Science • Technology • Quality • Regulatory • Community

PDA Letter

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2005 PDA Annual Meeting: Bringing the Community Together

2005 has started out as a challenging year for the pharmaceutical and biopharmaceutical industry. Recent events have brought scrutiny to products and reduced profits, but they have also demonstrated a need for industry, regulators and academia to pull together and find solutions for the issues facing us.

This can only be achieved through coming together, sharing ideas and learning experiences, our visions and goals to achieve and improve how we work together to gain a better understanding of our processes, products and their contribution to the betterment of public health care and our quality of life.

The 2005 PDA Annual Meeting in Chicago, Ill., April 4-8, is an ideal opportunity to learn new concepts, hone new skills and network with peers and regulators to jump start this process. This is not a time to go to ground; this is a time for action.

Michael Miller, PhD
Eli Lilly and Company

The 2005 PDA Annual Meeting features 20 new case studies, four FDA updates and two exceptional keynote speakers. **Jeffrey Macher,** PhD, Georgetown University, will talk about the new extended FDA study on risk-based inspection while introducing the results of the industry survey on best practices. **Ajaz Hussain,** PhD, CDER, FDA, will provide the latest on PAT and FDA's "Desired State" for industry. The meeting also includes 10 new PDA Training and Research Institute lecture courses for *Career-long Learning*™. Additionally, the sold-out exhibition will feature leading-edge exhibitors offering you the latest in scientific technology to improve your regulatory compliance and manufacturing environment.

As program chairman for 2005, I am pleased to have the opportunity to invite you to join your colleagues in Chicago for this not-to-miss event; meet and share your challenges, ideas, goals and opportunities. Only by leveraging our experience and combined knowledge of science, technology and regulation can we lead the way forward to ensuring a better, more effective and scientifically sound solution for the future. This event is guaranteed to help ensure your success.

More on the 2005 PDA Annual Meeting, page 14

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Neal G. Koller
PDA President

President's Message

PDA Offers A Variety of Ways to Volunteer and Participate

All that PDA does —technical reports and books, science-based regulatory comments, training courses and conferences—are the direct result of the hard work and dedication of our professional members.

PDA exists to provide its members with the avenues they need to *Advance pharmaceutical and biopharmaceutical science and technology internationally by promoting scientifically sound and practical technical information and education for industry and regulatory agencies.*

In the latter months of 2004, the PDA Board of Directors established four new PDA Advisory Boards, expanding the opportunities for member involvement and input into our processes. These Advisory Boards will operate in four critical areas of PDA activity: biopharmaceuticals, programs and conferences, the Training and Research Institute, and Europe. Each of these Advisory Boards will play a major role in developing new tools for our community.

Creation of a Biopharmaceuticals Advisory Board (BioAB) was an important step for PDA in solidifying our commitment to the growing biopharmaceutical segment of our community. The BioAB will help us establish a strategic perspective and provide oversight for our scientific, technical and regulatory activities in the biopharmaceutical area. **Gail Sofer,** Director, Regulatory Compliance, GE Healthcare, and **John Geigert,** PhD, President, Biopharmaceutical Quality Solutions, are the co-chairs of this 12-volunteer group. Congratulations to all those named to this important Advisory Board.

The Program Advisory Board (PAB) and the Training and Research Institute Advisory Board (TRIAB) also will help us fulfill our Mission by providing expert input into our conferences and training courses, enhancing their value to our community. The PAB will focus, in particular, on conference purpose, theme and topic selection, as well as communicating and coordinating with other PDA committees, advisory boards and activities. The TRIAB will provide expert input to guide TRI in providing high value and cutting-edge educational laboratory and lecture courses.

Europe is an important region for the PDA community. PDA activity there has been on the increase in recent years. The Europe Advisory Board will keep PDA tuned into the regulatory, *Career-long Learning*™ and

science and technology needs of our European professionals and further assure European issues are defined and articulated to the PDA global community.

Right now, PDA is looking for volunteers to provide input into the *PDA Letter*. A call for volunteers for the *PDA Letter* Editorial Committee (PLEC) appears on page 8 of this issue and on the PDA Web site (www.pda.org/volunteer). The PLEC will help PDA ensure that the newsletter contains articles and information that are relevant to our growing community.

Of course, the best way for PDA members to get involved, influence and improve professional success is to participate on a PDA Science Advisory Board (SAB) Task Force to write a Technical Report or a PDA Regulatory Affairs and Quality Committee (RAQC) Task Force to draft comments on regulatory policy. Announcements for specific Task Force openings appear in the *PDA Letter* and on the volunteer page of the PDA Web site (www.pda.org/volunteer). Also, members are encouraged to join this list of expert volunteers for PDA participation—used by PDA to assemble experts for specific volunteer opportunities. To sign up, go to the volunteer page of the Web site.

On behalf of PDA, I want to thank all the members who volunteered in 2004. For those who want to get involved, keep an eye out for future opportunities to participate and steer PDA's ever evolving course. PDA is a great place to make a personal impact on our careers, our companies, our industries and our communities.

Volunteer Opportunity: *PDA Letter* Editorial Committee

PDA is looking for member volunteers to serve on the new Editorial Committee for the *PDA Letter*. As PDA's primary publication on science, technology, quality, regulatory and our community, the *PDA Letter* requires member input to remain focused on and relevant to their evolving needs.

The *PDA Letter* Editorial Committee (PLEC) will meet periodically each year via teleconference, and at the PDA Annual Meeting and the PDA/FDA Joint Regulatory Conference. The PLEC will work to develop a 10-month editorial calendar of topics, comment on potential interview and feature story subjects and help PDA staff solicit articles from the membership.

The inaugural PLEC meeting will take place at the PDA Annual Meeting in Chicago, April 4-8, 2005.

If you would like to volunteer, please forward a brief summary of your professional experience and your contact information to PDA Senior Editor Walter Morris at +1 (301) 656-5900, ext. 148 or morris@pda.org by March 15.

PDA is always looking for volunteers to populate our Science Advisory Board (SAB) and Regulatory Affairs and Quality Committee (RAQC) Task Forces, Advisory Boards, etc. We encourage you to register if you are interested in working on future PDA Technical Reports, PDA comments to a regulatory guidance or policy, joining an Advisory Board, helping at a PDA conference or training course, or participating in other PDA volunteer opportunities. Just contact PDA VP of Quality and Regulatory Victoria Dedrick (dedrick@pda.org) and/or VP of Science and Technology George Robertson (robertson@pda.org).

PDA's Strategic Planning Committee: Making a Difference

Lance Hoboy, PDA

In October 2003, the PDA Board of Directors assigned a new team of volunteers to the Strategic Planning Committee, led by PDA Chair Nikki Mehringer (Eli Lilly). This reorganized committee was charged with reviewing PDA's existing Strategic Plan to ensure that its goals and objectives remain consistent with the needs of the association's members.

One of the first projects of the committee was to conduct a thorough environmental assessment that included comprehensive issue development interviews, focus groups and quantitative survey, in which many of you participated. Though a formal restatement of the PDA Strategic Plan is not anticipated until sometime later this year, the efforts of the committee have already resulted in a number of new initiatives and activities:

1. The establishment of the new PDA Student Programs including the Annual Graduate Research Symposium, the Pre-Doctoral Fellowship Program and the Student Poster Sessions
2. Formation of additional committees
3. The engagement of regional editors for the PDA Journal
4. Implementation of Learning Maps at specific conferences.

Special thanks goes to PDA members **Bob Dana, Georg Roessling, Bob Myers, Floyd Benjamin, Nikki Mehringer, Rich Levy, Stephanie Gray, John Shabushnig, John Elvig, Ed Fry, Jerold Martin, Zena Kaufman, Lee Kirsch, Doris Conrad, Ted Meltzer, Louise Henry, Becky Devine, Laura Thoma, Terri Polson, Kathleen Greene, Michael Miller, Maik Jornitz, and Jim Fernandez,** who, with the assistance of Neal Koller, President, Vicki Dedrick, VP Science & Technology, and myself, all made significant contributions to this effort.

George A. Robertson
Vice President, Science and Technology

Vice President's Message

PDA Technical Reports On The Move

As we begin 2005, I am pleased to announce that three Technical Reports will be out to the membership in the near future, thanks to the hard work of highly dedicated and knowledgeable Science Advisory Board Task Forces.

