2007
ANNUAL REPORT

Connecting People, Science and Regulation®

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About PDA

The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. As a nonprofit organization, we are committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of our more than 11,000 members worldwide.

Mission

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership.

PDA Mission Elements

- Promote advances in pharmaceutical and biopharmaceutical science
- Provide global forums for the scientific community, regulators and industry professionals
- Facilitate development, testing and qualification of new technologies
- Facilitate training and education on a global level
- Deliver unique hands-on training through PDA's Training and Research Institute
- Foster *Career-long Learning*SM and professional development
- Enable scientific information-sharing with industry peers
- Continue to be a leading and influential contributor of information for the global regulatory and harmonization processes

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Message from the PDA Board of Directors Chair

Chair, PDA Board of Directors
Vincent Anicetti
Genentech, Inc.

First and foremost, on behalf of the PDA Board of Directors, I would like to thank the PDA staff for their tremendous contributions in 2007. Under the leadership of Bob Myers, PDA operations are more sustainable through solid financial performance and truly becoming the global organization to which we aspire. To be clear, our mission is not about making money, it is to develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership. All of our human and financial resources are used to support this mission.

However, achieving our mission is dependent on our ability to manage PDA as a sustainable nonprofit organization with adequate reserves to survive "rainy days" and solid business systems to allow predictable performance. Unfortunately, during my previous decade as a PDA Board member essentially all of our energy was focused on making ends meet and far too little time was spent on pursuing our mission. Developing the financial plan and infrastructure to provide this security to PDA and its membership has been a major goal over the past two years, and I am very pleased to report we have achieved an important milestone, six months of operating reserves.

This is extremely important to the organization for two reasons. First, if you are constantly thinking about the bottom line, you will not look very far into the future. Second, it allows us to take some risks with programs that have great scientific content but may not draw a large audience. I want PDA to be able to pursue its activities based on science and need, not simply the bottom line.

Our first goal in becoming a global organization was to consolidate our organization in Europe. Growth in Europe has increased beyond our expectations. The *PDA/EMEA Joint Conference* has become a significant event for the pharmaceutical industry and promises to be an institution in the same manner as the *PDA/FDA Joint Regulatory Conference* in the US. In addition, PDA held in excess of 20 European meetings in 2007 that added greatly to the scientific knowledge and capabilities of both regulatory and industry communities. Why the emphasis on Europe? Pharmaceutical development and manufacture is increasingly subject to regional regulatory requirements and inspectorates. To be effective in providing science-based education and guidance to both industry and regulators, PDA must address policy and practice on a global basis. I hope to use the PDA Europe model for establishing stronger PDA programs and presence in other parts of the globe. We hope that 2008-2009 will be the years that we see a PDA office established in Asia.

The year 2007 was also memorable because of the consolidation of the PDA Training and Research Institute (PDA TRI) with our headquarters in Bethesda, Md. This single site for PDA headquarters and training operations provides our members with a state of the art production and laboratory facility to perform "hands on" and classroom training a few steps away from the PDA staff and FDA. PDA has become the central, independent source for practical training needs for the regulatory, academic and industry communities. PDA's ability to bring an unbiased and best practices approach to hands-on training is extraordinary. I look forward to the expansion of our already impressive curriculum in the coming years.

Through the hard work and dedication of many volunteers and staff, PDA has led the advancement of parenteral drugs for more than sixty years. I am sure you are all as proud as I of the contributions PDA has made to patient safety and educating the professionals who help ensure it. Hopefully the progress we have made in building our organization the past two years will help in part to ensure that PDA remains a leader in the advancement of parenteral science for the next sixty years.

Message from the PDA President

President, PDA
Robert Myers
PDA

In the future, PDA members will look back on 2007 as a true milestone for the Association. So many paradigm-shifting goals were fulfilled, it is hard to determine which to highlight first. That being said, let me start by mentioning the consolidation of the PDA Training and Research Institute (PDA TRI) into our Bethesda location, because that is the most tangible accomplishment of 2007. Not only did we unify our North American operations and vastly upgrade our training capabilities, we constructed the new facility on time and received many more donations for the facility than originally expected. The outpouring of support for TRI by the various donors significantly raises the value of the new facility to our membership and endorses our view of how important the Institute is to us and our supporters.

Speaking of increasing the value of PDA membership, I am proud to highlight the creation of *International Pharmaceutical Quality* (IPQ). By working with former *Gold Sheet* editor Bill Paulson, PDA has launched IPQ, an exciting new source of regulatory information. Each issue is a comprehensive reference document on a specific global regulatory or harmonization topic. We look forward to increasing its visibility and respectability as a unique publication in the industry. We also published *PDA Technical Report No. 1, Revised 2007, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control,* a guide to manufacturers that harmonizes best practices from Europe and North America. Thanks to the hard work of two other PDA Task Forces, we also published *Technical Report No. 39, Revised 2007,* and *Technical Report No. 44*. Over the course of the year, the *PDA Letter* continued to evolve into one of the best membership magazines in the industry with contributions from a number of members, new sections highlighting PDA activities and volunteers, and a growing base of advertisers. PDA's new and improved publications have significantly enhanced the value of our membership.

Our programming continues to reach new levels year after year. In 2007, both the *PDA Annual Meeting* and the *PDA/FDA Joint Regulatory Conference* drew record numbers. Total attendance at the *PDA Annual Meeting* reached 1,000 and for the *PDA/FDA Joint Regulatory Conference,* nearly 1,200.

We also improved our ability to respond to member needs. For the global membership, we significantly increased the resources dedicated to membership services in our Bethesda headquarters and established a fully-staffed office in Berlin, Germany to service our rapidly expanding European operation. The new staff at both locations ensures more timely service to members all over the world. Going into 2007, we placed particular emphasis on increasing our offerings to members in Europe. As a result, we nearly doubled the value of our European operation. Overall, the Association grew to approximately 11,000 members in 2007, a 12% increase from the previous year.

Looking to 2008, PDA has many goals that, if met, will continue to enhance and grow the benefits of membership.

For one, we continue to work diligently to improve our support to our Chapters. Much was accomplished on this front in 2007, but we are ready to make further commitments in 2008.

We also anticipate publishing at least six PDA technical reports, doubling last year's effort. With the development of each technical report, we want to provide training and support to help members exploit the value of technical reports to the fullest. Our training workshops for TR-1 have received high marks and great attendance, and we plan at least one more in 2008 in Montreal, Canada. In the future, training on TR-1 will be expanded to include three supporting technical reports covering steam-in-place, parametric release and moist heat sterilization, as well as other related documents.

As for programming, we have many strong programs on the agenda to help our members enhance their careers and the industry as a whole. In February, we will hold our second joint conference with EMEA in Budapest, Hungary. The goal is to co-sponsor a regularly scheduled event with EMEA to bring even greater value to our membership. The *PDA 2008 Annual Meeting* in April in Colorado Springs, Colo., is officially branded as PDA's top science and technology meeting. In May, our *2008 Biennial Training Conference* will be held in New Orleans, La. For the 18th consecutive year, PDA and FDA will hold the *2008 PDA/FDA Joint Regulatory Conference*, once again in Washington, DC, in September. PDA's conferences on pre-filled syringes have been so popular that we are committed to holding one a year, alternating locations between Europe and North America; the 2008 event will be in October in San Diego, Calif.

Finally, I'm very excited to announce PDA's very first meeting in China—the *PDA/FDA Co-Sponsored Conference Series on Quality Systems*. PDA and FDA teamed up two times in 2007 for this two-day discussion of quality systems. In 2008, with the endorsement of China's State FDA, we will hold the workshop in Beijing (April 21-22) and in Shanghai (April 24-25), both important focal points of the industry in China.

As you can see, we are firmly committed to following a great 2007 with an even more successful 2008.

2007 PDA Officers and Board of Directors

Officers

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Genentech, Inc.

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Martin Van Trieste
Amgen

Anders Vinther, PhD
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Scientific and Regulatory Affairs

Through the Scientific and Regulatory Affairs Department, PDA publishes consensus documents—called PDA technical reports—for the pharmaceutical and biotechnology industries on issues where little or no other guidance or standards exists. Additionally, the Department is charged with publishing PDA's two major membership publications—the *PDA Journal of Pharmaceutical Science and Technology* and the *PDA Letter*, and manages the publication of PDA's newest membership publication, *International Pharmaceutical Quality* (IPQ). The Department also supports PDA members and the pharmaceutical and biopharmaceutical industries by reviewing and contributing to new regulations and guidances to assure that they are based on sound scientific principles.

Rich Levy, PhD, Senior Vice President of Scientific and Regulatory Affairs, and **Bob Dana,** Vice President of Quality and Regulatory Affairs, were focused in 2007 on the increasing level of member activities in Advisory Boards, Task Forces and Committees. **Iris Rice,** Executive Coordinator for the office, was instrumental in implementing both WebEx and PDA's knowledge management system InfoStrength for routine Task Force and Advisory Board activities. The addition of professional resources for project management and technical writing and editing in 2006 began to bear fruit as progress on existing and new task forces accelerated.

The year 2007 was noteworthy for increased Task Force activities, including face-to-face and public presentations to solicit industry feedback on draft technical reports.

In Europe, **Volker Eck, PhD,** Senior Director of Science and Technology ensured that European members interested in manufacturing science received additional attention. **Jim Lyda,** Senior Director of Regulatory Affairs continued his focus on the European regulatory scene and contributed to the development of regulatory responses through the Regulatory Affairs and Quality Committee (RAQC).

To strengthen the scientific, technological and regulatory content of the *PDA Letter* and the *PDA Journal of Pharmaceutical Science and Technology,* their respective staffs were linked directly to the Science and Regulatory Affairs staff by reporting into **Rich Levy.** The *PDA Journal* Staff, **Lee Kirsch, PhD,** and **Salil Desai,** effectively managed and published the *PDA Journal of Pharmaceutical Science and Technology,* one of the oldest American journals devoted to pharmaceutical technology. The *PDA Letter* staff, **Walter Morris, Lindsay Donofrio,** and **Emily Hough,** made significant strides by all measures in increasing the member content and page count, and introducing new sections and columns. In addition, **Walter Morris,** under the direction of the Department's head, contributed to the creation and publication of *International Pharmaceutical Quality*.

