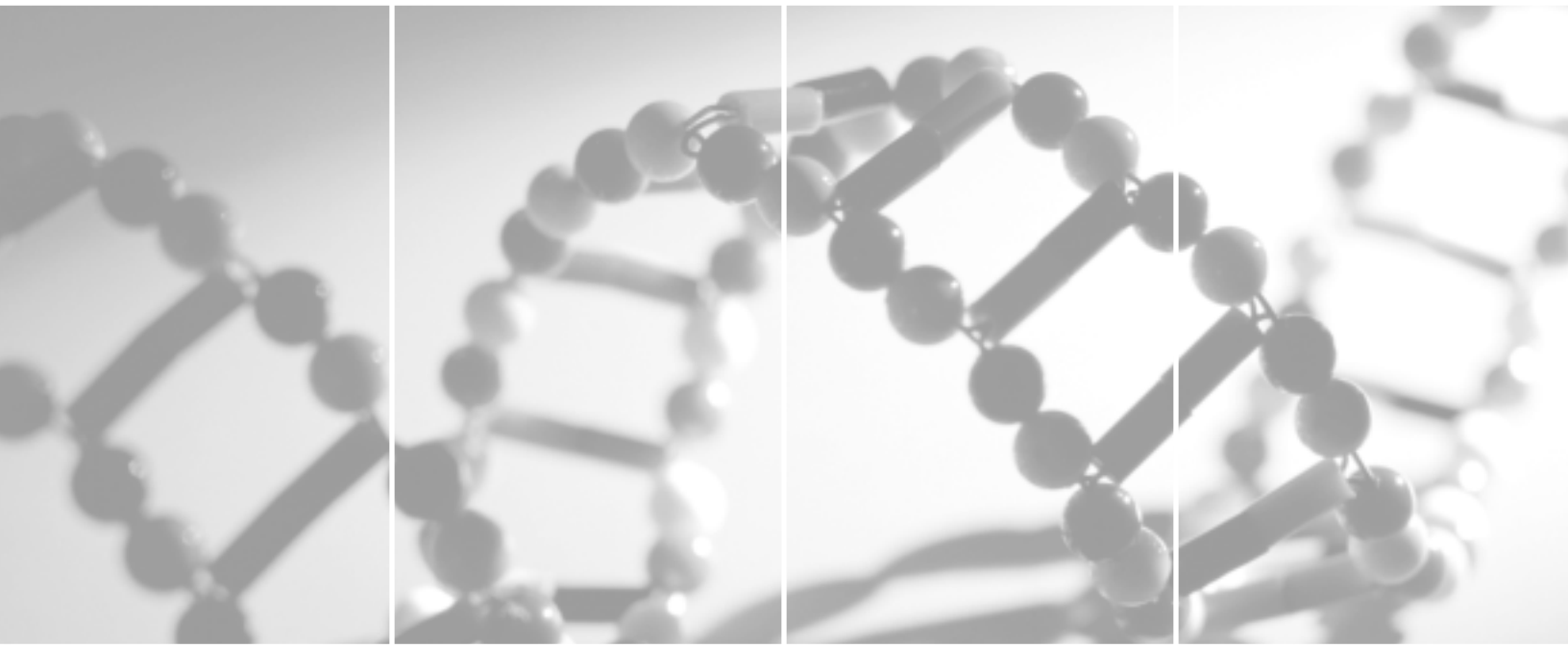
PDA

An International Association For Pharmaceutical Science And Technology

2000 Annual Report

PDA'S MISSION STATEMENT

To support the advancement of pharmaceutical technology by promoting scientifically sound and practical technical information and education for industry and regulatory agencies.



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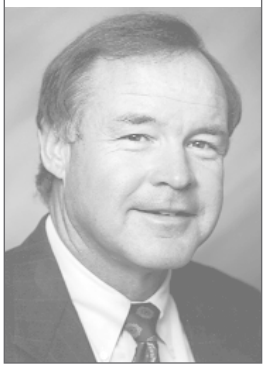
2000 ANNUAL REPORT

LETTER FROM THE CHAIR

by Robert B. Myers, PDA Chair



The first year of this new century saw PDA continue to flourish and expand. In my first year as Chair I was extremely pleased by the support received from Ed Fry and his professional staff and I congratulate them on having completed one of the most successful years the organization has experienced. There were many achievements in the timely presentation of important topics of current interest to our membership in the United States, in developing the PDA Training and Research Institute (PDA-TRI) into one of the most unique and viable training facilities in existence and in advancing our international presence.

