Volume XXXVII, No.1

PDA Letter

January 2001

A Monthly Communication for the Members of PDA—
An International Association for Pharmaceutical Science and Technology

PDA-TRI Courses go to Orlando, February 12–14, see page 28

FDA to Begin Pilot Program of "Systems-Based" Audits of Drug Companies

by William Stoedter, PDA

In a new pilot program, the FDA will inspect drug manufacturers using a "systems" approach. This program will start in January and take place for six months in six districts: New York, New Jersey, Philadelphia, Los Angeles, Dallas and San Juan, Puerto Rico. This systems approach is not meant to be the same as the Quality Systems Inspection Technique (QSIT) currently employed by CDRH in the inspections of device manufacturers. The systems chosen to be inspected would be from the sub chapters of the regulations, i.e., Quality, Facilities and Equipment, Laboratory, etc. The inspectors have the option of performing a full inspection or an abbreviated inspection of just a few of the systems. Observations on 483s will be organized by system. The FDA is hoping that this new approach will make drug company inspections more efficient and faster.

Since systems-based audits are a new concept for many in the drug and biologics industry, PDA and the FDA will hold three workshops to educate the industry on what to expect from the process, and how to prepare for these audits. These one-day workshops will be held:

- New Brunswick, NJ February 5, 2001
- Los Angeles, CA February 8, 2001
- San Juan, PR February 15, 2001

On the day following the Systems-Based Workshops, PDA-TRI will present systems based course offerings. Auditing Techniques for CGMP Compliance will be taught by Renee B. Galkin on February 6 in New Brunswick, New Jersey only. Documentation Systems and Practices will be taught by James L. Vesper at all three locations, and the Los Angeles and San Juan offerings also will feature the course on Design and Implementation of World Class Quality Systems taught by Robert G. Kieffer.

Registration information for the Workshops and Courses is available on www.pda.org, or upon request from PDA at info@pda.org, Tel: (301) 986-0293 or Fax: (301) 986-0296. Registration forms for these events is found on page 31. ■

PDA Comments on Draft Guidance on Analytical Procedures and Methods Validation

by William Stoedter, PDA

On August 18, 2000, the FDA issued for comment a Draft Guidance for Industry on Analytical Procedures and Methods Validation: Chemistry, Manufacturing and Controls Documentation. PDA assembled a task group chaired by Anders Vinther, Ph.D. of Novo Nordisk. Working on a short deadline via e-mail and conference calls, the task group made 43 specific comments on the draft document. After review and approval by the PDA Board of Directors, the comments were sent to the FDA.

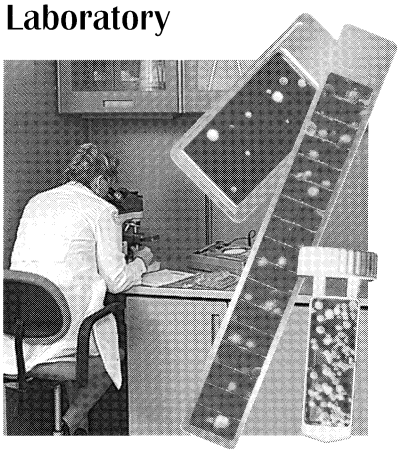
Continued on page 6

2000 PDA Election Results

We're pleased to announce the results of the recent election of Directors. The newly elected Directors joining the PDA Board for three-year terms are Robert L. Dana, Bristol-Myers Squibb Co., and Lisa M. Skeens, Ph.D., Baxter Healthcare Corporation. Re-elected to the PDA Board for three-year terms are Stephanie R. Gray, GlaxoWellcome Inc., and Glenn Wright, Eli Lilly and Company. Congratulations to them, and thank you to those members who voted. This year we received 1,514 ballots—an improvement over last year.

Continued on page 6

Contract Microbiology Laboratory



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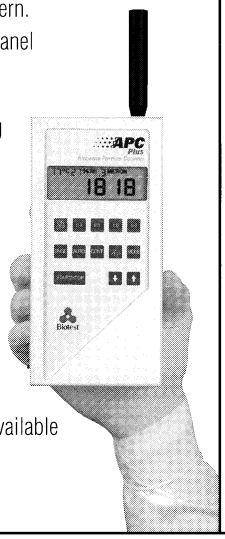

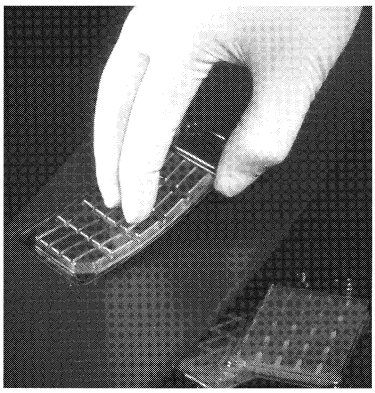

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Edmund M. Fry

Director, Communications & Marketing
Linda M. Williams

Manager, Publications & Production
Janet Raysick

Important Deadline...

- **Make your reservations at the Aladdin Resort & Casino by February 9th for the 2001 Spring Meeting in Las Vegas, NV—1-877-333-9474**

IN THIS ISSUE...

Fry

PDA-A$_3$P Memorandum of Understanding

by Edmund M. Fry

At the November 2000 Annual Meeting of the Association Pour les Produits Propres et Stériles in Biarritz, PDA and A$_3$P signed a Memorandum of Understanding to solidify the relationship between our associations. The French association, formerly known as the association for parenteral products, is now the "Association for Clean and Sterile Products." The name change signifies a broadening of the association's scope of activities, now incorporating other industries interested in clean manufacturing such as foods and medical devices. The MOU was signed by Gerard Rumpler, A$_3$P Chairman and Edmund M. Fry, PDA President.

The PDA-A$_3$P MOU establishes a framework for cooperation and friendship, recognizing that working together provides increased benefits for the members of both associations. The MOU provides for mutual dissemination of information about each other's events and activities, and for possible collaboration on events and technical projects. At the PDA Annual Meeting in December, discussions began among Didier Meyer, A$_3$P official representative, Suzanne Levesque, PDA Board of Directors and PDA staff to plan future joint activities in France to implement the MOU. Already underway are plans for A$_3$P to assist with the Annual Meeting of the PDA Canada Chapter in Montreal this fall.

The new MOU is an outgrowth of the multilateral MOU that previously existed among PDA and other European associations. PDA withdrew from the multilateral MOU last year, having concluded that individual MOUs provided better flexibility and responsiveness. The PDA Board of Directors believes that establishing and maintaining good working relationships with European associations that have similar missions will enhance the strength of all. ■

PDA and A$_3$P sign Memorandum of Understanding: Didier Meyer, Gerard Rumpler, Edmund M. Fry and Suzanne Levesque

PDA Awards

The PDA Awards were bestowed upon the deserving recipients during the Monday, December 4, Opening Session. PDA Chair Robert B. Myers of Schering-Plough presented the special awards to the following individuals:

Clarence Kemper, Ph.D., received **Honorary Membership,** PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award is given to recognize long-standing service of a very significant nature to PDA. This award requires the unanimous approval of the PDA Board of Directors (Honorary Members are not eligible for other awards in the same year).

Frank Bing, Abbott Laboratories, Inc., and **Robert Pazzano, P.D.**, Validation & Training Services, were presented the **Gordon Personeus Award**. Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award honors a PDA member, other than a Board member, for long-term acts or contributions that are of noteworthy or special importance to PDA.

Frederick J. Carleton Award was bestowed upon **Raymond Shaw, Jr., Ph.D.**, Wyeth-Ayerst Pharmaceuticals. A tribute to lifetime contributor, past President, past Executive Director, and Honorary Member Frederick J. Carleton, this award is designated for past or present Board members whose performance and service on the Board is determined by his/her peers as worthy of recognition.

Receiving the **Distinguished Service Award** for special acts, contributions or service that have contributed to the success and strength of PDA were **Julius Z. Knapp**, R&D Associates, Inc., **Duncan McVean, Ph.D.** and **Jeanne E. Moldenhauer, Ph.D.**

Recognized for outstanding performance in education was PDA faculty member **John M. Lindsay**, KMI/PAREXEL, LLC. This award is named for James P. Agalloco in honor of his work in developing the PDA education program.

Hongkee Sah, Ph.D. of the Catholic University of Daegu was the winner of the **Fred Simon Award** for Best Paper published in the *PDA Journal of Pharmaceutical Science and Technology* in 1999. The paper, titled "Protein Instability Toward Organic Solvent/Water Emulsification: Implications for Protein Microencapsulation Into Microspheres" was selected by the PDA Awards Committee because of its overall originality, technical quality and contribution to the pharmaceutical sciences. This award is named in honor of the late Fred Simon, former PDA Director, Scientific Affairs. ■

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

PDA Recognized for PQRI Efforts

Janet L. Woodcock, M.D., Director, Center for Drug Evaluation and Research (CDER), FDA, presented an award to PDA at CDER's Award Ceremony on November 3, 2000. The award citation reads, "For extraordinary innovative efforts and effectiveness in creating an institute that promotes CDER's mission and benefits the American public." Awards were presented to all member organizations on the Product Quality Research Institute (PQRI) Steering Committee. PDA is a founding member of PQRI, and a number of PDA members serve as volunteers in PQRI technical activities. Thank you, Dr. Woodcock, for this kind recognition of PDA's efforts. ■

Draft Guidance from cover

This draft document is an update of the "Guideline for Submitting Samples and Analytical Data for Methods Validation" from 1987. Since the last revision of the Guideline the International Conference on Harmonization (ICH) process has completed its first ten years of harmonization. Many new guideline documents have been harmonized among the three regions of Japan, the European Union and the USA. Most of the comments from the task group were recommendations to follow existing quality documents approved by the ICH.

