and the EMEA on a number of topics that included, aseptic processing and guide to GMPs. The April 2004 case study comments to EMEA on differences in inspection techniques and differences between the EU and U.S. guidance helped to facilitate several discussions between EMEA and FDA leading to harmonization between the previously divergent aseptic processing guidances.

World Health Organization

PDA continued to solidify its relationship with WHO by providing comments in several important areas including good distribution practices and sampling plans. PDA was commended by WHO for their assistance in providing a risk-based analysis of proposed sampling plans.

Other Activities

PDA RAQC members continued to interact with worldwide health authorities on behalf of PDA and speak at PDA conferences, workshops and courses. In addition, several visits were made to PDA Chapters around the Globe by PDA VP for Quality and Regulatory Affairs **Victoria Dedrick,** who helped arrange for more than 20 health authority speakers to contribute to PDA Chapter meetings during 2004.

Ms. Dedrick and other PDA staff participated in meetings with numerous international authorities around the world including the Jordanian Minister of Health and the head of their FDA, representatives from ministries of health in China, Singapore, Japan, Canada, Switzerland and the Australian government's trade ministry for biotechnology development. Ms. Dedrick also participated in a training program for the Pharmaceutical Bureau in Taipei, ROC on EU medical device regulation. In addition, PDA India Chapter President **Darshan Makhey** together with PDA's Gautam Maitra paid a curtesy call on the Indian Drug Controller General, **Ashwini Kumar,** in August 2004.

2004 PDA RAQC Health Authority Submissions

- FDA Draft Guidance for Industry – *Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice,* Task Force Chair: *Zena Kaufman, Pfizer Inc*
- PDA GMP in 21st Century: Risk and Quality Glossary, Task Force Chairs: *Michael Van Der Werf and Zena Kaufman, Pfizer Inc*
- FDA Draft Guidance for Industry – *Powder Blends and Finished Dosage Units – Stratified In-Process Dosage Unit Sampling and Assessment,* Task Force Chair: *Don Elinski, Eli Lilly and Company*
- WHO Working Document QAS/04.068: *Good Distribution Practices (GDP) for Pharmaceutical Products,* Task Force Chair: *Steven Bellis, IVAX Pharmaceuticals UK Ltd.*
- WHO Guideline for Sampling of Pharmaceuticals and Related Materials, Working Document QAS/03.066/Rev. 2, Task Force Chair: *Don Elinski, Eli Lilly and Company*
- EMEA Compilation of Case Studies Provided by Members of EFPIA and PDA Regarding Inspectional Issues with the EU GMP Annex 1 and the FDA Draft Guidance on Aseptic Processing, Task Force Chair: *Tim Marten, AstraZeneca*
- Addition to Chapter 1 to the EU Guide to Good Manufacturing Practice, Titled: Product Quality Review, Task Force Chair: *James Lyda, PAREXEL Consulting*
- Addition to Chapter 6 to the EU Guide to Good Manufacturing Practice, Task Force Chair: *James Lyda, PAREXEL Consulting*
- WHO Guidelines for Sampling of Pharmaceuticals and Related Materials: Risk Assessment with Respect to the n, r, p Plans, Task Force Chair: *Don Elinski, Eli Lilly and Company*
- PDA DRAFT Proposal for Guidance for Industry ChromPAC, Manufacturing Chromatography Systems Post-approval Changes: Chemistry, Manufacturing and Controls Document submitted to Docket #03N-0059-Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach, Task Force Chair: *John K. Towns, Eli Lilly and Company*
- FDA White Paper: *Defining the Customer in a Regulatory Agency,* submitted to Docket #2003N-0059 – Pharmaceutical cGMPS for the 21st Century: A Risk-Based Approach, Task Force Chair: *Cindy Rockel, Millipore*
- FDA White Paper: *Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model.* submitted to Docket #2003N-0059 – Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach, Task Force Chair: *Marie L. Breen, Schering Plough Corporation*
- FDA Draft Guidance for Industry – *Good Manufacturing Practices for Combination Products,* Task Force Chair: *Michael A. Gross, QLT, Inc.*
- FDA Draft Guidance for Industry – *Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations,* Task Force Chairs: *Michael Van Der Werf and Zena Kaufman, Pfizer Inc*
- FDA White Paper: *Office of New Drug Chemistry Reorganization Write-Up,* Task Force Chair: *Lisa M. Skeens, Baxter Healthcare Corporation*

EUROPE
Year in Review

PDA focused much energy and channeled new resources into its efforts to enhance services for our membership in Europe during 2004. As a result, a number of Chapters held successful events and the overall membership in Europe grew.

