2001
ANNUAL REPORT

PDA
An International Association For Pharmaceutical Science And Technology

AN INTERNATIONAL ASSOCIATION
DEDICATED TO ADVANCING
PHARMACEUTICAL TECHNOLOGY
BY PROMOTING SCIENTIFICALLY
SOUND AND PRACTICAL
TECHNICAL INFORMATION
AND EDUCATION FOR INDUSTRY
AND REGULATORY AGENCIES.

PDA

An International Association For Pharmaceutical Science And Technology

MISSION

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To support the advancement of pharmaceutical technology by

Statement

promoting scientifically sound and practical technical information and education for industry and regulatory agencies.

LETTER FROM THE

Chair

Robert B. Myers,
PDA Chair

2001 will be remembered for the profound impact of the 9/11 disaster and its effect on how we live, travel and do business. A large number of us experienced the tragedy near the US Capitol during the second day of our joint PDA/FDA Conference. Those from the US and visitors from overseas who were able to join the PDA management team and me in the President's Suite the evening of 9/11 shared a special bond of friendship and sense of loss that was felt by people all over the world that night. None of us who shared the experience will forget the day, and for that matter the entire week, as we struggled to determine direct impact on friends and relatives as well as finding our way home with the tremendous travel disruption.

While the long-term effects of the events of 2001 on PDA is still somewhat of a question, we as an organization look to the future with a sound financial position, an outstanding professional staff and a strong membership base.

The capital investment required during the past five years for the start-up of the Training and Research Institute (PDA-TRI) not only has been recovered, but also has showed a positive contribution to PDA's investment accounts in 2000 and 2001. Our cash position, something we seldom need to discuss, is the strongest ever. This was accomplished by focusing our training efforts at the Institute on our flagship course, Aseptic Processing, and emphasizing other very popular courses. I must recognize and congratulate Rick Rogers, PDA's current Vice President-Education, and his predecessor, Dr. Michael Korczynski as well as our excellent instructors. They are directly responsible for the outstanding success this endeavor has become. In addition to financial success, the Institute has created increased prestige and technical credibility for our organization which was one of the main goals for its creation.

In addition to the PDA-TRI financial turnaround, the annual membership dues were increased to cover the actual costs for support of our members. Our concentrated efforts to provide meaningful and current technical information in several formats which includes our Journal, Technical Reports and Newsletter has required an increase in staff and overall system expenses. This increase has been almost exactly matched by the increase in annual dues.

We now have more than 10,000 members. There are 18 chapters around the world and we have strengthened our presence in Europe. In April we conducted the first of what we hope will be biennial meetings in Taormina, Italy. The material presented in 2001 was outstanding and our hosts, Drs. Benati and Giannetto of SIFI created an exceptional forum for discussion during the spectacular days and evenings. This meeting will be held again in 2003 and I encourage anyone with an interest in current Regulatory Issues of the EU to review the agenda and attend. PDA also held a record number of workshops in 2001, entering new areas such as Viral Clearance (meetings are profiled later in this report).

I am deeply grateful for the hard work and support of the PDA Officers and members of the Board of Directors, who work tirelessly to insure that PDA performs at the highest level. My thanks also goes to the many volunteers who serve PDA as members of task groups, boards and committees, course faculty, and in any number of other ways.

I would like to express my sincere thanks to the professional staff under the guidance of Ed Fry for making my two years as Chair of the organization a pleasure and success. I feel we are ready for the uncertainties and opportunities of the future. We are working with many volunteers in conjunction with the staff to formulate a new Strategic Plan that will define our direction for the coming years and serve as guidance for each of our annual financial plans.

Finally, we all should be proud of our organization's significant contributions to the worldwide pharmaceutical industry. I look forward to serving the next two years on PDA's Executive Committee led by Floyd Benjamin, a longtime friend and our Chair for 2002 and 2003.

Board of Directors





OFFICERS

Chair
Robert B. Myers
Schering-Plough

Chair-Elect
Floyd Benjamin
Keystone Pharmaceuticals, Inc.

Secretary
Jennie Allewell
Cell Therapeutics, Inc.

Treasurer
Nikki V. Mehringer
Eli Lilly and Company

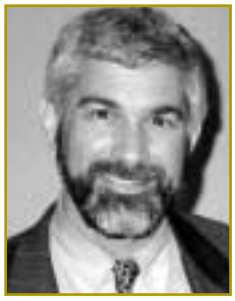
Immediate Past Chair
Joyce H. Aydlett
Aydlett and Associates, Inc.









DIRECTORS

Vince R. Anicetti
Genentech, Inc.

Robert L. Dana
Elkhorn Associates, Inc.

Stephanie R. Gray
GlaxoSmithKline

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

Suzanne Levesque
Sabex, Inc.

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

Robert J. Mello, Ph.D.
RJM Pharmaceutical Consultants

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

Georg Roessling
Schering AG

Kenneth B. Seamon, Ph.D.
Immunex Corporation

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

Glenn E. Wright
Eli Lilly and Company

Report from the President

Edmund M. Fry,
PDA President

WE began the process of updating our current Strategic Plan, under the direction of former Chair Joyce Aydlett. The current plan was approved in 1998, and it is appropriate to re-examine the changing environment in which we operate. We made good progress under the 1998 plan and need to set new goals for PDA to work toward in the next five years.

