PDA

An International Association For Pharmaceutical Science And Technology

2002

Annual Report

About PDA

Our Mission:
To advance
pharmaceutical and biopharmaceutical
science and technology
internationally
by promoting scientifically sound
and practical technical
information and education
for industry and regulatory agencies.

PDA was founded in 1946 by a small group of pharmaceutical professionals who recognized the need for an organization to disseminate technical information within the industry. In the years since its inception, PDA has continued to expand its leadership in the fields of sterile products, solid dosage forms, computer-related subjects, pharmaceutical and biotechnology topics, and other areas of interest to the industry.

Today, PDA is a nonprofit individual membership society of more than 10,300 scientists worldwide involved in the development, manufacture, quality control and regulation of pharmaceuticals, biopharmaceuticals and related products. An international organization, PDA coordinates its activities through its global headquarters in Bethesda, Maryland, USA; the European headquarters in Basel, Switzerland; and the Training and Research Institute in Baltimore, Maryland, USA—a first-of-its-kind training laboratory facility providing traditional lecture programs, as well as "hands-on" applied training in the pharmaceutical and biopharmaceutical sciences and associated technologies.

PDA draws its strength from the technical expertise of its membership. Through its expert working groups, PDA regularly analyzes and comments on regulatory initiatives worldwide, including those of the U.S. Food and Drug Administration (FDA), European Agency for the Evaluation of Medicinal Products (EMEA), and World Health Organization (WHO). By developing technical reports, technical bulletins and responses to regulatory initiatives, PDA and its members influence the future course of pharmaceutical and biopharmaceutical products technology.

PDA conducts conferences, meetings and open forums that bring together pharmaceutical and biopharmaceutical manufacturers, suppliers, academicians and regulatory officials to discuss issues of mutual interest. These exchanges of technical knowledge and expertise assist the advancement of pharmaceutical and biopharmaceutical science and technology in the interest of public health. PDA enjoys an active working relationship with the FDA, and the two bodies have a history of cooperatively sponsoring conferences on pressing industry topics. PDA continues to build relationships with industry and other regulatory bodies worldwide. Strong relationships with pharmaceutical and biopharmaceutical industry societies internationally are also important to PDA.

■ Task Groups

PDA Task Groups, the heart of the association's peer-reviewed science focus, are formed with specific objectives defined by an approved scope statement. They usually originate from an Interest Group, the PDA Board, or PDA staff. Task Groups may write technical research documents, prepare comments to proposed regulations, or prepare presentations at scientific forums.

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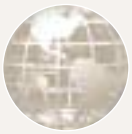
The PDA Vision

To be the preeminent international provider of easily accessible practical information, education and training in pharmaceutical and biopharmaceutical technology

and

To be recognized for leadership as an influential contributor to worldwide regulatory processes through scientifically sound information.



PDA's Strategic Plan

1. Increase accessibility of services, education and training offerings both internationally and domestically.
2. Build a stronger liaison with regulatory bodies.
3. Continually improve the relevance and quality of scientific information and programs offered by PDA to reach appropriate audiences.
4. Assure the financial resources are in place to support PDA's mission to be an international influence.
5. Continue to expand and market PDA.
6. Improve PDA's operating structure domestically and internationally.

■ Pharmaceutical Sci-Tech Discussion Group

Have a question? The Pharmaceutical Sci-Tech Discussion Group is designed to provide a vehicle for the free exchange of information in the areas of international pharmaceutical and biopharmaceutical manufacturing, quality control, process validation, and regulatory affairs, emphasizing, but not limited to, sterile products technology. This discussion group is available on the PDA Web site (www.pda.org) or via e-mail (requests@www2.pharmweb.net) and is open to anyone with an interest in pharmaceutical and biopharmaceutical science and technology. Although this online discussion group is sponsored and moderated by PDA, it is open to nonmember participation. PDA also hosts members-only listservs on selected topic areas.

■ PDA Web Site

The PDA Web site is a valuable source of information. The public area features: in-depth information about the association's science, technology and regulatory activities; an up-to-date calendar of activities; information about chapters and affiliates and the PDA Training and Research Institute; recent exhibitor extracts; Web seminars; online membership registration and renewals; online conference and course registration information; consultants' directories; and the PDA Job Bank.

In the Members Only area, you will find: the PDA Membership Directory, regulatory and draft technical documents, technical bulletins, *PDA Letter* archives, information on interest groups and task groups, FDA's Human Drug CGMP Notes, chapter leader resources and chapter newsletters. The Web site is also undergoing a comprehensive redesign to become an even more valuable information source.

■ PDA Publications

PDA offers a range of publications to both members and nonmembers, including PDA technical reports, books, conference proceedings, employee training resource videos, and regulatory documents, as well as books and technical reports from other publishers. The full list of titles is available in a hard copy catalog or may be viewed on the PDA Web site, www.pda.org.

■ PDA Chapters

PDA chapters play a key role in facilitating the interchange of scientific and regulatory information. Presently, there are 19 chapters worldwide:

- **Asia/Pacific:** Japan Chapter (Tokyo), Korea Chapter (Seoul), Taiwan Chapter (Tapei), Southeast Asia Chapter (Singapore), Australia Chapter (Melbourne)
- **Canada:** Canada Chapter (Toronto)
- **Europe/Middle East:** Central Europe Chapter (Basel), U.K./Ireland Chapter (London), Italy Chapter (Milan), Israel Chapter (Tel Aviv)
- **United States:** Capital Area Chapter (Gaithersburg, Md.), Delaware Valley Chapter (Malvern, Pa.), Metro Chapter (Clark, N.J.), Midwest Chapter (Northbrook-Chicago, Ill.), Mountain States Chapter (Boulder, Colo.), New England Chapter (Cambridge, Mass.), Southeast Chapter (Raleigh, N.C.), Southern California Chapter (Irvine, Calif.), West Coast Chapter (Burlingame, Calif.)

A chapter map and list of chapter officers appear on pages 17-19.

The information in this report highlights PDA activities during 2002. This information is organized by operational areas.

Letter from the Chair

Floyd Benjamin,
PDA Chair

As I reflect on my first year as Chairman of PDA's Board of Directors, it is quite clear to me that the year 2002 was one of tremendous change for the pharmaceutical and biopharmaceutical industries and for our association. We have seen an acceleration of large-scale corporate mergers, resulting in the formation of larger multinational companies with revenues tenfold that of a few years ago. These mergers have reduced the overall number of companies, thereby concentrating the impact they exert. In other words, we have fewer companies with greater impact and influence on the activities involved with the research and development, manufacture, and marketing of pharmaceutical and biopharmaceutical products throughout the world.

These multinational companies are essentially companies without borders. The products produced by these companies are also without borders. The need to develop harmonized standards that all products must meet—to be effectively manufactured and marketed throughout the world—has become a critical requirement for such multinational companies.

Regulatory agencies have recognized this and are responding to the new environment. They have accelerated their efforts to harmonize regulations with the goal of consistent compliance to acceptable standards for products introduced to consumers worldwide. The FDA has taken an active role in the development of the International Conference on Harmonisation (ICH) guidances where applicable. The impact this change will have on pharmaceutical and biopharmaceutical organizations will be profound, and will continue to influence the way our industries work for years to come.

"I would like to thank you all—the staff, the Board, and especially the members—for your support, and look forward to serving you through 2003."

What this means to PDA is that we, too, must adjust our focus to account for the impact this changing environment will have on our members. Our Strategic Plan was recently updated to recognize this and other important drivers impacting PDA over the next few years. The result of this planning effort established six comprehensive strategies, which you will find on page 3, that have and will direct PDA's activities to meet our vision.