The first report, *Sterilizing Filtration of Gasses,* is due to be included with the January/February issue of the *PDA Journal of Pharmaceutical Science and Technology*. The objective of the report is to assist the reader in the selection, qualification and validation of a filter that is appropriate for the application on hand. In this report, sterilizing filtration of a process gas stream is defined as the complete removal of all microbiological contaminants, excluding viruses. Under certain circumstances, other contaminants such as viruses and plasmids can also be removed by filtration. Thus, in the pharmaceutical industry, particularly in the production of parenterals, there is a wide range of processes for which sterilizing filtration of air or other process gases is appropriate and applicable. The report emphasizes that early and careful screening of potential filter types and configurations can result in fewer technical and regulatory problems, fewer delays, more efficient processing and greater sterility assurance. Although other types of filters can be employed in the control of particulate matter and removal of liquid droplets by coalescence, the focus of this Technical Report is limited to hydrophobic membrane filter elements. While most gas applications use hydrophobic filters, this does not preclude the use of hydrophilic filters in dry gas systems. For further information on the use of hydrophilic filters, refer to PDA Technical Report #26, *Sterilization Filtration of Liquids.*

The second is a revision of PDA Technical Report #28, *Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals*, that provides guidance relative to the validation of aseptic processing activities associated with the production of sterile bulk pharmaceutical chemicals. The preparation of sterile materials in the quantity and scale used in the manufacture of bulk pharmaceutical chemicals generally requires equipment and procedures quite different from those used in the manufacture of finished pharmaceuticals. The uniqueness of the production methods for sterile bulks precludes the direct extrapolation of the process simulation approaches employed for aseptically produced sterile formulations. The report draws upon the concepts and principles developed in PDA's and PhRMA's prior publications on aseptic processing technology. This effort expands upon those documents to provide assistance for individuals and firms producing sterile bulk pharmaceutical chemicals. The goal in this revision was to update the document to reflect six years of industry experience with it, as well as to acknowledge the acceptance criteria limitations that were present in the first edition. The revision also endeavored to address some of the issues raised by FDA in their review of the earlier edition.

Our final report, *Virus Filtration*, addresses virus removal filters that retain viruses by a size exclusion mechanism. It explains how they work, their selection, characterization, testing, and validation. This report is especially timely as biotechnological and biological therapeutic products are often manufactured using materials of animal or human origin including cultured primary or transformed cells; milk or other components from transgenic animals; natural extracts and human or animal blood plasma components. These products are usually proteins that are manufactured by complex manufacturing processes.
Although approved recombinant biotherapeutics have an excellent safety record, the risk of contamination by known or unknown pathogens exists. Virus filtration is performed as part of a manufacturer's overall virus safety strategy. In this context, virus filtration (size-based removal) is a complement to virus inactivation, both of which contribute to virus clearance. Implementation of virus clearance complements additional measures such as control over raw materials and testing of cell culture or plasma feedstocks. Collectively, these measures form the framework of a virus safety strategy.

I think we can all appreciate the breadth of knowledge and dedication that comprises the membership of PDA. I hope you take the time to review these documents when they arrive with the Journal.

Recent Sci-Tech Discussions

The following, unedited remarks are taken from the Pharmaceutical Sci-Tech Discussion Group, a PDA-sponsored Online Forum at www.pda.org. PDA Online Forums are free of charge and open to the public. They serve as a platform for exchanging practical and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. If you are not currently a member of a discussion group, we encourage you to visit our Web site and join: www.pharmweb.net/pwmirror/pwq/pharmwebq2.html.

Sampling of Incoming Chemical Raw Materials

Please advise as to current practice for OSD for sampling of incoming chemical RM.

Is statistical sampling of containers still OK? Or have the requirements evolved so that we must actually ID every single package of chemical (FTIR)?

Are the requirements the same for active and excipient materials?

Respondent 1

As far as sampling of Incoming R.M is concerned we can follow Identification test for each container and complete testing as per the formula Square root N+1.

The requirements are same for active and excipient materials.

Respondent 2

You could perform retrospective validation on your previous incoming raw material. You have to proof that your certain supplier for a certain raw material is reliable for time to time delivery. Then you could use the result as supportive data for not to do sampling for each container incoming raw material.

Respondent 3

EU guidance requires that there should be appropriate procedures to assure the identity of the contents of each container of starting material. This can be interpreted as single container ID. I would advise it for actives and for key excipients were mix ups have been known to happen with catastrophic consequences for the end users e.g. diethylene glycol mislabelled as propylene glycol or glycerin.

Respondent 4

The international standard body ISO 3951:1989 for inspection by variables is appropriate to use for a batch of a non-discrete materials like an APIs.

Respondent 5

The ANSI Z1.4 is indeed valid ONLY for the sampling of discrete populations of units. After one determines the number of sampled units (n) based on the total number of units (N) packed in Z boxes according to the ANSI Z1.4, one may randomly collect the n units from a selected number of these boxes if he does not want to open all boxes for whatever justifiable reason. This number of boxes can be a fixed percentage (e.g. 10%) of Z boxes or alternatively from Square root of Z +1 boxes. While doing this, each randomly picked box is sampled with an equal number of units.

The total number of units sampled from the whole lot is still based on statistical principles as set in the ANSI Z1.4. The application of Square root Z +1 is here suggested as an example of following a simple practical index to minimize the number of boxes actually sampled when one does not want to open all boxes. If one wishes to partition the whole lot into, for instance, 3 sublots based on some logic that establishes a better representative sampling (bottom, middle and upper; or beginning, middle and end), he may apply the Square root Z+1 on each sublot: i.e. n/3 is sampled from Square root Z'+1 boxes out of all Z' boxes in the sublot.

Examples of sampling from limited boxes or packages could be: testing for physical dimensions of sterile vials packed in trays of 100 units per tray and only Square root Z+1 of the trays will be opened for sampling and exposed to a non-sterile environment.

Respondent 6

I have not read the original question but from the replies given, the following ASTM standard may be appropriate.

ASTM 300-03 Standard Practice for Sampling Industrial Chemicals. It addresses liquids, solids, slurries, bulk materials and packages.

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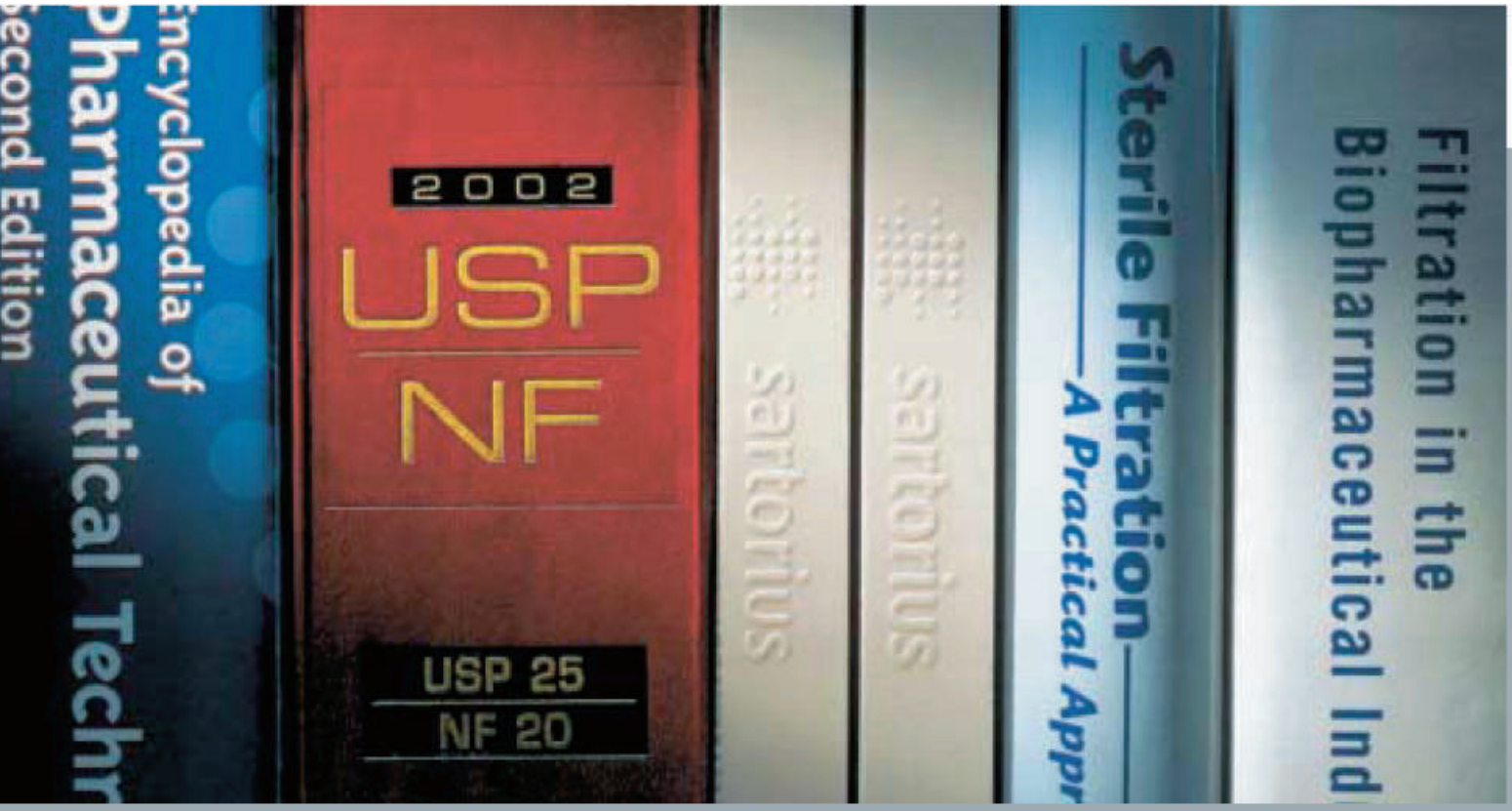