Ed and staff did an outstanding job in identifying and organizing conferences with joint regulatory and industry representation on important topics of current interest to our members. The tremendous response to the PDA/FDA Public Conference on Technical Implementation of 21 CFR Part 11, Electronic Records, Electronic Signatures in June made it one of the most timely and well attended meetings of all time. Almost a year later this subject remains one of high interest among the industry and will be for many years to come. Other significant US conferences include the groundbreaking PDA/FDA Conference on Team Biologics and the PDA/FDA Conference on the Validation of Manufacturing Processes for Biologics. This latter conference was so well received that plans are underway to conduct this meeting in Europe in 2001.

A primary component to achieving this success is the support of our volunteer program chairs. The continued participation of volunteers is critical to the success of our organization. PDA volunteers serve in many capacities–Officers and Board members; task group members; conference committee members, speakers, moderators and exhibitors; PDA-TRI faculty; publication authors and editors; and general good will ambassadors. As you read through this Annual Report, you will see the names of many of these dedicated individuals. It is my honor to thank them for their significant contributions that truly make PDA what it is today.

The PDA Training and Research Institute (PDA-TRI) reached a benchmark this year in providing unique training for our industry. In February, Rick Rogers succeeded Michael Korczynski as Vice President, Education and Training and had an excellent start. The PDA Board and I wish to thank Mike for his many years of outstanding work in developing the facility and programs that will take us long into the future.

While the Institute has been in existence for four years, 2000 marked its first year of operation at full capacity. The Aseptic Processing Course has become our flagship presentation. This unique two-week laboratory course provides critical hands-on training for sterile product testing and manufacturing.

In the international arena there was significant progress advancing PDA's presence in Europe and in other geographical areas. New Chapters were formed in the United Kingdom/Ireland and Italy and ties with other EU states and organizations were strengthened. Presently, there are 19 PDA Chapters worldwide with eight outside of the USA. Specifically, a Memorandum of Understanding is in place with A3P (France), Parenteral Society (UK) and the R³-Nordic (Sweden) defining our strong relationships with these societies, including reciprocal membership offerings.

In addition to the continued discussions on the precise structure of our European presence, Jim Lyda extended his tour in Europe. His efforts have enhanced our representation there, both through regulatory interactions and several special conferences such as the FDA Inspection Day Workshops (UK and Italy) and the Environmental Monitoring Forum (Basel).

PDA is recognized as the authoritative voice and leading technical organization in the field of pharmaceutical science and technology worldwide. Looking to the future I know that PDA will continue to grow as an organization, geographically and in scientific and compliance disciplines, by continuing to fulfill our mission to support the advancement of pharmaceutical technology by promoting scientifically sound and practical technical information and education for industry and regulatory agencies.

2000 PDA BOARD OF DIRECTORS



OFFICERS

Chair:
Robert B. Myers
Schering-Plough

Chair-Elect:
Floyd Benjamin
Akorn, 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.



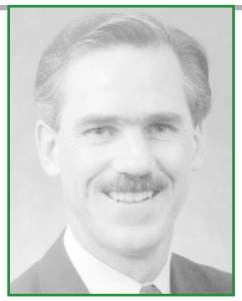

DIRECTORS

Vince R. Anicetti
Genentech, Inc.

Stephanie R. Gray
GlaxoSmithKline

Henry K. Kwan, Ph.D.

Suzanne Levesque
Sabex, Inc.

Richard V. Levy, Ph.D.
Millipore Corporation

P. Michael Masterson, P.E.
NewcoGen Group

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

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




Robert F. Morrissey, Ph.D.
Johnson & Johnson

Georg Roessling
Schering AG

Kenneth B. Seamon, Ph.D.
Immunex Corporation

Glenn E. Wright
Eli Lilly and Company

PRESIDENT'S REPORT

by Edmund M. Fry, PDA President

The year 2000 was an exceptional one for PDA. This fact is supported by the number of events co-sponsored with the Food and Drug Administration. These included:

- Public Conference on Technical Implementation of Part 11, June 19-20, Philadelphia, PA;
- PDA/FDA Joint Regulatory Conference, September 11-13, Washington, DC;
- Validation of Manufacturing Processes for Biologics, September 25-27, Washington, DC; and
- Team Biologics: A Three Year Review, December 7, Bethesda, MD.

The Public Conference on Part 11 was of particular importance, attracting an audience larger than any other PDA meeting last year. These co-sponsored events reflect the effective partnership between our association and FDA, and co-sponsorships will continue into future years.