PDA comments can be found on the PDA website, www.pda.org. The FDA draft Guidance can be found at www.fda.gov/cder/guidance/index.htm. ■

Election Results from cover

Retiring from the PDA Board are P. Michael Masterson, NewcoGen Group, and Robert F. Morrissey, Ph.D., Johnson & Johnson. Both of these retiring Board members have given much personal time and energy to making PDA successful, and they deserve our congratulations and gratitude.

The complete list of Officers and Directors for 2001 appears below. ■

Chair:
Robert B. Myers, Schering-Plough

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Jennie Allewell, Cell Therapeutics, Inc.

Treasurer:
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Immediate Past Chair:
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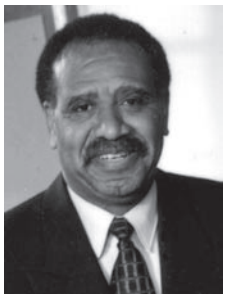
Stephanie R. Gray, GlaxoWellcome Inc.
Henry K. Kwan, Ph.D.
Suzanne Levesque, Sabex, Inc.
Richard V. Levy, Ph.D., Millipore Corporation
Robert J. Mello, Ph.D., RJM Pharmaceutical Consultants
Taiichi Mizuta, Ph.D., Shionogi & Co. Ltd.
Georg Roessling, Ph.D., Schering AG
Kenneth B. Seamon, Ph.D., Immunex Corporation
Lisa M. Skeens, Ph.D.
Glenn E. Wright, Eli Lilly and Company

2001 Officers


Robert B. Myers,
Chair


Floyd Benjamin,
Chair-elect


Jennie Allewell,
Secretary


Nikki Mehringer,
Treasurer


Joyce H. Aydlett,
Immediate Past
Chair

2001 Board of Directors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Stephanie R. Gray, Director


Henry K. Kwan, Ph.D., Director


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Richard V. Levy, Ph.D., Director


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Taiichi Mizuta, Ph.D., Director


Georg Roessling, Ph.D., Director


Kenneth B. Seamon, Ph.D., Director


Lisa M Skeens, Ph.D., Director


Glenn E. Wright, Director

Company, Colleague & Product Announcements

Eric Sheinin, Ph.D., Deputy Director for Science, Office of Pharmaceutical Science (OPS), will be retiring from FDA on February 10, 2001. Sheinin will spend his retirement with the United States Pharmacopeia as Vice President, General Policy and Requirements. ■

BioReliance Corporation announced that it has expanded its range of testing services wit the introduction of new quantitative polymerase chain reaction (Q-PCR) assays. Both assays can be used for product release, process development testing and for validation of DNA removal in the manufacturing purification steps. The Q-PCR assays use the TaqMan® 5' nucleasae fluorogenic probe technology, developed and owned by Roche Molecular Systems, Inc. and Hoffmann-La Roche Ltd. For more information contact Nancy Bakowski, 1-800-756-5658. ■

TR-32 UPDATE

by Mark Lester and Michael Wyrick, KMI/ PAREXEL, LLC

KMI/PAREXEL, LLC (KMI), a leading supplier of compliance and technology-related services for FDA-regulated industries, is proud to announce that it has entered into a Third Party Auditor Services Agreement with the Audit Repository Center (ARC). ARC is licensed by PDA to act as a facilitator of supplier audits, secure repository of audit information and metric data generated in accordance with the PDA Technical Report 32 Supplier Audit Process Model. The entire program (Audit Process Model and ARC) offers a standardized audit process and pool of certified auditors, which combine to reduce the time and cost burden of supplier audits, and to maximize the effectiveness and reliability of the supplier audit process.

Pharmaceutical company subscribers to ARC have the following options for auditing suppliers following the PDA Audit Process Model:

1. Conduct the audit themselves and then contribute the audit package to ARC;
2. Employ a qualified third party from the ARC auditor listing; or
3. Withdraw audits directly from ARC's inventory.

Suppliers who subscribe to ARC can have their products audited, following the PDA Audit Process Model by requesting ARC to broker the audit (ARC selects a qualified audit team) and place the audit in the repository for use by their clients.

KMI promotes Supplier Management as a Good Business Practice to our clients and fully supports the ARC process as a viable means of augmenting an internal Supplier Audit program. In the delivery of its Supplier Auditing Services, KMI follows the PDA Audit Process Model for ARC sanctioned audits. KMI has been involved with the PDA-sponsored initiative from the very beginning through active participation of two of our senior staff, which produced the Audit Process Model. KMI continues to demonstrate its support of the PDA Audit Process Model with our ongoing commitment to add to our current team of six PDA-qualified auditors. KMI encourages FDA-regulated industries, computer product and service suppliers, and other third party service providers to join KMI in supporting this PDA sanctioned audit repository initiative.

For more information about the audit repository visit ARC's website at www.auditcenter.com or www.pda.org

Availability of Audits

Currently twenty-nine audits are either available for distribution, in process or planned to be completed within the next six months.

Table 1.0 provides a summary of the audits that are currently available for distribution from the repository.

Table 1.0 Audits Currently Available in ARC

Supplier	Product
Accraply, Inc.	Label Applicators, Automatic Labeling Systems & Custom Designed and Self Adhesive Material Application Systems
Applied Biosystems	SQL*LIMS – Laboratory Information Management System including the QA Stability & Schedule Modules
Etrails.com, Inc.	Electronic Data Capture – EDC Electronic Patient Diaries – EPD Electronic Trail Management- ETM
Merant Inc.	PVCS Dimensions & PVCS Replicator Configuration Management Systems
Qumas, Ltd (Participating Supplier)	Qumas-Doc: Electronic Records Document Management Systems
Precision Solutions, Inc.	Custom Software Development. SLE capture of check-weight data.

Auditor Resources

Seventy-six auditors have been trained and qualified by the PDA during the year 2000. Forty-two percent of these auditors are from pharmaceutical industry companies, with seven percent coming from the European Union. Nine independent consulting firms have placed agreements in effect to provide qualified auditors to the industry.

For more information about the audit repository visit ARC's website at www.auditcenter.com or www.pda.org. ■

The following sums up selected recent regulatory announcements by FDA:

New Prescription Drug User Fees

The FDA announced the rates for prescription drug user fees for fiscal year 2001 in the Federal Register, December 18, 2000 (Volume 65, Number 243, pages 79107-79111). The Prescription Drug User Fee Act of 1992 (PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA), authorizes FDA to collect user fees. These fees are assessed on: (1) certain types of applications and supplements for the approval of drug and biological products; (2) certain establishments where such products are made; and (3) certain products. One-third of the total user fee revenue is projected to come from each of these three types of fees. When certain conditions are met per 21USC 379h (d), FDA may waive or reduce fees.

Fee Category	Fee Rates for Fiscal Year 2001
Applications requiring clinical data	$309,647
Applications not requiring clinical data	$154,823
Supplements requiring clinical data	$154,823
Establishments	$145,989
Products	$21,892

These fees are retroactive to October 1, 2000 and will remain in effect through September 30, 2001. The FDA will bill applicants who submitted lower application fees from October 1 to December 31, 2000, for the difference between the amount they submitted and the amount specified in the new fee schedule. Any application or supplement subject to fees under PDUFA that is submitted after December 31, 2000, must be accompanied by the appropriate application fee established in the new schedule.

For further information contact: Frank P. Claunts, Office of Management and Systems (HF-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

Application Integrity Policy Notice

An Application Integrity Policy (AIP) notice from the Food and Drug Administration can cause the review of all of your company's applications to be suspended. When the FDA believes there is evidence of wrongful conduct and/or unreliable data, they will issue an AIP notice. If the AIP notice is for a currently marketed product, the product is not necessarily removed from the market. The FDA will assess the validity of the data in your applications and that assessment will take priority over other applications you may have pending at the agency. The review of all other pending applications will not commence until all questions regarding data integrity are resolved.

Common data problems are ones that we should all be familiar with by now. Erased data, data written over, and incorrect calculations are some of the common culprits. The best way to address these problems is with a thorough audit of all documentation submitted to the agency. If you find data erased or written over, an investigation should be initiated. One option is to go back to raw or other data to substantiate the now questionable data. Many Quality Assurance Auditors will make a note on the documents stating that a writeover has been noted and where data supporting the current information can be found.

Clinical Trial Information on the Web Continues to Grow with ClinicalTrials.gov.

ClinicalTrials.gov provides patients, family members, health care professionals, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), has developed this site in close and ongoing collaboration with all NIH Institutes and the Food and Drug Administration (FDA).

This site currently contains approximately 5,000 clinical studies sponsored primarily by the National Institutes of Health. During the coming year, additional studies from other federal agencies and the pharmaceutical industry will be included. As new features and designs are developed, they will be incorporated into *ClinicalTrials.gov*. Check the site often for updates. The site also has many interesting links. Among them are the FDA, National Institutes of Health and the Center for Disease Control.

ClinicalTrials.gov is being developed as a result of the FDA Modernization Act which was passed into law in November 1997. Section 113 of this Act requires the Department of Health and Human Services, through the NIH, to establish a registry of clinical trials for both federally and privately funded trials of experimental treatments for serious or life-threatening diseases or conditions. The internet address is: http://clinicaltrials.gov.

continued on page 10

Address for written comment to FDA unless otherwise indicated:
Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

continued from page 9

Prescription Drug Labeling

The Food and Drug Administration has proposed a new format for prescription drug labeling that will help reduce medical errors. According to the National Academy of Sciences, prescription drug mislabeling may be responsible for as many as 98,000 deaths in the USA annually. FDA believes that this new, user- friendly format will reduce errors in drug prescribing.