Science and Technology Overview

Meetings, Conferences and Workshops

One of the main activities of the Scientific and Regulatory Affairs Department is to support the design, development and execution of PDA programs, conferences and workshops. Each of the senior members of the department spent significant time in 2007 representing PDA on the planning committees for meetings.

2007 was a notable year, as we supported the *Quality by Design for Biopharmaceuticals Workshop*, the *PDA 2008 Annual Meeting*, the *PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology*, the *PDA/FDA Joint Regulatory Conference*, the *PDA/FDA Co-Sponsored Conference on Quality Systems* held in Bethesda and in Ireland, the *Sneak Peek Technical Report Meeting* held at Amgen, *PDA Extractables/Leachables Forum, Pharmaceutical Cold Chain Management Conference,* and the *Japanese Regulatory Workshop.*.

In addition, PDA hosted a series of four educational conferences/trainings in North America and Europe on *PDA Technical Report No. 1, Revised 2007, Validation of Moist Heat Sterilization*. Europe hosted three of the conferences and one training course held in London, England; Cork, Ireland; and Pavia, Italy, respectively.

Publications

Technical Reports

PDA technical reports are produced by Task Forces which work under the auspices of the PDA Science Advisory Board (SAB), the Biotechnology Advisory Board (BioAB) and the Audit Guidance Advisory Board (AGAB). Technical reports go through a series of steps on the way to a finished document, including a membership review. Once the review process is completed, the draft document is submitted to the appropriate Advisory Board for technical and content review and balloting. When an Advisory Board approves a document for publication, the approved draft is forwarded to the PDA Board of Directors which decides whether it should be published, revised or abandoned. This rigorous PDA peer-review system ensures that PDA technical reports meet the highest scientific standards and are of maximum value to the membership and the industry at large.

In 2007, PDA published the following three technical reports as supplements to the *PDA Journal of Pharmaceutical Science and Technology,* bringing the number of active technical reports in PDA's library to 39:

- *PDA Technical Report No. 1, Revised 2007, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control*

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- *PDA Technical Report No. 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment*
- *PDA Technical Report No. 43, Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing.*

Of note is the effort which was undertaken to revise PDA's flagship *PDA Technical Monograph No. 1 on Moist Heat Sterilization*, first published in 1978. In 2006, the scope statement for the project was revised and narrowed by the PDA Board of Directors. A smaller team was engaged to complete the revision. Under the leadership of **Rich Levy,** this team completed its work in 2007. As part of the development process, this team sponsored member and industry feedback sessions in the United States and Europe. The result was a new draft which is global in scope. The team also initiated several complementary Task Forces including Steam-in-Place, Moist Heat Sterilizer Systems, and Parametric Release.

Also of note was the publication of TR-43; this Technical Report is novel in that it includes a photographic lexicon of glass defects on a CD.

Technical Books

The following PDA members authored or were editors of PDA/Davis Healthcare International Publishing (DHI) books in 2007:

- **Anne F. Booth,** *Ethylene Oxide Sterilization: Validation and Routine Operations Handbook*
- **Trevor Deeks, PhD,** *Bioprocess Validation: The Present and Future*
- **Nigel Halls, PhD,** *Essential Microbiology for QP Candidates*
- **Nigel Halls, PhD,** *Pharmaceutical Contamination Control: Practical Strategies for Compliance*
- **Stephan O. Krause, PhD,** *Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies*
- **Steven S. Kuwahara, PhD,** and **Simon Xiuwei Li,** *Chinese Drug GMP: An Unofficial Translation Including Related Sections of the Taiwanese, U.S. and ICH-API GMP*
- **Jeanne Moldenhauer, PhD,** *Systems Based Inspection for Pharmaceutical Manufacturers*
- **Richard Prince, PhD,** and **Diane Petitti,** *Confronting Variability: A Framework for Risk Assessment*
- **Scott Sutton, PhD,** *Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics*

PDA is grateful for the dedication of the Technical Books Advisory Board, which once again helped PDA target authors who could contribute valuable books to the PDA/DHI library.

PDA Journal of Pharmaceutical Science and Technology

The *PDA Journal of Pharmaceutical Science and Technology* published its 61st annual volume in 2007 under the leadership of **Lee Kirsch, PhD,** and with the outstanding support and diligent editorial assistance of **Salil Desai** (soon to be PhD as he completes his doctoral studies at the University of Iowa in 2008). The *PDA Journal* is the oldest American journal devoted to pharmaceutical technology and continues its long history of respected service to the industry and academia as a conduit for the dissemination of valuable scientific insight into the foundations of pharmaceutical development, manufacturing and quality assurance.

In 2007, the *PDA Journal* published 42 articles and received 104 manuscripts from all over the world including many contributions from China, India, Southeast Asia, Europe and South America.

In furthering the Journal's effort toward globalization, we have begun to seek out collaborative arrangements with new and established regional journals whose geographical focus has been in regions currently underserved by PDA. The purpose of these collaborations is to foster exchanges of ideas, knowledge and expertise between scientists and technologists served by each journal. Our first attempt at collaboration with a regional pharmaceutical science journal is with the *Thai Journal of Pharmaceutical Sciences* (TJPS). TJPS is a quarterly journal published for over thirty years by the Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand.

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Like the *PDA Journal*, TJPS publishes original research work and review articles. Its primary distribution is Southeast Asia. The editor of TJPS is Dr. Warangkana Warisnoicharoen of the Faculty of Pharmaceutical Sciences at Chula. A Memorandum of Agreement between the *PDA Journal* and TJPS specifically provides for the following collaborative endeavors: website linkages, cross-published table of contents, editorial advisor board positions for the respective editors, calendar of events exchange, fellowship program announcements and other jointly agreed to projects.

The *PDA Journal* sponsored two important student outreach programs including the Student Research Symposium at the *PDA 2007 Annual Meeting* and Pre-doctoral fellowship program which provide funds for the partial support of four graduate students pursuing doctoral research at various universities.

Lee Kirsch, PhD and his staff's efforts were assisted by a distinguished Editorial Advisory Board whose membership included **Jim Akers,** *Akers, Kennedy & Associates;* **Mike Akers,** *Baxter Pharmaceutical Solutions LLC;* **Larry Gatlin,** *Pfizer;* **Dana Guazzo,** *RxPax;* **Tony Hickey,** *University of North Carolina;* **David Hussong,** *FDA;* **Michael Jahnke,** *Wulfing Pharma;* **Maik Jornitz,** *Sartorius Stedim Biotech;* **Paul Myrdal,** *University of Arizona;* **Steven Nail,** *Baxter;* **Martin Redmon,** *Arqule;* **Laura Thoma,** *University of Tennessee; and* **Warangkana Warishoicharoen,** *Chulalongkorn University.*

PDA Letter

The *PDA Letter* continued to grow and evolve in 2007 with the addition of regular content meant to highlight new members, better inform the membership about the activities of the Association and promote volunteerism. With this new content, the average page count per issue grew 13%, resulting in a 45% spike in advertising revenue over the previous year.

Beginning with the January 2007 edition, PDA started publishing the "New Member List," which includes new members to the Association who joined during the four weeks prior to publication.

In the May 2007 issue, the "Science & Technology Snapshot" launched in the Letter. Each "Snapshot" provides members an update on a variety of PDA activities. For example:

- The Task Force Corner snapshot provides quick summaries of recent task force meetings.
- The Tech Report Watch snapshot allows members to follow the progress of technical reports as they go through the final stages of development, from draft to board review.
- The Journal Preview snapshot is just what is says—a preview of the upcoming issue of the *PDA Journal of Pharmaceutical Science and Technology*.
- The In Print snapshot includes an excerpt of the latest PDA/DHI technical book.

With the September issue of the *PDA Letter*, the "Quality & Regulatory Snapshot" was introduced, with similar updates on the Association's activities in these areas.

To encourage volunteerism and recognize the Association's many hard-working volunteers, the "Volunteer Spotlight" was launched with the September 2007 issue. The first volunteer highlighted was **John Shabushnig, PhD** who developed the concept for the Spotlight as a member of the PDA Membership Committee.

Scientific and Regulatory Affairs

Over the past several years, the *PDA Letter* editorial staff has made efforts to include the voice of PDA members in the Letter by assembling the *PDA Letter* Editorial Committee, developing editorial schedules and soliciting articles. These activities have resulted in a marked increase in the number of member-authored articles published in the *PDA Letter*, including feature-length articles and articles by chapter leaders, program committees and PDA advisory boards.