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PDA Interest Groups & Leaders

The following is a list of PDA Interest Groups (IGs). The list below includes the IG's name and contact information for each IG's leader, including the leader's affiliation and his or her e-mail address. More detailed information on PDA's Interest Groups and contact information is available on the PDA Web site at: www.pda.org/science/IGs.html.

Aseptic Processing

Richard Johnson
Abbott Laboratories
E-mail: richard.m.johnson@abbott.com

Biotechnology

Frank Matarrese
GxP Consulting
E-mail: Frank_matarrese@alamedanet.net

• European Branch

Roland Günther
Novartis
E-mail:
roland.guenther@pharma.novartis.com

Computer Systems

Barbara L. Meserve
Acculogix, Inc.
E-mail: bmeserve@acculogix-usa.com

Drug–Device Delivery Systems

Raymond A. Pritchard
Consultant
E-mail: raypri@comcast.net

• European Branch

Alexander Schlicker, PhD
Hoffmann La Roche Ltd
E-mail:Alexandra.schlicker@roche.com

Georgios Imanidis, PhD
Pharmaceutical Technology
E-mail: georgios.imanidis@unibas.ch

Filtration

Jack Cole
Jack Cole Associates
E-mail: jvcole@aol.com

• European Branch

Roger Seiler
Sartorius
E-mail:roger.seiler@sartorius.ch

Inspection Trends/Regulatory Affairs

Robert L. Dana
Elkhorn Associates Inc.
E-mail: elkhornassoc1@aol.com

Isolation Technology

TBD

Lyophilization

Edward H. Trappler
Lyophilization Techology
E-mail: etrappler@lyo-t.com

Microbiology/Environmental Monitoring

Jeanne E. Moldenhauer, PhD
Vectech Pharma. Consulting
E-mail:
jeannemoldenhauer@yahoo.com

Nanotechnology

D. F. Chowdhury
Aphton Corporation
E-mail: fazc@aol.com

Ophthalmics

Chris Danford
Alcon Laboratories Inc.
E-mail: chris.danford@alconlabs.com

Packaging Science

Edward J. Smith, PhD
Wyeth Pharmaceuticals
E-mail: smithej@wyeth.com

Pharmaceutical Water

Theodore H. Meltzer, PhD
Capitola Consulting Co.
E-mail: theodorehmeltzer@hotmail.com

Production and Engineering

Frank Bing
Consultant
E-mail: frankbingjr@aol.com

• European Branch

Philippe Gomez
Sartorius SA
E-mail: philippe.gomez@sartorius.com

Quality Assurance/ Quality Control

Don E. Elinski
Eli Lilly & Company
E-mail: elinski@aol.com

Stability

Rafik H. Bishara, PhD
Eli Lilly & Company
E-mail: rhb@lilly.com

Technology Transfer

Volker Eck, PhD
Nerviano Medical Science S.r.l.
E-mail: volker.eck@nervianoms.com

Zdenka Mrvova
Zentiva
E-mail: mrvova@leciva.cz

Training

Thomas W. Wilkin, EdD
University of New York
E-mail: twilkin@citytech.cuny.edu

Vaccines

Frank S. Kohn, PhD
FSK Associate
E-mail: fsk@lowatelecom.net

Validation

Bohdan M. Ferenc
Qualification Services
E-mail: biferenc@aol.com

Visual Inspection of Parenterals

John G. Shabushnig, PhD
Pfizer Inc.
E-mail: john.g.shabushnig@pfizer.com

• European Branch

Markus Lankers, PhD
APSYS GmbH
E-mail: markus.lankers@apsys.de

2005 PDA Annual Meeting

Pharmaceutical Manufacturing Science in the 21st Century: *Integration of Science, Technology and Regulation*

This year, PDA's Annual Meeting has been organized into three specialized learning tracks that, together, address *Pharmaceutical Manufacturing Science in the 21st Century: Integration of Science, Technology and Regulation.* The tracks cover quality and regulatory issues, manufacturing science – research and development, and manufacturing science – engineering.

Special focus was placed on ensuring that each track offered distinctive presentations, avoiding overlap and helping participants maximize the quality of their experience. Combined with PDA's new low price of US$ 895, the 2005 PDA Annual Meeting is truly a remarkable value.

The discussion of science, technology and regulation kicks off with **keynote speaker Jeffrey Macher,** PhD, Georgetown University, who will present publicly for the first time the preliminary results of his two-tiered Pharmaceutical Manufacturing Research Project. Macher launched the project in 2001 with his colleague, Jackson Nickerson, PhD, Washington University in St. Louis. Macher's keynote address provides an initial look at their results, which are expected to help the pharmaceutical industry in the same way they helped the semiconductor business.

The first tier of the study examines the model used by FDA to inspect pharmaceutical manufacturers. FDA has collaborated with the researchers as part of its strategic initiative to modernize the regulation of pharmaceutical manufacturing and product quality. The goals of the FDA inspection portion of the study are to: develop a risk based assessment of GMP outcomes (try to understand why and when FDA sees various outcomes); identify those attributes that are correlated with those inspection outcomes; and implement solutions at FDA.

The other tier of the Macher-Nickerson study explores unrealized efficiencies in pharmaceutical manufacturing. The researchers report strong participation from the industry. The manufacturing study aims to identify the managerial, organizational and technical practices that underlie good and poor manufacturing and regulatory performance, and then provide a confidential score card to specific manufacturing facilities on how they perform against other, anonymous manufacturers. Through this exercise, a standard set of benchmarks for measuring manufacturing and regulatory performance can be created.

Following Macher's keynote address, the opening plenary session continues with three timely presentations on the industry and regulatory "Move to Risk-Based Quality Systems."

Industry consultant **Michael Van Der Werf** will discuss FDA's draft guidance, *Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations,* released in September 2004. Van Der Werf co-chaired the PDA Regulatory Affairs and Quality Committee (RAQC) Task Force that authored comments on this important FDA guidance (see the *PDA Letter,* January 2005, p. 22). This presentation will help the community identify specific changes to the roles and responsibilities of management and customers.

FDA's White Paper on the new risk-based inspection criteria will be discussed next by **Marie Breen,** Senior Compliance Manager, Schering-Plough. Breen chaired the PDA RAQC Task Force that authored comments on this document.

The session concludes with a discussion of FDA's White Paper: *Defining the Customer in a Regulatory Agency,* by **Cindy Rockel,** Regulatory Affairs, Millipore Corporation. Rockel chaired the PDA RAQC Task Force that authored PDA's comments on this document.

The closing plenary sessions of the 2005 PDA Annual Meeting features FDA's **Ajaz Hussain,** PhD, CDER Office of Pharmaceutical Science, who will provide an up-to-date report on the status of FDA's Process Analytical Technology initiative and the latest developments in industry. Already, a number of firms have moved forward with the on-/at-/near-line sensor technologies and have experienced significant gains in efficiency and cost reductions.