PDA continued its productive partnership with FDA during 2001, having co-sponsored several conferences. One of the most interesting activities was the series of training workshops on the International Conference on Harmonisation document on GMPs for Active Pharmaceutical Ingredients known as Q7A. These conferences were co-sponsored with PhRMA, Generic Pharmaceutical Association and FDA, and represented a unique opportunity for training of industry and FDA people by representatives of the ICH Working Group.

Formation of the European Steering and Development Committee (ESDC) was approved by the Board of Directors, for the purpose of coordinating and steering PDA's European activities. Initially chaired by Georg Roessling, it will consist of the European chapters (and Israel), along with representatives of other countries that have large numbers of PDA members. The ESDC will recommend how European members will be represented on PDA's Board of Directors.

Internally, we implemented a new membership management system called Osprey for better data handling. The system integrates membership, registration and a wide variety of membership-related functions. It will provide database support for Web site member benefits, such as online enrollment and registrations.

At the close of the year, we looked forward to moving our headquarters offices. We have resided in our current premises for 10 years, and have outgrown them.

The Board of Directors increased individual membership dues to $195 effective January 1, 2002.

PDA HONOR AWARDS IN 2001

HONORARY MEMBERSHIP

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award is given in recognition of very long service, of a very significant nature, to PDA. The award requires unanimous approval of the PDA Board of Directors, and Honorary Members are not eligible for other awards in the same year.

Michael S. Korczynski, Ph.D.

Past Chairman of the PDA Research Committee, producing a number of Technical Reports. Author of several technical articles in PDA *Journal of Pharmaceutical Science and Technology*.

Conceived the need for Chapters in 1988; nurtured the development of the first Chapters in PDA.

Served on the Board of Directors several years, then served as PDA Second Vice President 1982, Vice President 1988-89, and President 1990-91.

Was Convenor of ISO Technical Committee 198 Working Group 9 (Aseptic Processing) and served as bridge between PDA and ISO.

Drove the initial international development of PDA; the first International Congress in Basel and the first international chapters in Canada and Japan were developed during his presidency. His international leadership is recognized through the Korczynski Grant used to bring overseas speakers to PDA conferences in the USA.

Named Researcher of the Year at Abbott Laboratories.

Chaired or served on many PDA Committees, including chairing the National Program Committee in the early 1980s, and several program committees over many years.

Was PDA's first VP, Education and Director of the new Training and Research Institute 1997-2000

Report from the President

GORDON PERSONEUS AWARD

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

Regina McCairns

Chaired or served on numerous program committees; worked effectively and diligently to develop high-quality PDA programs domestically and abroad.

Served on Training and Education Committee.

Tireless leader in the Delaware Valley Chapter; helped it grow from its founding to one of the largest and most successful

Taught courses for PDA.

FRED 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 performance and service on the Board is determined by his/her peers as worthy of recognition.

Joyce H. Aydlett

Chair of PDA 1998-99; served several years as Director on PDA Board of Directors.

Chaired Strategic Planning Committee; produced PDA's current Strategic Plan.

Served on PDA's Research Committee and chaired the Microbiology Subcommittee.

Served as a PDA liaison to ISO Technical Committee 198, Working Group 9 (Aseptic Processing).

Chaired the oversight of PDA's European development from 1998 to the present; facilitated the development of the European Steering Committee; served as PDA ambassador at numerous events abroad.

Served on several program committees over many years, and as presenter on many programs.

DISTINGUISHED SERVICE AWARDS

Given by the PDA Board of Directors for special acts, contributions or service that have contributed to the success and strength of PDA.

The following volunteers, among the original PDA Directors-at-large charged with chapter development, were responsible for founding chapters and worked tirelessly toward their success:

Robert L. Garnick, Ph.D.
(West Coast)

John Geigert, Ph.D.
(West Coast; also chaired Chapter Council for several years)

Charles J. Cherundolo
(Delaware Valley)

Edmund J. Fitzgerald
(Canada)
Photo unavailable

Additional Distinguished Service Awards:

Simon Rusmin, Ph.D.

One of PDA's first chapter Directors-at-large; worked at the chapter level in many activities.

Represented PDA in its expansion into Asian countries; arranged key meetings with Asian groups that led to founding the Taiwan Chapter and other member recruitment in Asia.

Recipient of PDA Research Award in 1976.

Served on other technical committees over many years.

Richard T. Wood, Ph.D.

Taught Design and Validation of Sterilization Processes and related courses for 10 years; helped train numerous industry professionals in this critical technology.

Published and spoke frequently for PDA.

Served on a number of program committees.

FREDERICK D. SIMON AWARD

Klaus-Peter Gerbling

Named in honor of Frederick D. Simon, a longtime PDA volunteer who served as PDA's first Director, Scientific Affairs. It is presented each year for the best paper published in the PDA *Journal of Pharmaceutical Science and Technology* during the previous calendar year, as determined by a distinguished committee of reviewers.