"Today's proposal is FDA's latest initiative to improve the labeling of the products it regulates," said Dr. Jane E. Henney, FDA Commissioner. "This proposal is particularly valuable because it will make important information available in a clear, consistent, and readable format that is essential to proper prescribing practices."

Prescription drug product labeling (also known as the package insert) represents a primary means of providing critical information about drugs to practitioners. As part of the drug review process, FDA reviews and approves drug product labeling that is initially proposed by manufacturers.

An FDA study showed that practitioners found drug product labeling to be lengthy, complex, and hard to use. The proposed new format would provide user-friendly labeling that would allow practitioners to quickly find the most important information about the product. One major change is inclusion of a new introductory "Highlights" section of bulleted prescribing information. This section would include the information that practitioners most commonly refer to and view as most important, and it would provide the location of further details elsewhere in the labeling.

Seven of the eleven drugs pulled off the market for safety problems since 1997 were banned in part because doctors kept prescribing them to the wrong patients despite label warnings.

Among the changes:

- Each package insert will begin with a "Highlights" section, leading with the most important warning.
- Next, doctors learn whether additional warnings have been added in the past year.
- The next item is the proper dose.
- Next comes other important side effects and, in bold print, the FDA's phone number to report suspected problems in patients.
- Doctors can then read the details of the package insert using a new index to each topic.
- The insert ends with a special "patient counseling" section, a checklist of everything patients should know about the prescription.

The proposed new labeling is expected to reduce practitioners' time spent looking for information, decrease the number of preventable medical errors, and improve treatment effectiveness. The information will be easier to find, read and use, and it should also enhance the safe and effective use of prescription drugs and reduce medical errors caused by inadequate communication. Since these labeling revisions represent considerable effort and are most critical for newer and less familiar drugs, the proposal will apply only to relatively new prescription drug products. For more information visit: http://www.fda.gov/bbs/topics/NEWS/NEW00745.html or review the Federal Register for December 21, 2000.

FDA Task Force on Antimicrobial Resistance: Key Recommendations

The FDA Task Force on Antimicrobial Resistance (TFAR) was formed with the goal of optimizing FDA's response to the growing public health threat of antimicrobial resistance. The Task Force represented all Centers and offices with interest and expertise in the area and built upon their previous efforts. The Task Force met weekly during the Spring of 1999 to consider various content areas, to discuss ongoing agency work, and to propose and consider specific action items. The Task Force kept a broad perspective ranging from such issues as the daily workings of the review process to potential new initiatives and approaches involving other agencies and groups. While many other agencies and groups need to be involved in the response to antibiotic resistance, we focused upon issues and areas where we believed FDA should, and could, play an important part and achieve specific and practical outcomes.

From its meetings, the Task Force developed a list of potential action items which it then ranked. Subsequently, a retreat was held to consider and reach consensus regarding the most highly ranked proposed actions and to then recommend actions for adoption by the agency.

The Task Force felt that FDA has responsibilities and the potential to improve public health through actions in four key areas:

1. Promptly and effectively responding to current threats from drug resistance.
2. Facilitating and encouraging development and appropriate use of products which help address the issue.
3. Facilitating the safe and effective use, and thus prolonging the life of products, by helping improve the quantity and quality of information available to consumers and health professionals regarding antibiotic resistance and principles of appropriate usage.
4. Maximizing and coordinating FDA's scientific research to address needs in antimicrobial resistance.

Key Recommendations of Task Force

I. *An Effective Response to Current Public Health Threats*

1. FDA should work to develop an appropriate

regulatory framework and explore other options to protect "drugs of last resort" (those drugs which may represent the last line of defense against otherwise resistant organisms). This may include post-marketing surveillance of both use and the development of resistance.

a. FDA should work jointly with NIH, CDC, AHRQ and others to plan and sponsor an inter-agency Consensus Conference on "Preserving Therapeutic Options for Resistant Organisms"

b. CDER should hold an Anti-infective Advisory Committee Meeting to provide specific input on FDA's role and possible approaches for preserving therapeutic options for resistant organisms.

2. FDA should strongly support effective implementation of the CVM Framework which addresses Antimicrobial Resistance due to food animal uses of antimicrobials.

a. In particular, the monitoring for and response to any threats to the efficacy of drugs critical to human medicine due to food animal uses must be sensitive, timely and decisive.

II. Facilitation of Product Development

3. FDA should continue to work within the agency and collaborate with outside experts in order to improve and facilitate innovative product development.

a. FDA should form a high-level, inter-center committee to seek outside input and consider issues related to incentives/exclusivity for optimal human and animal drug, vaccine, device (both anti-infective and diagnostic) and biologics development and appropriate use to meet antimicrobial resistance public health needs.

b. CDER should move forward in its efforts to facilitate product development by addressing issues such as use of surrogate markers and pre-clinical data, clinical trials for agents dealing with resistant pathogens and issue appropriate guidance(s).

c. FDA should meet with NIH, CDC and others to discuss the possibility of NIH involvement in, or development of, a clinical trial program which addresses otherwise unmet needs in antimicrobial resistance and product development.

d. CDRH (with CDER input) should continue to work towards developing standardized guidelines and a management structure for addressing resistance concerns in the review, labeling and promotion of antimicrobial containing devices.

e. CDRH, with CDER input, should work with NIH, CDC and others to develop workshops and other possible strategies to stimulate additional interest in rapid diagnostics and susceptibility determination.

III. Facilitating the Safe and Effective Use of Antimicrobials

4. CDER should complete, and the Agency strongly support, the proposed antimicrobial resistance labeling.

5. FDA should work with NIH, CDC, AHRQ and others (e.g., health professionals, industry, health care organizations) to organize a conference or other process to develop and promulgate "Basic Principles for Antimicrobial Use."

6. FDA should work towards assuring that patient educational materials are provided with each antibiotic prescription which includes content stressing appropriate antimicrobial use. FDA should use a variety of means (e.g., meetings, a new website feature with outside links, publications) to better provide enhanced and consistent information to consumers and professionals regarding antimicrobial use and resistance, new antimicrobial approvals and related issues.

7. CDER should develop a Guidance Document regarding both direct-to-consumer and professional promotion of antimicrobials which deals with key resistance issues and encourages appropriate promotion to preserve safety and efficacy of approved products.

IV. Coordinating FDA's Scientific Response to Antimicrobial Resistance

8. FDA should form an inter-center standing committee to identify and prioritize FDA research needs and goals concerning antimicrobial resistance. This committee should include laboratory scientists and clinicians from both veterinary and human medicine. The committee should perform an initial and periodic assessment of FDA AR research to help assure that it effectively meets the Agency's goals and fulfils clear and unmet Public health and regulatory needs.

9. This committee should also coordinate FDA resistance research activities with those of other Agencies (e.g., CDC, USDA, EPA) and arrange for the periodic outside review of FDA's antibiotic resistance research as a whole.

The full report with discussion and references can be found at http://www.fda.gov/oc/antimicrobial/taskforce2000.html ■

RAQC Summary of 2000 Activities

by Lisa M. Skeens, RAQC Chair

Names for photograph (left to right):
David Miner; Nikki Mehringer; William Stoedter; Vince Anicetti; Anders Vinther, Ph.D.; Lisa Skeens, Ph.D. (Chair); Michael Gross, Ph.D.; Jennie Allewell; Robert Mello, Ph.D.; Amy Scott-Billman, M.S.; Robert Dana; Russell Madsen
Not Pictured: Kristen Bacilgalupi; Donald Baker, J.D.; Rebecca Devine; John DeFoe; Don Elinski; Hiltrud Horn, Ph.D.; James Lyda; Tim Marten, Ph.D.; Steven Mendivil; Toshiaki Nishihata, Ph.D.

PDA's Regulatory and Quality Committee (RAQC) has the goal of increasing PDA's participation in regulatory initiatives that could potentially impact the PDA membership globally. In 2000 the committee was involved in a variety of PDA activities as described in the accompanying table. Important to our success last year was the addition of new committee members increasing representation from Europe and the biotech industry. For the coming year the committee will continue to focus on supporting and influencing scientifically based regulatory initiatives internationally.