A primary objective of PDA's updated Strategic Plan is to better focus the number of priority actions to assure the most effective application of PDA's resources to our critical strategic needs. A total of sixteen priority actions were developed to support the six comprehensive strategies.

This planning was designed to build upon PDA's strengths while expanding the scope of the association to meet the growing needs of the future. On the international front, PDA collaborated with regulatory agencies worldwide, including five training workshops on the ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs).

Our relationship building with FDA continued through the successful 2002 PDA/FDA Joint Regulatory Conference. The featured speaker, Lester M. Crawford, Ph.D., D.V.M., FDA Deputy Commissioner, informed conference delegates that the agency would soon embark on a major overhaul of the GMPs. FDA encouraged industry to implement new online technologies to monitor and control the quality parameters of pharmaceutical products as they are being manufactured, also known as Process Analytical Technology (PAT).

PDA, as a founding and current member of the Product Quality Research Institute (PQRI), participated in the development of new published recommended blend uniformity standards and began discussions on FDA's Aseptic Processing Concept Paper.

The final area I would like to review pertains to changes in PDA's infrastructure. The Strategic Plan requires that PDA expand its capabilities in science and technology, education, training, and in improving operating structures worldwide. To address these initiatives, an outside consulting group was commissioned to review PDA's structure and staffing level in order to determine its ability to meet the demands of the Strategic Plan. Recommendations were provided to PDA regarding the structure and headcount levels required to meet the standards we established in our mission. PDA has developed an action plan in response to these recommendations which is being implemented in 2003.

The resignations of PDA's President, Director of the PDA Training and Research Institute, and Director of Europe accelerated our action plan in the last quarter of 2002. Ed Fry's departure as President opened the opportunity to select a leader for PDA who will strengthen the infrastructure and implement systems necessary to grow PDA through the coming years. Robert J. Mello, Ph.D., a Board member, was hired to head the PDA Training and Research Institute. His scientific background strengthens the science and technical content of PDA's training programs. Gautam Maitra joined PDA as Director of Europe in September 2002. A chemist by training, he has worked for over 15 years within the pharmaceutical and OTC industries. He held project management positions with CIBA Geigy AG, and most recently with Novartis Pharma AG. Gautam has lived and worked throughout Europe and is fluent in a number of languages.

I would like to thank you all—the staff, the Board, and especially the members—for your support, and look forward to serving you through 2003.

President's Message

Neal Koller,
PDA President

I am honored and pleased to have had the opportunity to join PDA at the end of January 2003. Reviewing PDA's activities and accomplishments of 2002, I am happy to report that PDA, as a result of the opportunity presented by the ICH Q7A workshops, achieved remarkable profits in 2002. This was particularly noteworthy due to the number of challenges encountered in coping with the aftereffects of September 11th, including the economic uncertainties it created and the drastic cut in travel budgets that resulted. This climate was compounded by the complexities facing pharmaceutical and biopharmaceutical manufacturing and the pressures to remain cost-effective. The financial performance realized is evidence of the strength of PDA and the relevance of its scientific and technical work.

PDA added a number of new meeting topics during 2002 and provided new, cost-effective channels to offer information, education and training. The organization was able to effectively leverage its partnerships with a number of organizations worldwide to offer the latest in scientific publications and programs. The PDA Training and Research Institute expanded its course offerings, and its flagship course on aseptic processing continued to be its most successful program.

Regulatory officials play a key role in PDA, whether they are cooperating with us to reach an understanding on technical issues or appearing at our meetings worldwide to impart information directly to the membership. In June, in response to feedback from regulatory officials both in FDA and around the globe, PDA instituted a government category for individual membership. PDA has long enjoyed a close and productive relationship with regulatory officials and hopes to strengthen this relationship by establishing this new membership category.

"Perhaps the most significant development in regulation consisted of FDA's "Pharmaceutical Current Good Manufacturing Practices (CGMP) for the 21st Century" initiative, which was launched in September 2002. It was created to update regulations that were becoming increasingly outdated. This initiative has far-reaching implications for PDA, as it was designed to modernize the regulation of pharmaceutical and biopharmaceutical manufacturing and product quality. "

Perhaps the most significant development in regulation consisted of FDA's "Pharmaceutical Current Good Manufacturing Practices (CGMP) for the 21st Century" initiative, which was launched in September 2002. It was created to update regulations that were becoming increasingly outdated. This initiative has far-reaching implications for PDA, as it was designed to modernize the regulation of pharmaceutical and biopharmaceutical manufacturing and product quality. It aims at ensuring that regulatory review, compliance and inspection policies are based on state-of-the-art science and do not impede the rapid adoption of new technological advances by the pharmaceutical and biopharmaceutical industries. It also promises to enhance the safety and quality in drug manufacturing while increasing efficiencies. This program will affect the scope and nature of PDA's efforts for years to come.

In 2002, PDA further concentrated its efforts on providing the most relevant, up-to-date scientific and technical information through its many different avenues. The association maintained its leadership position in the fields of sterile products, solid dosage forms, computer-related subjects, and other pharmaceutical- and biopharmaceutical-related topics, and will continue to facilitate advancements in these fields. PDA is committed to scientific excellence and will work diligently to further establish PDA's influence worldwide.

"I am deeply appreciative of all of the contributions of our members; it is only through you that we as an organization can succeed in realizing our mission and our vision."

I am deeply appreciative of all of the contributions of our members; it is only through you that we as an organization can succeed in realizing our mission and our vision. I am fully committed to the association's Strategic Plan, providing you with the best science, technology, education, regulatory expertise and service to meet your needs. PDA has many exciting opportunities for the future. With your input and collaboration, we will continue to make significant contributions to the worldwide pharmaceutical and biopharmaceutical communities.

PDA Honor Awards in 2002

PDA's prestigious Honor Awards are bestowed every year at PDA's Annual Meeting to members who are recognized by their peers and by the PDA Board of Directors as having exceptional ability and dedication to PDA. Award recipients are selected from nominations assembled by an ad hoc Board subcommittee and ratified by the PDA Board. The awards and the recipients of 2002 are as follows:

■ Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award has usually been 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. The 2002 recipients of this award were **Joseph R. Robinson, Ph.D.**, and **R. Michael Enzinger, Ph.D**.

■ Frederick J. Carleton Award

Presented as a tribute to lifetime contributor, past President, past Executive Director, and current Honorary Member Frederick J. Carleton, this award is designated for past or present Board members whose performance and service on the Board is recognized by his/her peers as worthy of recognition. **Robert B. Myers**, Board member and this year's Immediate Past Chair, received the 2002 Frederick J. Carleton award.

■ Distinguished Service Award

This award is given for special acts, contributions or services that have contributed to the success and strength of PDA. The 2002 Distinguished Service Award was presented to **Raymond Gabler, Ph.D.** for his service as Treasurer and for the development of biotechnology content at PDA conferences in the 1980s and 1990s.

■ Frederick D. Simon Award

Each year PDA also presents the Frederick D. Simon Award, named in honor of the late Frederick D. Simon, who was PDA's Director of Scientific Affairs. In 2002 this award was presented to **Robert A. Bellantone**, **AKM Mustafa Kamal**, **Sivarama K. Nutalapati**, **Theodore Jochsberger**, and **Fotios M. Plakogiannis**.