"Alternative Microbial Testing: A Novel DNA-Based Detection System for Specified Microorganisms in Pharmaceutical Preparations", Vol. 54, No. 6, p. 470, *by Petra Merker (principal author), Jutta Ladewig, and Klaus-Peter Gerbling of Schering AG; and Lutz Grohmann, Roger Petersen, and Frank-Roman Lauter of GeneScan GmbH.*

JAMES P. AGALLOCO AWARD

Named in honor of James P. Agalloco in recognition of his work in developing the PDA education program. It is presented to the best faculty member in PDA's Education Program during the previous year, judged on the basis of student evaluations and overall contribution to the PDA education program.

James L. Vesper

Documentation Systems & Practices (PDA Course 487)

GMP Quality Auditing for the Pharmaceutical Industry (PDA Course 488)

Training for Performance (PDA Course 409)

GMP Fundamentals (PDA Course 493)

BOARD OF DIRECTOR ELECTIONS

In 2001, the following officers were elected to serve two-year terms:

Chair
Floyd Benjamin,
Keystone Pharmaceuticals, Inc.

Chair Elect
Nikki V. Mehringer,
Eli Lilly and Company

Secretary
Jennie Allewell, Cell Therapeutics, Inc.

Treasurer
Richard Levy, Millipore Corp.

The following were elected to three-year terms as Directors:

Tim R. Marten, AstraZeneca

Joyce H. Aydlett,
Aydlett & Associates, Inc.

Kathleen S. Greene,
Novartis Pharmaceuticals

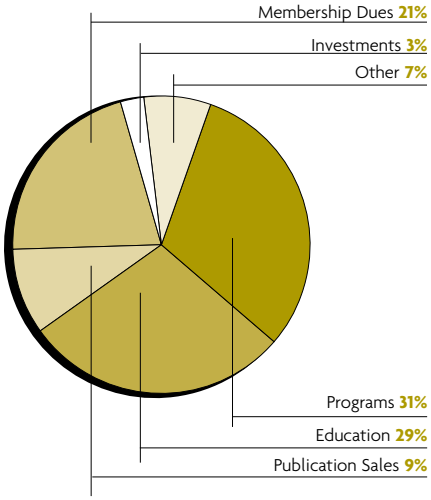
Suzanne Levesque, Sabex, Inc.

The PDA election was conducted on-line through a web site for the first time.

MEMBERSHIP

The PDA membership at the end of 2001 was 10,114.

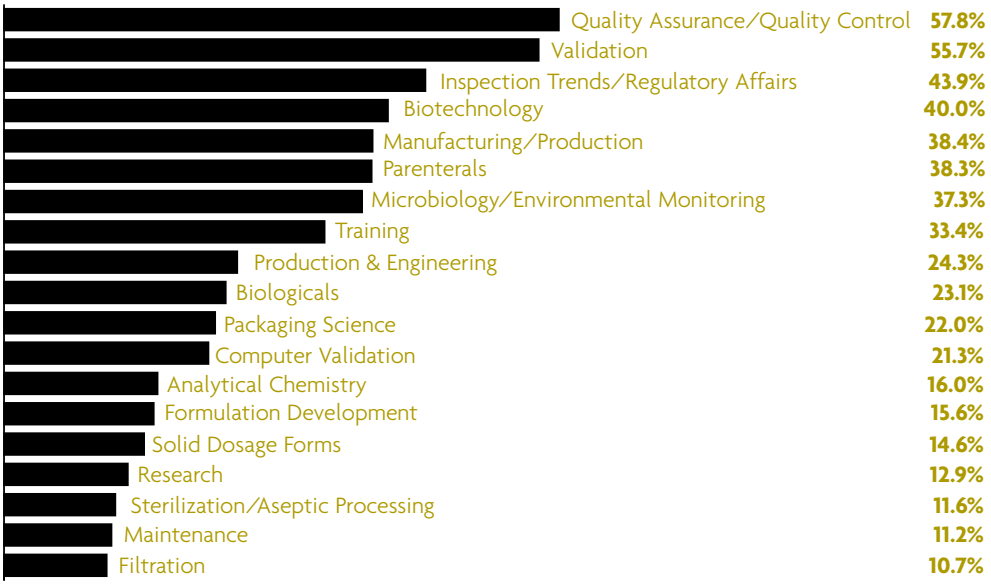
PDA's income sources were as follows:



ACKNOWLEDGEMENTS

Thanks to the PDA Award Committee Chaired by Henry Kwan, Ph.D., and to the Fred Simon Award Committee chaired by Galen W. Radebaugh, Ph.D., Schering-Plough Research Institute with the help of Dr. Karl Herzog, Dr. Steven Gordziel and Dr. Tom Julian.

PDA MEMBERSHIP BY PROFESSIONAL INTEREST



**Other (Less than 10%): Lyophilization: 9.4%; Liquids: 9.0%; Drug/Device Delivery Systems: 8.8%; Isolation Technology: 8.5%; Visual Inspection of Parenterals: 8.1%; Ophthalmics: 6.9%; Stability: 6.4%; Vaccines: 6.0%; Contract Manufacturing: 5.7%; Ointment: 5.7%; Blow/Fill/Seal: 4.5%; Aerosols: 3.6%; Calibration: 2.6%*

COMMITTEE REPORT

Regulatory Affairs

The PDA Regulatory Affairs and Quality Committee (RAQC) had a busy and productive year in 2001. The committee was chaired by Lisa Skeens, Ph.D. of Baxter Healthcare Corporation. The RAQC representative on the PDA Board of Directors is Jennie Allewell of Cell Therapeutics, Inc.