In 2007, the *PDA Letter* published the following feature-length articles by PDA members and other industry experts:

- "Articles of Interest to the Microbiologist: A Review of Microbiology-Related Research Published in Volume 60 (2006) of the *PDA Journal of Pharmaceutical Science and Technology,*" **Scott Sutton, PhD,** *Vectech Pharmaceutical Consultants*
- "Berlin Workshop on PDA's Technical Report No. 42, Biopharmaceutical Process Validation," **Norbert Hentschel, PhD,** *Boehringer Ingelheim* and **Chris Bussineau, PhD,** *Cambrex Biosciences*
- "BioAB Drives PDA's Biotech Strategy," **Gail Sofer,** *GE Healthcare;* **John Geigert, PhD,** *BioPharmaceutical Quality Solutions,* and **Rich Levy, PhD,** *PDA*
- "First PIC/S Industry Forum: New Opportunity to Discuss Global GMP Issues," **Tim Marten,** *AstraZeneca;* **Stephan Roenninger,** *F. Hoffmann L-Roche;* and **James Lyda,** *PDA*
- "Low Energy Electron Beam Applications in Aseptic Filling Operations," **Dieter Bachmann, PhD,** *Cilag* and **Ike Harper,** *Johnson & Johnson*
- "Management-Based Regulations New FDA Goal," **Rick Friedman,** *FDA*
- "Method Validation: An Overview of Global Standards," **Susan Schniepp, Mae Taylor, Dave Loffredo** and **John Vasinko,** *Hospira Inc.*
- "OOS Final Guidance: What has Changed?," **Lynn Torbeck, PhD,** *Torbeck & Associates*
- "PDA Survey on Analytical Methods for Cleaning Validation," **Destin LeBlanc,** *Cleaning Validation Technologies*
- "QbD: Still in Design?: A Report from PDA's QbD Workshop," **Bert Frohlich,** *Amgen*
- "Quality by Design for Biopharmaceuticals," **Rebecca Devine, PhD,** *Regulatory Consultant* and **Anurag Rathore, PhD,** *Amgen*
- "Quality Requirements for Clinical Trial Applications in the European Union: A Report from the 2006 PDA/FDA Conference," **Susanne Keitel, PhD,** *Federal Institute for Drugs and Medical Devices, Germany*
- "Quality Systems: An Evolving Environment," **Zena Kaufman,** *Abbott Laboratories*
- "Review of EMEA Guideline: Limiting Residues of Metal Catalysts," **Susan Schniepp,** *Hospira Inc.*
- "Review of USP Microbiology Chapters: A Report from the PDA Global Conference on Pharmaceutical Microbiology," **David Porter, PhD,** *Vectech Pharmaceutical Consultants*
- "Use of Microarrays to Evaluate Cell Culture Processes: Progress Report from a PDA Journal Student Grantee," **Michael Hanson,** *University of Maryland Baltimore County*

2007 PDA Letter Editorial Committee

Shelley Abrams, *Eli Lilly and Company*
Michael Awe, *American Pharmaceutical Partners*
Vinod Gupta, PhD, *Organon USA, Inc.*
Elizabeth Martinez, *Terra Farma, S.A.*
Rainer Newman, *Johnson & Johnson*
Kristina Nordhoff, *Genentech, Inc.*
Scott Sutton, PhD, *Vectech Pharmaceutical Consultants*

Task Forces

One of the key goals of the Science and Technology Department in 2007 was the continued revitalization of the PDA Task Force activities. Efforts begun in 2006 to re-engage existing Task Forces which had been inactive and to provide professional project management and technical editing assistance to those Task Forces in need of such assistance were continued.

By mid year of 2007, there were 37 Advisory Board approved Task Forces, 26 of which were sponsored by the Scientific Advisory Board (SAB), 11 by the Biotechnology Advisory Board (BioAB), and one by the Audit Guidance Advisory Board (AGAB). At the end of the year there were nine new Task Forces in pre-approval stage.

Scientific and Regulatory Affairs

To provide further direction to scientific activities, a Standard Operating Procedure was written for both the Science Advisory Board (SAB) and the Biotechnology Advisory Board (BioAB) in 2007. Efforts to create a *PDA Guide to Authors of Technical Reports,* initiated in 2006, progressed, with a comprehensive draft document completed by the end of 2007.

Advisory Boards

Audit Guidance Advisory Board (AGAB–formerly IAB)

PDA established the AGAB to periodically review and approve changes to the process model and data collection tools described in PDA *Technical Report No. 32, Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations*. The AGAB also monitors auditor qualification and requalification requirements and provides oversight of the SynTegra, LLC Audit Resource Center (ARC) to: ensure that the process remains current with respect to changing technology and regulatory environments; periodically analyze ARC's registration history, promotional efforts, service performance; and furnish ARC with suggestions, if any, for improvement.

The AGAB met six times through WebEx conferences in 2007. During the meetings, they reviewed the activities of the ARC, worked on revising their charter and procedures, and determined that TR-32 will be revised as a result of the work from the task group. In 2007, the AGAB chartered the Standard Audit Criteria Task Force (SACTF), under the Chairmanship of **Peter Miller,** to develop and document a standard set of Audit Criteria intended for the Pharmaceutical and Medical Device industry. In 2008, the SACTF will develop and prepare a technical report for Auditing with Standard Criteria related to FDA's Quality System approach and will generate documents or deliverables related to Auditing protocols.

Biotechnology Advisory Board (BioAB)

To complement the SAB and to further focus PDA's scientific efforts on biotechnology, PDA established a Biotechnology Advisory Board (BioAB). The BioAB has the responsibility for identifying biotechnology issues of interest to PDA members globally. Once an issue is identified, the BioAB either forms a task force to study and prepare written comments, or hands the issue off to the RAQC or SAB for action.

The BioAB was proactive in the identification of scientific/technical/regulatory issues affecting biotech products for which the recognition and reputation of PDA can provide a forum for discussion, with a focus on those scientific/technical areas

Audit Guidance Advisory Board (AGAB)

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Janis Olson, *EduQuest*

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Winnie Cappucci, *Bayer HealthCare*
Virginia Corbin, *Waters Corporation*
C. Wells Horton, *Procter & Gamble Pharmaceuticals*
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PDA Staff Liaisons
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Associate/Trainer
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Biotechnology Advisory Board (BioAB)

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Anita Derks, *F. Hoffman-La Roche Ltd.*
Rebecca A. Devine, PhD, *Regulatory Consultant*
John Geigert, PhD, *Biopharmaceutical Quality Solutions*
Brian D. Kelley, *Genentech, Inc.*
James G. Kenimer, PhD, *Biologics Consulting Group*
Peter F. Levy, *Peter Levy Consulting*
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Richard Levy, PhD, *Scientific and Regulatory Affairs*
James C. Lyda, *Regulatory Affairs, PDA Europe*

Scientific and Regulatory Affairs

in biotech that are still rapidly evolving. The BioAB also served to complement the activities of PDA's SAB and RAQC by, for example, providing technical input into regulatory documents and technical reports related to biopharmaceuticals.

In 2007, the BioAB agreed to sponsor a PDA led Survey on Bioburden and a PQRI Research Project Proposal on Reporting and Qualification Thresholds for Leachables in Parenteral and Ophthalmic Drug Products. The latter will be part of PQRI's 2007-2009 research portfolio.

The BioAB approved the following proposals for formation of Task Forces: Analytical Method Validation for Biotech Products, Cell Substrates, Appropriate Application of GMPs for Phase I/II Clinical Bioprocess API, Disposables Processing Technology, Cleaning Validation, and two Mycoplasma Task Forces: one focused on Plant and Complex Media and the other on Alternative Mycoplasma Testing Methods. The deliverables of these task forces are expected to be technical reports on each subject.

Task Forces were also approved to provide formal input on the *EMEA Draft Guideline on Virus-Safety Evaluation of Biotechnological Investigational Medicinal Products* and the *EMEA Draft Guideline: Product and Quality Control of Monoclonal Antibodies and Related Substances* and the *Draft Annex II GMP Regulations*. PDA input into the *Draft Viral Safety Guideline* was made as part of a special meeting held at EMEA headquarters in London with the Biological Working Party (BWP). PDA members presented PDA consensus opinions on four questions posed by the BWP to PDA and three other associations, each of which had provided comments on the Draft in 2006.

In addition, the BioAB approved PDA's new Advisory Board Standard Operating Procedures.

Scientific Advisory Board (SAB)

The PDA Science Advisory Board (SAB) establishes the strategic direction and provides oversight for PDA's scientific and technical activities through the development of guidelines, technical reports, and technical bulletins. Through its sister Advisory Board, the RAQC, the SAB interacts with regulatory authorities by participating in the development of consensus responses to regulatory draft and final guidance and directives.

The SAB is composed of individuals who have a demonstrated history of scientific and technical excellence within the scope of PDA's activities, drawn from industry, government, and academia.

In 2007, the SAB approved the following scope statements for new task forces: Cold Chain; Isolator Decontamination Cycles; the PQRI Research Project Proposal on Reporting and Qualification Thresholds for Leachables in Parenteral and Ophthalmic Drug Products; Glass Defects for Ampoules, Cartridges and Syringes; and Disposables Processing Technology.

A number of industry surveys were approved this year: the Quality Risk Management Practices Survey, a Proposal for Cleaning Validation Survey on Analytical Methods, a Risk Management Survey and a survey of the Pharmaceutical Water and Media-Fill Incubation Conditions.

The SAB approved three Technical Reports for publication in 2007:

- *PDA Technical Report No. 43, Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing*
- *PDA Technical Report No. 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature - Sensitive Medicinal Products through the Transportation Environment*
- *Filtration of Liquids Using Cellulose-Based Depth Filters*

Scientific Advisory Board (SAB)

Chair
Martin VanTrieste, *Bayer HealthCare*

Co-chair
Richard M. Johnson, *Fort Dodge Animal Health*

Members
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PDA Staff Liaisons
Richard Levy, PhD, *Scientific and Regulatory Affairs*
Robert Dana, *Quality and Regulatory Affairs*
Volker Eck, PhD, *Science and Technology, PDA Europe*

Scientific and Regulatory Affairs

In addition, the SAB approved new PDA Advisory Board Standard Operating Procedures, and a Memorandum of Understanding between the *PDA Journal* and the *Thai Journal of Pharmaceutical Sciences.*

Student Programs

In 2005, the *PDA Journal of Pharmaceutical Science and Technology* launched student programs designed to promote research within the pharmaceutical science and technology field.

The Annual Graduate Symposium invites graduate students to submit papers for presentation at the PDA Annual Meeting. The four applicants selected in 2007 were:

- **William T. Riordan,** *University of Wisconsin, Madison,* "Analysis of Impurity Clearance Using an Anion Exchange Membrane Adsorber"
- **Janjira Intra,** *University of Iowa,* "Preparation and Characterization of Cationic Microparticles Consisting of Polyethyleimine and Poly (lactide-co-glycolide) as Non-Viral Gene Delivery Carriers"
- **Stuart L. Cantor,** *University of Maryland,* "Application of NIR Spectroscopy in the Design and Characterization of a Unique Compacted Multiparticulate System for Modified Release (MR)"
- **Salil Desai,** *University of Iowa,* "Substituent Effects on Hydrolysis of Amides"

The Predoctoral Fellowship Program provides selected candidates with a stipend to assist them in their research.