The year was also unusual in that our formal comments on regulatory initiatives more often involved European documents than FDA drafts. This reflects both an increasing output of drafts for comment in Europe, along with increasing involvement of European volunteers in PDA regulatory analysis. PDA Vice President James Lyda continues to staff the PDA office in Basel, Switzerland from where he supports a broad range of efforts to grow PDA's membership and influence.

Most of all I am extremely pleased that PDA and PDA's Training and Research Institute (PDA-TRI) had a very financially successful year. PDA's investment in the TRI is paying off, both for our association and for our industry. The landmark aseptic processing lab courses provide a real solution for the industry, and Rick Rogers, PDA Vice President of Education, the faculty and staff of TRI deserve much credit for presenting these extremely complex educational offerings.

Membership

PDA's membership in 2000 was 10,465. See page six for a breakdown of the membership by professional interest.

Staff

I was very pleased to have Bill Stoedter join PDA's staff as Director, Regulatory Affairs. Bill came to PDA from the pharmaceutical industry and will work with Lisa Skeens, Baxter Healthcare (Chair of PDA's Regulatory Affairs and Quality Committee) as well as with other volunteer committees to manage PDA's regulatory participation.

Other new senior staff in 2000 included our Vice President of Education and Director of PDA-TRI, Rick Rogers; our Director of Programs, Leslie Zeck; and our Director of Communications and Marketing, Linda Williams. These talented professionals come to PDA with substantial association experience.

PRESIDENT'S REPORT

Awards

Awards bestowed at the 2000 Annual Meeting were:

PDA Honorary Membership:
Clarence Kemper

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.

Gordon Personeus Awards:
Frank Bing, Abbott Laboratories, Inc. and *Robert Pazzano*, Validation & Training Services

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.

Frederick J. Carleton Award:
Raymond Shaw, Jr., Wyeth-Ayerst Pharmaceuticals

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.

Distinguished Service Awards:
Jules Knapp, R&D Associates, Inc., *Jeanne E. Moldenhauer*, Vectech Pharmaceutical Consultants, Inc. and *Duncan McVean*

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

James P. Agalloco Award:
John M. Lindsay, Senior Consultant, KMI/PAREXEL, Inc.

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

Fred Simon Award for Best Paper published in the *PDA Journal of Pharmaceutical Science and Technology* in 1999:
Hongkee Sah, for "Protein Instability Toward Organic Solvent/Water Emulsification: Implications for Protein Microencapsulation Into Microspheres"

This award is named in honor of the late Fred Simon, who was PDA's Director, Scientific Affairs.

PDA Award Winners
(seated, left to right): Kemper, Knapp, Pazzano, Bing; (standing, left to right): Lindsay, PDA Chair Myers, McVean, Sah; (not pictured): Shaw, Moldenhauer.

PRESIDENT'S REPORT

2000 Elections

The following were elected to serve three-year terms as Directors, beginning January 1, 2001:

Robert Dana
Elkhorn Associates, Inc.

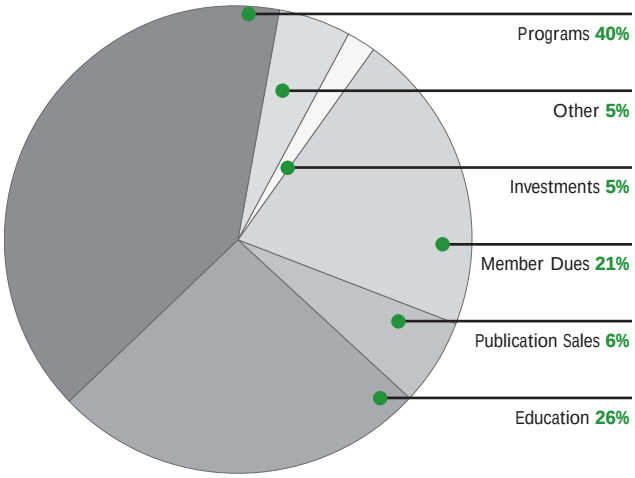
Stephanie R. Gray,
Vice President, Worldwide Quality, GlaxoSmithKline

Lisa Skeens, Ph.D.,
Associate Director, Regulatory Affairs,
Baxter Healthcare Corporation

Glenn E. Wright,
Quality Manager, Eli Lilly and Company

Those leaving the Board are P. Michael Masterson and Robert Morrissey. These retiring Board members have given much personal time and energy toward making PDA successful, and they deserve our congratulations and gratitude.