In between the opening and closing plenary sessions, the 2005 PDA Annual Meeting offers three specialized learning tracks on quality and regulatory, manufacturing science – research and development, and manufacturing science – engineering.

PDA is proud to introduce the **PDA Annual Graduate Research Symposium.** This session features three top fellows speaking on their original research in the area of pharmaceutical science. Also, PDA will introduce three new **PDA Technical Reports** at the this year's annual meeting. Please see PDA Science and Technology VP George Robertson's message in this issue of the *PDA Letter* for more information (page 10).

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NEW! — **Overview of Risk Assessment and Risk Management**

UPDATED! — **Basic Concepts of Cleaning and Cleaning Validation**

UPDATED! — **GMP Quality Auditing for the Pharmaceutical Industry**

2005 PDA Annual Meeting Exhibitor List

COMPANY	BOOTH
Accugenix	303
AES-Chemunex, Inc.	718
Amadeus International, Inc.	202
American Plastics Technologies	300
American Stelmi	615
Applied Biosystems	318
Aramark Cleanroom Services	301
Associates of Cape Cod	712
ATS Automation	310
Benchmark Products	307
Biolog	904
bioMerieux	413, 415, 514, 516
Biopharm International	200
BioProcess International	316
Bioscience International	515
Biotest Diagnostics	700
BOC Edwards Pharm. Systems	614
Cardinal Health	205
Carlisle Life Sciences	809
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Dupont Qualicon	814
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EMD Chemicals, Inc.	910
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Ellab, Inc.	906
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HunterLab	908
Hyaluron, Inc.	410
ITW Texwipe	501
Lancaster Laboratories	601
Lighthouse Instruments	510
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Pharmaceutical Technology	102
PharmaSys, Inc.	401
Phoenix Imaging	312
Pilgrim Software, Inc.	414
PML Microbiologicals	710
Precision Pharma Services, Inc.	313
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2005 PDA ANNUAL MEETING At a Glance

3 Specialized Learning Tracks:

— Quality & Regulatory

— Manufacturing Science/ Research & Development

— Manufacturing Science/ Engineering

20 New Case Studies

FDA Updates, including:

— Rapid Methods

— Viral Filtration

— Combination Products

— PAT

New PDA Annual Graduate Research Symposium

Over 40 Health Authority and Expert Industry Speakers

Enhanced Networking Opportunities

Career and Technology

— Leading-Edge Technology Exhibition

— New Career Fair

— PDA Annual *New Innovative Technology Exhibition™*

PDA Training and Research Institute Course Series

— 6 New Courses

— 4 Popular Courses Updated

Networking...2005 PDA Annual Meeting

Largest Networking Event of the Year!

Interest Groups

PDA paid particular attention to member suggestions regarding networking opportunities at the Annual Meeting. For starters, we have set aside dedicated times for the PDA Interest Groups to meet. IG gatherings provide one of the best networking experiences at PDA conferences and the perfect setting for getting your questions answered and ideas aired among your peers. At this year's Annual Meeting, over 10 PDA IG's are scheduled to meet.

Monday, April 4 • 4:00 – 5:15 p.m.
Tuesday, April 5 • 4:00 – 5:15 p.m.

Meet and Greet Reception

A preconference gathering to kick off the 2005 PDA Annual Meeting!

Sunday, April 3 • 5:00 – 7:00 p.m.

New Member Breakfast

All new PDA members are welcome to attend this special breakfast reception at no additional fee. Meet fellow PDA members and staff and learn how to maximize the potential of your PDA membership through professional growth and *Career-long Learning*™.

Monday, April 4 • 7:30 – 8:30 a.m.

Networking Reception

Meet with your colleagues in the community following the first full day of the 2005 Annual Meeting. Will take place in the Exhibition Hall

Monday, April 4 • 5:30 – 7:30 p.m.

Exhibition Hall

This year's theme, ***"The Integration of Science, Technology and Regulation,"*** lends itself to showcasing new products, services and other exciting innovations that will be of primary interest to the PDA community. Visit the Exhibition Hall each day for refreshment breaks, lunches and student poster presentations! See opposite page for a complete list of Exhibitors.

Also featured this year is the ***New Innovative Technology Exhibition***™. Launched at the 2004 PDA Annual Meeting, the *New Innovative Technologies Exhibition*™ (NIT) program brings to the community the latest scientific and technological advances in pharmaceutical manufacturing. NIT involves the PDA peer review process to ensure that only the most innovative technologies and those most relevant to our community are presented.

Monday, April 4 •
10:00 a.m. – 7:30 p.m.
Tuesday, April 5 •
10:00 a.m. – 4:15 p.m.

Career Fair

With the Student Symposium and Student Poster Presentations included in the 2005 PDA Annual Meeting for the first time, the Career Fair provides an excellent opportunity to recruit students for future positions within your organization. Your participation includes meeting with candidates at the Career Fair, as well as access to a database containing the resumes of all Career Fair attendees. Come and join us!!! For more information contact Dorothea McGuire 301-656-5900 ext 150 or mcguire@pda.org.

Monday, April 4 •
8:00 a.m. – 5:00 p.m.

Gala Dinner & Educational Event

This optional event (US$ 85) will take place at the Chicago Museum of Science and Industry. Come join your colleagues for biggest networking event of the meeting and lots of fun!

Tuesday, April 5 • 6:30 – 9:30 p.m.

2005 Annual Meeting Sponsors

PDA thanks the following sponsors and advertisers for their generous support of the PDA Annual Meeting, Courses & Exhibition:

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PDA wants to send a special thank you to bioMerieux for sponsoring a lunch symposium on Tuesday, April 5, in the Exhibits Hall.

PDA Calendar of Events for North America

Please visit www.pda.org for the most up-to-date event information, lodging and registration.

Conferences

February 17-18, 2005
Aseptic Processing Training Workshop
San Francisco, California

March 14-15, 2005
Aseptic Processing Training Workshop
Philadelphia, Pennsylvania

April 4-8, 2005
2005 PDA Annual Meeting
Chicago, Illinois

May 16-18, 2005
PDA Viral and TSE Safety Conference
Bethesda, Maryland

May 23-25, 2005
PDA Extractables/Leachables Forum
Bethesda, Maryland

September 11-14, 2005
PDA/FDA Joint Regulatory Conference, Courses and Exhibition
Washington, DC

Training

Lab and Lecture calendar events are held at PDA-TRI Baltimore, MD unless otherwise indicated.

Laboratory Courses

February 7-11, 2005
Aseptic Processing Training Program (Week 1)
Week 2: March 14-18

February 24-25, 2005
Environmental Mycology Identification Workshop

March 3-4, 2005
Developing and Validating Cleaning and Disinfection Programs for Controlled Environments

March 7-9, 2005
Cleaning Validation

March 22-23, 2005
Validating a Steam Sterilizer

April 18-22, 2005
Aseptic Processing Training Program (Week 1)
Week 2: May 16-20

May 25-27,2005
Cleaning Validation

June 2-3, 2005
Environmental Mycology Identification Workshop

Lecture Courses

February 17-18, 2005
Computer Products Supplier Auditing Process Model: Auditor Qualification

May 2-3, 2005
Computer Products Supplier Auditing Process Model: Auditor Qualification

June 13-14, 2005
Computer Products Supplier Auditing Process Model: Auditor Qualification

September 26-27, 2005
Computer Products Supplier Auditing Process Model: Auditor Qualification

Course Series

March 7-9, 2005
Biopharmaceutical Course Series
San Francisco, California

April 7-8, 2005
PDA Annual Meeting
Chicago, Illinois

May 2-4, 2005
Pharmaceutical Course Series
Princeton, New Jersey

Chapters

February 2, 2005
PDA Metro Chapter
FDA Inspection Trends in New Jersey
Clark, New Jersey

March 16, 2005
PDA Metro Chapter
Risk Analysis
Clark, New Jersey

April 11, 2005
PDA Canada Chapter
Annual Meeting
Toronto, Ontario, Canada

April 20, 2005
PDA New England Chapter
Genzyme Tour and Networking Dinner
Boston, MA

April 27, 2005
PDA Metro Chapter
Real Quality
Clark, New Jersey

June 1, 2005
PDA Metro Chapter
Isolator Technology
Clark, New Jersey

PDA Calendar of Events for Europe/India/Asia Pacific

Please visit www.pda.org for the most up-to-date event information, lodging and registration.