Gautam Maitra, PDA European Director, continues to work out of his office in Basel, Switzerland, a major center for the pharmaceutical and biopharmaceutical industries. PDA is committed to maintaining a presence there.

PDA strengthened its bonds with members in Europe in other ways. First, we introduced new "European Branches" for seven PDA Interest Groups: Biotechnology, Drug-Device Delivery Systems, Filtration, Production and Engineering, Nanotechnology, Technology Transfer and Visual Inspection. These branches provide our members in Europe a chance to meet and discuss these important scientific topics.

In addition, PDA reached out to help several of our European Chapters develop and deliver a successful series of strong science and regulatory programs for the pharmaceutical and biopharmaceutical communities throughout the year. The Italy, Central Europe, France, Prague, Spain, and UK & Ireland Chapters each held successful meetings and workshops in 2004. In addition, the European Branch of the Biotechnology Interest Group sponsored a workshop during the year with the help of the Italy Chapter.

The PDA Training and Research Institute (PDA TRI) held laboratory courses in Europe for the first time. PDA TRI's course on blow/fill/seal processing, developed in cooperation with the Pharmaceutical BFS International Operators Association, in Sulzback-Laufen, Germany, was a great success. Later in the year, PDA TRI offered its well-known hands-on aseptic processing training in Basel.

PDA's role in the development of regulatory guidance in Europe was boosted in 2004 when we worked with the European Federation of Pharmaceutical Industries and Associations (EFPIA) to develop and submit case studies to the EMEA concerning Annex 1 revisions. In addition, PDA was asked by the World Health Organization (WHO) to comment on its draft sampling guidance in 2004.

A significant enhancement was the reorganization and addition of staff dedicated to serving European member needs. We established an office in Brussels to make it more convenient, easier and less costly for members in Europe to interact with PDA. This provides PDA European members with direct access to and support for:

- Membership Services
- Registrations
- Meeting Planning
- Exhibition Management
- Sponsorship Management
- Publications Management

These achievements not only reflect PDA's focus on Europe in 2004, they set the stage for an exciting and productive 2005.

TRAINING AND RESEARCH INSTITUTE
Year in Review

Career-long Learning™ is the core of PDA's mission and the PDA Training and Research Institute (PDA TRI) continues to provide up-do-date and relevant training to the pharmaceutical/ biopharmaceutical communities around the world. During 2004, PDA TRI served 740 students in the lecture setting with 60 lecture courses and 200 students in the laboratory setting with eight different hands-on laboratory courses, including TRI's premier two-week Aseptic Processing Training and the three-day Aseptic Europe course.

The focus of PDA TRI in 2004 was to align with PDA's strategic initiatives to develop and deliver training courses with greatest impact to the largest audience. Contributing to this success was PDA's hiring of a VP for Education from the U.S. FDA with expertise in management and education to promote the development of a highly respected curricula for the industry. **Gail Sherman's** depth of experience greatly enhances PDA's ability to meet our communities evolving and diverse educational needs.

PDA thanks all of the highly-qualified faculty who participated in our program last year (see page 12).

Laboratory Course Training

The PDA Training and Research Institute continued it's extremely popular Aseptic Processing course at its facility in Baltimore, Md. This course is one of the few training programs world-wide that provides hands-on real experiences in an aseptic processing facility dedicated to this important training for pharmaceutical and biopharmaceutical manufacturers. The two-week course was held five times in 2004, training over 100 industry and health authority professionals to effectively work in an aseptic processing environment within the boundaries of regulatory expectations.

Additional laboratory courses were held at the PDA Training and Research Institute facility in 2004, with over 100 participants benefiting from this unique hands-on laboratory learning experience. In 2004, for the first time, PDA TRI piloted a three-day combination lecture and laboratory course on Practical Aspects of Aseptic Processing at the University of Basel in Switzerland. The PDA TRI courses held at the Baltimore facility in 2004 included:

- Cleaning Validation
- Environmental Mycology Identification Workshop
- Validating a Steam Sterilizer
- Developing a Moist Heat Sterilization Program within FDA Requirements
- Advanced Environmental Mycology (New in 2004)
- Rapid Microbiological Methods
- Developing and Validating Cleaning and Disinfection Programs for Controlled Environments

Lecture Course Training

In 2004, PDA's Training and Research Institute provided lecture courses at its facility in Baltimore, Maryland, and in the following U.S. cities: Lake Tahoe, Nevada; San Diego, California; Boston, Massachusetts; and Chicago, Illinois. Additionally, Course Series were offered with the followng PDA conferences: the International Congress in Basel, Switzerland; the Sci-Tech Summit and Annual Meeting in Orlando, Florida; the PDA/FDA Joint Regulatory Conference in Washington, D.C.; and the Biennial Training Conference in San Juan, Puerto Rico.