Two $9,000 stipends were awarded in 2007 to:

- **Hari R. Desu,** *University of Tennessee, Memphis,* "Development of Methylprednisolone Sodium, Succinate Loaded Integrin Receptor Targeted Fluorescent Liposomes for Detection of Inflammation"
- **Janjira Intra,** *University of Iowa,* "Preparation and Characterization of Cationic Microparticles Consisting of Polyethyleimine and Poly (lactide-co-glycolide) as Non-Viral Gene Delivery Carriers"

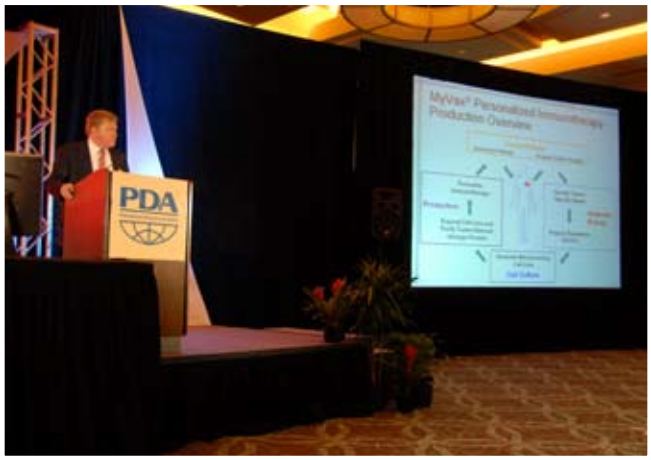
PDA recognizes the work of the *PDA Journal's* lead editor, **Lee Kirsch, PhD,** *University of Iowa,* for his efforts in support of these student programs.

Interest Groups

PDA's Interest Groups continued to flourish in 2007. Interest Groups desiring to meet at both the *PDA 2007 Annual Meeting* and the *2007 PDA/FDA Joint Regulatory Conference* filled all the available slots, and there was also continued interest in Europe. The *PDA 2007 Annual Meeting* featured a multiple session program jointly sponsored by four Interest Groups: the Lyophilization, Packaging Science, Vaccines and Visual Inspection of Parenterals Interest Groups. In addition, the newly formed Pharmaceutical Cold Chain and the Clinical Trial Materials Interest Groups combined for a session on the appropriate controls for the storage and transportation of temperature-sensitive clinical trial materials at the *PDA 2007 Annual Meeting*; and the Process Validation and the Clinical Trial Materials Interest Groups combined to sponsor a session at the *2007 PDA/FDA Joint Regulatory Conference*. Innovative approaches such as these help maximize the value that the Interest Groups bring to our members. Similar combined sessions are anticipated to take place in 2008.

In addition to the newly formed Pharmaceutical Cold Chain Interest Group (formerly the Pharmaceutical Cold Chain Discussion Group), the Prefilled Syringe Interest Group which had begun in Europe, expanded to include North American participation as well.

As the subjects which our members want to focus on continue to grow, we expect more new Interest Groups to form in 2008. Unfortunately, the planned restage of the Interest Group program, which will be vital to allow for continued growth and expansion, did not proceed as rapidly as planned. The restage will be an area of priority and focus in 2008.



Scientific and Regulatory Affairs

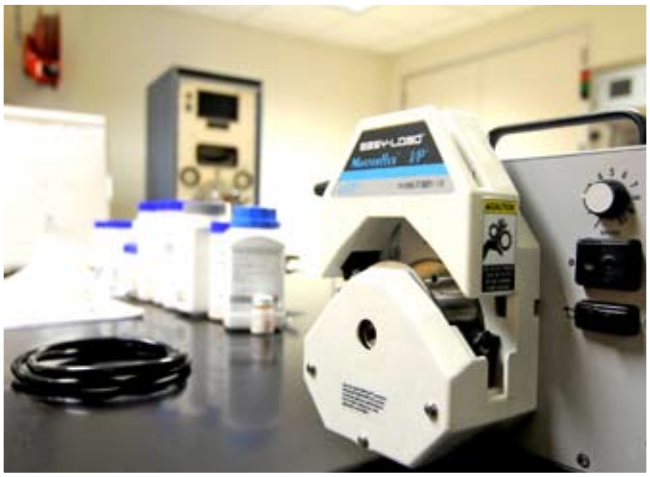
Interest Groups and Leaders

NORTH AMERICA INTEREST GROUPS

- **Biopharmaceutical Sciences**
  Biotechnology: Jill A. Myers, PhD, *BioPro Consulting, Inc.*
  Lyophilization: Edward H. Trappler, *Lyophilization Technology*
  Vaccines: Frank S. Kohn, PhD, *FSK Associates, Inc.*
- **Laboratory and Medical Sciences**
  Pharmaceutical Cold Chain: Rafik H. Bishara, PhD, *Eli Lilly and Company (ret.)*
  Microbiology/Environmental Monitoring: Jeanne E. Moldenhauer, PhD, *Excellent Pharma Consulting*
  Visual Inspection of Parenterals: John G. Shabushnig, PhD, *Pfizer Inc*
- **Manufacturing Sciences**
  Facilities and Engineering: Christopher J. Smalley, PhD, *Wyeth*
  Filtration: Russell E. Madsen, *The Williamsburg Group*
  Pharmaceutical Water Systems: Theodore Meltzer, PhD, *Capitola Consulting Company*
  Sterile Processing: Richard M. Johnson, *Fort Dodge Animal Health*
- **Pharmaceutical Development**
  Clinical Trial Materials: Vince L. Mathews, *Eli Lilly and Company*
  Combination Products: Michael A. Gross, PhD, *Chimera Consulting*
  Packaging Science: Edward Smith, PhD, *Wyeth*
  Process Validation: Harold S. Baseman, *ValSource, LLC*
- **Quality Systems and Regulatory Affairs**
  Inspection Trends/Regulatory Affairs: Robert Dana, *PDA*
  Quality Systems: David A. Mayorga, *Global Quality Assurance, LLC*

EUROPE INTEREST GROUPS

- **Biotechnology**
  Hannelore Willkommen, PhD, *RBS Consulting*
- **Visual Inspection of Parenterals**
  Markus Lankers, PhD, *Rap.ID GmbH*
- **Facilities and Engineering**
  Phillippe Gomez, *Sartorius Corporation*
- **Filtration**
  Roger Seiler, *Sartorius AG*
- **Pre-filled Syringes and Injection Devices**
  Thomas Schoenknecht, PhD, *Gerresheimer*
- **Drug Device Delivery Combination Products**
  Alexandra Schlicker, PhD, *F. Hoffman La Roche AG*
- **Nanotechnology**
  D.F. Chowdhury, *Aphton BioPharma*
- **Technology Transfer**
  Volker Eck, PhD, *PDA Europe*
  Zdenka Mrvova, *Zentiva*



Scientific and Regulatory Affairs

Quality and Regulatory Affairs Overview

PDA's Quality and Regulatory Affairs Committee (RAQC) continued to actively consider, review and provide comments outlining PDA's position on global regulatory proposals in 2007. These comments were prepared by various RAQC Task Forces, all led by and composed of member volunteers. PDA's positions were provided on the following regulatory proposals in 2007:

Chapter 1 (Quality Management) of the *EU GMP Guideline for Human and Veterinary Products*. Major points made in the PDA comments were that Quality Risk Management (QRM) is based on principles and does not suggest that an organizational unit be established for this function, a Committee on Human Medicinal Products (CHMP) guidance to address the application of QRM principles by reviewers would be useful and the ICH Q9 guidance should be recognized as optional, not a requirement. (EC and EMEA)

Content of the Batch Release Certificate Referred to in Article 13.3 of Directive 2001/20/EC. Specific points made include the fact that comparator products should be excluded from the scope of the guidance, adjustments in the requirements as they apply to placebos should be made and the importance of maintaining blinding for investigational medicinal products should be reflected in the requirements for the batch release certificate. (EMEA)

Revisions to the Canadian GMPs. PDA's comments focused on the proposed increase in testing requirements upon import into Canada and the proposed location of retention samples within Canada. PDA pointed out that the proposed changes placed an additional financial burden on the regulated industry which would not be offset by an increase in the protection of the public health. (Health Canada)

Draft Guidance Q10 Pharmaceutical Quality Systems. In our comments, we expressed strong support for the concept of life cycle thinking, but pointed out that more meaningful examples in the Guidance would be helpful. In addition, we suggested modifications to some of the language in the draft Guidance to encompass various business models likely to be employed by both large and small firms, and emphasized the importance of defining roles and responsibilities as well as decision making processes. (US FDA and EMEA for transmission to ICH)

Guideline on Production and Quality Control of Monoclonal Antibodies and Related Substances. The comments emphasized the need for the Guideline to not be overly prescriptive in order to facilitate the development of new and innovative processes and procedures. In addition, the comments encouraged further adoption of Quality by Design (QbD) principles as outlined in ICH Q8 and as supported by ICH Q9 and Q10, and encouraged recognition of the greater knowledge and control these principles allow as policies are implemented by regulatory agencies. (EMEA)

Regulatory Affairs and Quality Control Committee (RAQC)

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Steven Mendivil, *Amgen, Inc.*

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Asia-Pacific Representative
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Janeen Skutnik, *Pfizer Inc*
Michael Vanderwerf, *GSK*
Barbara Zinck, *Cambrex Bio Science*

PDA Staff Liaisons
Robert Dana, *Quality and Regulatory Affairs*
James Lyda, *Regulatory Affairs, PDA Europe*

To assist with the governance of RAQC functions and the succession planning process, the Committee named **Steve Mendivil,** Executive Director of Global Quality Compliance at Amgen as RAQC Co-Chair. Mendivil will assume the role of Chair when current Chair **Zena Kaufman**'s term expires in June 2008.