RAQC initiatives are successful thanks to the many PDA members who actively participate and assume leadership positions on the various committees. We want to encourage and foster future involvement from our diverse membership base. Our efforts do make a difference! ■

RAQC
Summary of 2000 Activities

Topic	Activity	Lead	Status
CPMP Note for Guidance on Process Validation	Comments Submitted	Hiltrud Horn Michael Reitze	Submitted 2/25/00
EU Annex 15 (Process Validation)	Comments Submitted	Hiltrud Horn/ Steve Bellis	Submitted 2/25/00
PIC/S and CPMP Draft Guidances on Parametric Release	Comments Submitted	Klaus Haberer/ Jim Lya	Submitted 9/29/2000
ICH Q7A, GMPs for APIs	Comments Submitted	Dan Gold	Submitted to US, EU, Japan 9/2000 (Electronically to FDA)
Canadian TPP Sterile Product GMP Revision10/2000	Comments Submitted	Suzanne Levesque/ Bill Stoedter	Submitted
FDA Draft Guidance on Analytical Procedures and Methods Validation CMC Documentation	Comments Submitted	Anders Vinther	Submitted 11/2000
PDA/FDA Conference on Part 11	Conference	Russ Madsen, RAQC contact	June, 2000
PDA/FDA Joint Conference	Conference	Amy Scott	September 11–13, 2000
PDA/FDA Conference on Validation of Manufacturing Processes for Biologics	Conference	Vince Anicetti	September 25–27, 2000
PDA/FDA Conference on Team Biologics	Conference	Ed Fry	December 8, 2000
Strategic Meeting with the European Medicines Evaluation Agency	Meeting	Jim Lyda	November, 2000
Future of ICH – FDA Public Meeting	Remarks presented on PDA's behalf	Lisa Skeens	Remarks made at 5/16/00 FDA meeting
USP Quinquennial	Attendance	Russ Madsen	April, 2000
OPS Trade Association Meetings	Attendance	Allewell, Madsen, Mello, Skeens, Stoedter	Meetings 2/2000, 6/2000, 10/2000
ICH-5	Attendance	Allewell, Skeens, Stoedter, Vinther	Attended November, 2000
GMP Harmonization Task Force	Task Force Formed/Forming	John Defoe	Ongoing (presentation at PDA/FDA)
FDA Draft Guidances on Process Validation for Biologics Products	Standing Task Force Forming	Vince Anicetti	Waiting for FDA drafts (anticipated this fall)
FDA Revised Guidance on Blend Uniformity	Previous Task Force will be reconvened	Don Elinski	Waiting for FDA draft (anticipated soon)
Newsletter Articles	Author Articles to Inform Membership	Various	Ongoing

Software Engineering Institute to Perform a Case Study of PDA/ARC Supplier Audit Program

by Russell Madsen, PDA

Russell Madsen, PDA, Harvey Greenawalt, Audit Repository Center, LLC, John F. Murray, Jr., CDRH, FDA, and George Grigonis, Merck & Co., Inc. (former lead of Supplier Auditing Task Group for TR 32), met with the Software Engineering Institute (SEI) on November 15, 2000 to explore future collaborative work initiatives involving software engineering methods for acquisition of COTS products and the Supplier Audit Program.

SEI was established by the U.S. Department of Defense (DoD) to advance the state and practice of software engineering practice through independent research and private industry affiliates. As a chartered R&D organization, SEI develops and transfers important new technology advances to the private sector so that Government can benefit from a wider, broader base of expertise, facilitating the adoption of high-payoff software engineering practices by the DoD supplier chain.

The concepts established by PDA TR 32 in the acquisition of commercial off-the-shelf (COTS) software technology are in many ways similar to those principles advocated by the SEI to evaluate COTS suppliers. Presently, SEI's COTS-Based Systems Initiative is looking to evaluate various industry practices that involve the design, construction, service and evolution of COTS-based system solutions. Within the pharmaceutical industry many of our computer systems projects are characterized by COTS type acquisitions and integration, which are challenging from a computer validation perspective. PDA is uniquely positioned as a professional organization to support a collaboration with SEI in an effort to advance computer validation industry goals while promoting supplier evaluations and audits through ARC and TR 32 processes.

The SEI was encouraged by the results of the meeting and is looking forward to working with PDA in the immediate future. Several collaborative work arrangements have been proposed and are presently being considered by Science and Technology for 2001—

(1) SEI will document a case study of PDA's vendor evaluation approach. This would be a SEI led activity that would result in a SEI technical report.

(2) SEI will deliver sessions of the COTS courses under a structured offering with the PDA Training and Research Institute (PDA-TRI).

(3) SEI will invite PDA and select organizations to assess its "Evaluation Tutorial" and work with reviewers in integrating feedback to the curriculum.

(4) SEI would like to explore ways that the COTS Usage Risk Evaluation (CURE) may become integrated in systems engineering and computer validation practices within the pharmaceutical industry in the long term. In the short term, SEI would like to explore candidate opportunities to pilot CURE within pharmaceutical company IT organizations as part of the maturation process for this work. Based on the appropriate application, SEI would be willing to internally fund our involvement in the CURE opportunity. ■

Recent Sci-Tech Discussions

Fill Volume for Stability

Compiled by Russell E. Madsen, PDA. The question and answers were selected from the Sci-Tech discussion group archive.

The following exchange taken from the Pharmaceutical Sci-Tech Discussion Group on the Internet provides interesting and current perspectives on practical—and sometimes theoretical—issues affecting the pharmaceutical industry on a day-to-day basis.

For information about becoming a member of the discussion group see the PDA website at www.pda.org.

Question

The discussions on lower fill volume for media fills prompts another question. In early clinical studies, every mL of product is precious. Has anyone ever performed a stability study with intentionally under-filled vials? Like the media fill, all container surfaces would be contacted and it could be argued that this would be a worst case challenge since the surface contact to volume ratio would be much greater.

Response 1

As a retired FDAer I can only say that under-filled vials are out of specification and should be rejected. Stability samples are not to be treated differently from any other samples. If so the natural thing to do would be to save money by only using the rejected samples for stability.

Stability samples should mirror what the actual marketing sample will be. Your samples fail stabili-

ty when any one of your specifications is not met, ergo, below minimum fill, minimum dosage(s) amount plus the compendial designated overage for that volume, should stop your stability study.

Follow any other procedure, get caught during an audit and you're back to square one with your stability studies. Is it worth the risk economically to your company? It can get extremely expensive if such practices are found out after the product is marketed. All production from the time of the submission of that data could be subject to recall.

My advice, do it right the first time and never have to worry about it again. Long term it's the safest and least costly route. Recent news reports, in the last six months, for parenterals, I believe, show the wisdom of this approach, as did the Generic Drug Scandal of years ago.

Response 2

I don't think this answer quite touches on early stability studies to justify an expiration date for a clinical trial. This is not an issue about saving money, but not having enough manufactured product to do a stability study to give you the data you need due to the inherent small volumes produced in the early phases of biopharmaceutical production. Any Suggestions?

Response 3

Perhaps we should add this to the list of things up with which we will no longer put?

Response 4

When I read the original posting my first impression was that this was not a bad idea and I could not think of any solid scientific reasoning against it. I was going to respond to that effect with the caution that there would be a significant regulatory risk and that the idea should be approved by the reviewer assigned to your submission. The ex-FDA (now a consultant) response was a great demonstration of how for all our shouting about how science should be the last word, in the end it's all about compliance.

Response 5

In this particular instance science does play a very important role. Your fill volume can affect a number of your results.

I would suggest, for the benefit of all, you might enlighten us as to where the science is wrong. Compliance is not a bad word. It doesn't generally arise until there is abuse, the same as new laws and new Agencies. Look at the recent tire industry problem as a recent example.

I would also remind you that before requirements and standards are set they are published, have times for responses and criticism and are then either put on hold, modified and published or published as is. The willingness of the industry to respond to some of the FR publications has at times been practically non-existent. The response after final publication, however, has generally been great, or as you put it "for all of our shouting." My advice is to shout at the right time or live with what you've as an industry accepted.

I have always been an advocate of good science and those who know me, have had their products reviewed by me, or are familiar with the area of photostability testing can attest to that fact. In fact I personally think that FDA should have to scientifically justify all of its positions. Not the current situation in every case.

The easiest way to delay any approval is to deviate from compendial standards and guidelines. Do your own thing, don't talk to the Reviewer, be argumentative in not following the established methods (if they work), put them in a decision making role between your variation versus the normal method and your probability of getting a deficiency letter greatly increases. Reviewers have to have knowledge in many fields not just stability.

The average new drug product, if it is truly not a me too type drug, generates about $10 million dollars a month and the average deficiency letter takes 1–3 months to resolve. Economics should dictate the easiest road. I don't think that the cost of materials comes anywhere near this figure.

Response 6

Compliance for a NDA, science for an IND?

Response 7

While I do not agree with the thought that it be necessary for the clinical development you should stop and think about the overall development process. Stability data are necessary for the submission and you cannot generate two years of stability data in six month. So you should start as early as possible generating the data. Therefore it would not hurt designing your studies to include the amount of material needed for the stability testing. If no data at all are available, you should run the testing under each circumstance, because what is out in the field for the clinical trial should be monitored for its usability. You might have to stop the use of trial medication because of stability problems. If you do not have anything within your facility to test you won't notice.

Has anyone ever performed a stability study with intentionally underfilled vials?

Join this lively online discussion group, where more than 2,000 of your colleagues from around the globe meet and find solutions to complex issues. Access is open to both PDA members and nonmembers, and discussions may be accessed via e-mail or the web.

See the PDA website at **www.pda.org** to sign up via the web. Send an e-mail to *requests@www2. pharmweb.net* if you don't have web access, with one of the following commands placed in the body of the message: "subscribe PharmTech" (to receive individual messages daily), or "subscribe digest PharmTech" (to receive one daily digest). Replace "subscribe" with "unsubscribe" to leave the list. For help topics, type "help PharmTech" in the body of the message and send.

Response 8

I don't disagree with your contention that a choice of non-standard methods would require careful communication with FDA and a sound scientific explanation of the non-standard choice. However, I've been involved in the standard setting process and I can tell you that while science plays a role so do precedence and politics. Some standards have been written to reflect a committee's view of what was standard practice. This has in some cases been done without a critical scientific evaluation of the standard practice.

In general I can understand deficiency letters written because of poor adherence to scientific standards, but unfortunately some of the deficiency letters I've seen in the field of aseptic processing are subjective in nature and are in fact based upon someone's opinion and not infrequently that opinion lacks scientific substantiation.

Many things have become CGMP in our business because someone wrote them in to a 483 or issued them from the podium. Once a few firms start implementing this opinion it becomes a standard practice and it in essence becomes law without any possibility of review.