Courses offered covered a multitude of topics, including: manufacturing sciences; regulatory compliance; computer auditing; GMPs; change control and documentation; validation; training; and managing FDA inspections.

Applied Research

The PDA Training and Research Institute also lends its facility to firms who wish to test new analytical tools and manufacturing equipment. We thank all those companies that lent or donated high quality supplies and equipment to PDA TRI (see page 11 for a complete list of 2004 contributors).

TRAINING AND RESEARCH INSTITUTE

2004 Contributors

Advanced Analytical	Equipment support
AES-Chemunex	Equipment
Alcan Packaging	Vials
Atlantic Technical Systems	Calibrations Service
Becton Dickinson	Microbiology supplies
bioMerieux Industry	Supplies, Equipment
Bioscience International	Equipment
Biotest Diagnostics Corp.	Service
Biolog	Equipment
Cardinal Health	Supplies
Charter Medical, Inc.	Supplies
Cole-Parmer	Supplies
Contec, Inc.	Supplies
Corning	Supplies
DeconLabs	Supplies
DuPont Qualicon	Equipment
Dycem	Equipment
EMD	Supplies, Equipment
EM Technologies	Services
GEKaye Instruments, Inc	Equipment, Service
GE Ionics	Services, Supplies
General Econopak, Inc.	Supplies
Hach Ultra Analytics	Services
ITW Texwipe	Equipment
Kimberly-Clark	Supplies
PAREXEL Consulting	Equipment
Liberty Industries	Equipment
Lyophilization Technology	Lyophilizer, Service
Microbiologics	Supplies
Micronova Manufacturing, Inc.	Supplies
MIDI	Equipment
Millipore Corporation	Supplies
National Instruments Co.	Services
PALL	Equipment
Particle Measuring Systems	Equipment, Service
Perfex Corporation	Supplies
Raven Biologicals Lab	Supplies
Remel	Supplies
Sartorius AG	Equipment, Service
Scientific Device	Supplies
Shire Biologics	Supplies
Veltek Associates, Inc.	Supplies
West Pharmaceutical Services	Supplies
Wilco AG	Services

TRAINING AND RESEARCH INSTITUTE

2004 Faculty

Michael J. Akers, PhD
Baxter Pharmaceutical Solutions, LLC

Mark L. Balboni
PAREXEL Consulting

Harold Baseman
ValSource LLC

Christopher Bohn
Holopack Verpackungstechnik GmbH

John Brecker
Decon Laboratories, Inc

Goran Bringert
GE Kaye Instruments

Carolyn Broughton
Genentech, Inc.

Patricia Butts
The Atlas Group

Anthony Cannon
Lyophilization Technology

Susannah Childers
AH HA!

William Collentro
Water Consulting Specialists, Inc

Nate Conover
PathWise, Inc.

James Cooper
Endotoxin Consulting Services

Cheryl Custard
Aventis Pasteur, Inc

Anne Marie Dixon
Cleanroom Management Associates, Inc.

Gayle Dolecek, PhD
AAC Consulting Group, Inc

Jayne B. Dovin
GlaxoSmithKline

Joseph K. Farrington, PhD
Eli Lilly and Company

Michael Finger
PAREXEL Consulting

Hubert L. Fleming, PhD
Black Diamond Group

Renee B. Galkin
R.B. Galkin and Associates

David A. Gallup, Ed.D.
Training & Communications Group, Inc.

John Geigert, PhD, RAC
BioPharmaceutical Quality Solutions

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

Joseph G. Habarta, PhD
J. Habarta Consulting

Klaus Haberer, PhD
GmBH

Martin Haerer, PhD
Holopack Verpackungstechnik GmbH/Germany

Mark Hallworth
Particle Measuring Systems, Inc

Peter Holman
Genentech, Inc

Sylvia Isaacson
Millipore Corporation

Robert G. Kieffer, PhD
RGK Consulting

Peter Koger
PMT Partikel

Michael Korczynski
MIKKOR, Inc

Image courtesy of West Pharmaceutical Services.