The purpose of the RAQC is to participate in all regulatory initiatives within PDA's mission, e.g., quality, manufacturing, CMCs and GMPs in the USA and Europe. PDA believes that regulatory requirements should be harmonized internationally and that terms should be consistent. When commenting on proposed regulations, the goal of the RAQC Task Force is to achieve scientifically sound regulations without generating redundant or unnecessary requirements. PDA achieves this through information sharing of technical issues, formal comments on proposed guidances and regulations, education events, conferences, and courses.

Comments were submitted on the following subjects in 2001:

- Proposed Rule; Good Tissue Practices for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement
- Note for Guidance on Quality of Water for Pharmaceutical Use (CPMP/QWP/158/01draft) Task Force Chair, Steve Bellis
- Draft Good Manufacturing Guidelines (Canada) Task Force Chair, Suzanne Levesque
- PDA developed and submitted a set of draft "change tables" to open a dialogue with FDA for the development of a Post Approval Change (PAC) for sterile Products. Task Force Chair, Lisa Skeens
- Draft Guidance for Industry, Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components. Task Force Chair, Amy Scott-Billman

The following Co-sponsorships with FDA were held in the year 2001:

- PDA/FDA Joint Conference, Chair, Kathleen Greene
- Three System Based Inspections Workshops, Lead, William Stoedter
- Two Q7A Workshops on GMPs for Active Pharmaceutical Ingredients, Lead, William Stoedter
- PDA/FDA Viral Clearance Forum, Co-Leads, Kurt Brorson, Ph.D. and Richard Levy, Ph.D.

Members of the RAQC and PDA staff participated in the following meetings:

- Two Office of Pharmaceutical Science Trade Association Meetings, 4/01, 10/01;
- Meeting of the Science Board to the FDA;
- FDA Meeting for comments on PDUFA III; and
- Transmissible Spongiform Encephalopathies (TSE) Advisory Committee.

RAQC Meetings:

- The RAQC meets by teleconference on the last Tuesday of every month except March, September and December.
- The RAQC meets in person at the PDA Spring Meeting in March, the PDA/FDA Meeting in September, and the PDA Annual Meeting in December.

2001 REGULATORY AFFAIRS /QUALITY COMMITTEE

Lisa Skeens, Ph.D. (Chair)
Baxter Healthcare Corp.

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech, Inc.

Donald Baker
Fujisawa Healthcare, Inc.

Robert Dana
Elkhorn Associates, Inc.

John DeFoe
Pfizer, Inc.

Rebecca Devine
Independent Consultant

Don Elinski
Johnson & Johnson Merck

Michael Gross
Aventis Behring

Hiltrud Horn, Ph.D.
Knoll AG

Suzanne Levesque
Sabex, Inc.

Russell Madsen
PDA

Tim Marten, D.Phil.
AstraZeneca

Nikki Mehringer
Eli Lilly & Company

Robert Mello, Ph.D.
RJM Pharmaceutical Consultants

Steven Mendivil
Amgen, Inc.

David Miner
Eli Lilly & Company

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

Amy Scott-Billman
GlaxoSmithKline

William Stoedter
PDA

Anders Vinther
CMC Biotech A/S

Science & Technology

PDA published three Technical Reports (TR) and a report on Good Practice and Compliance for Electronic Records and Signatures, Part 2 in 2001:

- TR No. 13: Revised, Fundamentals of an Environmental Monitoring Program, prepared by a task group headed by Jeanne E. Moldenhauer;
- TR No. 34: Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products, prepared by a task group headed by James P. Agalloco and James E. Akers, Ph.D.;
- TR No. 35: A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry, prepared by a task group headed by Richard Prince; and
- Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures, co-published with ISPE

PDA's task groups and technical committees are also working on significant revisions to existing PDA technical reports and developing new ones. The revision to Technical Monograph No. 1: Validation of Moist Heat Sterilization, is nearing completion. Work continues on revising PDA Technical Report No. 28: Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals.

Other technical publications in process include:

- Technical Report No. 36: Current Practices in the Validation of Aseptic Processing;
- Technical Report No. XX: Validation of Biologic Manufacturing Processes;
- Technical Report No. XX: Visual Inspection of Finished Parenteral Solutions in Clear Glass Containers;
- Technical Report No. XX: Validation of Plasma Fractionation Processes;
- Technical Report No. XX: Validation of Lyophilization Processes;
- Technical Report No. XX: Aseptic Processing Guidelines;
- Good Electronic Records Management (co-published with ISPE); and
- Models for System Implementation and Evolution (co-published with ISPE).

Task Groups

PDA Environmental Monitoring Task Force

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

Aijaz Ahmad
Genentech, Inc.

Susan E. Arrigoni
Ortho-Clinical Diagnostics

Anthony M. Cundell, Ph.D.
Wyeth-Ayerst Pharmaceuticals

Gary E. Strayer
Merck & Company, Inc.

John H. Ducote
Chiron Corporation

Susan F. Elder
GlaxoSmithKline

Mary Beth Grace
Genentech, Inc.

David A. Ness
Abbott Laboratories, Inc.