I agree that industry should be more diligent about responding to Federal Register notices or Pharmacopeial Forum stimuli to revision. However, industry has difficulty responding to opinion in the form of 483 comment, or "podium standards" that evolve into CGMP expectations.

The financial equation that you gave, i.e., $10 million/month in sales tied up in a three month argument with FDA is a principal reason that subjective, opinion-based regulation has become such a problem. Even when an inspector suggests a firm do something that clearly makes no scientific sense, most firms are loathe to argue out of fear of delayed approval.

Simply put, we need a better system. Rules should not be made up as we go along.

Response 9

Your original email was correct in that it's not worth the regulatory risk to fill less than full volume. It's not a matter of the science being wrong (sorry can't enlighten anyone), science simply was not considered in your response. Pure and simple you said this is the regulation if you don't follow it you're out of compliance.

As I said in my previous email I can't think of any solid scientific reasoning against using a lower fill volume for stability samples. You state in your response that "Your fill volume can affect a number of your results." While I'd still like to know what it may affect, the bottom line, as you so strongly demonstrated in your previous posting, is that it really does not matter.

As I said in my original email, "I was going to respond to that effect with the caution that there would be a significant regulatory risk and that the idea should be approved by the reviewer assigned to your submission." The reviewer may take your stance that if it's not what's in the regulations it's unacceptable, end of argument. He/she would be completely within their rights for doing so. The burden of proof is always on industry, as it should be. My problem is the number of times I've seen statements on this forum that it's our own fault for having to put up with regulatory decisions we do not agree with as we did not argue our point hard enough. As you've made very clear, sometimes it's just not worth it.

Response 10

During the discussion regarding lower fill volume the point came up that there was no scientific rationale against using lower fill volume for stability samples. I believe there is. When you lower the fill volume, the head space in your vial increases. Unless you are purging and filling the vial with inert gases and you are sure that there is absolutely no exchange of gases via the stopper upon storage, this usually means that the lower fill volume protein "sees" more oxygen. This increase in head space can, in case of certain proteins, lead to increased degradation in lower volume. It is my understanding that this is the reason why we cannot claim that the stability of 1-ml fills in a 3-ml vial and a 10-ml vial are the same. Of course, one can argue that if it is a minor error in filling these distinctions may not be important. However, that is something we can ascertain only by monitoring the stability of a slightly under-filled vial and demonstrating comparability with the "normal" fill.

Having said that, I also believe that the above scenario (lower fill volume) in all likelihood represents a worse-case scenario since the lower fill volume stability sample might degrade faster than your product. But that is something that can be claimed by experimentation and not by reasoning.

I do not know whether the original question was with reference to non-protein products, in which case my comment may be irrelevant. ■

Veltek ad sent in separately

EU GMP Annex 15 Revised Draft Review by Inspectors Working Group

by Stephen J. Bellis, AstraZeneca, UK, and James C. Lyda, PDA

Approximately one year ago, PDA's Process Validation Task Force was convened to evaluate and prepare comments on the draft EU GMP Annex 15 covering validation master planning, design qualification, non-sterile process validation and cleaning validation. PDA submitted comments to the European Commission on February 25, 2000. Major PDA comments included:

- Annex 15 needs to be compatible with guidance in other ICH regions;
- The Annex may go beyond the requirements in USA and Japan and would therefore be inconsistent with international harmonization goals;
- Annex 15 should be consistent with the draft CPMP Note for Guidance on Process Validation (CPMP/QWP/848/96 draft) in terminology and principles and regulatory expectation; and
- The tutorial nature of the document was not well-suited for GMP guidance.

In late November 2000 the European Commission released a revised draft of Annex 15. A cursory review of the document before the press deadline of the *PDA Letter* suggests that many of the PDA comments were recognized and incorporated into the new text. A preliminary assessment suggests the entire document will be more compatible with existing industry practice and terminology. Some of the Glossary terms are different from PDA recommendations but could be considered equivalent.

The revised text was the subject of a meeting of the EMEA Inspectors Working Group December 13, in London. At press time the final content of the Annex, and the date for publication and implementation, were not known.

Watch the PDA Letter for additional information. Members can view the original PDA comments at www.pda.org [also see the April 2000 issue of the *PDA Letter*]. ■

See page 38 for Registration Form

Free Access to the Parenteral Database for PDA Members

PDA members are invited to take advantage of a special promotion offered by PharmQuest — free access to the Parenteral Database on its website http://www.pharmquest.com through the end of January 2001.

The Parenteral Database includes crucial data points for over 2,000 parenteral products approved by the FDA through April 2000. These data points, such as active ingredients, concentration, purpose, monograph, indication, and route of administration are essential for formulation scientists, QA/QC, toxicologists. This database is fully relational and searchable and uses OLAP technology. The information can be searched using any of the key criteria, such as Route of Administration, Excipient Function, Company name, Product name.

To access the Parenteral Database go to http://www.pharmquest.com, or go directly to http://www.pharmquest.com/jsp/parenterals_alpha/parwelcome.jsp. Click on the promotional ticker on the page to enter the database. On the promotional page, provide your PDA membership number along with your name and email address and you will get instant access to the database. Please note that you have to be a PharmQuest member to avail this opportunity. PharmQuest membership is free of cost and you can register to be a PharmQuest member on their website or by directly going to http://www.pharmquest.com/jsp/forms/index.jsp. Enjoy your free access to PharmQuest's Parenteral Database. ■

International Calendar

February 19-23, 2001
PDA International Congress
In cooperation with PDA Japan Chapter
Bridging the Healthcare and Pharmaceutical World in the New Millennium
Kyoto International Conference Hall
Kyoto, Japan
PDA-TRI Education Courses
February 22-23
· Designing Training That Works
· Practical and Suitable Measures for FDA Inspections

March 26-28, 2001
IV European Parenteral Conference
Supported by the European Sterile Products Confederation (ESPC)
Barcelona, Spain
Contact:
Organization Secretary, International Meetings
Capitan Arenas, 3-5 bajos
08034 Barcelona
TEL: +34 93 2039293
FAX: +34 93 2804643

March 29-30, 2001
Pestivirus Contaminations of Bovine Sera and Other Bovine Virus Contaminations
Home Plazza Hotel
Paris, France
Contact:
http://www.pheur.org or
European Directorate for the Quality (EDQM) at info@pheur.org.

April 5-6, 2001
PDA & PDA Italy Chapter
Conference on
Global Pharmaceutical Manufacturing and Quality Strategies
Grand Hotel Timeo
Taormina, Italy

Contact PDA or go to *www.pda.org* for additional details on PDA events

Contact Information for PDA Europe

Mailing Address:
PDA
Postfach 620
CH-4144 Arlesheim
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Reminder: the following numbers should be used to contact Jim Lyda and the PDA European Office:
phone +41 61 703 1688,
fax (analog) +41 61 703 1689.

PDA Membership Application

Return your completed PDA membership application, with payment made to: **PDA, Inc., P.O. Box 79465, Baltimore, MD 21279-0465 USA** or fax it to: (301) 986-1093. *(If form is faxed, it must include necessary credit card information.)*

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- ❑ Pharmacy
- ❑ Recruiter
- ❑ Other

Professional Interest (check all that apply)

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- ❑ Analytical Chemistry
- ❑ Blow-Fill-Seal
- ❑ Biologicals
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- ❑ Drug/Device Delivery Systems
- ❑ Formulation Development
- ❑ Filtration
- ❑ GMP Compliance/Inspection Trends
- ❑ Inspection Trends/Regulatory Affairs
- ❑ Isolation Technology
- ❑ Liquids
- ❑ Lyophilization
- ❑ Manufacturing/Production
- ❑ Microbiology/Environmental Monitoring
- ❑ Maintenance
- ❑ Ointments
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- ❑ Packaging Science
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PDA Annual Meeting 2000 Highlights

More than 700 industry executives convened for the 2000 PDA Annual Meeting, Courses and Exhibition that was held December 4–8 in Philadelphia, Pennsylvania. Themed "Compliance and Cost: Controls in Conflict" the four-day event, chaired by James P. Agalloco, featured more than 35 sessions including the highly interactive Roundtable Breakfast Topics and the Interest Group meetings. Additionally, registrants visited with representatives from the 173 participating companies in the sold-out exhibit hall, and even found time to network with old friends and new acquaintances during the social events.

The New Members breakfast provides a perfect opportunity for new PDA members to network.

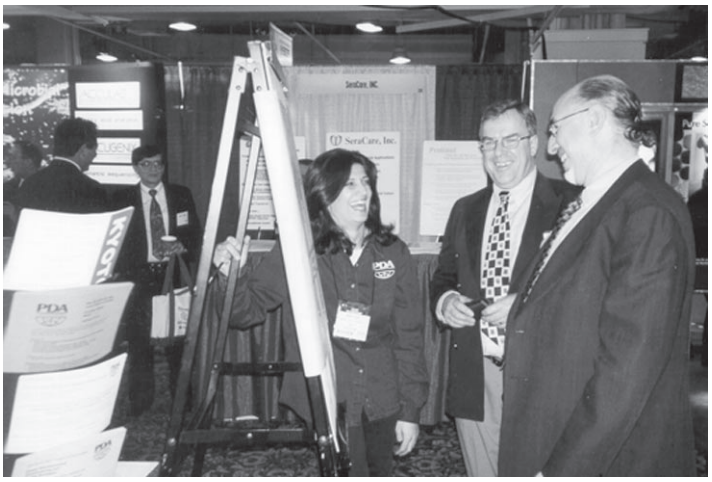
Mark Trotter, Sartorius Corp., receives a commemorative plaque from PDA President Edmund M. Fry for his three years of service as Chair of the PDA Exhibits Committee.