Ronald Kraus
PAREXEL Consulting

Destin LeBlanc
Cleaning Validation Technologies

George Levinson
Compliance Software Solutions Corporation

John Lindsay
Aseptic Solutions, Inc

Bengt Ljungqvist, PhD
KTH (Royal Institute of Technology) Stockholm

Sandra A. Lowery
Quality Systems Consulting, Inc

John D. Ludwig
Pfizer Inc

Dave Manley
Biomeriuex, Inc

Jeffrey L. Masten
Genentech, Inc

David Matsuhiro
Cleanroom Compliance, Inc

Deborah Harrell Meehan
Consultant

Theodore H. Meltzer, PhD
Capitola Consulting Company

Steven Messick
Genentech, Inc

Jeanne Moldenhauer, PhD
Vectech Pharma Consultants, Inc

Carol Molinaro
GlaxoSmithKline

Charles Montague
Consultant

Antonio Moreira, PhD
SPI USA, Inc.
University Of Maryland, Baltimore County

Maureen Mueller
Quality Systems Consulting, Inc

Kenneth Muhvich, PhD
Micro-Reliance LLC

Alan Newbery
PAREXEL Consulting

Robert O'Brien
Consultant

Danielle Palmiotto
Merck & Co., Inc.

Diane Paskiet
Monarch Analytical Laboratories, Inc

Ken Peterson
PathWise, Inc

Elaine Lehecka Pratt
Lehecka Pratt Associates, Inc

Thomas Reidy
Syntonix Pharmaceuticals

Berit Reinmüller, PhD
KTH (Royal Institute of Technology) Stockholm

Rick Rogers
Consultant

Richard T. Sands
RTS Training Services

Dale Seiberling, B.Sc.
Electrol Specialties Company

Anne Shandy
Aseptic Solutions, Inc.

Alan Smith, PhD
Consultant

Edward J. Smith, PhD
Wyeth Pharmaceuticals

Jenny Stevens
Merck & Co, Inc

Ronald Tetzlaff, PhD
PAREXEL Consulting

Lynn D. Torbeck
Torbeck and Associates, Inc

Edward Trappler
Lyophilization Technology

Veronique Van Buynder
Genzyme Flanders NV

Barbara van der Schalie
MedImmune

Art Vellutato, Jr.
Veltek Associates, Inc

James L. Vesper
LearningPlus, Inc

Jon Voss
Genzyme Corporation

Charles M. Waite
Process Design Consultants, Inc.

Steven R. Wiseman
Amgen, Inc.

PROGRAMS AND MEETINGS
Year in Review

PDA implemented two milestone changes during 2004 with respect to its Programs and Meetings.

PDA first launched a revamped audio conference program to help deliver practical and cost-effective *Career-long Learning*™ to our community. Although the audio conference program resumed at the end of the first quarter, PDA managed to sponsor 22 very successful audio conferences for the year.

Next, PDA established a new formula for planning conferences and workshops, based on membership feedback suggesting that meetings focused on one topic are very valuable. Under this formula, most PDA meetings will address a singular timely topic, except for our three annual flagship events (the International Congress, the Annual Meeting and the PDA/FDA Joint Regulatory Conference) which will remain multi-tracked. PDA used this formula last year to plan several "focus meetings" for 2005: Aseptic Processing Guidance (February, March and May), Viral and TSE Safety (May) and Extractables/Leachables (May).

Overall, 2004 was another good year for PDA's programs and meetings with professionals from more than 750 companies, academics from more than 20 universities and officials representing over a dozen health authorities from around the world attending our events. The year culminated with the incredibly successful PDA/FDA Joint Regulatory Conference, which drew over 900 participants for the meeting, training and exhibition.