PDA's Income sources were as follows:



PDA MEMBERSHIP BY PROFESSIONAL INTEREST

Quality Assurance/Quality Control	57.8%
Validation	55.7%
Inspection Trends/Regulatory Affairs	43.9%
Biotechnology	40.0%
Manufacturing/Production	38.4%
Parenterals	38.3%
Microbiology/Environmental Monitoring	37.3%
Training	33.4%
Production & Engineering	24.3%
Biologicals	23.1%
Packaging Science	22.0%
Computer Validation	21.3%
Analytical Chemistry	16.0%
Formulation Development	15.6%
Solid Dosage Forms	14.6%
Research	12.9%
Sterilization/Aseptic Processing	11.6%
Maintenance	11.2%
Filtration	10.7%

**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%*

REGULATORY AFFAIRS

The PDA Regulatory Affairs & Quality Committee (RAQC) was busy and productive in the year 2000. Lisa Skeens, Ph.D., Baxter Healthcare Corporation, is the committee Chair. Jennie Allewell of Cell Therapeutics, Inc. is the RAQC representative on the Board of Directors.

The intent of the committee is to participate in all regulatory initiatives within PDA's mission, e.g., quality, manufacturing, CMCs and GMPs in the USA and Europe. In the future, PDA will increase its participation in Japan and the surrounding region. PDA believes that requirements should be harmonized internationally and that terms should be consistent. The ultimate goal of the task forces formed by the RAQC is to achieve scientifically sound regulation without generating redundant or unnecessary regulations. PDA achieves this through information sharing of a technical nature, formal comments on proposed guidances and regulations, education events, conferences and courses.

Comments were submitted on the following guidances during the past year:

- *Draft CPMP Note for Guidance on Process Validation*, Task Force Chairs, Hiltrud Horn and Steve Bellis.
- *Draft Annex 15 to EU GMP, Process Validation*, Task Force Chairs, Hiltrud Horn and Steve Bellis.
- *Draft Annex 17 to EU GMP, Parametric Release*, Task Force Chair, Klaus Haberer.
- *ICH Q7A, GMPs for APIs*, Chair, Daniel Gold.
- *Canadian TPP Sterile Product GMP Revision*, Chair, Suzanne Levesque.
- *FDA Draft Guidance on Analytical Procedures and Methods Validation CMC Documentation*, Chair, Anders Vinther.

The following Co-sponsorships with FDA were held in the year 2000:

- PDA/FDA Conference on Part 11, Lead, Russell E. Madsen.
- PDA/FDA Joint Conference, Lead, Amy Scott-Billman.
- PDA/FDA Conference on Validation of Manufacturing Processes for Biologicals, Lead, Vince Anicetti.
- PDA/FDA Conference on Team Biologics, Lead, Edmund M. Fry.

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

- Strategic Meeting with the European Medicines Evaluation Agency, James Lyda.
- Future of ICH, FDA Public Meeting, Remarks presented on PDA's behalf by Lisa Skeens.
- USP Quinquennial, attended by Russell E. Madsen.
- Three OPS Trade Association Meetings (2/00, 6/00, 10/00), attended by Jennie Allewell, Russell E. Madsen, Robert Mello, Lisa Skeens, William Stoedter.
- ICH-5, attended by Jennie Allewell, Lisa Skeens, Anders Vinther, William Stoedter.

The following activities are ongoing:

- GMP Harmonization Task Force, John Defoe is forming the task force.
- Newsletter articles are authored by RAQC members whenever there is a need to inform PDA members about various activities.

2000 REGULATORY AFFAIRS/QUALITY COMMITTEE

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech

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

Robert L. Dana
Elkhorn Associates, Inc.

Rebecca Devine
Regulatory Consultant

John DeFoe
Pfizer, Inc.

Don E. Elinski
Geneva Pharmaceuticals, Inc.

Michael A. Gross, Ph.D.
Aventis Behring

Hiltrud Horn, Ph.D.
Knoll AG

James C. Lyda
PDA

Russell E. Madsen
PDA

Tim R. Marten, Ph.D.
AstraZeneca

Nikki V. Mehringer
Eli Lilly and Company

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

Steven R. Mendivil
Amgen, Inc.

Toshiaki Nishihata
Santen Pharmaceutical Co.