The Committee also initiated strategic activities to update the procedures governing its operations in 2007. These efforts are expected to be complete in 2008, with implementation beginning immediately after completion.

PDA Training and Research Institute

The PDA Training and Research Institute (PDA TRI) strives to establish unprecedented worldwide education, training and applied research in pharmaceutical sciences and associated technologies. In 2007, we reached new heights in our training programs, both in the US and abroad and moved our facility from its location in Baltimore, Md. to the PDA headquarters facility in Bethesda, Md. without disruption in the management and conduct of our training programs.

PDA TRI developed two training sessions for 40 staff members from the Kazakhstan Ministry of Health and the National Center for the Assessment of Drugs, Items for Medical Purposes and Medical Equipment and ran these programs concurrently. For the first time, PDA had sole responsibility for conducting this training with a focus on the Kazakhstan inspectorate and review staff. All training materials and instruction, via simultaneous translation, were presented in Russian.

Following the 2006 decision of the Board of Directors vote to consolidate PDA TRI and PDA headquarters in Bethesda, we began working with architects from Vectech Pharmaceutical Consulting, a TRI platinum donor, to design a state of the art training facility including an Aseptic Processing Suite, a microbiology laboratory, a biotech laboratory, a CIP laboratory and two classrooms. Construction began in March 2007 with a move-in date of June 30. Our first course was conducted in the new facility on August 1.

Several PDA supporters provided equipment for the new facility, including our platinum donors: Fedegari Autoclavia (autoclave); Groninger (syringe filler); Sartorius Stedim Biotech (bioreactors); Particle Measuring Systems (EM equipment); AMGEN (incubators, and other laboratory equipment) and Veltek (consumables and EM system). Additional donations were received from other supporters (see donor list on page 15). The new facility was dedicated on September 26 with much ado.

Our focus on *Career-long Learning* serves as a precedent for PDA TRI to continually evaluate the curriculum and update and add courses to provide the most current information in both our laboratory and lecture courses. We take seriously the recommendations of our students and instructors when developing training programs for our members and others in the pharmaceutical and biopharmaceutical communities.

The PDA Training and Research Institute distinguishes itself with its hands-on laboratory training. Our popular ten-day *Aseptic Processing Training Program* ran four times this year, selling out all four sessions. The *Practical Aspects of Aseptic Processing* course was conducted once in Basel, Switzerland. Additional new lab courses in 2007 included *Introduction to Visual Inspection; DoE for PAT; and Downstream Processing: Separations, Purifications and Virus Removal.*

We conducted 14 laboratory courses in addition to our ever popular *Aseptic Processing Training Program* during this year.

We continued a concept first implemented in 2006 where we offered training courses with focus conferences as well as the PDA signature conferences. These conferences included: *The 2007 PDA Visual Inspection Forum* and the *PDA 2nd Annual Global Conference on Pharmaceutical Microbiology* in the US; and *Pharmaceutical Cold Chain Management* and *The Universe of Pre-filled Syringes and Injection Devices* in Europe.

The PDA Training and Research Institute provided lecture-based training in its facilities in Baltimore, Md. and Bethesda, Md., and also traveled to the following cities: Philadelphia, Pa. and San Diego, Calif. Course series were also run in conjunction with PDA Meetings and Conferences: the *PDA 2007 Annual Meeting* in Las Vegas, Nev., the *2007 PDA/ FDA Joint Regulatory Conference* in Washington, DC and the *Pharmaceutical Microbiology Conference* in Bethesda, Md. We worked closely with the Chapter leadership on developing the content for many of these series. In addition to providing training in the US, we held courses in Cork and Dublin, Ireland and Berlin, Germany. We also conducted training "in-company" that was designed and delivered to meet a specific, intact audience need.

The PDA Training and Research Institute extends a sincere thank you to those companies that lent or donated high-quality supplies and equipment to PDA TRI (see page 15 for a complete list of 2007 contributors) . We also extend our appreciation to the expert faculty who spent considerable hours developing and conducting training programs for TRI. (see page 16). Your support helps us achieve our goals.

PDA Training and Research Institute

PDA Donors

- **Equipment**
  Amgen
  Eisai Machinery
  Elkhorn Associates
  Fedegari Autoclavi
  Groninger
  Novatek, Inc.
  PALL Life Sciences
  Particle Measuring Systems
  Sartorius Stedim Biotech GmbH
  Veltek Associates Inc.
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Göran Bringert
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Adam Warner, *Bioquell, Inc.*
Tom Weaver, *Weaver Consulting, LLC*
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Programs and Meetings

Opportunities to connect with industry peers in today's technology-driven world are endless. However, face-to-face discussions and networking still rank at the top of the list in terms of the most valuable means of communication for the PDA members. For that reason, in 2007, the ten meetings and two signature conferences – the *PDA Annual Meeting* and the *PDA/FDA Joint Regulatory Conference* – in the United States were well received by more than 7,800 conference participants globally.

The success of the 2007 US meetings can be contributed to the 195 volunteer Program Planning Committee members and the support of the Programs Advisory Board (PAB), whose mission is to serve the PDA membership by identifying trends and new best practices in pharmaceutical meetings and programs that add value to the recognition, reputation and expertise of PDA. The mission is also to help drive scientific advancement by identifying opportunities for optimizing the practices, communication and resource utilization carried out by the PDA programming staff. PDA Europe hosted 20 meetings in 2007, all of which were very successful.

Exhibitions

PDA exhibitions provide new and innovative technologies for conference attendees. PDA offered exhibitions during its two signature meetings in 2007: the *PDA 2007 Annual Meeting* and the *2007 PDA/FDA Joint Regulatory Conference*. With more than 100 exhibitors, the *PDA Annual Meeting* continues to be our largest event.

Although not as large in attendance as PDA's signature meetings, the focus conferences were just as appealing to exhibitors and sponsors. The *Universe of Pre-filled Syringes and Injection Devices* and *PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology* each hosted more than 40 exhibitors.

PDA exhibitions continue to support conferences and our professional community with the most up-to-date commercially available products and services. PDA would like to thank the 2007 Exhibit Committee for their dedication and efforts in planning successful and valuable exhibitions this year.

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Programs and Meetings

2007 PDA Conferences, Forums and Workshops

PDA Emerging Manufacturing and Quality Control Technologies Global Conference
January 29 - 31 | San Diego, Calif. US

Designing a Cleaning and Disinfection Programme for a GMP Environment
January 31 - February 1| Vienna, Austria

Rapid Microbiology Methods: Make Them Work, Get Them Approved
February 5 - 6 | Verona, Italy

Anti-Counterfeiting
February 6 - 7 | Berlin, Germany

PDA 2007 Annual Meeting
March 19 – 23 | Las Vegas, Nev. US

Continuous Improvement in the Pharmaceutical Industry & Impact of ICH Q10
March 26 – 27 | Verona, Italy

Good Practices for Investigational Medicinal Products
May 3 - 4 | Lyon, France

Best Practices in Aseptic Manufacturing
May 8 - 9 | Milan, Italy

Quality by Design for Biopharmaceuticals: Concepts and Implementation – A PDA Workshop
May 21 – 22 | Bethesda, Md. US

PDA Global PAT Conference
May 22 – 23 | Bethesda, Md. US

2007 PDA Pharmaceutical Cold Chain Management Conference
June 13 – 14 | Bethesda, Md. US

PDA/EBE Conference on Biopharmaceutical Development and Manufacturing
June 20 - 21 | Berlin, Germany

PDA Technical Report No. 1, 2007 Revision, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control
June 26 – 27 | Chicago, Ill. US

Pharmaceutical Freeze Drying and Spray Drying
September 11 – 12 | Cologne, Germany

Technology Transfer Today
September 12 – 13 | Basel, Switzerland

2007 PDA/FDA Joint Regulatory Conference
September 24 – 26 | Washington, D.C. US

Cleanrooms/RABS/Isolators
October 9 - 10 | Berlin, Germany

Workshop on ICH Q10 (Draft): Pharmaceutical Quality System – Impact and Challenges
October 9 | Milan, Italy
October 11 | Berlin, Germany

2007 PDA Visual Inspection Forum
October 15 - 16, 2007 | Bethesda, Md. US

Pharmaceutical Cold Chain Management
October 17 - 18 | Berlin, Germany

Supplier Quality and Global cGMPs
October 26 | Rome, Italy

Lonza Executive Awareness Seminar
October 29 – 30 | Leesburg, Va. US

PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology
October 29 - November 2 | Bethesda, Md. US

PDA/FDA Co-Sponsored Conference Series on Quality Systems
November 1 - 2 | Bethesda, Md. US

PDA Technical Report – A Sneak Peek
November 5 | Thousand Oaks, Calif. US

2007 PDA Extractables/Leachables Forum
November 6 – 8 | Bethesda, Md. US

Workshop Series on PDA Technical Report No.1, Revised 2007, Validation of Moist Heat Sterilization Processes
November 6 | Södertälje-Stockholm, Sweden
November 8 | London, United Kingdom
November 13| Milan, Italy

PDA/R³ Nordic Conference on Modern Aseptic Production
Co-sponsored with R³ Nordic
November 7 - 8 | Södertälje-Stockholm, Sweden

The Universe of Pre-filled Syringes and Injection Devices
November 27 - 28 | Berlin, Germany

PDA/FDA Co-Sponsored Conference Series on Quality Systems
December 10 – 11 | Dublin, Ireland

Pharmaceutical Industry and Contaminant Removal
December 6 - 7 | Paris, France

Programs and Meetings

Web Seminars

In addition to face-to-face communication and networking as valuable means of communication for pharmaceutical and biopharmaceutical professionals taking part in PDA activities, PDA offers another successful way to deliver information to its members. Cost-effective Web Seminars and live simulcasting provide an alternative method of learning for those professionals seeking information from the convenience of their home or office.