■ PDA Chapter Award

The PDA Chapter Award recognizes the contributions of PDA members who participate at the chapter level. The following PDA members received the PDA Chapter Award in 2002: **Rande Leibowitz** from the Capital Area Chapter, **Mitchell Garber, Ph.D.** from the Delaware Valley Chapter, and **Marco Budini** from the Italy Chapter.

■ James P. Agalloco Award

One of the hallmarks of PDA laboratory training and lecture courses is reflected in the quality of the faculty. Participants in every course offering, as well as PDA staff, continuously evaluate faculty and course content to ensure that PDA members receive excellent education and training. Nowhere is this excellence better exemplified than in our faculty teaching award at the PDA Training and Research Institute. Selection of an individual to receive the James P. Agalloco Award for Excellence in Teaching is not an easy task; criteria for this award is based on evaluations completed by the course participants and the overall efforts of the faculty member in contributing to PDA educational initiatives. In 2002, PDA was pleased to present this award to **Göran Bringert**, Director of Pharma and Biotech Markets at Kaye Instruments, Inc. Bringert is a process engineer with extensive process control and instrumentation experience in both Europe and the U.S. His background includes electronics development and systems implementation in the pharmaceutical/biotechnology, aerospace, semiconductor, and metals industry.

Award Selection Committees

PDA Awards
Chair, Henry K. Kwan, Ph.D.
Kwan Consulting

Edmund M. Fry
PDA

Russell E. Madsen
PDA

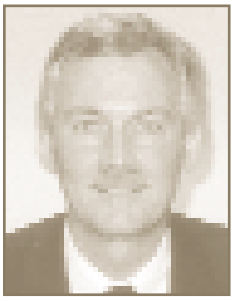
Robert B. Myers
Beacon Pointe Group

PDA Frederick D. Simon Award Committee
Chair, Galen W. Radebaugh, Ph.D.
Schering-Plough Research Institute

Donald Chambers, Ph.D.
Schering-Plough Research Institute

2002 Board of Directors




OFFICERS

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Floyd Benjamin
Keystone Pharmaceuticals, Inc.

Chair-elect
Nikki V. Mehringer
Eli Lilly and Company

Secretary
Jennie Allewell
Cell Therapeutics, Inc.

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Richard V. Levy, Ph.D.
KMI, a division of PAREXEL International, LLC

Immediate Past Chair
Robert B. Myers
Beacon Pointe Group




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Vince R. Anicetti
Genentech, Inc.

Joyce H. Aydlett
Aydlett and Associates, Inc.

Robert L. Dana
Elkhorn Associates, Inc.

Stephanie R. Gray
GlaxoSmithKline




Kathleen S. Greene
Novartis Pharmaceuticals

Henry K. Kwan, Ph.D.
Kwan Consulting, Inc.

Suzanne Levesque
Sabex, Inc.

Tim R. Marten, D.Phil.
AstraZeneca




Robert J. Mello, Ph.D.
PDA

Taiichi Mizuta, Ph.D.
Shionogi & Co. Ltd.

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

Glenn E. Wright
Eli Lilly and Company

Science and Technology

Science and technology are the foundations upon which PDA was built. They remain today the center of our society. PDA's reputation for delivering state-of-the-art, foundational scientific and technical information is unparalleled. This information is delivered in a number of ways:

■ PDA Technical Reports

PDA Technical Reports cover a wide variety of subjects relating to pharmaceutical production, validation and quality assurance. They are widely recognized by industry and regulators worldwide as core scientific and technical information. These reports are prepared by Task Groups and technical committees composed of experts in the areas directly related to the subject of the particular report. The experts are industry scientists and engineers, and often include regulators, such as FDA representatives. This level of expertise ensures the completed report will reflect the best thinking and practice currently available.

PDA has published a total of 36 Technical Reports, and to assure that the society stays at the leading edge in this dynamic environment, ten new Technical Reports are currently being developed, and four Technical Reports are currently being revised. Archived with the *PDA Journal of Pharmaceutical Science and Technology,* members receive free copies of Technical Reports as they are published. Technical Reports are the basis for PDA technical forums, where they are discussed by a panel of experts and subjected to questioning by the audience. These forums have been extremely valuable in pointing out needed clarifications prior to publication.

During 2002, PDA's Task Groups and technical committees worked on significant revisions to existing PDA Technical Reports and developed new ones. PDA published Technical Report No. 36 (TR-36), *Current Practices in the Validation of Aseptic Processing–2001* which encapsulated the results of the 2001 aseptic processing survey. Begun in 1986, this survey is updated every five years and provides a means of following the evolution of new aseptic processing practices over time.

Science Advisory Board

The PDA Science Advisory Board (SAB) is comprised of experts in various pharmaceutical industries. It establishes the strategic perspective and provides oversight for PDA's scientific and technical activities through the development of guidelines, technical monographs and interaction with regulatory authorities.

The members of the 2002 Science Advisory Board were:

Co-Chair:
James P. Agalloco
Agalloco & Associates

Co-Chair:
James L. Fernandez
Fernandez and Associates

Members
Michael J. Akers, Ph.D.
Baxter Pharmaceutical Solutions, LLC

Frank Bing
Abbott Laboratories, Inc.

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

Volker Eck, Ph.D.
Pfizer, Inc. & Italia S.p.A.

Jens H. Eilertsen, Ph.D.
Novo Nordisk A/S

Don E. Elinski
Eli Lilly and Company

Gordon J. Farquharson
Bovis Lend Lease Pharmaceutical

Lothar Hartmann
F. Hoffmann-La Roche

Karl L. Hofmann
Bristol-Myers Squibb Co.

David Hussong, Ph.D.
U.S. Food and
Drug Administration

Richard M. Johnson
Abbott Laboratories, Inc.

Kunio Kawamura, Ph.D.
Otsuka Pharmaceutical Company, Ltd.

Carol M. Lampe
Baxter Healthcare Corporation

Russell E. Madsen
PDA

Gautam Maitra
PDA

Robert J. Mello, Ph.D.
PDA Training and
Research Institute

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

Jean I. Olsen
GlaxoSmithKline

Georg L. Roessling, Ph.D.
Schering AG

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

Gail Sofer
BioReliance Corporation

William H. Stoedter, RAC
PDA

Ignacio Tintore, Ph.D.
Tiselab SL

Lynn D. Torbeck
Torbeck and Associates, Inc.

Glenn E. Wright
Eli Lilly and Company

■ PDA Technical Bulletins

PDA became aware of a need for short position papers responding to issues raised during regulatory inspections around the world, so for the first time in 2002, we began to provide a series of scientifically-based Technical Bulletins to address these issues. These documents can be used to support an industry response to a regulatory concern. They address a single issue in one to 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.

PDA published two Technical Bulletins in 2002:

- Technical Bulletin No. 2002-01, *Vent Filters for Terminal Sterilization Autoclaves*
- Technical Bulletin No. 2002-02, *Pre-Use Integrity Testing of Sterilizing-Grade Filters*

Good Electronic Records Management (GERM), Part 1

George J. Grigonis, Jr. of Software Safety, Inc.
acted as the Chairman and lead. The core team consisted of:

Lowrie Beacham
Duke Clinical Research Institute

Steve Coates
Wyeth

Nick A. Dayton
Abbott Laboratories

Christie Deitz
Emerson Performance Solutions

Marta Fields
Amgen, Inc.

Bob Froelich
Eli Lilly and Company

Ron Hinkel
Centocor, Inc.

C. Wells Horton
Procter & Gamble Pharmaceuticals

Colin Jones
Conformity Ltd. (GAMP)

Victoria Lander
NuGenesis Technologies

Orlando Lopez
McNeil Consumer Healthcare

Kevin C. Martin
CimQuest, Inc.