EUROPE

February 2, 2005
PDA and the PDA UK/Ireland Chapter present
Biotechnology Conference: Risk, Regulation and Resource
Oxford, United Kingdom

February 24, 2005
PDA Australia Chapter
Biotechnology

March 1-4, 2005
2005 PDA International Congress,Courses and Exhibition
Rome, Italy

May 3-4, 2005
Aseptic Processing Guidance Training Workshop
London, England

May 12, 2005
PDA EuroForum
PDA and the and the PDA UK/Ireland Chapter present
Pharmaceutical Packaging
London, England

June 1-3, 2005
PDA Training & Research Institute Laboratory Course
Practical Aspects of Aseptic Processing
Basel, Switzerland

June 2, 2005
PDA EuroForum
PDA and the PDA Prague Chapter present
PAT - Industry, Regulator and Academic
Budapest, Hungary

June 2, 2005
PDA and the PDA Prague Chapter present
PDA EuroForum
Technology Transfer and Contract Manufacturing
Prague, Czech Republic

June 6, 2005
PDA EuroForum,
PDA and the PDA Spain Chapter present
IVIVC (In Vivo in Vitro Correlation) and
BPC (Biopharmaceutical Classification System)
Barcelona, Spain

June 13, 2005
PDA EuroForum,
PDA and the and the PDA UK/Ireland Chapter present
Risk Analysis
London, England

INDIA

March 18-19
PDA IndiaForum
PDA and the PDA India Chapter present
IVIVC / BPC
Mumbai, India

May 20-21
PDA IndiaForum
PDA and the PDA India Chapter present
Risk-based Validation
Goa, India

July 19-20, 2005
PDA IndiaForum
PDA and the PDA India Chapter present
Q7A Update
TBD

August 23-24, 2005
PDA IndiaForum

August 26-27, 2005
PDA IndiaForum

September 16-17
PDA IndiaForum
PDA and the PDA India Chapter present
Certificate of Suitability CEP
TBD

ASIA/PACIFIC

February 25, 2005
PDA Japan Chapter
PAT Symposium
March 18, 2005
PDA Japan Chapter
Training Course: Auditing to CMO

June 2005
PDA Japan Chapter
Training Course: Aseptic Processing

June 2005
PDA Taiwan Chapter
Annual Meeting

November 2005
PDA Japan Chapter
Annual Meeting

Victoria Ann Dedrick
Vice President, Quality and Regulatory Affairs

Vice President's Message

PDA Experts Contribute to Science-based Guidance & Regulations

I would like to take the opportunity this month to highlight an example of how PDA can and does contribute to achieving science-based regulation and guidance on a global basis.

In mid-2003, the World Health Organization (WHO) published a guidance for comment titled *Who Guidance for Sampling of Pharmaceuticals and Related Materials.* PDA's RAQC established a Task Force led by **Don Elinski,** Eli Lilly, to provide comments to the guideline. These were submitted in October of 2003.

With the WHO's second revision to the document in early 2004, PDA again requested that WHO consider PDA'S comments that there may be inherent risks in the sampling process identified in the guidelines. Following consultation in Geneva, in July 2004, WHO wrote to PDA specifically requesting input on the risks observed with the proposed n,r,p plan for sampling.

Again, Don Elinski rallied an expert Task Force of statisticians (see below) to produce a well developed, scientifically-based position on why n,r,p-plan sampling would not be appropriate. PDA was pleased to submit extensive comments and justifications to WHO describing five clear risks presented by the sampling plan and providing justification for a more scientifically sound sampling approach.

WHO thanked PDA for its feedback and response regarding the sampling plans and stated their usefulness to the consultative process within WHO.

One of the goals of PDA is to provide a value added service to health authorities. To provide sound science-based solutions and become a 'go-to partner' in the consultative and development process for regulatory issues and guidance globally. By consistently working with health authorities globally PDA contributes to the humanization of science-based regulation and guidelines.

I would like to sincerely thank Gautam Maitra, our PDA Director for Europe, for being instrumental in the establishment of our good relations with WHO and the RAQC Task Force that mobilized itself twice to respond to WHO's request. Finally I would like to thank **Sabine Koop,** PhD, WHO for consistently considering PDA as a partner in their consultative process.

To read PDA's comments to the WHO guideline on sampling pharmaceuticals, go to the PDA Web site at www.pda.org/regulatory/RegComments.html.

PDA Task Force Members for the WHO Guideline for Sampling of Pharmaceuticals and Related Materials	
Don Elinski, PhD Eli Lilly and Company	Wayne Taylor, PhD Baxter Healthcare
David LeBlond Abbott	Stephen Bellis Ivax
Mark Varney Abbott	Lynn Torbeck Torbeck Associates
Jerry Planchard, PhD Pantheon	Janet Stevens Eli Lilly and Company
Russ Madsen Williamsburg Associates	

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New England Chapter Wins 2004 PDA Chapter Points Program

Kelly Coates, PDA

PDA is proud to announce the winner of the 2004 Chapter Points Program. The **New England Chapter** came out on top with an impressive 470 points for the year. This award reflects the Chapter's contribution to PDA and the pharmaceutical and biopharmaceutical science and technology community.

The New England Chapter was extremely active throughout 2004. They earned points for holding Chapter events, sending Chapter members to PDA events, providing comments on Health Authority guidances and SAB science and technology drafts, having Chapter members on PDA task forces and interest groups, submitting articles to PDA publications, and recruiting new PDA members. They even earned bonus points for holding five Chapter events and submitting four articles to PDA publications in one year. All of their effort pays off with a reward of US$ 5,000 to be used in support of New England Chapter activities in 2005.

PDA would like to recognize the 2004 New England Chapter officers: President, **Mark Staples,** PhD; President-Elect, **Myron Dittmer,** and Treasurer/Secretary, **Roger Deschenes.** Their hard work and dedication allowed the New England Chapter to succeed with its programming. We also appreciate the many Chapter members who assisted with and participated in the activities of the Chapter.

The PDA Chapter Points Program was launched in 2004 to assist and encourage Chapters to pursue the PDA Strategic Plan. The program rewards Chapters for engaging in activities that increase the accessibility of programs, enhance interaction with regulatory bodies, improve scientific information and programs, assure financial stability, and increase awareness of PDA. Chapters earn points for these activities and then receive monetary rewards based on the points earned for the year. This money is used to fund Chapter events and programming in the following year.

The **UK & Ireland Chapter,** led by Chapter President **Frank Talbot,** earned second place with 415 points and will receive US$ 3,000 to support Chapter operations in 2005. Many of these points came from submitting six articles to PDA publications and providing comments on two draft documents over the course of the year. These activities not only earned the Chapter points, but also gave them an opportunity to share knowledge with their peers and contribute to the regulatory process.

The **Taiwan Chapter,** led by Chapter President **Shin-Yi Hsu,** earned third place and US$ 2,000 to support Chapter activities with 345 points for the year. The Chapter provided comments on two draft documents and submitted three articles to PDA publications.

All Chapters with over 250 points will receive US$ 1,000 to support Chapter operations in 2005. These include the Midwest, Puerto Rico, Japan, Metro and Capital Area Chapters.

The **Midwest Chapter,** led by Chapter President **Amy Gotham,** contributed significantly to the exchange of scientific information. In addition to holding four Chapter events, this Chapter has 110 Chapter members involved in PDA interest groups and 42 on PDA task forces.

The **Puerto Rico Chapter,** led by Chapter President **Silma Bladuell,** was very active in submitting articles to PDA publications; they submitted four articles in 2004. The Chapter also provided comments on a draft document and increased the PDA community by 28 new members.

The **Japan Chapter,** led by Chapter President **Katsutoshi Mise,** held five events and significantly increased the scope of PDA's network of members. They referred 136 new members to PDA in 2004.

The **Metro Chapter,** led by President **Nate Manco,** held four events and participated significantly in PDA activities. In addition to Chapter members attending four PDA events, 63 Chapter members were involved in PDA interest groups and 16 were on PDA task forces.

The **Capital Area Chapter,** led by Chapter President **Barry Friedman,** PhD, held four Chapter events and submitted two articles to PDA publications. They also had 17 Chapter members involved in PDA interest groups and 16 on PDA task forces.

All of these award winning Chapters should be proud of their efforts in 2004. The Chapter Points earned are a reflection of their success at meeting the needs of their local community and contributing to and promoting PDA and the pharmaceutical and biopharmaceutical industry.