2004 PDA Conferences and Workshops

2004 PDA International Congress, Courses and Exhibition
February 16-20 • Basel, Switzerland

2004 PDA SciTech Summit (and Annual Meeting)
March 8-12 • Orlando, Florida

2004 PDA Biennial Training Conference, Courses and Vendor Exhibit
May 17-21 • Puerto Rico, Mexico

2004 PDA Pacific Rim Congress
May 17-21 • Singapore

2004 PDA/R^3 Nordic: *Science, Industrial, and Regulatory Aspects of Clean Products and Devices*
June 7-8 • *Stockholm, Sweden*

2004 PDA/FDA Joint Regulatory Conference: *The New Guidances*
September 20-24 • *Washington, DC*

2004 Aseptic Processing: The New Guidance
October 29 • *Washington, DC*

2004 Aseptic Processing: The New Guidance
November 16 • *Frankfurt, Germany*

2004 PDA Audio Conferences

1. Applying Risk Assessment Tools to Computer System Compliance
2. Understanding and Implementing the Final Bar Code Rule
3. Risk Strategies for CAPA Programs
4. Best Practices for Recall Preparation (Parts 1 & 2)
5. How to Manage A Quality Product Recall (Parts 1 & 2)
6. Risk/Science-based Approach to Validation
7. FDA`s New Barcode Requirement: When, Where and How to Comply
8. Implementing a Global Risk Standard to Assess Risk & Improve Quality
9. How to Justify ROI and Obtain Management Buy-in for Rapid Microbial Methods
10. Failure Investigation: Objective and Effective Analysis of Root Cause
11. Five Steps to Establishing Computer System Validation
12. Understanding GERM3 Models Document
13. PDA Technical Report #32
14. Managing Change Control Process: Understanding Your Role
15. Implementing a Global Risk Standard to Assess Risk and Improve Quality
16. Minimizing the Legal, Quality and Compliance Pitfalls of Contract Manufacturing
17. PAT: Identifying Opportunities and Boundaries
18. Building an Efficient Biotech Cleaning Validation Program
19. EU Regulatory Update – The Evolving Landscape
20. Quality from the Start – A Primer on FDA`s Draft Quality Guidance
21. Six Tools for Common Cause Variability Reduction
22. ICH Q9: Quality Risk Management with an Update from Yokohama

Exhibitions

PDA's exhibitions continue to provide the community access to the products and services they need most. In 2004, the New Innovative Technology Exhibition™ was unveiled at the Annual Meeting. PDA thanks the hard work and effort of the Exhibit Advisory Committee for helping plan successful and valuable exhibitions in 2004:

CHAIR: Howard Drake
Saint Gobain Desjonquers

Carol Dellicicchi
Pall Corporation

Douglas Hostetler
Lancaster Laboratories

Carol Julich
Biotest Diagnostic Corporation

Jerry Kirkpatrick
Anatel Corporation

Richard Levy, PhD
PAREXEL Consulting

Katie Pepler
Schott Forma Vitrum

Lawrence Pepper
Genesis Machinery Products

Melissa Rossi
Associates of Cape Cod

Debbie Rothwell
ITW Texwipe

Art Vellutato, Jr.
Veltek Associates Inc.

Nahid Kiani
PDA

Wanda Neal-Ballard
PDA

MEMBERSHIP AND CHAPTERS
Year in Review

PDA placed great emphasis on membership in 2004. The strategic planning process produced tangible results that will enhance the value and benefits of PDA membership. The most important enhancement made as a result of this process was the creation of three new membership categories, making PDA more accessible to important segments of the PDA community.

Looking at the PDA Mission and Strategic Plan, a few words stand out which help explain the rationale for our decision to implement the most sweeping enhancements to our membership program in years. These words are *internationally, scientifically sound* and *education.*

To better seve those in our community in areas of the world that are evolving economically, we adopted the new **Developing Economy** membership category. Developing countries like China and India represent key markets for the manufacturers in our community. The Developing Economy membership makes it easier for scientists and engineers working in these emerging nations to participate in PDA and share the common threads of peer review, training and *Career-long Learning*™.

Ensuring that the PDA community is exposed to the latest science and technology was the goal behind the new **Academic** membership type. Professional educators, teachers and professors have been making valuable contributions to PDA for several decades. The new Academic membership category simply fortifies what has historically been a significant contribution sector.

As one of the top nonprofit sources of *Career-long Learning*™ in the pharmaceutical and biopharmaceutical industries, PDA wants to reach out to the next generation of professionals. To that end, the new **Student** membership type provides aspiring students a cost-effective introduction to all that PDA has to offer. In an effort to help science and engineering students assimilate into the community of professionals, as well as contribute to collective learning, the Student membership category was created for all full-time students attending accredited institutions of higher learning.

As a whole, PDA's membership count remained steady worldwide in 2004, however, the association's number of members representing health authorities worldwide increased by nearly 50%. By year's end, 30 health authorities from around the world were represented.