Craig McGill
Abbott Laboratories

John McKenney
SEC Associates, Inc.

Paul Motise
FDA/ORA

Karen Nichols
Genzyme

Lisa Olson
SEC Associates, Inc.

Michele Pontinen
Price Waterhouse Coopers

Bryan Raybuck
Baxter Healthcare Corporation

Marti Turocy
Quality Systems Integrators

Phyllis Weldon
Data Scout Software, Inc.

Robert Williams
Cohasset Associates, Inc.

■ Good Electronic Records Management (GERM), Part 1

PDA collaborated with the International Society for Pharmaceutical Engineering (ISPE) and several industry groups (FDA-regulated companies, system suppliers, legal experts and consultants) to produce the Good Electronic Records Management (GERM), Part 1 of the series on Good Practice and Compliance for Electronic Records and Electronic Signatures. It represents a compendium of current thinking on good electronic record management from an FDA-regulated industry perspective. The document covers the concepts and principles that need to be considered when building, maintaining, managing and transitioning electronic records environments. Focusing on requirements and concepts rather than technical implementation details, this resource document is a valuable tool for the architects of electronic records environments.

■ PDA Technical Archive on CD-ROM

The PDA Technical Archive on CD-ROM provides easy access to more than 55 years of research papers written by highly qualified research scientists in the pharmaceutical industry. All PDA *Journal* articles, Technical Reports and Monographs, and selected Meeting Proceedings are available on this fully-searchable CD-ROM. The Archive is updated each year, adding six issues of the PDA *Journal*, all PDA Technical Reports and Monographs, and selected PDA Meeting Proceedings.

■ PDA Technical Books

PDA continues to publish titles in pharmaceutical and biopharmaceutical topics through its collaboration with Davis Horwood Publications, Inc. The titles released in 2002 were:

- *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry*, Third Edition, by Milton A. Anderson
- *Laboratory Systems Validation Testing and Practice*, by Paul Coombes
- *Microbiological Monitoring of Pharmaceutical Process Water*, by Michael Jahnke
- *Sorting Out the Critical Variables: A Worked Example for the Non-Statistician*, by Alfred Wachter
- *Steam Sterilization: A Practitioner's Guide*, by Jeanne E. Moldenhauer, Ph.D.
- *The Validation Master Plan*, by Trevor Deeks

■ PDA Audit Repository Center

PDA developed a Supplier Audit Process Model, which established a standardized framework for conducting audits of suppliers that provide computer products or services to the regulated pharmaceutical and biopharmaceutical industries. From this model, a secure, global central repository, the Audit Repository Center (ARC) was created to maintain audit information. PDA licenses ARC to administer the audit program. This repository has succeeded in lowering costs, inconsistencies and redundancies in the auditing process. Suppliers seeking to place their audit information in the repository for use by their pharmaceutical, biopharmaceutical and other industry clients have found the information obtained from the auditor training to be extremely beneficial in expediting the audit process and in the internal benchmarking of their quality systems. In 2002, ARC performed 13 audits.

■ Interest Groups

Interest Groups are a unique feature of PDA that enable members to meet on specific topics of special interest to them. They provide a vehicle for people with common interests to interact within the association and to exchange information, and they serve as a gateway for new PDA members to become more active in the organization. Any PDA member may join one or more Interest Groups. Interest Groups are an excellent source of information, and provide a forum to initiate new Task Group activities to address regulatory concerns, advances in technology, and industry practices and issues.

PDA/ARC Industry Advisory Board

Chairman
Robert J. Mello, Ph.D.
PDA Training and Research Institute

Mark Brazier
KMI, a division of PAREXEL International, LLC

Maggy Burnes
SSA Global Technologies

Winnie Cappucci
Berlex Laboratories, Inc.

Virginia Corbin
Waters Corporation

William Goebel
CimQuest, Inc.

Harvey Greenawalt
Audit Respository Center

George Grigonis
Consultant

Janis Halvorsen
EduQuest Inc.

James John
Brock Solutions U.S., Inc.

Jeffrey Lee
ISIS Pharmaceuticals

Russell Madsen
PDA

Tom Rudzinski
Pfizer, Inc.

George Serafin
SAP Labs, Inc.

Kola Stucker
Bristol-Myers Squibb Co.

Elien Young
Novartis Pharmaceuticals Corporation

2002 PDA Interest Groups and Leaders

Biotechnology
Frank Matarrese
Chiron Corporation

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

Contract Manufacturing
Michael R. Porter
Eli Lilly and Company

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

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

QA/QC
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
FSK Associates, Inc.

Validation
Bohdan M. Ferenc
Qualification Services

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

Regulatory Affairs

2002 RAQC Committee

The 2002 RAQC committee consisted of the following individuals:

Chair
Suzanne Levesque
Sabex, Inc.

Jennie Allewell
Cell Therapeutics, Inc.

Vince R. Anicetti
Genentech, Inc.

Donald E. Baker, J.D.
Fujisawa Healthcare, Inc.

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
Cap Gemini Ernst and Young
Deutschland GmbH

James C. Lyda
KMI, a division of
PAREXEL International, LLC

Russell E. Madsen
PDA

Gautam Maitra
PDA

Tim R. Marten, D. Phil.
Astra Zeneca

Nikki V. Mehringer
Eli Lilly and Company

Robert J. Mello, Ph.D.
PDA Training and Research Institute

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Amgen, Inc.

David J. Miner
Eli Lilly and Company

Toshiaki Nishihata
Santen Pharmaceutical Company, Ltd.

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

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

William H. Stoedter
PDA

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

PDA's Regulatory Affairs department works with global regulatory agencies to help develop guidances that reflect the real world of pharmaceutical and biopharmaceutical manufacturing to ensure that these guidances are based on sound scientific principles, without generating redundant or unnecessary requirements. Utilizing this information, the Regulatory Affairs department publishes news necessary for our members to understand and comply with regulatory expectations.

PDA's Regulatory Affairs and Quality Committee (RAQC) addresses all regulatory initiatives within PDA's mission—quality, manufacturing, chemistry and manufacturing controls, and GMPs worldwide. PDA believes that regulatory requirements should be harmonized internationally and that the terms should be consistent. PDA achieves these objectives by hosting educational events, conferences and courses, and by sharing information regarding technical issues.

The year 2002 brought many interesting developments in the regulatory arena. The most groundbreaking event was the launch of FDA's program to overhaul the quality regulations, called the "Pharmaceutical cGMPs for the 21st Century: A Risked-Based Approach." This initiative will impact all quality-related aspects of the regulatory process from chemistry, manufacturing and control submissions to CGMP inspections. The primary driver of the initiative is FDA's desire to facilitate the use of advanced technologies and sound science in pharmaceutical manufacturing processes. The initiative reinforces the role PDA plays in facilitating the advancement of science and technology for pharmaceuticals and biopharmaceuticals, and is a topic of great interest among our members.

In a letter written to the Center for Drug Evaluation and Research Director Janet Woodcock, M.D., PDA asserted that FDA's May 3, 1996 Proposed Rule amending Current Good Manufacturing Practices for Certain Finished Pharmaceuticals not be finalized. Dr. Woodcock agreed with PDA's stance that the Proposed Rule not be finalized at that time because it did not represent current GMP practice. FDA then decided to implement a new initiative to review and revise all GMPs.