Thaddeus G. Pullano, Ph.D.
Wyeth-Lederle Vaccines and Pediatrics

James F. Quebbeman
Parke-Davis & Company

Berit Reinmüller
Royal Institute of Technology

Miriam Rozo
Ortho-Clinical Diagnostics

Lydia Troutman
Schering-Plough Corporation

PDA Isolation Technology Task Force

James P. Agalloco, Co-Chair
Agalloco & Associates

James E. Akers, Ph.D., Co-Chair
Akers Kennedy & Associates

Uwe-Peter Dammann
ASTA Medica AG

Thomas G. Freund
Mallinckrodt Inc.

William R. Frieben, Ph.D.
Pharmacia Corporation

Richard M. Johnson
Abbott Laboratories, Inc.

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

Jean-Michel Khoury
Aventis Pharma

Bengt C. Ljungqvist, Ph.D.
Royal Institute of Technology

Jack P. Lysfjord
TL Systems Corp.

Russell E. Madsen, Jr.
PDA

Didier A. Meyer
La Calhéne

George O. Phariss
Abbott Laboratories, Inc.

Scott L. Pool
B. Braun Medical, Inc.

Berit M. Reinmüller
Royal Institute of Technology

Scott Sutton, Ph.D.
Alcon Laboratories, Inc.

Carmen M. Wagner, Ph.D.
Merix Bioscience, Inc.

PDA Subcommittee on Microbiology Training

Richard Prince, Chair
Richard Prince Associates, Inc.

Ted Collins
Celltech Pharmaceuticals

Strother Dixon
PDA Training and Research Institute

Jayne Dovin
GlaxoSmithKline

Kimberly Fitzsimmons
Aventis Behring

Robert Friedel
Perritt Laboratories

Jill Giulianelli
Wyeth-Ayerst ESI

John Lindsay
Aseptic Solutions, Inc.

David McAlister
Amgen, Inc.

William Miele
Bayer Corporation

Ann O'Leary
Ricerca

Maureen Reagan
Quality Systems Consulting, Inc.

Rick Rogers
PDA Training and Research Institute

Simon Rusmin
Consultant

Jamie Stanek
Merck & Co.

Albert Wellstein
Consultant

COMMITTEE REPORT

Technical Council

The Technical Council serves as the communication and co-ordination body for PDA Interest Groups and Task Groups. Its membership consists of the Interest Group Chairs, one or more Board members, and PDA staff representatives.

Interest Groups are a unique feature of PDA designed to enable members to focus on specific topics of special interest to them. The program for all PDA meetings includes a listing of the various Interest Group sessions to be held concurrently during the meeting. Interest Groups provide a vehicle for people with common interests to interact within the association.

They provide information exchange and networking opportunities and an avenue for member involvement. Interest Groups often serve as a gateway for new PDA members to become more active in the organization, as they serve as a source of task group members, program ideas and materials, and future PDA leadership. Any PDA member can participate in one or more interest groups by simply attending a session at a PDA meeting. There is no formal sign up and no obligation.

There are currently 21 Interest Groups. Interest Group sessions continued to be an integral part of the programming at PDA national meetings. The response was very positive, attendees "voted with their feet" to participate in Interest Group sessions in expanding numbers. The content of these sessions vary with the needs and desires of the group, from formal presentations by external presenters, to informal facilitated discussions of current "hot topics."

In the Five Year Strategic Plan approved by the PDA Board in 1998, Interest Groups were recognized as a unique and valuable membership service. The Strategic Plan calls for increased support for Interest Group programs in the future, including developing means for Interest Groups to better operate and communicate throughout the year.

PDA Task Groups are formed with a specific objective defined by an approved scope statement. They usually originate from an Interest Group, the PDA Board, or PDA staff. Task Groups may write a technical document, prepare comments to a proposed regulation, or prepare a presentation. Some of the task group activities are described in the Science and Technology portion of this annual report.

Many thanks to all of our members who have volunteered their time and energies to make this unique series of programs so successful. All PDA members are welcomed to participate in Interest Group sessions, this is your opportunity to customize the agenda at PDA meetings to meet your personal needs for technical information and networking.

PDA Interest Groups and Leaders

Biotechnology
Frank Matarrese
Chiron Corporation

Computer Systems
TBA

Contract Manufacturing
Michael R. Porter
Eli Lilly & Co.

Drug/Device Delivery Systems
Michael A. Gross, Ph.D.
Becton Dickinson & Co.

Filtration
Jack Cole
Jack Cole Associates

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 Trappler
Lyophilization Technology

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

Ophthalmics
Chris Danford
Alcon Laboratories, Inc.

Packaging Science
Edward J. Smith, Ph.D.
Packaging Science Resources

Production and Engineering
David W. Maynard
Maynard & Associates, LLC

Quality Assurance/Quality Control
Don E. Elinski
Geneva Pharmaceuticals, Inc.

Solid Dosage Forms
Pedro J. Jimenez, Ph.D.
Eli Lilly & Co.

Stability
Rafik H. Bishara, Ph.D.
Eli Lilly & Co.