2004 Membership Enhancements

Improved *PDA Letter*: The *PDA Letter* was enhanced to a new, 4-color magazine, while maintaining the personal touch our members have come to expect from PDA, providing greater value for both our members and advertisers. With greater topic-specific coverage, this transition allows PDA to increase both the depth and breadth of our features stories.

Revised PDA Technical Report: Technical Report #32 was developed by PDA to address FDA's concerns about the need for regulatory agencies to standardize the auditing process for suppliers of computer products and services and establish a global repository for sharing auditing information. This comprehensive report was delivered to members with the November/December PDA Journal.

New PDA Chapter: In 2004, PDA added one new Chapter to the global roster, bringing our total Chapter count to 24. The India Chapter, led by Darshan Makhey, PhD, enjoyed a very successful first year in operation.

PDA Chapter Points Program: The PDA Chapter Points Program was started in January 2004 to reward Chapters for engaging in activities that support PDA's Strategic Plan. Chapters earn points for activities and are then eligible to receive monetary rewards based on the total points earned throughout the year. This program is one way that PDA supports its Chapters in developing programs, enhancing education and contributing to the industry and our members worldwide.

A global reach – in 2004, PDA members represented the following regions worldwide:

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

Asia
Afghanistan, Bangladesh, China, India, Pakistan

Caribbean, Central & South America
Argentina, Brazil, Chile, Colombia, Costa Rica, Curacao, Dominican Republic, Ecuador, 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, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom, Yugoslavia

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

North America
Canada, Mexico, United States

Pacific Rim
Australia, Hong Kong, Indonesia, Japan, Malaysia, New Zealand, Singapore, South Korea, Taiwan, Thailand, Vietnam

MEMBERSHIP AND CHAPTERS
A Global Reach

Chapters

Asia Pacific

Australia Chapter
Ken P. Dibble
Millipore Australia

India Chapter
Darshan Makhey, PhD
Nicholas Piramal India

Japan Chapter
Katsutoshi Mise, PhD
Pharmaceuticals and Medical Devices Agency

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

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

Tawain 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

Italy Chapter
Vincenzo F. Baselli
Pall Italia Srl

Prague Chapter
Zdenka Mrvova
Zentiva a.s.

Spain Chapter
Jordi Botet, PhD
STE Compliance Services & QTI

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

Middle East

Israel Chapter
Benny Klener
Teva Pharmaceutical Industries Ltd.

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
Amy K. Gotham
Amgen, Inc.

Mountain States Chapter
Paul E. Bilodeau
Western Separations

New England Chapter
Mark A. Staples, PhD
MicroCHIPS, Inc.

Puerto Rico Chapter
Silma L. Bladuell
Wyeth

Southeast Chapter
Lisa E. Eklund
Hospira, Inc.

Southern California Chapter
Kikoo Tejwani
B. Braun Medical, Inc.

West Coast Chapter
Randall Tedder
IconNova

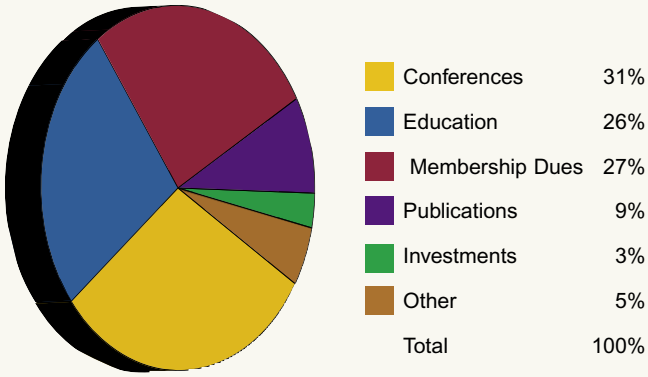
FINANCIAL
Report

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.

The first half of 2004 continued to prove financially challenging for a variety of reasons. First, the 2004 PDA Annual Meeting (called the SciTech Summit) was not widely recognized by the membership as PDA's first springtime annual meeting, resulting in lower than expected participation. Second, attendance at PDA's two international congresses was very low, possibly due to continued travel restrictions among the membership. On the other hand, PDA experienced dramatic improvement over the second half of the year with financial results exceeding budgeted expectations. Four elements of PDA's wide offerings contributed to this success: 1) The reinvigorated PDA Audio Conference program generated solid revenues in this period. 2) The success of the 2004 PDA/FDA Joint Regulatory Conference in September drew record attendance. 3) PDA's timely one-day "Aseptic Processing: The New Guidance," workshops held in Washington, D.C., and in Frankfurt, Germany, generated strong attendance. 4) Congress activity increased in Europe in the second half of the year with solid contributions from the Pre-filled Syringe Meeting in Hanover, Germany and the Visual Inspections Meeting in Berlin, Germany.