PDA submitted comments on the following regulatory guidances in 2002:

- FDA's dispute resolution process, part of Pharmaceutical *CGMPs for the 21st Century—A Risk-Based Approach*, for which comments were presented at the December 18, 2002 FDA OPS trade association meeting
- Draft comments on the FDA concept paper on aseptic processing, which was presented at the PDA Metro chapter meeting.
- Letter to PIC/S secretariat regarding PIC/S draft recommendation on the *Isolators Used for Aseptic Processing and Sterility Testing*.
- Letter and proposal to Ajaz S. Hussain, Ph.D. Deputy Director, Office of Pharmaceutical Science, FDA, regarding PAC for sterile products.
- Comments on FDA's preliminary concept paper, "Sterile Drug Products Produced by Aseptic Processing", which were presented to FDA's Pharmaceutical Science Advisory Committee on October 22, 2002.

The full text of these comments may be found on PDA's Web site at www.pda.org.

■ Product Quality Research Institute

PDA was a founding member and holds a seat on the Board of the Product Quality Research Institute (PQRI). Incorporated in 1999 as a nonprofit corporation, PQRI provides a neutral environment where industry, academia and FDA cooperatively collaborate on pharmaceutical product quality research and development in support of policy relating to the regulation of drug products. The PQRI mission is to bring together industry, academia and FDA to perform research that will help streamline regulatory requirements. The PQRI Blend Uniformity Working Group completed the collection and analysis of data on blend uniformity, and a final proposal, *The Use of Stratified Sampling of Blend and Dosage Units to Demonstrate Adequacy of Mix for Powder Blends*, was submitted to FDA. PQRI also held a meeting for working groups to explain the process of performing scientific studies intended to improve FDA regulatory policies.

PDA Training and Research Institute

In 1997, PDA opened its Training and Research Institute to provide worldwide education and training in the pharmaceutical and biopharmaceutical sciences and associated technologies. Today, it has become the preeminent provider of training in the industry. The PDA Training and Research Institute is a first-of-its-kind training facility that offers comprehensive education, training, and applied research programs in the pharmaceutical sciences and associated technologies worldwide. In addition to traditional educational programs offered globally, the PDA Training and Research Institute provides unique “hands on” laboratory training at its state-of-the-art facility in Baltimore, Maryland, USA.

■ Highlights

The year 2002 brought a wealth of opportunity to PDA’s membership, due to the breadth and depth of courses that the PDA Training and Research Institute offered. The aseptic processing course was the Institute’s most successful course, and remains one of the industry’s most popular hands-on courses. The Institute also presented 66 lecture classes throughout the world at international congresses, national conferences, stand-alone course series, forums and chapter-associated course events. The Lake Tahoe, Vermont and Tampa Training Conferences were extremely successful with strong faculty and programs. The Las Vegas Training Conference and the Mountain States Chapter Course were well attended. Three new training qualification courses were added to the curriculum in 2002, as well.

■ Facility and Laboratories

PDA is known throughout the world for its outstanding lectures and laboratory courses and maintains its state-of-the-art training facility near Baltimore, Maryland. It offers one-of-a-kind modern classroom and laboratory facilities. Two classrooms provide meeting space for both education and conference events. At the centerpiece of the Institute are three teaching labs. Each of these labs simulates real production facilities and allows participants in the classes to practice hands-on skills association with a wide range of production and lab activities. These laboratories consist of: (1) a general chemistry/microbiology lab, which demonstrates laboratory equipment and methods; (2) an aseptic processing lab, which focuses on product filling and lyophilization; and (3) a process development lab in which steam sterilization, clean-in-place and temperature monitoring training is conducted.

The Institute’s laboratory and classroom spaces are also used by a variety of firms for applied research. Both equipment and processes can be tested in the Institute’s open-ended environment without fear of endangering the firm’s vital, and often-times validated production processes. FDA frequently uses the Institute’s facilities for their own inspector training programs.

While the lecture courses are a critical component of PDA Training and Research Institute’s offerings, it is the "hands-on" courses held at the Institute's laboratory facilities that set it apart from all others; it remains the only association-based “hands-on” laboratory training program that is invaluable in linking theory and practice.

Faculty

PDA would like to express its gratitude to the following individuals who gave their time to teach the courses offered through the PDA Training and Research Institute:

James P. Agalloco
Kadambi Ajit-Simh
James E. Akers, Ph.D.
Harold Baseman
John Brecker
Göran Bringert
Carolyn Broughton, Ph.D.
Anthony Cannon
Richard Cavallaro
Susannah Childers
Rod Chu
Samuel Clark
William V. Collentro
Dr. James F. Cooper
Cheryl Ann Custard
Gayle Dolecek
Jayne Dovin
Anne Marie Dixon
Amnon Eylath
David Gallup, Ed.D.
John Geigert, Ph.D.
William Goebel
Daniel H. Gold, Ph.D.
Harvey Greenawalt
Dr. Nigel A. Halls
Mark Hallworth
Peter T. Holman
Sylvia M. Isaacson
Cecily K. Kaufman
Robert Kieffer, Ph.D.
Ronald J. Kraus
Steven S. Kuwahara, Ph.D.
David Lansky, Ph.D.
Max Lazar
Destin A. LeBlanc
Mike Leonard
George Levinson
John Lindsay
Sandra A. Lowery
Dave Manley
Jeffrey L. Masten
Bernice Marshall
David Matsuhiro
Laura Mayer
Deborah Harrell Meehan
Steven Messick
Jeanne E. Moldenhauer, Ph.D.
Kenneth Muhvich
Clifford Nilsen
Robert O’Brien
Diane Paskiet
Elaine Lehecka Pratt
Maureen Reagan
Thomas Reidy
Rick H. Rogers
Richard Sands
John Schlottig
Karen Schroyer
Dale Seiberling
John Shirtz
Edward S. Smith, Ph.D.
Ron Stellon
Blane Stroh
Ronald Tetzlaff, Ph.D.
Lynn D. Torbeck
Edward Trappler
Arthur Vellutato, Jr.
James L. Vesper
Jon Voss
Charlie Waite
Steven R. Wiseman
Richard T. Wood, Ph.D.
Jeff Yuen

Lecture Courses

Designed to maintain and advance knowledge within the pharmaceutical and biopharmaceutical industries, PDA Training and Research Institute lecture courses are applicable to all individuals employed in industry, government and academia worldwide. In 2002, the Institute offered a broad range of lecture courses, specifically:

- Training for Trainers
- Metrology and Calibration
- Part 11 Computer Issues
- Validation
  - General
  - Chemical Assays
  - Biological Assays
  - Process
  - Cleaning
- GMP Fundamentals
- Compliance Issues
  - Change Control
  - OOS (out of specification) Investigations
- Regulatory Submissions and Pre-Approval Inspections
- Aseptic Processing
  - Contamination Control
  - Environmental Monitoring
- API Manufacturing
- Auditing
  - Computer Systems
  - Microbiology Labs
  - Foreign API Manufacturers
- Pharmaceutical Systems Design
  - Water
  - HVAC

Contributors

PDA is grateful to the following companies for the donations they made to the PDA Training and Research Institute in 2002:

Company	Donation
Alcan Packaging	Wheaton Vials
Allegiance	Sterile Gowning Materials
BD	EM Microbiology Materials
Berkshire Corporation	Aseptic Wipes, Cleanroom Masks
BioMerieux, Inc.	Microbiology Materials
Bonfiglioli Pharmaceutical Machinery	Vial Leak Tester
Charter Medical	Bio-Packaging
Cole-Parmer	Tubing
Contec	Aseptic Wipes
Corning Inc. Life Sciences	Sterile Plastic Supplies
Dale Seiberling/Electrol Specialties Consortium	Mini Clean-in-Place Skid
Dupont	Tyvek Gowns
EM Chemicals	Reagents
General Econopak	Packaging Tyvek Materials
Ionics Corporation	Updated Total Organic Carbon Analyzer
Kimberly Clark Corp.	Cleanroom Supplies
Microbiologics	Microbiology Materials
Millipore	Filters
Perfex Corporation	Mopping Materials
Remel	Microbiology Materials
Scientific Device Labs	Mycology Materials
Veltek Associates, Inc.	Disinfectants, Sanitizers, Alcohol
West Pharmaceuticals	Stoppers and Caps

Laboratory Courses

The laboratory courses offered in 2002 were:

- Aseptic Processing
- Steam Sterilization Validation
- Steam Sterilization Cycle Development
- Thermal Measurement
- Biological Indicator Assessments: D, F, and Z-Values
- Mycology Identification
- Cleaning Validation

Not only do these courses offer state-of-the art technology, but they provide a unique venue in which participants can network with fellow members of the industry. PDA's Training and Research Institute in Baltimore offers an educational opportunity that is unique to the industry.