Amy Scott-Billman
GlaxoSmithKline

Lisa Skeens, Ph.D.
Baxter Healthcare Corporation

William H. Stoedter
PDA

Anders Vinther
CMC Biotech

SCIENCE AND TECHNOLOGY REPORT

PDA published one Technical Report in 2000:

No. 33, "Evaluation, Validation and Implementation of New Microbiological Testing Methods," prepared by a Task Group headed by Anthony M. Cundell, Ph.D., Wyeth-Ayerst Pharmaceuticals.

PDA's task groups and technical committees are also working on significant revisions to existing PDA Technical Reports and developing new ones. Technical Report No. 34, "Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products," is under final review. Revisions to Technical Monograph No. 1, "Validation of Moist Heat Sterilization," and Technical Report No. 13, "Fundamentals of a Microbiological Environmental Monitoring Program," are nearing completion. Work continues on revising PDA Technical Report No. 28, "Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals."

Other projects include developing guidelines on validating existing plasma fractionation processes, sterilizing filtration of air and gases, the use and calibration of biological indicators, and validating aseptic manufacturing processes.

PDA TECHNICAL REPORT NO. 33, "EVALUATION, VALIDATION AND IMPLEMENTATION OF NEW MICROBIOLOGICAL TESTING METHODS" TASK FORCE

Anthony M. Cundell, Ph.D. (Chair)
Wyeth-Ayerst Pharmaceuticals

Brian Bauer, Ph.D.
Merck & Co., Inc.

Mark Claerbout
Eli Lilly and Company

Warren Casey, Ph.D.
GlaxoSmithKline

Martin Easter, Ph.D.
Celsis Ltd.

Edward Fitzgerald, Ph.D.
Fitzgerald Consulting

Carol Gravens
bioMerieux, Inc.

David Hussong, Ph.D.
CDER, FDA

Michael Korcynzski, Ph.D.
Mikkor Enterprises, Inc.

Robin Lerchen
American Pharmaceutical Partners, Inc.

Frederic J. Marsik, Ph.D.
CDER, FDA

Amy Meszaros
STATPROBE, Inc.

Jeanne Moldenhauer, Ph.D.
Vectech Pharm. Consult., Inc.

Manju Sethi
Qualicon

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

Martin Tricarico
Amersham Pharmacia Biotech, Inc.

Amanda Turton
Millipore Corporation

Christine Vojt
Ortho-Clinical Diagnostics

Kirsty Wills
Celsis Ltd.

Jon Wuannlund
Becton Dickinson & Company

TECHNICAL COUNCIL REPORT

The Technical Council serves as the communication and coordination body for PDA Interest Groups and Task Groups. It consists of the Interest Group leaders, 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 22 Interest Groups. Interest Group sessions continue to be an integral part of the programming at PDA national meetings. The response has been positive. Attendees have "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 volunteered their time and energy to make this unique series of programs so successful. We welcome all PDA members 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. We look forward to seeing you there!

2000 PDA INTEREST GROUP LEADERS

Biotechnology
Frank Matarrese
Chiron Corporation

Blow-Fill-Seal
Garry W. Schmitt
PharmTech, Inc.

Computer Validation
Michael L. Wyrick
KMI/Parexel, Inc.

Contract Manufacturing
Michael R. Porter
Eli Lilly and Company

Drug/Device Delivery Systems
Michael A. Gross, Ph.D.
Aventis Behring

Filtration
James D. Wilson
The Validation Group

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 Pharm. Consult., Inc.

Opthalmics
Richard M. Johnson
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 and Company

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

Sterilization/Aseptic Processing
James P. Agalloco
Agalloco & Associates

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

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

Validation
Bohdan M. Ferenc

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

PDA EUROPE

Bernard Kronenberg, Bakrona Basel AG, Switzerland and President of the PDA European Chapter; and Carlo Voellmy, Novartic Pharma AG, Switzerland and Program Chair– at the 4th Annual PDA European Forum 2000.

PDA continued to enhance and strengthen its operations in Europe for the year 2000. Five technical conferences, the creation of two new Chapters, a high level of regulatory participation, and record membership were the key milestones of the year.

Meetings and Conference

Meetings and conferences offer a means of involving members, promoting identity, promoting member growth and engaging the regulatory authorities.