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, 2004. The full financial statements and notes are available upon request from PDA headquarters.

2004 Income Sources



The chart below contains three columns for 2004: Budgeted, Audited (actual) and Comparative. Because of PDA's partnership with PennWell Publishing Company for the 2004 Annual Meeting (SciTech Summit), PDA did not record revenues and expenses in it's usual manner for this event. To allow for a consistent comparison to 2003, the "Comparative" column shows what 2004 actual year-end result would have been had PDA recorded revenues and expenses for the 2004 Annual Meeting in the same way it did for the 2003 conference.

Our investments, which are primarily in conservative instruments appropriate for a nonprofit association, experienced capital gains of $69,810 (U.S.), consistent with the relatively flat financial markets during 2004.

During 2004, PDA's net assets decreased by $719,191, 16%, from that recorded at the end of 2003. At the year-end 2004, our reserve ratio stood at 39%, which compares against the industry average of 47% among associations of PDA's size.

2004 Income and Expenses

	2004 Actual	2004 Comparative	2004 Budget	2003 Actual
Total Revenues	7,714,589	8,099,055	9,406,534	8,113,279
Total Expenses	8,450,774	8,835,240	9,461,491	8,700,104
Excess revenues over expenses from operations	(736,185)	(736,185)	(54,957)	(586,825)
Unrealized gains (losses) on investments	16,993	16,993	80,000	368,155
Increase (decrease) in net reserves	(719,192)	(719,192)	25,043	(218,670)
Net reserves at beginning of year	4,024,489	4,024,489	4,024,489	4,243,159
Net reserves at end of year	3,305,297	3,305,297	4,049,532	4,024,489
Reserve ratio (net reserves/annual expenses)	39.1%			46.3%

2004 PDA
Honor Awards

The following awards were bestowed at the 2005 PDA Annual Meeting.

Honorary Membership

This award is given in recognition of very long service of a significant nature to PDA and confers lifetime membership benefits to the recipient. The award requires unanimous approval of the PDA Board of Directors.

Robert Myers, Beacon Pointe Group. Bob has been a PDA member since 1977 and has been a member of many PDA committees. He served as Program Chair for two PDA meetings and represented PDA at the Joint FDA and Industry ICH meetings and the FDA and PQRI meetings. Bob served on the Board from 1984 to 2003, and was Secretary in 1990, Chair-Elect 1998-99 and Chair 2000-01. During his tenure as Past Chair in 2002, he led efforts to assure the continued support of TRI and other important PDA initiatives in Europe and other locations.

Gordon R. Personeus Award

Presented in memory of the late Gordon R. 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.

Daniel Gold, PhD, D.H. Gold Associates Inc. Dan served on the PDA Board in the 1980s and 1990s. He has participated in many program committees in the United States, Japan and Europe, and has conducted numerous presentations and training courses. He has consistently supported PDA for at least 25 years and has contributed to many PDA technical documents.

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.

Glenn Wright, Eli Lilly and Company. Glenn served on the PDA Board of Directors for six years from 1998-2003. He has participated in planning, moderating and presenting at PDA events. Glenn is heavily involved in the new PDA Aseptic Processing Training Program and co-chaired the Task Force that prepared Points to Consider for Aseptic Processing. He is an active member of the SAB, has served as Chapter liaison and co-chaired the Interest Group restructuring initiative.

Distinguished Service Award

This award is given for special acts, contributions or service that have contributed to the success and strength of PDA.

Robert Coleman, Food and Drug Administration. Bob is a National Expert Investigator, ORA, FDA. He continually makes himself available for candid interchange with industry, facilitating a better understanding between government and industry. Bob has contributed selflessly over the years as a speaker and contributor to PDA Regional conferences, the PDA/FDA Joint Regulatory Conference and the PDA Training Conference.

Amy Davis, Davis Healthcare International Publishing. Amy is the CEO of Davis Healthcare International Publishing, the publishing house PDA partners with to produce many technical and trade books. She identifies and cultivates the authors and editors who ultimately bring good science to print through her publishing company for the entire pharmaceutical and biopharmaceutical community to enjoy. Amy is also a member of the PDA Technical Books Advisory Board.