PDA Web Seminars combine technological innovation with quality educational content and exceptional member service to give members the best learning experience available online.

With the help of WebEx technology, PDA is able to bring a wealth of lectures covering a wide range of topics that are specific, educational, interactive and cost-effective to participants anywhere they have internet access.

In addition, PDA continues to provide a vast selection of On-Demand Web Seminars. These recordings of previous Web Seminars and select conference sessions feature synched audio and presentation, including Q&A. PDA On-Demand Web Seminars allow customers to schedule learning at their convenience.

PDA 2007 Web Seminars

Applications and Advantages of Online Vacuum Filling and Stoppering Technology in Pre-Filled Syringes
Shawn D. Kinney, PhD, *Hyaluron Contract Manfacturing*
January 10, 2007

Parametric Release of Drug Products Terminally Sterilized by Moist Heat
Marla Stevens-Riley, PhD
January 18, 2007

Process Validation of Protein Manufacturing - PDA Technical Report No. 42
Christopher Bussineau, PhD, *Cambrex Bio Science Inc.*
Stephen M. Notarnicola, PhD, *Biogen Idec*
January 25, 2007

Quality in Healthcare – Anticipation and Management
Daniel Diermeier, PhD, *Northwestern University*
February 1, 2007

Online Liquid Chromatography as a PAT in Biotech Process Development and Manufacturing
Rick E. Cooley, *Dionex Corporation and Eli Lilly and Company (retired)*
February 15, 2007

FDA Final Guidance: Investigating Out of Specification Test Results
Lynn Torbeck, *Torbeck and Associates*
March 8, 2007

The Closed Vial Technology: A New Concept in Aseptic Filling to Increase Patient Safety
Benoît Verjans, *Aseptic Technologies*
April 19, 2007

Applying Lean Six Sigma Principles to Environmental Monitoring Processes
Thomas Decker, *GE Healthcare*
Chet Shemanski, *MODA Technology Partners*
April 26, 2007

The FDA Perspective on the Future of QbD
Janet Woodcock, MD, *FDA*
May 22, 2007

Pharmaceutical Cold Chain Management Conference: Global Regulatory Requirements
Ian Holloway, *MHRA*
Rosa Motta, *FDA*
Barry Rothman, *FDA*
Jeanne Taborsky, *USP*
Vincent Tong, *Health Canada*
July 7, 2007

Oversight Program for Transport Providers of Shipments of Temperature Sensitive Products
Gwyn Murdoch, *Eli Lilly and Company*
Rafik Bishara, PhD
July 12, 2007

PDA Technical Report No. 1: Sterilization Science and Technology (Section 3)
Kris Evans, *Amgen*
Keith Shuttleworth, *Keith Shuttleworth and Associates Ltd.*
July 25, 2007

PDA Technical Report No. 1: Sterilization Process Development (Section 4)
Kevin Trupp, *Hospira*
August 7, 2007

PDA Technical Report No. 1: Process Performance Qualification (Section 5)
Mike Sadowski, *Baxter Healthcare; Ian Symonds, GSK UK*
August 21, 2007

FDA's "Guidance for Industry Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production" - An Overview
Paul Haynie, *FDA*
November 15, 2007

Membership and Chapters

2007 Membership Accomplishments

Membership Advisory Board (MAB)

In 2007 PDA formed the Membership Advisory Board (MAB) to enhance the value of the PDA membership experience. Long time volunteer and author **Sue Schniepp** was elected Chair with **John Shabushnig, PhD** as PDA Board Liaison. The mission of the MAB in 2008 is to serve as representatives for the PDA community as they strive to improve, expand and enrich PDA member benefits and the PDA community.

Strengthening Volunteer Focus

In an effort to recognize and reward PDA volunteers and to expand membership participation, in 2007 PDA created online volunteer resources, began publishing Volunteer Spotlights in the *PDA Letter* and plan to begin volunteer luncheons at signature PDA conferences in 2008.

The online volunteer resources serve as an educational tool for all volunteer activities and allow visitors to submit an application electronically. The promotion of these resources has substantially increased membership participation and improved membership communication.

The Volunteer Spotlight in each issue of the *PDA Letter* was created to recognize and reward PDA volunteers. Each issue highlights two volunteers who have substantially contributed to the PDA community.

In 2008 PDA will begin hosting Volunteer Luncheons at the *PDA Annual Meeting* and other signature conferences. These luncheons will educate members on the value of all the career-enhancing opportunities PDA offers. Speakers will include veteran volunteers and staff members who are experts in their respective field.

Increasing Membership Recruitment

In 2007 PDA partnered with Marketing General Incorporated (MGI) to improve membership retention and acquisition efforts. In this capacity, MGI will conduct membership market research, create a unique value proposition, redesign the membership branding and launch four acquisition campaigns in 2008.

2007 Chapter Accomplishments

A Renewed Commitment to PDA Chapters

Building on the success of the Chapter Council Co-Chair positions introduced in 2006, PDA set to work on honoring its renewed commitment to fostering the growth and development of Chapters. Staff members from the Membership Department attended more chapter events in 2007 than ever before. The Board of Directors also confirmed its intention to give full support to the considerable efforts of chapter volunteers around the world who make PDA a global leader in the pharmaceutical industry.

New Chapter Websites

Among the new efforts to build and enrich PDA's global presence through its local chapters was the introduction of new chapter websites. PDA staff worked extensively with Chapter Leaders to develop websites that combined the unique characteristics of each chapter with the overall look and feel of the global PDA brand. One of the new capabilities enabled by these sites is the option to offer online registration for chapter events – a service provided by PDA Headquarters to ease the workload of busy chapter volunteers.

First Student Chapters

In 2007 the New England Chapter was nearing completion of the formation of the first ever student chapter. With an eye toward the future of PDA and the industry, the New England Chapter cultivated a relationship with students and faculty at Middlesex Community College in Massachusetts. This relationship will result in the creation of the first student chapter in early 2008. Several other chapters in the US and Europe also began to explore the possibility of forming student chapters of their own. Working hard towards developing the industry leaders of tomorrow will ensure that PDA remains a vital contributor to the fields of microbiology, biotechnology and pharmaceutics for years to come.

Membership and Chapters

PDA Global Chapters and Leaders

ASIA-PACIFIC

Australia Chapter
President: Anna Corke, *Medical Developments International*
President-elect: Vincent Chung, *CSL*
Treasurer: Greg Jordan, *ICS Analytics*
Secretary: Malcolm Tipping, *Synertec*

Japan Chapter
President: Katsuhide Terada, PhD, *Toho University*
President-elect: Takashi Sonobe, PhD, *University of Shizuoka*
President-elect: Shigeo Kojima, PhD, *Pharmaceuticals and Medical Devices Agency*
Treasurer: Yukio Hiyama, PhD, *National Institute of Health Sciences*
Secretary: Taiichi Mizuta, PhD

Korea Chapter
President: Woo-Hyun Paik, PhD, *Korea Pharm. Tech. Education Center*
Treasurer: Young Kou Jeong, *Pall Korea Life Sciences*

Taiwan Chapter
President: Shin-Yi Hsu, *Otsuka Pharmaceutical Company Ltd.*

EUROPE

Central Europe Chapter
President: Andreas Wenng, PhD, *Chemgineering*

France Chapter
President: Jean Louis Saubion, PhD, *UFCH-BP*
Treasurer: Jean-Luc Clavelin, *Eli Lilly and Company*

Ireland Chapter
President: Frank Hallinan, PhD, *Wyeth*
President-elect: Casey Coleman, *University College Cork*
Treasurer: Joan Fitzgerald, *Allergan*
Secretary: Paul A. Louge, *Elan Corporation*

Israel Chapter
President: Raphael Bar, *BR Consulting*
President-elect: Izar Mordechai, PhD, *Ludan*
Treasurer: Karin Baer, PhD, *Omrix-Biopharmaceuticals LTD*
Secretary: Karen S. Ginsbury, *PCI Pharmaceutical Consulting Israel*

Italy Chapter
President: Stefano Maccio, *CTP Technologie di Processo*
President-elect: Claudia Nardini, PhD, *Kedrion Spa*
Treasurer: Paulo Curto, *D.O.C. S.r.l.*
Secretary: Barbara Sambucco, PhD, *Bristol Myers Squibb*

United Kingdom Chapter
President: Siegfried Schmitt, *PAREXEL Consulting*
Treasurer: John Moys, *Sartorius Stedim Biotech*

NORTH AMERICA

Canada Chapter
President: Patrick Bronsard, *SNC-Lavalin Pharma Inc.*
Treasurer: Vagiha Hussain, *SNC-Lavalin Pharma Inc.*
Secretary: Arun Malaviya, *Bimeda-MTC Animal Health*

Capital Area Chapter
President: Allen Burgenson, *Lonza*
Treasurer: Barry Friedman, PhD, *Cambrex Corporation*
Secretary: Stephen Rochelle, *Rochelle & Associates*

Delaware Valley Chapter
President: Arthur Vellutato, Jr., *Veltek Associates, Inc.*
Treasurer: Marlene Raschiatore, *Wyeth*
Secretary: Stephen S. Trombetta, *Veltek Associates, Inc.*

Metro Chapter
President: Nate Manco, *ECO Animal Health*
President-elect: Naomi Baer, *Millipore Corporation*
Treasurer: Xiaoming Wang, *Imclone Systems Incorporated*
Secretary: Nancy Tomoney, *CSSC, Inc.*

Midwest Chapter
President: Madhu Ahluwalia, *cGxP*
President-elect: Peter Noverini, *Baxter*
Secretary: Matthew Anderson, *Hospira, Inc.*

Mountain States Chapter
President: Sara Hendricks, *Commissioning Agents, Inc.*
President-elect: Robert Buchholz, *Global Quality Alliance, LLC*
Treasurer: Sheri Glaub, PhD, *Glaub Consulting Services*