PDA International Congress and Courses, "*Regulatory and Technological Challenges for One World*"
Basel, Switzerland
February 14-18, 2000

Workshop and Course,
"A Day with FDA"
Verona, Italy
May 3-4, 2000

Workshop and Course,
"A Day with FDA"
London, England
June 27-28, 2000

Conference and Course, *"The Future of Validation: Evolving Requirements for Pharmaceutical Development and Manufacturing"*
Milan, Italy
October 10-12, 2000

PDA European Forum 2000 and Course, *"Environmental Monitoring for Aseptic Processing of Medicinal Products"*
Basel, Switzerland
November 6-8, 2000

Regulatory Participation

Regulatory participation continued and strengthened during 2000 through conference participation, newsletter reporting, and direct commentary. Highlights include:

- *Draft Annex 15 to EU GMP, Process Validation*– PDA comments submitted to the EU Commission on February 25. The Task Force work was headed by Hiltrud Horn and Steve Bellis.
- *Draft CPMP Note for Guidance on Process Validation*– PDA comments were submitted to the CPMP on February 25. Comments prepared by the same Task Force as Annex 15.
- *Draft Annex 17 to EU GMP, Parametric Release*– The PDA Task Force that drafted PDA Technical Report 30, 'Parametric Release of Pharmaceuticals Terminally Sterilized in the Final Containers', also prepared comments on draft Annex 17 which were submitted to the EU Commission on September 29, 2000. Task force headed by Klaus Haberer.
- *ICH Q7A, GMPs for API's*– Several PDA Members from Europe participated on the committee that submitted comments to FDA on September 2, 2000.
- *FDA Draft Guidance on Analytical Procedures and Methods Validation*– For one of the few times in PDA history, the Task Force preparing these comments on a US regulatory issue was chaired by a member from Europe. The comments were submitted in November 2000, and the work was headed by Anders Vinther.
- *PDA Regulatory Affairs and Quality Committee*– European membership and participation in this critical standing committee has been expanded.

Science and Technology

Science and Technology activities continued in 2000 primarily by reactivation of the Europe component of the PDA Steam Sterilization Committee which is focusing on a redrafting of PDA Technical Report #1 on "Validation of Steam Sterilization Cycles".

PDA Letter and Bulletins for European Members

Contributions continued to the *PDA Letter* on developments of interest to members in Europe. A series of bulletins were created on an as needed basis for PDA members in Europe.

PDA Chapters

2000 witnessed the founding of two new PDA chapters in Europe:

- The UK and Ireland Chapter was formally chartered in November 1999.
- The PDA Italy Chapter was formally chartered in June 2000.

PDA Membership in Europe

PDA European members continue to increase:

- Membership 1993: *300*
- Membership December 1997: *1,400*
- Membership December 1999: *1,675*
- Membership December 2000: *1,850*

- Scandinavia has the largest concentration of members.
- Ireland and Denmark have the highest number of members per capita population.
- Italy has shown the most increase in membership.

PDA TRAINING AND RESEARCH INSTITUTE (PDA-TRI)

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 associated products. Ongoing curricula are offered in pharmaceutical sciences, biotechnology, solid and parenteral dosage forms, medical devices, regulatory affairs and much more. Courses are presented at PDA's Training and Research Institute (PDA-TRI) located in Maryland, as well as locations throughout the United States and around the world. PDA is the preeminent provider of this type of industry training.

Facility

PDA maintains a state-of-the-art training facility in Catonsville, Maryland, just outside of Baltimore. PDA-TRI offers over 11,000 square feet of modern classroom and laboratory facilities. Four classrooms provide meeting space for both education and conference events. These facilities are used by both PDA and industry groups, as well as by the University of Maryland, Baltimore County on which 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 class participants to practice the hands-on skills associated with a wide range of production and lab activities. Students work in real analytical and microbiological lab settings to gain insight into critical areas of production organization. In the process lab, students 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-TRI serves a worldwide membership with a slate of conveniently located courses. Many of the courses are held within the United States, while others are held in other parts of the world. While 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 unique to the industry.

Personnel

One of PDA's most significant services to its membership is reflected in its commitment to education and training. But the real commitment of any educational organization can be found in its faculty and staff. PDA prides itself in its ability to count some of the finest teachers in the industry among its faculty. PDA-TRI in 2000 utilized over 80 individuals to present its courses. Many of these individuals are nationally and internationally recognized leaders and researchers. Many are published authors in their areas of expertise. All are excellent instructors who teach for PDA out of a sense of community to the industry.

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

2000 Highlights

The year 2000 marked a turning point for PDA-TRI. The unit has been in operation for approximately four years. During that time over 7,500 students have attended nearly 500 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 2000, PDA-TRI offered a total of about 110 classes. Current plans are to expand that number significantly as each year new courses are added to the educational mix in order to meet our membership's constantly changing needs.

A recent trend is that a significant portion of PDA-TRI's curriculum is now being offered overseas. Courses are available in more than a half dozen countries in Europe and Asia.