Sterilization/Aseptic Processing
James P. Agalloco
Agalloco & Associates

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

Vaccines
Frank S. Kohn, Ph.D.
Wyeth-Lederle Vaccines & Pediatrics

Validation
Bohdan M. Ferenc
Qualification Services

Visual Inspection of Parenterals
John G. Shabushnig, Ph.D.
Pharmacia Corp.

PDA Europe

PDA continued to enhance and strengthen its operations in Europe during 2001. Seven technical conferences and courses, a high level of regulatory participation, and record membership were the key milestones of the year.

Meetings and Conferences

- PDA-TRI & R3-Nordic, Pharmaceutical Water: System Design and Validation Course, January 29-31, Stockholm, Sweden.
- PDA and PDA Italy Chapter Conference on Global Pharmaceutical Manufacturing and Quality Strategies, April 5-6, 2001, Taormina, Italy.
- PDA-TRI & R3-Nordic, Computer Products Supplier Auditing Process Model: Auditor Training course, May 17-18, Stockholm, Sweden.
- UK and Ireland Chapter held a Round Table Meeting on Technical Monograph No. 1 -Industrial Moist Heat Sterilization in Autoclaves, August 14, Chorleywood, Herts.
- PDA/IABs Conference on Process Validation for the Manufacturing of Biologics and Biotechnology Products, September 6-7, Berlin, Germany.
- PDA Italy Chapter presented Highlights of the 2001 PDA/FDA Joint Regulatory Conference, October 22 in Milan, and October 24 in Rome.
- PDA Central Europe Chapter presented the PDA Scientific Forum on Visual Inspection, November 30, in Berlin, Germany.

Regulatory Participation

Regulatory participation continued and strengthened during 2001 through conference participation, newsletter reporting, and direct commentary. Highlights include:

- ISO/DIS 14644-7 - Cleanrooms and Associated Controlled Environments - Part 7: Separative enclosures (clean air hoods, gloveboxes, isolators and minienvironments). Dated February 2, 2001: PDA submitted comments to the US TAG to ISO/TC 209 on June 29, 2001.
- PIC/S Draft Recommendation on the Isolators Used for Aseptic Processing and Sterility Testing, PE 004-1 (Draft 3): PDA submitted comments to PIC/S Secretariat on September 4, 2001.
- CPMP draft Note for Guidance on Quality of Water for Pharmaceutical Use (CPMP/QWP/158/01 draft, 1 March 2001). PDA submitted technical comments to EMEA on August 29, 2001. These comments also were sent to the European Pharmacopoeia, Japan Pharmacopoeia, USP and FDA. Task Group work was headed by Steve Bellis, AstraZeneca.
- PDA Regulatory Affairs and Quality Committee - European membership and participation in this critical standing committee remains strong.

Science and Technology

Science and Technology activities continued in 2001. BSE/TSE issues relative to pharmaceutical products first came the forefront in Europe.

PDA Letter

Contributions continued to the *PDA Letter* on developments of interest to members in Europe. A series of articles about the various European authorities was developed this year.

PDA Chapters

In response to the emergence of new chapters in Europe, the European Chapter was renamed the Central Europe Chapter to more appropriately reflect its membership base.

PDA-TRI

PDA Training & Research Institute

Serving Our Membership

PDA provides its members with the finest education and training available in scientific, technical, and regulatory matters related to the manufacturing of pharmaceutical and related products. Ongoing curriculum are offered in pharmaceutical sciences, biotechnology, solid and parenteral dosage forms, medical devices, regulatory affairs, and more. Courses are presented at PDA's Training and Research Institute (PDA-TRI) located near Baltimore, MD as well as other domestic and international locations. PDA-TRI is the preeminent provider of training in the industry.

Facility

PDA maintains its state-of-the-art training facility in Catonsville, Maryland, just outside of Baltimore. The Training and Research Institute offers over 9,000 square feet of modern classroom and laboratory facilities. Two classrooms provide meeting space for both education and conference events. These facilities are used by both PDA and industry groups, as well as the University of Maryland, Baltimore County on whose campus the facility is located.

At the centerpiece of the Institute are three teaching labs. Each of these labs simulates real production facilities and allows participants in our classes to practice the hands-on skills associated with a wide range of production and lab activities. Students can work in a real analytical and microbiological lab setting to gain insight into those critical areas of every production organization. In the process, lab students can work with sterilization technologies, CIP/SIP processes, production support systems, and much more. The production laboratory offers PDA's membership a unique opportunity to actually produce parenteral and lyophilized products, then follow through with all the related testing activities that would be part of any organization's release activities.

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. The FDA frequently uses the Institute's facilities for their own inspector training programs.

PDA serves a worldwide membership. PDA strives to offer its membership the convenience of courses located within a reasonable traveling distance. To accomplish this, PDA-TRI will offer many of its courses at various locations within the United States and around the world. But where there is no substitute for the benefit to be gained from actual hands-on experience with a process, PDA's Training and Research Institute in Baltimore offers an educational opportunity that is unique to the industry.

Personnel

PDA's major service to its membership is education and training. As such, faculty and staff reside at the heart of the organization. PDA prides itself in counting some of the finest teachers in the industry among its faculty. In 2001, PDA-TRI utilized over 80 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 excellent teachers who teach for PDA out of a sense of community to the industry.