Faculty

PDA's instructors come from among the industry's most respected experts. In 2002, the PDA Training and Research Institute utilized over 70 individuals to present its courses. Many of these individuals are nationally-recognized leaders and researchers. Many are published authors in their areas of expertise. All are outstanding instructors, as judged by participant evaluations.

Programs and Meetings

PDA is respected globally for providing unparalleled education, training and research in pharmaceutical science and associated technologies. In 2002, PDA offered an unprecedented number and variety of educational, scientific, and technical programs. Without the tireless efforts of the 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 2002:

Basel 2002: PDA International Congress, Courses and Exhibition
Adding Value to the Pharmaceutical Industry-Leveraging the Future
Co-chairs: Nigel Halls, NHC-Nigel Halls Consulting U.K. and
Lisa M. Skeens, Ph.D., Baxter Healthcare Corporation, USA

Training Workshops
ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
Offered five times in the U.S. and Europe in 2002

2002 PDA Spring Conference, Courses and Tabletop Exhibition
Current Practices in Aseptic Processing: Reaching a Common Understanding of the Regulatory and Technical Requirements
Chair: Richard Prince, Ph.D., Richard Prince Associates, Inc.

Audio Conference Series
Process Analytical Technologies;
Summary: PDA/USP Joint Conference on Sterile Product Manufacturing

PDA Isolation Technology: User Issues Conference, Courses and Tabletop Exhibition
Chair: Dimitri Wirchansky, Jacobs Engineering

PDA/USP Joint Conference on Sterile Product Manufacturing

PDA/AAPS Workshop:
The Paperless Laboratory – Finally a Reality: Defining the Criteria for a Quality System

2002 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibition
Chair: Elizabeth Leininger, Ph.D., Biologics Consulting Group

PDA 2002 Biennial Training Conference, Courses and Exhibition
Charting a Course for Success
Chair: Robin O. Wachter, Eli Lilly and Company

2002 PDA Annual Meeting, Courses and Tabletop Exhibition
Chair: Laura Thoma, Pharm.D., University of Tennessee-Memphis

Of particular note was the one-time ICH Q7A training (five workshops in 2002), which delivered targeted training on international harmonized guidance to industry. These were the only joint ICH Q7A training workshops officially sponsored by FDA and conducted by members of the Expert Working Group that developed the guidance.

PDA was pleased to collaborate with a number of other organizations during the year. The association teamed with the U.S. Pharmacopeia to offer a Joint Conference on Sterile Product Manufacturing. PDA worked with the American Association of Pharmaceutical Scientists to deliver a workshop on The Paperless Laboratory. In the fall, PDA collaborated with FDA to offer its annual Joint Regulatory Conference. Then Acting FDA Commissioner Lester M. Crawford, Ph.D., D.V.M., spoke about the release of the long-awaited Draft Concept Paper on Aseptic Processing at this meeting. In working together with all of these other organizations, PDA provided broader, content-enriched opportunities for industry professionals.

Another important milestone in 2002 was the 7th PDA International Congress in Basel which brought together the FDA and European health authorities. This was especially beneficial because it enabled face-to-face contact between the FDA and interested parties in Europe. PDA launched an audio-conference series beginning with the PDA/USP Joint Conference on Sterile Product Manufacturing that allowed participating members to obtain timely scientific and regulatory information in a cost-effective manner, without leaving their offices.

As part of its meetings, PDA offered networking and leadership opportunities at the local, national and international levels. Throughout the year, PDA continued to provide enhanced opportunities for exhibiting companies to display the latest technical and scientific advances as well as products and services to industry. PDA further established itself as the definitive source for meetings and education in the industry and ensured that members stay on top of the latest developments in the pharmaceutical and biopharmaceutical industries.

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Meridian Medical Technology

Barry Bardo
Meissner Filtration Products

Carol Dellicicchi
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Howard Drake
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Wanda Neal
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Arthur Vellutato, Jr.
Veltek Associates, Inc.

Vicky Wuerful
Pharmaceutical Systems, Inc.

Membership and Chapters

PDA is proud to provide access to the foremost group of scientific, industry and academic experts who influence industry practice and regulatory policy worldwide. By joining PDA, members reap the benefits of an unparalled body of technical expertise and knowledge applicable to real-world challenges. Membership in PDA allows individuals to learn what they need to know to advance in their profession and to contribute to their company's overall success.

PDA offers superior value and services to its members. In addition, by joining PDA, members receive:

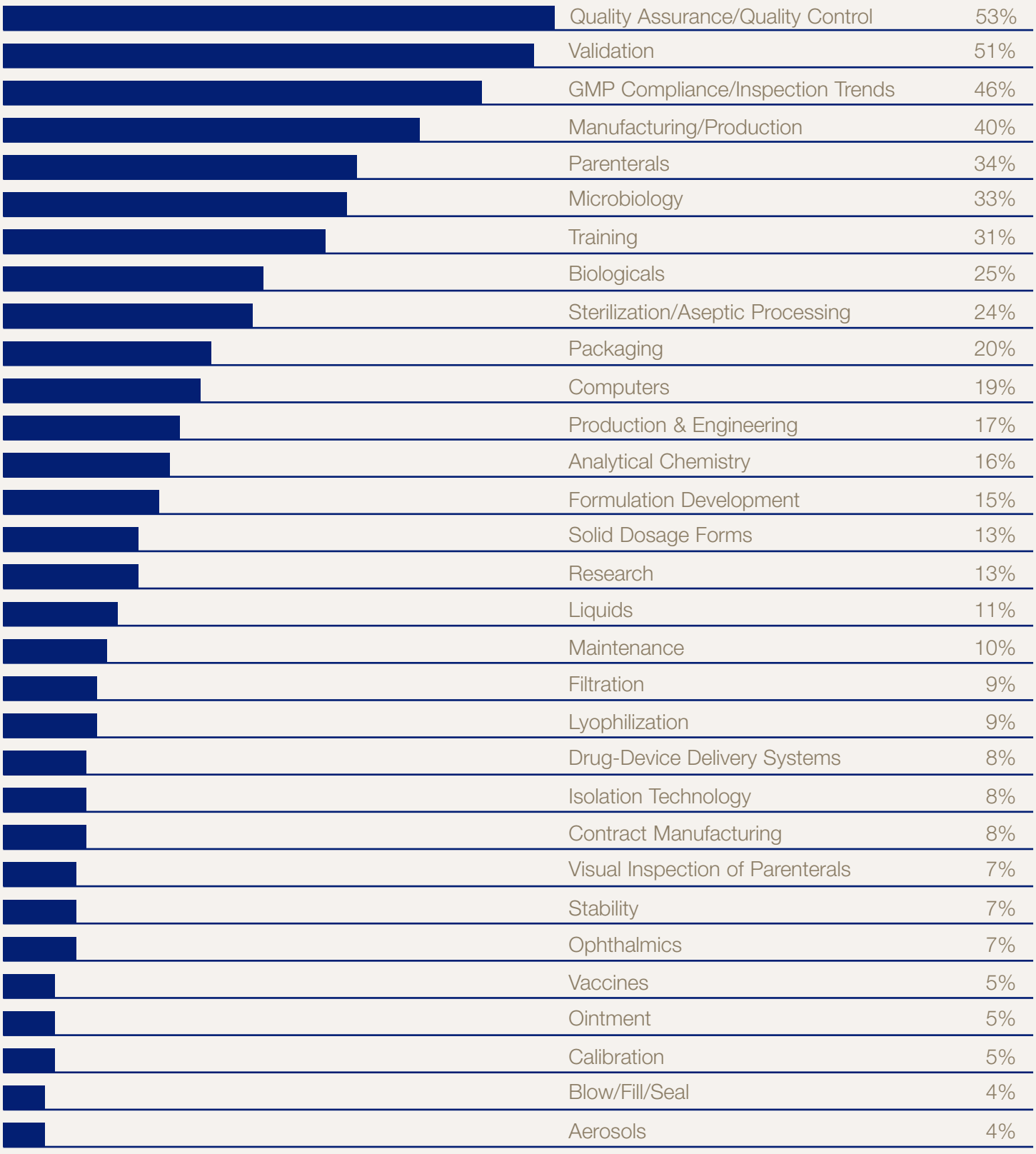
- Opportunities to participate in PDA's Scientific Committees, Interest Groups and Task Groups
- Invaluable opportunities to network with industry representatives from large and small companies worldwide, biotechnology companies, medical device manufacturers, equipment vendors, government agencies, academic institutions and consulting firms
- Access to world-class instructors and hands-on laboratory courses at the PDA Training and Research Institute
- The *PDA Journal of Pharmaceutical Science and Technology*, a peer-reviewed, bimonthly publication which centers on articles, research papers and editorials in the biotechnology/pharmaceutical fields. Established in 1946, it presents the most relevant, outstanding peer-reviewed pharmaceutical scientific and technical papers. The *Journal* is a PDA member benefit. but subscriptions are also available to industry, universities, public libraries, as well as government agencies.
- The *PDA Letter* is a monthly members-only newsletter designed to keep members informed of the latest information in the scientific arena along with regulatory happenings within the association and the industry. It also contains details on upcoming PDA events, as well as worldwide Chapter activities, industry news, and education and employment opportunities in the pharmaceutical industry
- PDA Technical Reports, which cover a wide variety of subjects relating to pharmaceutical production, validation and quality assurance (see p. 8)
- PDA Technical Bulletins, as they are published (see p. 9)
- Access to PDA's Online Membership Directory
- Access to the Members-Only area of PDA's Web site, containing
  - Draft Technical Documents
  - *PDA Letter* Archive
  - FDA's Human Drug CGMP Notes Archive
  - Technical Presentations Archive
  - Interest Group Minutes and Presentations
- Significant discounts on all PDA publications, including discounts off the list price for selected publishers
- Easy access to PDA local Chapters
- The ability to earn continuing pharmaceutical education credits
- Reciprocal membership opportunities with PDA's affiliated international organizations, the R3-Nordic (Sweden) and the Parenteral Society (U.K.)
- PDA activity updates and E-mail news briefs

A global reach–
members representing
70 countries worldwide

In 2002, the association was pleased to add a number of new benefits. First, there were a number of Web enhancements. Among these were the creation of online registration and the PDA Job Bank. PDA began a new tradition with the issuance of special commemorative pins that are given to recognize long-term members of PDA for their years of support. These pins are given to those individuals who have been members of PDA for 10, 20 or 30 years.

PDA Membership by Professional Interest

The active PDA membership count for year-end 2002 was 10,368.
Percent total is greater than 100% because many members have multiple areas of interest.



Chapters

PDA Chapters provide an excellent opportunity to participate on a local level, and PDA offers a number of chapters worldwide. PDA Chapters welcome the input and expertise of their members. Chapter events range from dinner meetings to sports outings to workshops to international congresses. The 2002 Chapter Officers were as follows:

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Millipore Australia

Treasurer
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Secretary
Bryan Martin
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Membership Secretary
Sean J. Wattam
Pall Life Sciences

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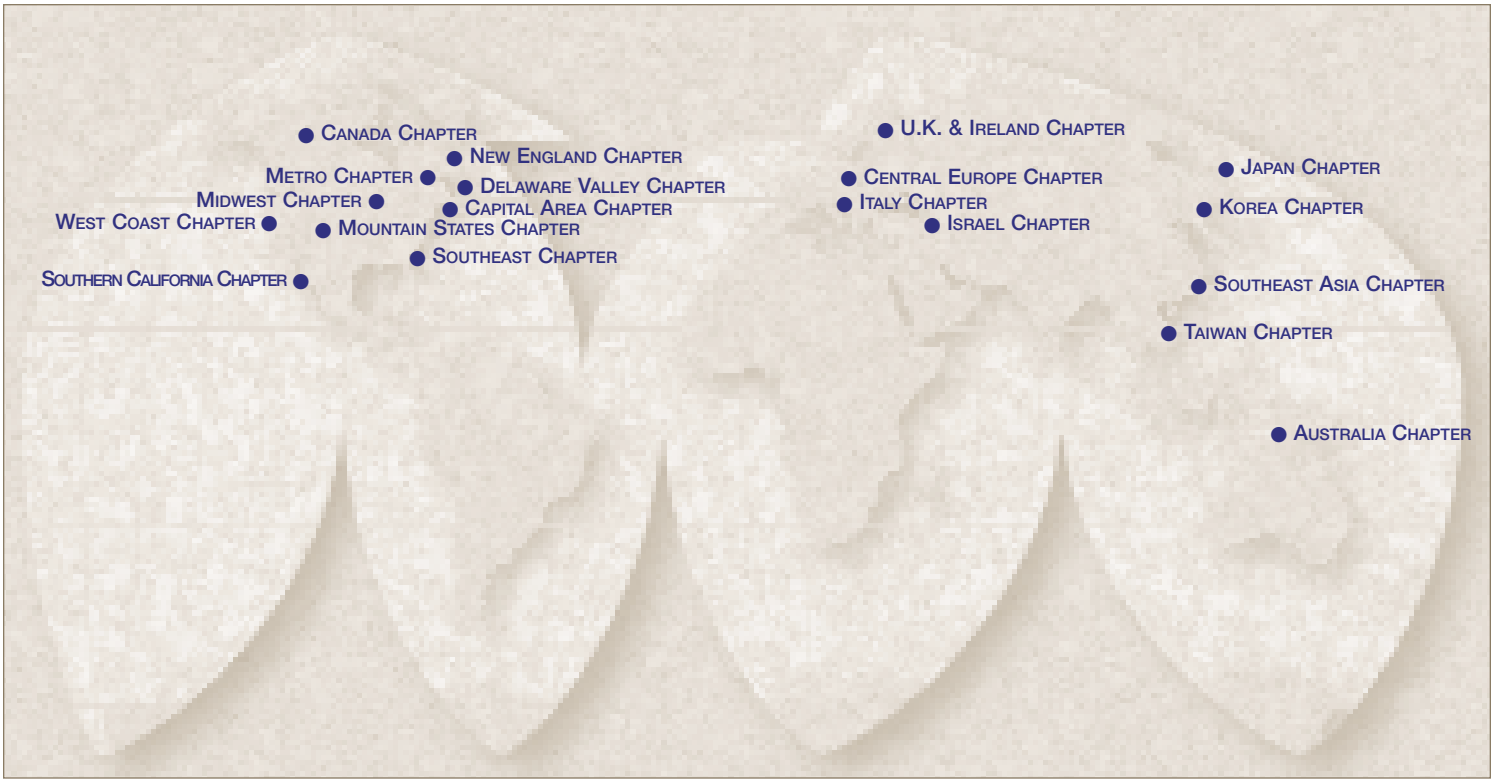
PDA Training and Research Institute

Treasurer
Daniel T. Bauer
Pall Corporation

Secretary
Stephen J. Rochelle
Rochelle & Associates, Inc.