New England Chapter
President: Louis Zaczkiewicz, *Hyaluron Contract Manufacturing*
President-elect: Gerald Boudreault, *Drug Development Resources, Inc.*
Treasurer: Russell Morrison, *Commissioning Agents, Inc.*
Secretary: Melissa Smith, *MJ Quality Solutions*

Puerto Rico Chapter
President: Manuel Melendez, *Amgen*
President-elect: Evelyn Marchany, *Schering-Plough*
Treasurer: Frederick Fontanez, *GlaxoSmithKline*
Secretary: Gloria Martinez, *Amgen*

Southeast Chapter
President: Patrick Sabourin, *Clarkston Consulting*
President-elect: Michele Creech, *Talecris Biotherapeutics*
Treasurer: Bruce Craven, *BE&K Engineering*
Secretary: Beth Meinig, *Integrated Compliance Consulting*

Southern California Chapter
President: Saeed Tafreshi, *Intelitec Corporation*
President-elect: Kenneth Cairns, II, *Irvine Analytical Laboratories*
Treasurer: Gregory Burnham, *Millipore Corporation*

West Coast Chapter
President: John Ferreira, *Bänziger Systems Inc.*
President-elect: Elizabeth Leininger, PhD, *Stemcells, Inc*
Treasurer: Michael Place, *Bayer*
Secretary: Kristina Nordhoff, *Genentech, Inc.*

PDA Europe

The People

During 2007, **Georg Roessling**'s second year as head of PDA Europe, change, growth and member service were evident everywhere. The year started with a staff of four: Roessling, **James Lyda,** Regulatory Affairs; **Volker Eck, PhD,** Science and Technology; and **Antje Petzholdt,** Administration and Membership. The staff increased during the year with the addition of: **Frederike Graeper,** Event Manager; **Astrid Guenther,** Marketing Manager; and **Katharina Keisers-Engstfeld,** Event Manager – Exhibition.

The Place

In 2007 PDA Europe celebrated its first full year in permanent office space in the Glienicke suburb of Berlin, Germany. The new office is located in a beautiful tree-lined area and has a 'green' orientation. There is ample room for expansion of the staff (which was needed in 2007), with options on additional space for future growth.

The Impact – Regulator Relations

PDA's ongoing tradition of sound science and practical application was continued in 2007 by building positive, constructive relationships with regulators and health authorities. This came primarily in the form of direct commentary/consultation on proposed rules and guidances, and also collaborative activities of benefit to all. Some highlights follow.

European Medicines Agency (EMEA)

A priority of the expanded staff in Europe is to build a business-like and collaborative relationship with the EMEA and its associated working groups. Highlights from 2007 include:

- **PDA/EMEA Joint Conference:** Building on the success of the *2006 PDA/EMEA Joint Conference*, the EMEA approved and participated in planning for the *2008 PDA/EMEA Joint Conference* scheduled for Budapest, Hungary, February 20-21, 2008. **Emer Cooke,** Head of the Inspections Sector, and **David Cockburn** of the staff, have been instrumental in the planning, with Cockburn serving as one of the co-chairs of the conference.
- **Interested Parties Meeting:** PDA was well-represented at the Inspections Sector's Interested Parties Meeting on September 26, 2007, where the latest GMP and inspection issues were discussed in detail. Attending for PDA were **Stephan Roenninger,** *Roche;* **Peter Reichert,** *Novo Nordisk;* **Gabriele Gori,** *Bausch & Lomb;* **Pete Gough,** *David Begg Associates;* **Claudia Nardini,** *Kedrion*; and **Jim Lyda**. A report on the meeting and the briefing on the status of ICH Q10 implementation in Europe was prepared and sent to all PDA members.
- **EMEA/Biologics Working Party.** A PDA delegation was invited to the EMEA / Biologics Working Party (BWP) to discuss the PDA commentary on the draft viral safety guidance for IMPs. The seven-person delegation, including **Rich Levy, PhD,** *PDA;* **Juergen Hubert Blusch,** *Novartis AG;* **Yuling Li,** *Human Genome Sciences, Inc.;* **Barbara Potts,** *Genentech; Inc.;* **Michael Ruffing,** *Boehringer-Ingelheim;* **Valerie M. Stealey,** *GlaxoSmithKline;* and, **Hannelore Willkommen,** *RBS Consulting*, met with the BWP on September 12, 2007 in London.
- **Inspector Training in Quality Risk Management:** A PDA delegation was invited to EMEA on December 17, 2007 to provide industrial perspectives on several issues relating to Quality Risk Management (QRM), including how it should be assessed during inspections, and how it should be implemented in the Inspectorates. The PDA delegation consisted of **Stephan Roenninger,** *Roche;* **Pete Gough,** *David Begg Associates;***Peter Reichert,** *Novo Nordisk;* **Luisa Paulo,** *Hovione;* and **Jim Lyda,** *PDA*. (Note: this activity was co-sponsored by PIC/S, see below.)

PDA Europe

Pharmaceutical Inspection Cooperation Scheme (PIC/S)

It is also a priority for PDA to strengthen our relationship with PIC/S as it grows in influence and definition of global GMP. Following the first ever PIC/S industry forum in November 2006, PDA pursued a collaborative path with PIC/S during 2007:

- Following the forum, PDA wrote a series of reports for the membership on the importance of PIC/S and the upcoming FDA membership.
- Inspector Training in QRM: PDA met with PIC/S several times in 2007 to discuss collaborative activities regarding inspector training. In December PDA met with inspectors at EMEA to discuss this issue (See EMEA note above). Going into 2008 PDA will be conducting a workshop with PIC/S on QRM associated with sterile products.

Regulatory Commentary/Consultation for 2007

- **EU GMP Guide, Chapter 1 – Quality Management.** Adds reference to quality risk management (QRM) principles. Release for consultation January 2007, comments by PDA April 30, 2007.
- **Content of the Batch Release certificate referred to in Art. 13.3 of Directive 2001/20/EC**. Released for consultation May 2007, Comments due August 31, 2007.
- ***Guideline on Virus Safety Evaluation of Biotechnological IMPs.*** Original PDA comments submitted December 28, 2006, resulting in an invitation to PDA from the EMEA Biologics Working Party (BWP) for scientific discussions which were held on September 12, 2007.
- **EMEA Reflection Paper…minor deviations from… Marketing Authorisation ("QP Discretion").** Reflection Paper published March 10, 2006. EMEA requested industry feedback on the paper with results discussed with on September 26, 2007.
- ***EMEA: Draft Guideline on Production & QC of Monoclonal Antibodies & Related Substances.*** Released for consultation May 24, 2007, comments submitted November 30, 2007.
- **Note for Guidance on Pharmaceutical Quality System (ICH Q10).** Step 5 adoption of the ICH harmonized guidance. Released for consultation May 2007, comments submitted November 27, 2007.

Science and Technology Highlights

Where science and technology become the driving force, PDA Europe helped illuminate two key issues the industry faces. First, continuous improvement is becoming a question of prosper or perish for many companies. Recently improvement is being facilitated by new regulations as well. The latest draft of ICH Q10 is a reflection of this fact. Second, the increasing complexity and vulnerability of the supply chain has become an increasing risk to drug manufacturers. Negligence in managing this important aspect of pharmaceutical manufacturing will have a harmful cost. PDA is proud of being once again in the forefront of sharing best practices and solutions with industry and regulators in these two areas.

Task Forces, Working Groups, Informal Meetings

Being a member driven organization, PDA draws its reputation from the input of volunteer experts who share their knowledge. In Europe, several groups have been formed in the course of 2007 to address issues important to pharmaceutical professionals including:

- March 2007, Informal Meeting on Draft Annex 1, EU-GMP Guide, Verona, Italy
- October 2007, Informal Meeting on Rapid Microbiology Methods, Rome, Italy
- December 2007, formation of a Working Group on Endotoxin, Paris, France

PDA has also continued partnership with other organizations with a common interest. A good example was the meeting preceding the Pharmintech Fair, June 2007, Bologna, Italy, on the subject of Innovation in Pharmaceutical Manufacturing, jointly organized by the PDA Italy Chapter and the ISPE Italy affiliate.

Workshops and Conferences

PDA Europe organized a number of successful technical conferences in 2007. See the Programs and Meetings section for a complete listing.

Honor Awards

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.

Bengt Ljungqvist, PhD is a Professor and Department Head at The Royal Institute of Technology. Ljungqvist received his PhD in 1978 and has been a Professor of Safety Ventilation since 1986. He has worked in the field of safety ventilation, both as a scientist and as a consultant, and is frequently contracted by pharmaceutical companies, hospitals, laboratories and others to solve problems within the field.

Berit Reinmuller, PhD is a Senior Researcher at The Royal Institute of Technology. Reinmuller received her PhD in 2001 and has spent 30 years in the pharmaceutical manufacturing field specializing in the areas of contamination control, environmental monitoring, validation and microbiological risk assessment. She also consults in the cleanroom industry.

Ljungqvist and Reinmuller have been members and committed supporters of PDA for over 20 years. They have jointly published three books on cleanroom technology with PDA and have prepared numerous articles for the *PDA Journal of Science and Technology*. Together they have promoted PDA in Europe for many years and have assisted PDA in developing strong membership in that region. Ljungqvist and Reinmuller continue to support PDA with their time and energy, and most recently as co-chairs of the very successful *PDA/R³ Nordic Conference on Modern Aseptic Production* outside Stockholm in November 2007.

Frederick J. Carleton Award

Presented as a tribute to lifetime contributor, past President, past Executive Director and Honorary Member Frederick J. Carleton, this award is designated for a past or present Board member whose services on the Board are determined by his/her peers as worthy of such recognition.