The sold-out Annual Meeting Exhibit Hall was a hub of activity. Registrants visited with suppliers, enjoyed complimentary beverages, and a few lucky folks won prizes during the wheel of fortune drawings.

The Exhibitor Profiles from the Annual Meeting may be found on the PDA website, www.pda.org. Also online in "Members Only" are the available presentation handouts from the meeting.

Among the highlights of the meeting was the presentation of the PDA Awards by Chair Robert B. Myers (see page 4 for awards summary).

Mark your calendars—the 2001 PDA Annual Meeting, Courses and Exhibition will take place December 3–7 at the Marriott Wardman Park in Washington, DC. Exhibitors: Call now to reserve your booth; the hall is already 50% sold. ■



PDA's Nahid Kiani (left) advises Ian Sellick and Jerry Martin of Pall Corporation as they determine their booth location for the 2001 PDA Annual Meeting in Washington, DC.

Compliance and Cost: Controls in Conflict

From the PDA Annual Meeting in Philadelphia, December 4–8, 2000

The Closing Plenary Session

by William Stoedter, PDA

Agalloco

James Agalloco of Agalloco and Associates, Chair of the Annual Meeting moderated this Plenary Session that was titled "Compliance and Cost: Controls in Conflict."

Doug Dean of PricewaterhouseCoopers presented "The Economics of Quality and Compliance."

This model of cost and compliance starts with the premise that the company must first understand what level of compliance they are currently achieving, and secondly, what level of risk they are willing to accept. To understand the level of compliance a company has, there are many tools that can be used. An example is batch record review and analysis. If twenty records are reviewed, four with errors and there are ten instances of data input in each record (opportunities for error), then the compliance in the execution of batch records can be calculated. Many companies, when working toward compliance goals reach a point past which increasing the spending of resources does not increase the level of compliance. At that point, the company must assess what level of compliance their infrastructure is capable of. The company must look for new methods to improve compliance, such as: investing in training, removing tedious repetitive tasks through batch record automation and the introduction of electronic document management systems. If a company can be in compliance at less cost than their competitors, that makes for a competitive advantage. There was some controversy over a few of the slides used in the presentation. Some audience members felt that the slide presentation gave the impression that it was acceptable for a company to strive for less than 100% compliance. Mr. Dean acknowledged their point and stated that he was not advocating less than 100% compliance, but that just as a company cannot perform a sterility test on every vial, the company must have verified systems in place and then rely on those systems.

Paul D'Eramo, Johnson and Johnson Executive Director of Worldwide Policy & Compliance Management presented "Compliance in a Global Business Environment."

Johnson and Johnson (J&J) is a broad-based health care business consisting of Pharmaceuticals, Consumer Goods, Devices, Diagnostics, Nutraceuticals, Foods and Biotechnology with 190 operating companies and more than 100,000 employees worldwide. Quality is a top priority of upper management and is considered a competitive advantage in the marketplace. The company employs quality tools such as Six Sigma and Design Excellence to assure process excellence. Although J&J uses standard tools such as reviewing warning letters available from FOI to anticipate

regulatory trends, they go a step further by making the Quality Unit a business partner. The Quality Organization is a member of the management board that makes strategic decisions. They see the quality function not as the cop-out to catch problems, but as a catalyst for systems improvement. Typically, organizations perform audits, make a list of observations and leave it for company management to clean up. J&J performs assessments to identify opportunities for system improvement, then the assessors work with management to identify and chart a course of corrective action. The measurement of failure does not lead to success.

With such a widespread worldwide organization, the need to interact efficiently with all business units is vital. The company has established a Worldwide Quality Steering Committee to raise quality issues to the highest levels within J&J and to establish worldwide quality policies. One of the tools used in this effort is the Compliance Early Warning System (CEWS), the first web-based business measurement tool. CEWS offers real time quality and compliance reporting and a "Cost of Non-Conformance Model." This model is a spreadsheet tool used to show the true cost of non-conformance, taking into account the costs of scrap, rework, inventory, product replacement, lost sales, retests, investigations, complaints, recalls and returned goods.

Another challenge to the company is where they will find quality professionals in the future. To meet this challenge they have established a Quality Leadership Development Program. Working with academia and other organizations, J&J has defined required skill sets necessary for quality professionals, outlined quality career paths, standardized job requirements, performed worldwide talent reviews and established a quality career recruitment program. The goal of this program is to institutionalize quality's role in J&J companies and develop the leaders that can achieve that goal.

Russell E. Madsen, PDA VP of Scientific and Technical Affairs presented "Real Compliance and How to Achieve It."

Much of Madsen's presentation was intended to stimulate the audience to "think outside the box." He started by comparing "Regulatory Compliance" with "Real Compliance." He defined regulatory compliance as activities like following procedures, conforming to the CGMP regulations and the avoidance of regulatory citations. While those activities are required and necessary, real compliance adds the element of operating in a state of control, basing decisions on science and technology, having effective control and information systems and being proactive. The benefits of compliance are batch to batch product equivalence, high quality products, a reduced regulatory burden, expedited product approval, reduced time to market and low rework, rejection and recall rates. Operating in reaction to the "observation of the month" is reactive, disruptive and costly. With this type of regulatory compliance, changes in regulations and guidelines can upset operating and control systems and employees must be frequently retrained on the changed systems and procedures. A strong compliance program contains all of the elements of regulatory compliance and real compliance.

The most important features of a strong compliance program are:

- Consistency. Every action produces the expected results every time. It is intolerable if a car turned left when steered right one out of 1,000 times.
- A well characterized process. This is developed through effective technical transfer, scale-up, process validation and process monitoring.
- Confirmatory process checks. Process checks confirm rather than control or adjust the process output and cease dependance on inspection and testing to achieve quality. You can't test quality into a product.
- Feedback loops. An essential mechanism to show the process is operating as intended and providing real time information about the operation.
- Warning indicators and failure alarms. Systems that can check themselves for proper operation with personnel responding appropriately to the information.
- Redundancy. Dual systems to prevent or minimize the consequences of failure.
- Instructions and procedures. Clearly written, describing who, what, when, where, how and especially why a particular function or process step must be performed.
- Verification of critical operations. To verify that critical steps have been performed correctly, typically recorded as "done by" and "checked by" signatures.
- Documentation. Good records can show the state of control of the process and aid in problem investigations. If it isn't recorded, it's just a rumor.
- Sufficient number of adequately trained people. There must be sufficient staff to perform all necessary operations. Training needs to be followed by a test to determine if the workers know and understand the training.
- An immune system. Incorporate self-correcting systems and procedures. This includes the effective use of information, adequate investigations and determining the "root cause" of problems.

Real compliance reduces cost and makes good business sense. ■

PDA Spring Conference, Courses and Tabletop Exhibit 2001

by Leslie Zeck, PDA

Modern Pharmaceutical Microbiology: Advancing the Science

PDA will host its annual Spring Conference from March 12–16, 2001 at the new Aladdin Hotel in Las Vegas, Nevada. Participants will discover the latest advances in modern pharmaceutical microbiology and significantly expand their international scientific networks. While the meeting has an overarching microbiology theme, sessions will focus on a broad range of important pharmaceutical and scientific topics. These include aseptic processing, cleaning validation, environmental monitoring, GMPs, 21 CFR Part 11, and changes to the USP, isolator technology, quality auditing, rapid methods in microbiology, stability, sterilization, and sterility and LAL testing. Plenary sessions are designed to include 20-minute presentations by industry experts, with opportunities for interactive question and answer.

The 2001 PDA Spring Conference will also featured two days of interactive *Interest Group* discussions and roundtable breakfast discussions to provide additional forums for information exchange and to expand networking opportunities.

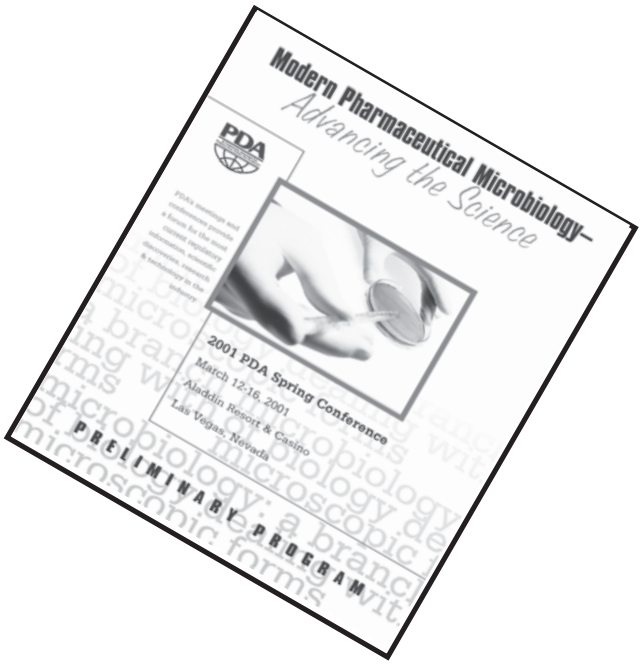
PDA-TRI education courses being offered in conjunction with this conference include:

- Cleanroom Management
- Environmental Surveillance and Control
- Introduction to Validation
- Identification of Microorganisms Using Comparative DNA Sequencing
- PDA Computer Products Supplier Audit Management: Overview Training
- How to Design an Effective Regulatory Training Program
- Writing and Auditing CGMP Documentation
- Environmental Mycology

Conference attendees will benefit from the informative and educational Exhibit Hall that includes the latest displays in science and technology. All registrants receive access to the full exhibition, providing the opportunity to interact with representatives from more than 75 exhibiting companies. Also, Exhibitors will host the popular r*oundtable lunch discussion groups*, providing a unique forum for information exchange on the industry's latest technologies and products.