PDA TRAINING AND RESEARCH INSTITUTE *(PDA-TRI)*

Sponsors and Contributors

Individuals and/or companies are acknowledged as PDA-TRI Sponsors if equipment or funds are donated. Contributors are those companies that either loan equipment or provide a reduced purchase price for equipment used at the Institute.

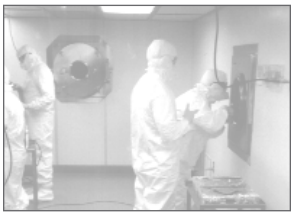


TABLE 1

2000 EDUCATION AND TRAINING ACTIVITY

Courses Taught

Total number of Lecture Courses	93
Total number of Laboratory Courses	14
TOTAL	107

Total number of participants at PDA Training Courses 1,838

PDA TRAINING AND RESEARCH INSTITUTE SPONSORS

Abbott Laboratories
Allegiance Healthcare Corporation
Alma, Inc.
Becton Dickinson & Company
Berkshire Corporation
Biolog, Inc.
bioMerieux Vitek, Inc.
Biotest Diagnostics Corporation
Chemunex, Inc.
Cole-Parmer
Comar, Inc.
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MEETINGS REPORT

In 2000, meetings continued to support PDA's mission of advancing pharmaceutical technology and knowledge. Hundreds of new members were introduced to the benefits of membership through meeting attendance, and returning attendees expanded and reinforced their international scientific networks. PDA exhibits continued to showcase the latest on industry products and services for meeting attendees, and all PDA exhibits were sold to capacity.

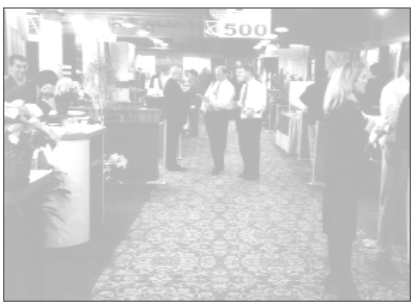
PDA enjoyed excellent participation by FDA and other regulatory agencies in all programs thereby reinforcing PDA's mission of influencing the direction of regulation based on sound scientific and practical knowledge.

PDA's impact outside the USA was evidenced by significant international attendance (approximately 20%) at the Annual Meeting and eleventh annual PDA/FDA Joint Conference. [See PDA Europe for details on European conferences.]

Joseph D. Famulare, Director, Division of Manufacturing and Product Quality, FDA, addresses attendees at the 2000 PDA/FDA Joint Regulatory Conference

PDA 2000 Conferences and Chairs

- PDA International Congress, Courses & Exhibition (Basel)
  Regulatory and Technological Challenges for One World
  Co-chairs:
  Jennie Allewell, Cell Therapeutics, Inc.
  Klaus Haberer, Compliance Advice and Services in Microbiology GmbH
- PDA Spring Conference, Courses & Tabletop Exhibit
  Prescription for Successful Contracting: Your Product from Concept to Commercialization
  Chair:
  Duncan E. McVean, Ph.D.
- PDA/FDA Public Conference on Technical Implementation of Part 11 (21 CFR Part 11, Electronic Records; Electronic Signatures)
  Chair:
  George Grigonis, Merck & Co., Inc.
- PDA/FDA Joint Conference, Courses & Tabletop Exhibit
  Global Harmonization: Challenges and Opportunities for Compliance
  Chair:
  Amy Scott Billman, GlaxoSmithKline
- PDA Special Scientific Forum on Visual Inspection
  Chair:
  John Shabushnig, Pharmacia Corporation
- PDA/FDA Conference on the Validation of Manufacturing Processes for Biologics
  Co-chairs:
  Vince Anicetti, Genentech, Inc.
  Christopher Joneckis, FDA
- PDA Training Conference, Courses & Tabletop Exhibits
  New Century, New Challenges, New Solutions
  Co-chairs:
  Robin Wachter, Eli Lilly and Company
  Joyce Winters, Wyeth-Ayerst Labs, Inc.
- PDA Conference on Isolation Technology, Course & Tabletop Exhibit
  Co-chairs:
  James P. Agalloco, Agalloco & Associates
- PDA/FDA Conference on Team Biologics
  Co-chairs:
  Frank S. Kohn, Ph.D., Wyeth-Lederle Vaccines & Pediatrics
  Steven A. Masiello, FDA
- PDA Annual Meeting, Courses & Exhibition
  Compliance and Cost: Controls in Conflict
  Chair:
  James P. Agalloco, Agalloco & Associates



Exhibition Hall at 2000 PDA Annual Meeting in Philadelphia, PA

Fulvio Tavellini, Lilly Italia; Andrea Raso,Lilly Italia; David Hussong, CDER, FDA, USA; Klaus Haberer, Compliance-ASIM, GmbH, Germany; and Russell E. Madsen, PDA, USA– at the 4th Annual PDA European Forum 2000.