Richard Johnson, Abbot Laboratories. Richard is an active member of the RAQC and SAB, has worked on numerous PDA Task Forces, and was the original leader of the PDA Ophthalmic Interest Group. He is heavily involved in the new PDA Aseptic Processing Training Program and contributed to the recently published Points to Consider for Aseptic Processing. Richard is the Chair of the PDA Program Advisory Committee and co-chair of the U.S. Sub-TAG for the ISO Aseptic Processing.

Ronald Tetzlaff, PhD, PAREXEL Consulting. Ron's leadership as a speaker, mentor and committee member is legendary. His talks and training sessions are always informative and frequently lead regulatory thinking forward. Through his leadership by example, Ron has led the way for many excellent contributions of his firm, both through individual participation and corporate sponsorship.

2004 PDA
Honor Awards

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.

John Brecker, Decon Laboratories Inc. John has been an instructor for PDA TRI since 2001 in both the 10-day Aseptic Processing hands-on laboratory program and more recently the Environmental Mycology Identification Workshop and Advanced Mycology Courses. John developed both of these courses for PDA TRI and it has been through his enthusiasm and dedication to teaching that these courses are always fully subscribed.

Frederick D. Simon Award

This 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.

2004 Award:
Wei Wang, PhD, Tian-Yi Cui, MD, Y. John Wang, PhD, and **Sheryl Martin-Moe, PhD** for "Oxidation of Protein by Vaporized Sanitizing Agents"

2003 Award:
Gunnel Lundahl for "A Method of Increasing Test Range and Accuracy of Bioindicators: *Geobacillus Stearothermophilus* Spores"

Michael S. Korczynski Grant

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

Stephen Bellis, IVAX Pharmaceuticals. Stephen has made substantial contributions to the Annex 1 project in the area of Aseptic Processing. He has played several important roles in promoting good science for PDA projects and meetings worldwide and is very active with the PDA UK/ Ireland Chapter.

Chapter Volunteer Award

This award recognizes the contributions of PDA members who participate at the chapter level.

Allen Burgenson, Cambrex Bio Science (Capital Area Chapter). Allen served as Chapter President and now manages the Chapter's dinner meetings. He also served as Program Committee Chair for the most recent PDA/FDA Joint Regulatory Conference.

Markus Lankers, PhD, rap.ID GmbH (Central Europe Chapter). Markus serves as the European Visual Inspection Interest Group leader and contributed significantly to the Visual Inspection meeting in Berlin.

Arun Malaviya, Bimeda MTC Animal Health (Canada Chapter). Arun is the Chapter Program Chair and contributes significantly to the success of the Chapter's events.

Jason Mattis, GlaxoSmithKline (Delaware Valley Chapter). Jason has served on the Chapter planning committee and devoted countless hours to developing the Chapter's vendor support system and vendor night show.

Taraneh Roshan, B. Braun Medical, Inc. (Southern California Chapter). In her role as Chapter Event Coordinator, Tarra has helped to obtain several speakers for key Chapter events in 2004.

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.

James Agalloco, Agalloco & Associates, for *Validation of Sterilization Processes*

Lucia Clontz, Diosynth Biotechnology, for *Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections*

Maik Jornitz, Sartorius Corp., for *Filtration Handbook: Liquids*

Theodore Meltzer, PhD, Capitola Consulting Co., for *Filtration Handbook: Liquids*

Jeanne Moldenhauer, PhD, Vectech, for *Laboratory Validation: A Practitioner's Guide* and *Steam Sterilization: A Practitioner's Guide*

2005 PDA
Board of Directors

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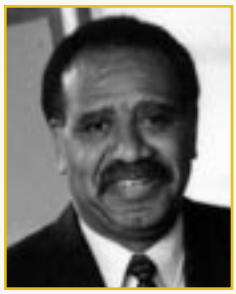
Nikki V. Mehringer
Eli Lilly and Company

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
Consultant

Kathleen S. Greene
Novartis Pharmaceuticals Corporation

Yoshihito Hashimoto
Chiyoda Corporation

Maik W. Jornitz
Sartorius Corporation

Tim R. Marten, PhD
Astra Zeneca

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

2005 PDA
Staff

Senior Staff

Robert Myers
President

Gail Sherman
Vice President of Education/Director of TRI

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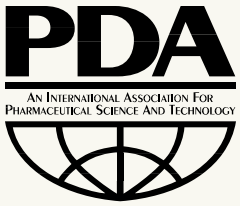

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