PDA's meetings and conferences provide a forum for the most current regulatory information, scientific discoveries, research and technology in the industry. Those interested in pharmaceutical science and technology in the research and generic pharmaceutical, biotechnology, bulk chemical, medical device and related industries will benefit from participation in this cutting-edge conference. Consider registering today or sending a member of your staff to participate in this conference.

Be a winner in Las Vegas by attending the PDA Spring Conference, Courses and Tabletop Exhibit! ■



Registration brochures for the 2001 PDA Spring Conference, Courses and Tabletop Exhibit have been mailed to the membership. This information will also be available from www.pda.org or obtained upon request by contacting PDA at

Tel: (301) 986-0293
Fax: (301) 986-0296
Email: info@pda.org
Web: www.pda.org

REGISTRATION FORM

2001 PDA Spring Conference • March 12-16, 2001 • Aladdin Resort & Casino • Las Vegas, Nevada

1. Please type or print your name, address and affiliation.

❑ Dr. ❑ Mr. ❑ Ms.

First Name | Middle Initial | Last Name

Job Title | Membership Number if known

Company (indicate full company name)

Business Address

City | State/Province | ZIP+4/Postal Code | Country

Business Phone | Fax | E-mail

❑ Substituting for _____

(Check only if you are substituting for a previously enrolled colleague. If you are a nonmember substituting for a member, the additional nonmember fee must be paid.)

2. Fees

Individuals registering at the nonmember rate receive one full year of PDA membership. *(If you DO NOT want to become a PDA member, please check this box ❑).* Nonmembers registering for multiple events need only pay the nonmember fee once.

Spring Conference Registration	PDA Member	Nonmember
❑ Full Annual Meeting:*(does not include courses)*	$995	$1145
❑ Monday, March 12 Only:*	$595	$745
❑ Tuesday, March 13 Only:*	$595	$745
❑ Wednesday, March 14 Only:*	$295	$445
Optional Event Registration (included in Full Registration)		
❑ Viva Las Vegas Reception, Monday, March 12*	$75	$75
❑ Exhibit Hall Lunch, Monday, March 12*	$30	$30
PDA-TRI Courses Registration		
❑ PDA Computer Products Supplier Audit Management: Overview Training (PDA #499)	$380	$530
❑ How to Design an Effective Regulatory Training Program (PDA #414)	$350	$500
❑ Identification of Microorganisms Using Comparative DNA Sequencing (PDA #234)	$680	$830
❑ Cleanroom Management (PDA #361)	$1010	$1160
❑ Environmental Surveillance and Control (PDA #247)	$1010	$1160
❑ Introduction to Validation (PDA #375)	$1010	$1160
❑ Environmental Mycology (PDA #203)	$680	$830
❑ Writing and Auditing CGMP Documentation (PDA #755)	$680	$830
TOTAL FEES	$_____	$_____

**Additional Conference Event Registration (these events are included in full registration)*

Business Environment (check one)

❑ Pharmaceutical Manufacturing
❑ Engineering and Construction
❑ Industry Supplier
❑ Consultant
❑ Employee of Government Regulatory Agency
❑ Academic
❑ Medical Device Manufacturer
❑ Recruiter
❑ Pharmacy
❑ Laboratory
❑ Contract Manufacturing
❑ Other

Areas of Interest (check one or more)

❑ Aerosols
❑ Analytical Chemistry
❑ Biotechnology
❑ Blow-Fill-Seal
❑ Computer Validation
❑ Contract Manufacturing
❑ Drug/Device Delivery Systems
❑ Production and Engineering
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❑ Formulation Development
❑ Inspection Trends/Regulatory Affairs
❑ Isolation Technology
❑ Lyophilization
❑ Microbiology/Environmental Monitoring
❑ Ointments
❑ Ophthalmic
❑ Packaging Science
❑ Parenterals
❑ Quality Assurance/Quality Control
❑ Research
❑ Solid Dosage Forms
❑ Stability
❑ Sterilization/Aseptic Processing
❑ Training
❑ Vaccines
❑ Validation
❑ Visual Inspection of Parenterals

3. Please check the appropriate box:

❑ Check enclosed ❑ Wire Transfer Charge to: ❑ MasterCard ❑ VISA ❑ AMEX

Account Number | Exp. Date | Name exactly as on card

Signature | Date

4. Return completed form with payment made to:

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P.O. Box 79465
Baltimore, MD 21279-0465 USA
Fax: (301) 986-1093 (credit cards only)

Payments must be made to PDA in U.S. dollars by check drawn on a U.S. bank, by electronic money transfer (SunTrust Bank ABA #051000020, PDA Account #209364254, Swift #UVBIUS33), net of all bank charges; by MasterCard, VISA, or American Express.

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PDA USE: Date: | Check: | Amount: | Account:

PDA-TRI Course Series, Orlando

February 12–14, 2001
Grosvenor Resort, Orlando, Florida

Using Authentication and Encryption Technology for 21 CFR 11 Solutions (PDA #654), February 12—*taught by Thomas P. Quinn, President, The Hollis Group;* $680 members/$830 nonmembers.

Root Cause Analysis (PDA #754), February 12—*taught by Robert G. Kieffer, RGK Consulting*; $380 members/$530 nonmembers.

Introduction to Process Validation (PDA #501), February 12—*taught by John Voss, cGMP Systems, Inc.;* $350 members/$500 nonmembers.

A Practical Guide to Change Control (PDA #398), February 12—*taught by Steven R. Wiseman, Amgen, Inc.;* $680 members/$830 nonmembers.

LabStat: Introductory Laboratory Statistics (PDA #107), February 12–14—*taught by Lynn D. Torbeck, Torbeck and Associates;* $1440 members/$1590 nonmembers.

Computer-related Systems Validation (PDA #651), February 13–14—*taught by A. Samuel Clark, KMI/Parexel, and Jon Voss, cGMP Systems, Inc.;* $1010 members/$1160 nonmembers.

Viable Environmental Monitoring (Introductory Level) (PDA #208), February 13–14—*taught by Chris Breuninger, Senior Manager Microbiological Services, Wyeth Lederle Vaccines; and Kenneth Baker, Manager of Microbiology, Biomatrix, Inc.*; $1010 members/$1160 nonmembers.

Process Assessments/Auditing (PDA #477), February 13–14—*taught by Robert G. Kieffer, RGK Consulting;* $1010 members/$1160 nonmembers. ■

Grosvenor Resort
Downtown Disney
1850 Hotel Plaza Blvd.
Lake Buena Vista, FL 32830
Tel: **(800)-624-4109**
Fax: **(407) 828-8192**
Rate: **$105 single/double**

Use the form on page 29 to register for PDA-TRI courses.

PDA-TRI Courses Go to Sunny Orlando

PDA-TRI kicks-off its 2001 course series in Orlando, Florida. This, the first of four course series to be held throughout the USA this year, will be held February 12-14 at the Grosvenor Disney Resort in Orlando, Florida. A total of eight courses will be offered in Orlando, with ACPE continuing education credits available for all.

PDA-TRI has put together an exceptional program and faculty for these three days of courses. Courses topics will be: Using Authentication and Encryption Technology for 21 CFR 11 Solutions; Root Cause Analysis; Introduction to Process Validation; A Practical Guide to Change Control; LabStat—Introductory Laboratory Statistics; Computer-related Systems Validation; Viable Environmental Monitoring (Introductory Level); and Process Assessments/Auditing.

Registration information on the Orlando series has been sent to the membership. The brochure may be downloaded in PDF format from www.pda.org. To request a fax copy or mail copy of the registration brochure, call PDA at (301) 986-0293, fax to (302) 986-0296 or email info@pda.org. ■

PDA-TRI Thanks the Following...

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If you work in pharmaceutical science, PDA has technical and scientific documents that will likely provide you valuable assistance

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1. Please type or print your name, address and affiliation.

❑ Mr. ❑ Ms. ❑ Dr. First Name Middle Initial Last Name

Membership Number

Job Title Company

Business Address

City State/Province ZIP/Postal Code

Tel Fax E-mail

❑ Substituting for (Check only if you are substituting for a previously enrolled colleague; nonmember substituting for member must pay the additional fee.)

2. Indicate the course(s) you'd like to attend (please print). Individuals registering at the nonmember rate receive one full year of PDA membership. Nonmembers registering for multiple events need only pay the nonmember fee once. (If you do **NOT** want to become a PDA member, please check here ❑).

COURSE TITLE	COURSE #	DATE	LOCATION	PRICE (member or nonmember)
			TOTAL :	$

3. Please check the appropriate box:

❑ **Check** enclosed ❑ Wire Transfer ***Charge:*** ❑ MC/EuroCard ❑ VISA ❑ AMEX

Account Number_____ Exp. Date _____

Name _____
(exactly as on card)

Signature_____ Date _____

Payments must be made to PDA in US dollars by check drawn on a US bank, by electronic money transfer **(SunTrust Bank ABA #051000020, PDA Account #209364254, Swift#UVBIUS33), net of all bank charges**; by American Express, MasterCard, or VISA.