The Chapter Points program is one way that PDA supports its Chapters in developing programming, enhancing education, and contributing to the industry and the association. We hope that Chapters will take advantage of PDA resources and earn more Chapter Points in 2005. If you have any questions about the PDA Chapter Points program or resources available to PDA Chapters, please contact Kelly Coates, PDA Manager of Membership and Chapters, at +1 (301) 656-5900 ext. 149 or coates@pda.org.

Congratulations to all of the winners and best of luck in 2005!

PDA's New Academic Programs: Bringing Innovative Science to PDA Members

Kelly Coates, PDA

PDA's new academic initiatives create an incredible opportunity for PDA members. The academic community often pushes the envelope in scientific and technological change via innovative research and study. By inviting their involvement in PDA through our new academic programs, PDA has opened a new door through which our members will be exposed to a wealth of scientific knowledge.

PDA recently implemented several programs to facilitate the recognition of student achievement in pharmaceutical and biopharmaceutical science and technology. These students, in turn, are excited to learn about pharmaceutical/biopharmaceutical manufacturing, microbiology, and nanotechnology. Globally, students are competing for the opportunity to help make a difference in our community.

First, we created the new **PDA Student Membership**. At only US$ 30, this membership type will provide students a cost-effective means to benefit from all PDA's offerings: publications, services, training, and support. This is a wonderful opportunity for young professionals to learn and become involved in the industry.

Three new Student Scientific Programs were recently launched. The **Annual Graduate Research Symposium** awards travel grants for students to present their papers at the PDA Annual Meeting. The **Pre-Doctoral Fellowship Program** awards a fellowship stipend for students to complete their dissertation research project. The **Student Poster Sessions** will be added to the PDA Annual Meeting to provide another opportunity for students to present their research to the community.

The PDA Student Scientific Programs increase the exchange of scientific and technical information, promote the pharmaceutical and biopharmaceutical industry, and develop relationships between academia and industry.

Comprehensive, *Career-long Learning*™

Whether you are looking to round out your subject-matter knowledge or need the latest scientific publication, you will find it in PDA's E-store collection. Here is just a sample:

Information Technology

Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations, Technical Report No. 32 revised
(2004) 150 pages. Member: US$ 100, Nonmember: $ 295 – Item 01032
CD-Rom version: Member: US$ 75 member, Nonmember: US$ 270 – Item 01132

Good Practice and Compliance for Electronic Records and Signatures, Part 3 – Models for Systems Implementation and Evolution
(2004) 66 pages. Member: US$ 95, Nonmember: US$ 190 – Item 13003

Report on the Validation of Computer-Related Systems, Technical Report No. 18
(1995) 17 pages. Member: US$ 75, Nonmember: US$ 270 – Item 01018

Validation and Qualification of Computerized Laboratory Data Acquisition Systems, Technical Report No. 31
(1999) 12 pages. Member: US$ 75, Nonmember: US$ 270 – Item 01031

Electronic Records, Electronic Signatures Compliance Assessment
Authors: Chris Reid and Barbara Mullendore
(2001) Hardcover, 58 pages. ISBN: 1-930114-26-5. Member: US$ 90 Nonmember: US$ 109 – Item 17177

Commercial Off-The-Shelf Software Validation for 21 CFR Part 11
Authors: David Nettleton and Janet Gough
(2003) Hardcover, 130 pages. ISBN: 1-930114-35-9. Member: US$ 185 Nonmember: US$ 229 – Item 17200

Computer Validation – The Big Picture
Author: Teri Stokes
(1999) 32 pages. Member: US$ 60 Nonmember: US$ 69 – Item 18016

Biopharmaceuticals/Biotechnology

Cleaning and Cleaning Validation: A Biotechnology Perspective
(1995) 190 pages. Member: US$ 125, Nonmember: US$ 320 – Item 13002

Microbiological Monitoring of Pharmaceutical Process Water
Author: Michael Jahnke
(2002) 70 pages. ISBN: 1-930114-42-7. Member: US$ 90, Nonmember: US$ 109 – Item 17193

Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation
Authors: Kenneth Avis and Vincent Wu
(1996) 400 pages. ISBN: 1574910167. Member: $165, Nonmember: $189.95 – Item 06071

Biotechnology: Quality Assurance and Validation
Editors: Kenneth Avis, Carmen Wagner, and Vincent Wu
(1998) 288 pages. ISBN: 1574910892. Member: $165, Nonmember: $189.95 – Item 06172

Introduction to the Pharmaceutical Regulatory Process
Author: Ira R. Berry
(2004) Hardcover, 650 pages. ISBN: 0-8247-5464-6. Member: US$ 132 Nonmember: US$ 165 – Item 05628

Training CD:
Cross Contamination in the Production of Pharmaceuticals and Bio-Pharmaceuticals
22 minutes presentation with 43 slides.
Member: US$ 300, Nonmember: US$ 895 – Item 11002

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For more information, and to order your copy of these or any other PDA publication, please visit the publications store on our Web site or contact us by e-mail at info@pda.org or by phone: +1 (301) 656-5900.

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PDA
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PDA HEADQUARTERS
3 Bethesda Metro Center
Suite 1500
Bethesda, MD 20814 USA
TEL: +1(301)656-5900
FAX: +1(301)986-0296

Chapter Contacts

The following is a list of the PDA Chapters, organized by the area of the world they are located. Included are the Chapter name, the area(s) served, the Chapter contact person and their e-mail address. Where applicable, the Chapter's Web site is listed. More information on PDA Chapters is available at www.pda.org/chapters/index.html.

Asia Pacific

Australia Chapter
Contact: Ken Dibble
E-mail: ken_dibble@millipore.com

India Chapter
Contact: Darshan Makhey, PhD
E-mail:
dmakhey@nicholaspiramal.co.in

Japan Chapter
Contact: Hiroshi Harada
E-mail: hharada@medissue.co.jp
Web site: www.j-pda.jp

Korea Chapter
Contact: Jun Yeon Park
E-mail: jun_yeon_park@pall.com

Southeast Asia Chapter
Contact: K. P. P. Prasad, PhD
E-mail: prasad.kpp@pfizer.com

Taiwan Chapter
Contact: Tuan-Tuan Su
E-mail: pdatc@ms17.hinet.net
Web site: www.pdatc.org.tw

Europe

Central Europe Chapter
Contact: Erich Sturzenegger, PhD
E-mail:
erich.sturzenegger@pharma.novartis.com

France Chapter
Contact: Philippe Gomez
E-mail:
philippe.gomez@sartorius.com

Italy Chapter
Contact: Vincenzo Baselli
E-mail:
vincenzo_baselli@europe.pall.com
Web site: www.pda-it.org

Prague Chapter
Contact: Zdenka Mrvova
E-mail: zdenka.mrvova@zentiva.cz

Spain Chapter
Contact: Jordi Botet, PhD
E-mail: jbotet@stegroup.com

United Kingdom and Ireland Chapter
Contact: John Moys
E-mail: john.moys@sartorius.com

Middle East

Israel Chapter
Contact: Karen S. Ginsbury
E-mail: kstaylor@netvision.net.il

North America

Canada Chapter
Contact: Hein Wick
E-mail: hwick@hwmr.ca
Web site: www.pdacanada.org

Capital Area Chapter
Areas Served: MD, DC, VA, WV
Contact: Barry A. Friedman, PhD
E-mail:
barry.friedman@cambrex.com
Web site: www.pdacapitalchapter.org

Delaware Valley Chapter
Areas Served: DE, NJ, PA
Contact: Art Vellutato, Jr.
E-mail: artjr@sterile.com
Web site: www.pdadv.org

Metro Chapter
Areas Served: NJ, NY
Contact: Nate Manco
E-mail: natemanco@optonline.net
Web site: www.pdametro.org

Midwest Chapter
Areas Served: IL, IN, OH, WI, IA, MN
Contact: Amy Gotham
E-mail: pda-midwest@comcast.net

Mountain States Chapter
Areas Served: CO, WY, UT, ID, NE, KS, OK, MT
Contact: Jeff Beste
E-mail: cmdjeff@aol.com
Web site: www.mspda.org

New England Chapter
Areas Served: MA, CT, RI, NH, VT, ME
Contact: Myron Dittmer, Jr.
E-mail: mdittmer@hyaluron.com

Puerto Rico Chapter
Contact: Silma Bladuell
E-mail: bladues@wyeth.com

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Contact: Lisa Eklund
E-mail: lisa.eklund@hospira.com
Web site: www.pdase.org