During the past decade, PDA has made great strides to recruit overseas members and to establish relationships with pharmaceutical associations abroad. Today, nearly 40% of PDA's members reside outside the United States. Our chapters are expanding to all corners of the globe, and PDA's international presence reaffirms PDA's vision to be recognized worldwide as an authoritative, easily accessible source of global scientific, technical and regulatory information in the pharmaceutical and biopharmaceutical fields.

Chapters (continued)

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PDA Taiwan Chapter

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She-Shong Tsai
PDA Taiwan Chapter

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Chiron Corporation

Events
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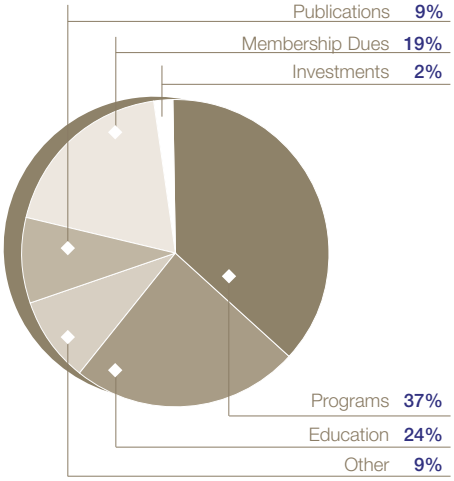
Genentech, Inc.

Membership
Thomas Chan
Genentech, Inc.

Financial Report

PDA is a financially independent, not-for-profit organization. Its primary sources of revenue are programs (meetings and conferences), education (training), membership dues and publication sales.

PDA's income sources in 2002 were as follows:



2002 was a remarkable year for revenues and profits

As a result of the number of successful PDA programs and courses offered in response to new regulations, 2002 was a remarkable year for revenues and profits. Revenues for 2002 were 17% higher than for 2001. Total expenses increased 11%, reflecting continued investment in PDA staff and programs.

	Years ended December 31, 2002*	2001
Total revenues:	$ 8,320,623	$ 7,120,072
Total expenses:	7,392,375	6,652,846
Excess revenues over expenses from operations:	$ 928,248	$ 467,226
Unrealized (losses) gains on investments:	(115.620)	56,733
Increase in net assets (reserves):	$ 812,628	$ 523,959
Net assets at beginning of year:	3,430,531	2,906,572
Net assets at end of year:	4,243,159	3,430,531
Reserve Ratio (reserves/annual expenses):	57.4%	51.6%

*Note: 2002 performance was impacted by the one-time ICH Q7A program, which accounted for $994,484 of the total revenue.

Our investments, which are primarily in conservative instruments appropriate for a nonprofit association, experienced unrealized capital losses of $115,620 (compared to a gain of $56,733 in 2001) which reflects the challenging financial market which existed in 2002. This loss, however, was offset by $170,301 in investment revenue (interest, dividends and realized gains).

Net assets (reserves) at the beginning of 2002 were 18% higher than at the beginning of 2001. During 2002, PDA's net assets increased by $812,628, an increase of 24% over that recorded at the end of 2001. At year-end 2002, our reserve ratio stood at 57%, which compares quite favorably against the industry average of 47% among associations of PDA's size.

Leadership

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Keystone Pharmaceuticals, Inc.

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AstraZeneca

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Schering AG

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

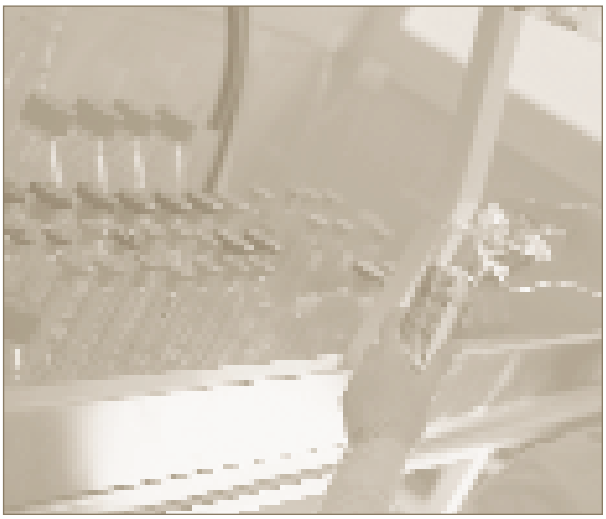
Lisa M. Skeens, Ph.D.
Baxter Healthcare Corporation

Glenn E. Wright
Eli Lilly and Company

PDA Past Presidents/Chairs*

1947	Rudolf N. Price
1948-1950	Paul A. Naef
1951-1952	Paul deHaen
1953	Joseph Ushkow
1954-1955	David Ashkenaz
1956-1957	L. James Graham
1958-1959	William S. Bucke
1960	John Henderson
1961-1962	Harold Dembo
1963-1964	Hubert Boyden
1965-1966	Nathan C. Kirsch
1967	Harold Blumberg
1968-1969	Kenneth E. Avis
1970-1971	Charles P. Schaufus
1972-1973	Gordon R. Personeus
1974-1975	William J. Artz
1976-1977	George H. Hopkins
1978-1979	Frederick J. Carleton
1980-1981	Jack Cole
1982-1983	Leon Lachman
1984-1985	Sol Motola
1986-1987	Robert Kieffer
1988-1989	James P. Agalloco
1990-1991	Michael S. Korczynski, Ph.D.
1992-1993	James E. Akers, Ph.D.
1994-1995	Clarence A. Kemper
1996-1997	Raymond Shaw, Jr.
1998-1999	Joyce H. Aydlett
2000-2001	Robert B. Myers

**The chief elected volunteer was known as PDA President until 1995. At that time, this position was renamed Chair.*



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Sopita Lapsomphop
Executive Assistant, Science & Technology and Regulatory Affairs

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Director, Regulatory Affairs

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Coordinator, Marketing Services

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Wanda Neal, CMP
Assistant Director, Programs and Meetings

Andrea Agalloco
Meetings Coordinator

Kalisha Singleton
Meetings Coordinator

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Vice President, Finance and Strategic Planning

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Controller

Frank Sarlo
Computer Systems Manager

Feng Chen
IT Engineer

Deborah Taylor
Accountant

Jennifer Knode
Office Manager

Megan Lahti
Receptionist/Data Entry Specialist

Carol Harris
Manager, Information Systems and Reporting

Nickia Gouldbourne
Customer Account Representative

Dion Williams
Financial Systems Specialist

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PDA Training and Research Institute

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Beatrice Born
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