Jennie Allewell is Director II, Global Regulatory Affairs at Wyeth Research and has been a long-time supporter of PDA. She has served on the PDA Board both as Secretary for two terms and as a Director for three terms. Allewell has also chaired the Awards Committee since 2003, as well as co-chaired two Asia Pacific congresses, recruiting new members and volunteers and creating opportunities for PDA to collaborate with our Asian colleagues.

In addition, Allewell has chaired several task forces to develop PDA comments on draft FDA guidances, made presentations at PDA conferences in the US and in Europe and participated on various program committees. Her dedication, tireless efforts and countless accomplishments as a volunteer have contributed to PDA and its membership.

Nikki Mehringer is the Director of Quality for Global Patient Safety at Eli Lilly & Co. She has been a long time supporter of PDA, first as a member and then in a number of key leadership roles. Mehringer has served on the Board of Directors as Treasurer and Chair. While Chair, she effectively led the organization though a difficult and critical period. Her steady leadership style, warm personality and accomplished listening skills are highly regarded and well respected by Board members, members and staff.

Distinguished Service Award

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

Rafik Bishara, PhD is a retired Director of Quality Knowledge Management and Technical Support at Eli Lilly & Co. He has been a long time PDA member who has championed PDA's efforts in drug product stability and thermal management. Bishara chaired the Task Force that developed *PDA Technical Report No. 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products*. He has represented PDA in Cold Chain harmonization discussions with the Cold Chain Committee and the Pharmaceutical Logistics Forum, and has consistently promoted PDA's expertise and TR-39 at industry meetings. He is currently the Chair of the PDA Pharmaceutical Cold Chain Interest Group and has participated in countless task forces, interest groups and committees.

Yoshiaki Hara is Director of Marketing at Sartorius Stedim Biotech. Hara-san is an ambassador between PDA headquarters and the PDA Japan chapter. He actively participates in the planning of Japanese PDA conferences and has been on several planning committees. Hara-san frequently accompanies groups of Japanese colleagues from the Japan pharmaceutical industry to the US for PDA meetings and is also involved with training the Japan Health Authorities.

Vince Mathews is a Quality Assurance Consultant (QA for Global Development Operations) at Eli Lilly & Co. He has been active in PDA for many years where his invaluable contributions include Interest Group founder and Leader for Clinical Trial Materials, member of the *PDA/FDA Joint Regulatory Conference* Planning Committee (2006-2008), Co-Leader for the Joint PDA/ISPE Task Team addressing approaches for complying with the EU requirement for expiry dates on clinical trial materials and Co-Leader for the PDA task team addressing cGMPs by Phase for the Manufacture of Biotechnology Drugs.

Sue Schniepp is a Consultant for Schniepp and Associates, LLC. She is a long-term member and supporter of many PDA areas which required volunteer input including presenting at a number of PDA meetings and participating on several Committees including chairing the very successful *2007 PDA/FDA Joint Regulatory Conference* Planning Committee. Schniepp is a member of the Program Advisory Board and the Membership Committee, and is a book author for PDA, where she received the distinguished author award in 2006.

Honor Awards

James P. Agalloco Award

The James P. Agalloco Award is presented annually to the PDA faculty member who exemplifies outstanding performance in education. The selection is based on student and faculty evaluations and is named for James P. Agalloco in honor of his work in developing the PDA education program.

Jeanne Moldenhauer, PhD is Vice President of Excellent Pharma Consulting. She is a PDA TRI faculty member, an Interest Group Leader for Microbiology and Environmental Monitoring at PDA, Chair of the Rapid Microbiology User's Group and a member of the Scientific Advisory Board. Moldenhauer is a published author, editor and the winner of the 2005 Distinguished Editor/Author Award.

Frederick D. Simon Award

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

Yves Mayeresse, Cyrille Nomine, Philippe Sibille and **Romain Veillon**
Freeze-Drying Process Monitoring using a Cold Plasma Ionization Device, Vol. 61, No. 3, May/June 2007

Yves Mayeresse is a Senior Freeze-Drying Manager Head at GlaxoSmithKline Biologicals. Mayeresse has more than fifteen years of experience in the pharmaceutical sector and has managed activities such as parenterals production, set-up of new freeze-drying facilities, design of freeze-drying cycle and development of new stabilizers for freeze-dried products.

Cyrille Nomine is a Research and Development Engineer at Adixen Vacuum Technology. Nomine has experience working on advanced solutions in the instrumentation and vacuum field and is currently project manager for Adixen's plasma sensors.

Philippe Sibille is a Key Account Manager at Adixen Vacuum Technology. Educated as an engineer for the nuclear industry, Sibille moved into a marketing position in 1978 and is currently focused on high tech applications such as thin film coatings, new materials research and freeze drying processes.

Romain Veillon is a Freeze-Drying Scientist at GlaxoSmithKline Biologicals. Veillon is an industrial pharmacist specializing in microbiology. He is currently focused on new vaccine industrialization, performing process development, evaluation and validation.

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, for their long-term acts or contributions that are of noteworthy or special importance to PDA.

Richard Johnson is an industry consultant. He is a very active member of PDA and has been a key contributor and keen volunteer over many years. Johnson consistently dedicates time and efforts towards PDA, and never shies away from tasks and programs which require support, even when his work schedule is full. He has been, and continues to be a role model for new members and volunteers.

Korczynski Award

This grant recognizes the contributions made toward the development of PDA's international activities by Michael S. Korczynski, PhD.

Hannelore Willkommen, PhD is a Consultant for Regulatory Affairs & Biological Safety of Biopharmaceuticals at RBS Consulting. She leads the PDA Biotech Interest Group in Europe. Willkommen has been involved in numerous PDA Europe activities and has successfully motivated others to become involved with PDA.

Distinguished Editor/Author Award

This award is presented annually for the best editor/author of PDA-DHI co-published books as selected by PDA members.

Stephan O. Krause, PhD
Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies

Stephan O. Krause, PhD is Director, Quality Control at Favrille, Inc. In addition to authoring PDA/DHI publications, Krause is an active PDA conference presenter and is the PDA Task Force Team Leader for Analytical Method Validation for Commercial Biopharmaceutical Products.

Scott Sutton, PhD
Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics

Scott Sutton, PhD is Senior Director, Microbiology Services at Vectech. Sutton is an active author and speaker for PDA. He is also the current President of the Pharmaceutical Microbiology Forum at PDA. In addition to his volunteer efforts at PDA, Sutton has been involved with the USP Analytical Microbiology Committee of Experts since 1993.

President's Award

This award recognizes a PDA staff member, other than Senior Staff, whose exemplary performance has contributed to PDA's success during the previous year.

Patresa Day is Assistant Manager of Registration and Customer Accounts. Day received this award for her dedicated performance in helping the Programs and Registration Services Department streamline and improve registration.

James Wamsley is Senior Manager, Laboratory Education at PDA's Training and Research Institute. Wamsley received this award for his key role as Project Lead in the redesign and relocation of the new Training and Research Institute facility in Bethesda, Md.

2008 PDA Officers and Board of Directors

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John Shabushnig, PhD
Pfizer Inc

Chair-elect
Maik Jornitz
Sartorius Stedim Biotech

Secretary
Rebecca Devine, PhD
Regulatory Consultant

Treasurer
Anders Vinther, PhD
Genentech, Inc.

Immediate Past Chair
Vincent Anicetti
Genentech, Inc.

Directors

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Valsource LLC

Véronique Davoust, PhD
Pfizer Inc

Lothar Hartmann, PhD
F. Hoffmann – La Roche

Yoshihito Hashimoto
Chiyoda Corp

Louise Johnson
Aptuit

Stefan Köhler
AstraZeneca

Steven Mendivil
Amgen

Michael Sadowski
Baxter Healthcare Corp.

Amy Scott-Billman
GlaxoSmithKline

Gail Sofer
GE Healthcare

Laura Thoma, PharmD
University of Tennessee College of Pharmacy

Martin Van Trieste
Amgen

2008 PDA Staff

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Tracie Hopkins, Executive Assistant

Regulatory Affairs Department

Richard Levy, PhD, Senior Vice President, Scientific and Regulatory Affairs

Robert Dana, Vice President, Quality and Regulatory Affairs

Iris Rice, Coordinator, Scientific and Regulatory Affairs

Office of Science and Technology

Richard Levy, PhD, Senior Vice President, Scientific and Regulatory Affairs

Emily Hough, Writer/Editor

Walter Morris, III, Director of Publications

Iris Rice, Coordinator, Scientific and Regulatory Affairs

James A. Spangle, Publication Design Specialist

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Janny Chua, Manager, Product Operations

LaShawn Debnam, Coordinator, Publications

Hassana Howe, Assistant Manager, Membership Services and Chapters

Ta-Méla Jeffries, Coordinator, Membership Services and Chapters

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PDA Training and Research Institute

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Rachel Davis, Laboratory Education Coordinator

Stephanie Ko, Manager, Lecture Education

James Wamsley, Senior Manager, Laboratory Education

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Tim Morris, Assistant Manager

Julia Onder, Assistant Manager

Carrie Weaver, Assistant Manager

Programs and Registration Services

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Tristan Alexander, Meetings Manager

Jason E. Brown, Programs Manager

Patresa Day, Assistant Manager of Registration and Customer Accounts

Meaghan Dowd, Senior Programs Coordinator

Leslie Edmonds, Programs and Meetings Coordinator

Leslie Meritt, Programs Coordinator

Paula Pagano, Senior Manager

Andrea Viera, Senior Registration and Customer Accounts Specialist

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Feng Chen, Senior Manager, Information Systems

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Gareth Harrison, Controller

Shanna Morgan, Accounts Receivable Specialist

Julie Queen, Accounts Payable Analyst

Europe

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Volker Eck, PhD, Senior Director, Science and Technology

Frederike Graeper, Event Manager

Astrid Guenther, Marketing Manager

Katharina Keisers-Engstfeld, Event Manager – Exhibition

Jim Lyda, Senior Director, Regulatory Affairs

Antje Petzholdt, Assistant, Administration and Membership

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