Southern California Chapter
Areas Served: Southern California
Contact: Kikoo Tejwani
E-mail: kikoo.tejwani@bbrawn.com
Web site: www.pdasc.org

West Coast Chapter
Areas Served: Northern California
Contact: Randall Tedder
E-mail: randall@iconnova.com
Web site: www.istep.com/~randallt/wccpda

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   Edited by Jeanne Moldenhauer Item No. 17201, PDA member: US$ 250, PDA nonmember: US$ 309
2. PDA CD Archive Set
   CD Archive Set (includes 2003 CD Update) – Item No. 01101 PDA member: US$ 395, PDA nonmember: US$ 590. 2003 CD Update – Item no. 01002, PDA member: US$ 95, PDA nonmember: US$ 290
3. Excellence Through Validation
   By U. G. Barad - Item No. 17205, PDA member: US$ 160, PDA nonmember: US$ 199
4. Filtration Handbook: Liquids
   By Maik W. Jornitz and Theodore H. Meltzer Item No. 17208, PDA member: US$ 185, PDA nonmember: US$ 229
5. Microbiology in Pharmaceutical Manufacturing
   Edited by Richard Prince - Item No. 17185, PDA member: US$ 240, PDA nonmember: US$ 299
6. Pharmaceutical Quality
   Edited by Richard Prince - Item No. 17207, PDA member: US$ 240, PDA nonmember: US$ 299
7. The Essence of GMPs: A Concise Practitioner's Guide
   By U. G. Barad - Item No. 17203, PDA member: US$ 185, PDA nonmember: US$ 229
8. Quality Assurance: A Practitioner's Guide
   By U. G. Barad - Item No. 17212, PDA member: US$ 185, PDA nonmember: US$ 229
9. Steam Sterilization: A Practitioner's Guide
   Edited by Jeanne Moldenhauer - Item No. 17183, PDA member: US$ 215, PDA nonmemvber: US$ 269
10. Good Practice and Compliance for Electronic Records and Signatures - Part 3: Models for Systems Implementation and Evolution
    Item No. 13003, PDA member: US$ 95, PDA nonmember: US$ 190

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2005 PDA International Congress: *Bringing Practicality To Science*

Paul McKellips, PDA

The "eternal city" of Rome, Italy serves as the backdrop for this year's PDA International Congress, Courses and Exhibition—a three day exchange of solutions to meet regulatory compliance in a changing, global market.

This year's International Congress features:

3 Specialized Learning Tracks:
- Quality & Regulatory
- Manufacturing & Engineering
- Research & Development

10 Presentations on Emerging Technologies and Manufacturing Innovations in:
- Aseptic Processing
- Biological Safety
- Cleaning Salidation

15 Presentations on Regulatory Compliance:
- Avoid OOS
- Post-Approval Changes
- CAPA

6 Updates from International Regulatory Authorities:
- CBER & the Critical Path
- EU Clinical Trials Directive
- FDA cGMP Clinical Trials

9 Presentations on Risk Management:
- Case Study: Aseptic Processes
- ICH Q8 & Q9
- Case Study: Sterilization

9 Presentations on Regulatory Quality Inititiatves:
- ICH Q10
- Case Study: QS Risk Analysis
- FDA 21st Century cGMPs
- EU 2004/2005 QS Initiatives

8 Presentations on Aseptic Processing Technologies:
- Closed Vial Filling
- Case Study: Disposal Systems
- Environmental Monitoring
- Sterilizing Equip. Validation

Plus,

New Presentations:
- Biotechnology
- Information Technology
- Process Analytical Technology

Plenary Sessions on:
- EU Pharmaceutical Innovation
- Inspections: Aseptic Processing
- Future of Biopharmaceuticals in Europe

8 New and Updated Training Courses from the PDA Training and Research Institute

2005 PDA International Congress Exhibitors List

COMPANY	BOOTH
A&LCO/PMT	20
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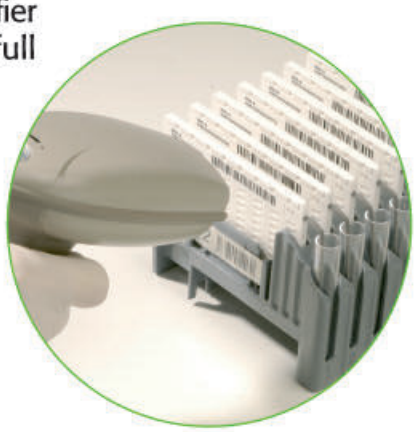

Focus on what's important in bacterial identification. Please visit Booth #413 at the PDA Annual Meeting and be the first to know about the new VITEK 2 Compact.

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BIOMÉRIEUX INDUSTRY

A Look Ahead: PDA's Viral and TSE Safety Conference

Kurt Brorson, PhD, Program Chair (CBER, FDA)

On May 16-18, 2005, PDA will sponsor the **PDA Viral and TSE Safety Conference: "Updating the Strategy for the 21st Century,"** at the Hyatt Regency, Bethesda, Md.

This event represents a continuation of PDA's tradition of cosponsoring state of the art workshops on virus and pathogen safety; a tradition established in 2001 at the PDA/FDA Viral Clearance Forum (Bethesda, Maryland), in 2003 at the PDA/EMEA European Virus Safety Forum and in 2004 at the Viral Safety and TSE Risks workshop.

The 2005 conference will be truly international in scope by bringing together representatives from both EMEA and FDA and biopharmaceutical manufacturers, manufacturers of enabling technologies and contract testing organizations. Cosponsored for the first time by both EMEA and FDA, the three-day event will provide opportunities for dialog on current guidance, critical issues, and new technology and approaches to viral and TSE safety.

A diverse conference committee, lead by co-chairs Richard Levy (PAREXEL Consulting), Glenda Silvester (EMEA) and myself, has drawn expertise on biotech, plasma and tissue products from industry, FDA and EMEA. Critical and timely topics identified for coverage by the committee include:

- Current and future **viral clearance technologies**;
- Current opinions on the need for **standardization** in viral clearance studies;
- Evaluating and understanding of the **robustness** of common clearance steps;
- Testing, history and controls for **cell substrates** from novel sources.
- Contamination control, **risk assessment and mitigation** including facility-wide decontamination, segregation and inactivation procedures (e.g. resin and membrane cleaning);
- Current issues in **TSE safety**;
- Risk mitigation and control of **animal and human derived raw materials** (e.g. transgenics, plasma products, tissue products); and,
- Current **regulatory perspectives** from EMEA, FDA and industry.

The committee has received dozens of high quality abstracts from industry, consultants, enabling suppliers and regulatory authorities, guaranteeing a high caliber, educational and interactive meeting. Although final agenda development is on-going, care is being taken during speaker selection to provide balance between divergent viewpoints on controversial issues such as robustness, testing requirements and chromatography resin reuse. Negotiations to secure high profile keynote speakers are being pursued—stay tuned to *PDA Letter* for developments. To attract a wide, scientifically directed audience, special government, academic and affordable student rates are available.

Don't miss the viral safety event of the year: the **PDA Viral and TSE safety Conference: "Updating the Strategy for the 21st Century"**.

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***PDA Letter* Editor**
Walter Morris
+1 (301) 656-5900, ext. 148
morris@pda.org

Advertising
Dorothea McGuire, Sales
+1 (301) 656-5900
mcguire@pda.org

Production Staff
Peter Marinovich, Manager, Web & Production
Scarlett Anderson, Print and Web Production Asssitant

PDA Global Headquarters
3 Bethesda Metro Center, Suite 1500
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
E-mail: *info@pda.org*
Web site: www.pda.org

PDA Office of European Director
R-1059.747 Postfach
Schwarzwaldalle 215
CH-4002 Basel, Switzerland
Tel: +41 61 321 56 30
Fax: +41 61 321 83 48

PDA European Headquarters
287 Avenue Louise
BE-1050 Brussels, Belgium
Tel: +32-2-643-2045
Fax: +32-2-645-2671

PDA Training & Research Institute
c/o UMBC Technology Center
1450 S. Rolling Road
Baltimore, MD 21227 USA
Tel: +1 (410) 455-5800
Fax: +1 (410) 455-5802
E-mail: *info-tri@pda.org*

Vice President's Message

Gail Sherman

Help Us Help You…Train Your Staff

Only one month into the New Year and already the PDA Training and Research Institute (TRI) calendar is filling up!