In addition to the faculty, the Institute maintains a staff of five in Baltimore to support its training and education activities. One of these persons supports TRI's on-site lab training courses. Another devotes their time to the non-lab or lecture courses. The group also includes two who are teachers themselves and who can be found on the platform at almost all PDA-TRI training events. Together, the staff brings almost 50 years of experience to the presentation of educational and training activities to PDA's membership.

2001 Highlights

The year 2001 marked a high point for the Training and Research Institute. The unit has been in operation for approximately five years. During that time over 9,500 students have attended over 600 classes. The number of lab courses offered each year in Baltimore has tripled. A decade ago PDA might have offered a dozen or so courses a year. In 2001, PDA-TRI offered a total of about 100 classes around the world. Each year new courses are added to the educational mix in order to meet PDA's membership's constantly changing needs. Part of this change is evidenced in the fact that a significant portion of the Institute's curriculum has recently been offered overseas. Courses are now being offered in more than a half dozen countries in Europe and Asia.

2001 Faculty Award

One of the hallmarks of PDA training and education 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 annual faculty teaching award. 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.

PDA-TRI: PDA Training & Research Institute (continued)

In 2001, Jim Vesper with LearningPlus won the Agalloco award. Vesper is one of PDA-TRI's most valuable contributors. He has taught more students for PDA-TRI during the past year than any other faculty member. He has consistently fulfilled his teaching obligations with a completeness and affability unmatched by any other faculty, even when called on to deliver on short notice. These efforts have resulted in considerable contributions to PDA's financial and operational well being, as well as PDA's standing as a leading provider of scientific and technical education.

Vesper has been a valued member of the PDA-TRI faculty for several years. He has been consistently one of the highest ranked instructors among PDA's entire faculty. This is reflected not only in his course evaluations, but also in the many personal comments made to PDA staff by his students.

PDA members attending Vesper's courses have benefited from the knowledge and skills conveyed through his active and professionally sound instructional designs. His courses always leave the participants with a valuable to do list of activities to apply on the job back at the organization.

Vesper is an internationally recognized figure in the field of CGMP training with more than 18 years experience in the pharmaceutical industry. He is the founder and president of LearningPlus, Inc.

Prior to establishing LearningPlus, Inc., Vesper worked 11 years at Eli Lilly and Co. Since 1991, he has been creating innovative instructional products for the pharmaceutical and heathcare industries using video and computer technologies as more effective and efficient delivery media. Vesper speaks and writes for various international technical and professional organizations, including ISPE, GMP TEA, PDA, Pharmaceutical Sciences Group, and PharmTech.

Educational Plan for 2002

In 2002, PDA-TRI will continue to review and redevelop course offerings. The expansion of course evaluation to include second level participant evaluations will also be expanded. Each faculty member and course offering will be evaluated against the ongoing needs of PDA's membership.

Plans are being developed to expand our course delivery to include the new technologies of Distance Learning.

PDA Training and Research Institute 2001 Supporters

PDA-TRI extends appreciation to the following companies for their generous contributions of equipment, materials, and technical resources to our 2001 laboratory training programs.

As a non-profit organization, PDA relies heavily on the contributions of these companies to offset the vast expenses associated with providing state-of-the-art technology for hands-on laboratory programs.

Algroup Wheaton

Allegiance Healthcare Corporation

Becton Dickinson Microbiology Systems

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SGM Biotech

Millipore

National Instruments

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West Pharmaceutical Services

2001 PDA Meetings Report

PDA offered a variety of educational, scientific and technical programs, networking, and leadership opportunities at the local, national, and international levels. By hosting a variety of events, including educational meetings and conferences, workshops, exhibitions, roundtable discussion groups and networking receptions, PDA has been successful in providing a forum for members and industry leaders to exchange ideas and experiences.

PDA has earned credibility as the definitive source for meetings and education. PDA meetings are widely regarded as the most comprehensive and up-to-date educational events in the industry.

PDA 2001 Conference Chairs

PDA Japan Congress (Kyoto), Courses & Exhibition
Theme: Bridging the Healthcare and Pharmaceutical World in the New Millennium
Co-chairs: Taiichi Mizuta, Ph.D. and Thomas Wilkin, Ed.D., Schering-Plough Corp.

PDA Spring Conference, Courses & Tabletop Exhibit
Theme: Modern Pharmaceutical Microbiology – Advancing the Science
Chair: Michael J. Miller, Ph.D., Bausch & Lomb, Inc.

PDA Conference on Good Electronic Records Management
Chairs: Marta Fields, Amgen, Inc. and John McKenney, SEC Associates

Special PDA International Conference
Theme: Global Pharmaceutical Manufacturing and Quality Strategies
Co-chairs: Antonino Giannetto, S.I.F.I. and Robert B. Myers, Schering-Plough

PDA/FDA Joint Regulatory Conference, Courses & Tabletop Exhibit
Theme: Emerging Global Regulatory Issues
Chair: Kathleen S. Greene, Novartis Pharmaceuticals Corporation

Process Validation for Manufacturing of Biologics and Biotechnology Products
Co-chairs: Brendan Hughes, Ph.D., GlaxoSmithKline and Vincent Anicetti, Genentech, Inc.