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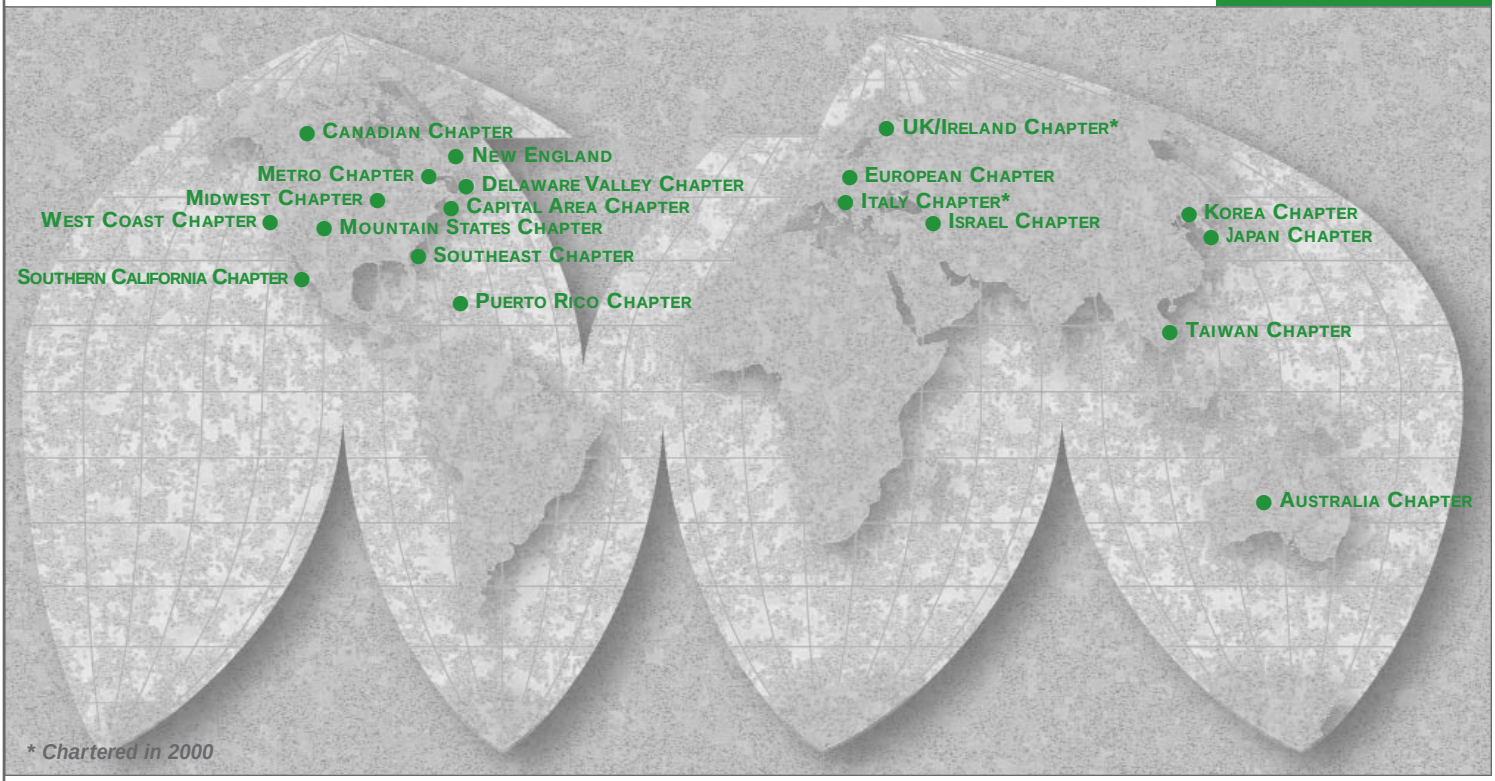

During the past decade PDA has made great strides to recruit overseas members and establish relationships with pharmaceutical associations abroad. Today, over 30% of PDA's members reside outside the United States. Our chapters are expanding to all corners of the globe and PDA's international presence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

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