This will be a busy year for PDA TRI as we roll out new laboratory and lecture courses and continue with many of our most popular programs. In addition, we are working with companies and talking to health authorities worldwide about individualized training for their staff. I encourage anyone in our community interested in bringing a highly qualified TRI lecturer to their site for training, or who wants to customize a course, to contact us. That is the best way of helping us help you!

On February 1, TRI sponsored an Open House and met with potential clients in the local area to preview its resources and capabilities. Attendees had the opportunity to meet with PDA and TRI staff, exhibitors and TRI instructors and tour our laboratory facilities.

Interacting with the community at events like our Open House provide the TRI staff the insight we need to develop courses that meet your needs.

Another way TRI can target the right courses for the community is through the TRI Advisory Board (TRIAB). This group had its first meeting in February to determine what directions to pursue in product development and delivery. The TRIAB will be establishing task groups and subcommittees to develop new courseware, and we will be looking at e-learning opportunities. Within the next few months, we should be launching a short survey to gauge interest in this learning methodology.

So here's how you can help us help you—send us your ideas, volunteer your time, become an instructor, develop courseware, and/or call us and chat!

See you in Rome, San Francisco, Denver, Princeton, Zurich, New Orleans, Chicago, Washington, D.C. and of course at TRI in Baltimore, Md.!

Happy Training!

Exciting Year at TRI!

New Labs, New Course Series, Plenty of *Career-long Learning™*

James Wamsley and Strother Dixon, PDA Training and Research Institute

2005 is shaping up to be an exciting one as we bring to you a revised roster of laboratory courses that includes updated content as well as some exciting new offerings. Last year, we brought you **four** new laboratory courses in Baltimore and offered a laboratory course for the first time in Europe.

In January, we developed a new four-day course, ***Pharmaceutical and Biopharmaceutical Microbiology 101.*** The course was intended to provide attendees, with or without significant microbiological lab experience, an extensive overview of current testing, sampling and identification techniques. Judging from the feedback it was extremely successful.

The four new hands-on laboratory courses we offered at the TRI facility in 2004 were: • ***Developing and Validating a Cleaning and Disinfection Program for Controlled Environments*** • ***Advanced Environmental Mycology*** • ***Rapid Microbiological Methods*** • ***Developing a Moist Heat Sterilization Program within FDA Requirements.*** These are on the schedule for 2005 due to their success last year.

Practical Aspects of Aseptic Processing, PDA's first laboratory course in Europe will be offered two times this year, once in June and again in November and will be held at the University of Basel; Basel Switzerland. This three-day course is based on the always sold out 10-day course offered at the TRI facility.

To keep up with the release of the new Aseptic Processing Guidance by the FDA in September 2004, almost every section of the 10-day ***Aseptic Processing Training Program*** has been updated for 2005, to reflect the new and updated material.

For more information on these courses and everything else we offer at TRI be sure to check our webpage at www.pda.org/tri or e-mail us at info_tri@pda.org. Be on the lookout for even more new courses as we move through 2005 and into 2006.

For 2005, PDA TRI has planned seven unique lecture course series for our global community.

Things get underway with the **Rome Course Series,** March 4, held in conjunction with the 2005 PDA International Congress. PDA TRI's highly esteemed faculty will be offering **seven new** courses:

- **Principles and Applications of CGMPs in Biopharmaceutical Manufacturing**
- **Basic Principles of Cleaning Validation**
- **The Impact of the EU Clinical Trials Directive on the Clinical Supply Chain and Clinical Manufacturing Facilities**
- **Cleanroom Microbiology**
- **Applied Quality Systems**
- **Dissolution Rate: Quality and Bioequivalence Aspects**
- **Stability Testing Requirements: From Development to Marketing.**

Next, TRI turns to San Francisco, Ca., for its **Pharmaceutical and Biopharmaceutical Course Series,** March 7-9, 2005. Ten interactive courses on emerging quality, validation, training and compliance trends paramount to the PDA community will be offered:

- **Conducting Compliant Deviation Investigations**
- **Achieving cGMP Compliance during Development of a Biotechnology Product**
- **Validation by Design**
- **GMP Training Manager Workshop**
- **Introduction to Change Control**
- **Overview of Risk Assessment and Risk Management**
- **Documentation Systems and Practices**
- **Minimizing the Legal, Quality and Compliance Pitfalls of Contract Manufacturing**
- **Z1.4 Attribute Inspection Sampling in a cGMP Environment.**

The other unique lecture series to be offered this year will be: PDA Annual Meeting in • **Chicago, IL, April 7-8 (see page 16 for more information)** • **Princeton , New Jersey, May 2-4** • **PDA EuroForum, June 14-15** • **PDA/FDA in Washington, D.C., September 15-16** • **Denver, Colorado, October 24 – 26** • **New Orleans, Louisiana, November 29 – December 1.**

For updates and to learn more about other *Career-long Learning™* opportunities visit www.pda.org.

PDA
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presents

PDA Viral & TSE Safety Conference

Updating the Strategy for the 21st Century

In Co-Sponsorship with EMEA **and** FDA

Overview

This three-day international conference, **co-sponsored for the first time by both EMEA and FDA,** will provide opportunities for dialog on current guidance, critical issues, and new technology and approaches to viral and and TSE safety.

The conference will be truly international in scope by bringing together representatives from both EMEA and FDA with biopharmaceutical manufacturers, manufacturers of enabling technologies and contract testing organizations.

By participating in this conference you will receive the latest information on:

- Current and future **viral clearance technologies**;
- Current opinions on the need for **standardization** in viral clearance studies;
- Evaluating and understanding of the **robustness** of common clearance steps;
- Contamination control, **risk assessment and mitigation** including facility-wide decontamination, segregation and inactivation procedures (e.g. resin and membrane cleaning);
- Current issues in **TSE safety**;
- Risk mitigation and control of **animal and human derived raw materials** (e.g. trangenics, plasma products, tissue products); and,
- Current **regulatory perspectives** from EMEA, FDA and industry.

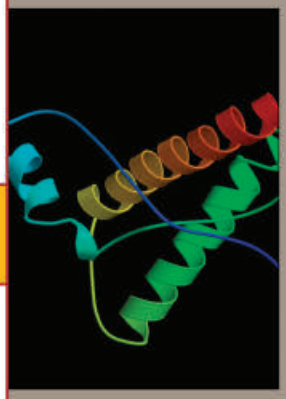
Who Should Attend

This conference will be of value to mid- and senior-level professionals with specific interest in the viral and TSE safety and evaluation of medicinal products, including:

- ✓ **Pharmaceutical**
- ✓ **Biotechnology**
- ✓ **Manufacturing Sciences**
- ✓ **Pathogen Safety Groups**
- ✓ **Quality Assurance**
- ✓ **Quality Control**
- ✓ **Process Development**
- ✓ **Risk Assessment**
- ✓ **Academia**
- ✓ **Suppliers**
- ✓ **Regulatory Authorities**
- ✓ **Regulatory Affairs Professionals**

Washington, D.C.

May 16-18, 2005



Venue

Washington, D.C.
Hyatt Regency Bethesda
One Bethesda Metro Center
Bethesda, MD 20814

+1 (301) 657-1234 or
+1 (888) 591-1234

Room rate: $209 + tax

Reservations can be made until Friday, April 22, 2005

Registration Fees

PDA Member	**US$ 1,050**
Nonmember	**US$ 1,245**
Government	**US$ 430**
Student	**US$ 160**

To Register

Online at **www.pda.org/viral2005**

OR: complete the attached registration form and fax or mail to:

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Conference	Exhibition	PDA TRI Training Courses
April 4-6, 2005	April 4-5, 2005	April 7-8, 2005

April 4-8, 2005
Chicago, Illinois

- 3 Specialized Learning Tracks
  - Quality & Regulatory
  - Manufacturing & Engineering
  - Academic & Research and Development
- 20 New Case Studies
- 4 FDA Updates
  - Rapid Methods
  - Viral Filtration
  - PAT
  - Combination Products
- 3 New PDA Technical Reports
  - Viral Filtration
  - Validation of Protein Manufacturing
  - Sterile Filtration of Gasses
- 2 Exceptional Keynote Presentations
  - Refining Risk Management Approaches - The FDA Collaborative Project
  - Implementing PAT: Advantages for Industry
- 10 Interactive Training Courses
- PDA *New Innovative Technologies*™ (NIT) in the Exhibition
- New PDA Annual Graduate Research Symposium
- Career Fair

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