PDA/FDA Viral Clearance Forum
Co-chairs: Richard V. Levy, Ph.D., Millipore Corporation and Kurt Brorson, Ph.D., CBER, FDA

The Extractables Puzzle: Putting the Pieces Together – Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Solutions
Co-chairs: Michael Gross, Ph.D., Aventis Behring and Edward J. Smith, Ph.D., Packaging Science Resources

PDA Annual Meeting, Courses & Exhibition
Theme: Compliance: Challenges and Pragmatic Solutions
Chair: John Geigert, Ph.D., BioPharmaceutical Quality Solutions

Pictured left to right: PDA Chair Robert B. Myers, 2001 Korczynski Lecturer, Brian R. Matthews, PDA President Ed Fry, and Michael S. Korczynski. The Korczynski Lecture Award was established to bring international speakers to the PDA Annual Meeting to address important topics of the day. Matthews spoke about BSE/TSE issues.

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2001 PDA

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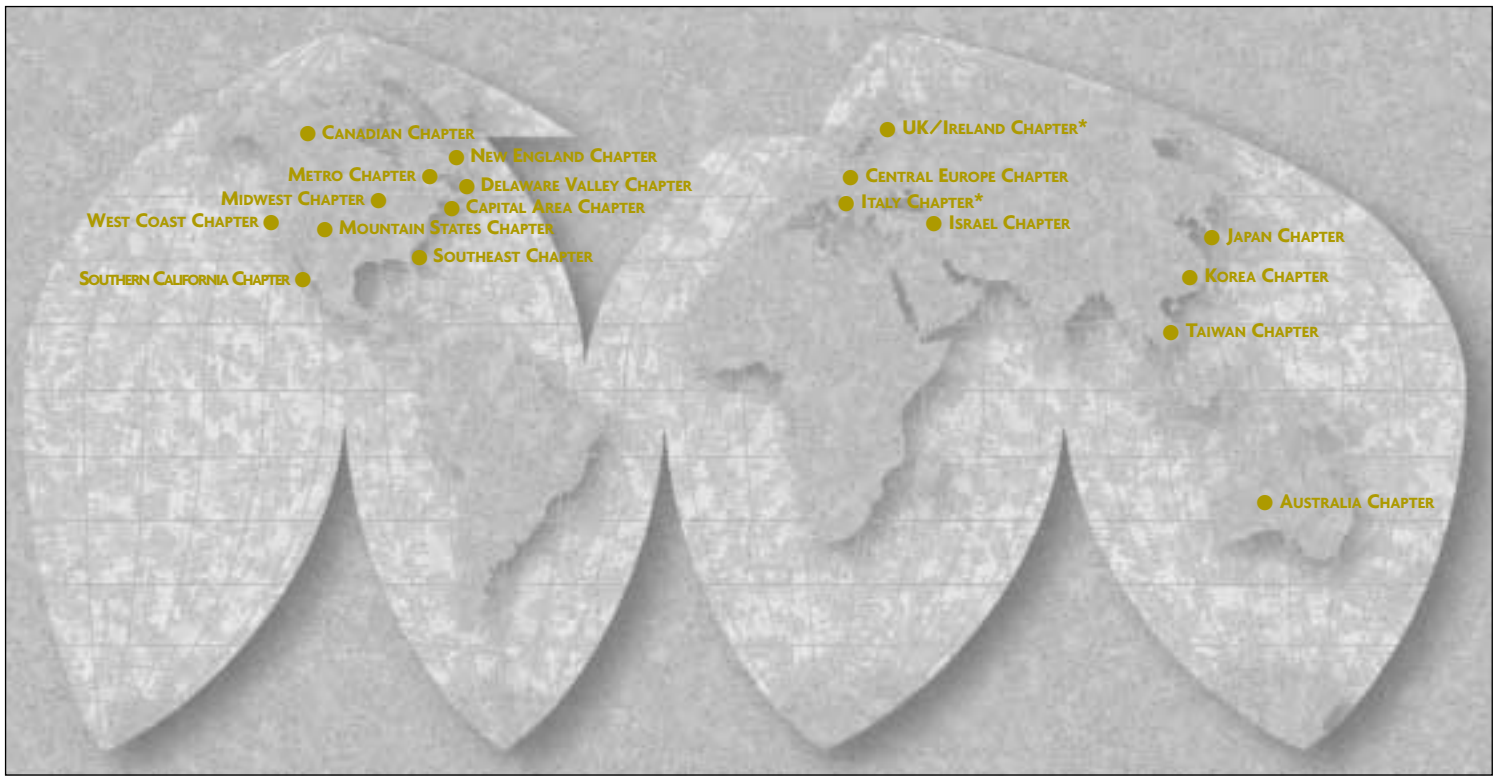

During the past decade PDA has made great strides to recruit overseas members and establish relationships with pharmaceutical associations abroad. Today, over 30% of PDA's members reside outside the United States. Our chapters are expanding to all corners of the globe and PDA's international presence reaffirms PDA's vision to be recognized worldwide as an authoritative, easily accessible source of global technical and regulatory information about pharmaceutical technology.

2002 PDA

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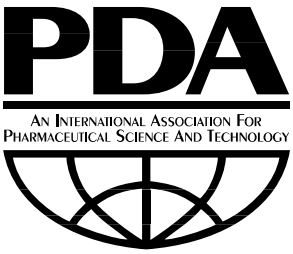

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