4. Return completed form with payment made to:

PDA, Inc.
P.O. Box 79465
Baltimore, MD 21279-0465 USA
USA Fax: (301) 986-1093 (credit cards only)

Payment must be included to be considered registered.

Federal Tax I.D. #52-1906152

Deadline: *Enrollment is limited for the benefit of all attendees; this necessitates early registration. Paid registrations must be received one week prior to the event.*
Confirmation: *Written confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event.*
Substitutions: *If a registrant is unable to attend, substitutions are welcome and can be made at any time, even on-site. If you are pre-registering as a substitute attendee, indicate this on the registration form.*
Refunds: *Refund requests must be in writing. If received one month prior to start of an event (course series, conference, etc.), a full refund, minus a $35.00 handling fee, will be made. If received two weeks prior to the event, one-half of the registration fee will be refunded. After that time, no refunds will be made.*
Event Cancellation: *PDA reserves the right to modify the material or instructors without notice or to cancel an event. If the event must be canceled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.*

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Date:_____ Check:_____ Amount:_____ Account:_____

HACCP Discussed at Capital Area Chapter Event

by William Stoedter, PDA

The PDA Capital Area Chapter held a dinner meeting on November 1, 2000, at the PDA Training and Research Institute (PDA-TRI) in Baltimore. The featured speaker was Cdr. Joseph Salyer, RS, MPH, Medical Device HACCP Training Coordinator, CDRH, FDA. The topic was Hazard Analysis and Critical Control Points (HACCP).

HACCP is a management tool used for a systematic approach to the identification, evaluation and control of hazards or product defects. The FDA first required HACCP for food processing in 1973 for canned goods. In December of 1997 HACCP became a requirement for seafood processors. In January 1998 HACCP became a requirement for large processors of meat and poultry. CDRH is using a HACCP approach in a pilot inspection program to determine if it identifies critical problems with devices more efficiently than traditional inspections.

There are seven principles of HACCP:

1. Conduct a hazard analysis on each material, component and processing step for the product. Prepare a list of steps in the manufacturing process where significant hazards can occur and identify preventive measures.
2. Identify the critical control points (CCP). A CCP is a step or procedure at which control can be applied to prevent, eliminate, or reduce hazards to acceptable levels.
3. Establish critical limits for preventive measures associated with each CCP identified.
4. Establish CCP monitoring requirements. Establish procedures for using monitoring results to adjust the process and maintain control.
5. Establish corrective actions to be taken when a critical limit deviation occurs.
6. Establish procedures for verification that the HACCP system is working correctly.
7. Establish effective record keeping procedures that document the HACCP system.

The use of Hazard Analysis and Critical Control Points, while not required by CDER or CBER, is still a useful tool for the analysis the production process. HACCP will help you understand your process and could even reveal problems with the process that were not considered in the original design. To learn more about HACCP go to www.fda.gov/cdrh/gmp/haccp.html and www.medicalhaccp.org and www.fda.gov/cdrhleveraging/casestudies.html. ■

TRI Explores Training Opportunities with UK & Ireland Chapter

In November Rick Rogers, PDA's Vice President for Education and Director of the PDA Training and Research Institute (PDA-TRI), visited with leaders of the UK and Ireland Chapter (UKIC) to determine opportunities for PDA sponsored training and educational programs. In a sweep through London, Portsmouth, Brighton and Ghent, Belgium, Rogers, accompanied by Jim Lyda, visited with many members including those on the UKIC Executive Board. As an outcome of the visit PDA is moving ahead with plans to offer the popular Aseptic Processing course in Europe in the near future. ■

Taking a break. The staff of Micron Training Intl. visit with Rick Rogers after completing the first massive PDA membership drive in for the UKIC. Micron, a well known producer of quality videos and training programs for industrial pharmaceutical use (all available through PDA), recently mailed out several thousand information packages to potential PDA members working in the UKIC area. Tony Waring, Chief Executive of Micron, is a member of the UKIC Executive Board and a long-time member of PDA. Pictured left to right at the company's offices are Micron staff Leigh Heath, Simon Reynolds, Christine Nash, Jill Asker Browne, PDA's Rick Rogers, Steve Marshall, Tony Waring, Kay Lawes.

See page 33 for a list of PDA Chapter Contacts in your area

Registration Form

FDA System Based Inspections of Drug Companies / PDA-TRI System Based Education Courses

1. Please type or print your name, address and affiliation.

_____

❑ Mr. ❑ Ms. ❑ Dr. First Name Middle Initial Last Name

Membership Number_____

Job Title_____ Company _____

Business Address _____

City _____State/Province_____ ZIP/Postal Code _____

Tel _____ Fax_____ E-mail_____

❑ Substituting for _____

(Check only if you are substituting for a previously enrolled colleague; nonmember substituting for member must pay the additional fee.)

2. Indicate the course(s) you'd like to attend. Individuals registering at the nonmember rate receive one full year of PDA membership. Nonmembers registering for multiple events need only pay the nonmember fee once. (If you do **NOT** want to become a PDA member, please check here ❑).

CHECK OFF THE WORKSHOP & COURSES YOU WOULD LIKE TO ATTEND	PDA Member	Nonmember
WORKSHOP FDA System Based Inspections of Drug Companies ❍ New Brunswick, NJ—February 5, 2001 ❍ Los Angeles, CA—February 8, 2001 ❍ San Juan, Puerto Rico—February 15, 2001	$325	$475
PDA-TRI COURSES (Choose one course only)–*NOTE: These courses not co-sponsored by FDA* A Auditing Techniques for CGMP Compliance (#496) ❍ New Brunswick, NJ—February 6, 2001 ***ONLY OFFERED IN NEW BRUNSWICK, NJ*** B Documentation Systems and Practices (#487) ❍ New Brunswick, NJ—February 6, 2001 ❍ Los Angeles, CA—February 9, 2001 ❍ San Juan, Puerto Rico—February 16, 2001 C Design and Implementation of World Class Quality Systems (#367) ❍ Los Angeles, CA—February 9, 2001 ❍ San Juan, Puerto Rico—February 16, 2001 ***NOT OFFERED IN NEW BRUNSWICK, NJ***	$680	$830
TOTAL $		

Payment must be included to be considered registered.

Federal Tax I.D. #52-1906152

Payments must be made to PDA in US dollars by check drawn on a US bank, by electronic money transfer **(SunTrust Bank ABA #051000020, PDA Account #209364254, Swift#UVBIUS33), net of all bank charges**; by American Express, MasterCard, or VISA.

3. Please check the appropriate box:

❑ **Check** enclosed ❑ **Wire Transfer** ***Charge:*** ❑MC/EuroCard ❑ VISA ❑ AMEX

Account Number _____ Exp. Date _____

Name _____

Signature*(exactly as on card)* _____ Date _____

4. Return completed form with payment made to:

PDA, Inc.
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***Deadline**: Enrollment is limited for the benefit of all attendees; this necessitates early registration. Paid registrations must be received one week prior to the event. **Confirmation**: Written confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. **Substitutions**: If a registrant is unable to attend, substitutions are welcome and can be made at any time, even on-site. If you are pre-registering as a substitute attendee, indicate this on the registration form. **Refunds**: Refund requests must be in writing. If received one month prior to start of an event (course series, conference, etc.), a full refund, minus a $35.00 handling fee, will be made. If received two weeks prior to the event, one-half of the registration fee will be refunded. After that time, no refunds will be made. **Event Cancellation**: PDA reserves the right to modify the material or instructors without notice or to cancel an event. If the event must be canceled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.*

PDA USE:

Date:_____ Check:_____ Amount:_____ Account:_____

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An International Association For Pharmaceutical Science And Technology

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❍ Industry Supplier
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❍ Academic
❍ Medical Device Manufacturer
❍ Pharmacy
❍ Recruiter
❍ Contract Manufacturing
❍ Other

Professional Interest

(check all that apply)

❍ Aerosols
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❍ Contract Manufacturing
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❍ Production & Engineering
❍ Filtration
❍ Formulation Development
❍ GMP Compliance/ Inspection Trends
❍ Isolation Technology
❍ Liquids
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❍ Maintenance
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❍ Visual Inspection of Parenterals

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We Don't Want to Lose Touch with You!

Keep your PDA mailings coming and ensure that your friends and colleagues in PDA know how to reach you. Send us your updated address, phone, fax or e-mail today! Remember, PDA's Online Directory is updated weekly—you'll want your most current information available.

Simply fill out the form below and fax it to PDA at (301) 986-0296. If you would prefer, e-mail your updated information to *info@pda.org*.

Member Info

Please type or print clearly

Last Name _____

First Name _____ Middle Initial _____

Member Number (if known) _____

Degree/Credential _____

Job Title _____

Company _____

Address _____

City _____ State/Province _____ Zip+4/Postal Code _____

Country _____

Business Phone# _____ Fax# _____

E-mail _____

Fax completed form to PDA at (301) 986-0296 or e-mail to *info@pda.org*

New members are forwarded to chapter mailing lists on an ongoing basis. For immediate notification of chapter events, please contact your local representative below and ask to be placed on the chapter mailing list.

Australia Chapter
Contact: **Mary Sontrop**
CSL Bioplasma
Tel: +61-3-9246-5401
Fax: +61-3-9246-5409
E-mail: *mary_sontrop@cslbio.com.au*

Canadian Chapter
Contact: **Grace Chin**
Pellemon, Inc.
Tel: (416) 422-4056 x230
Fax: (416) 422-4638
E-mail: *ching2@snc-lavalincom*
Website: ***www.pdacanada.org***

Capital Area Chapter
Areas Served: Maryland, District of Columbia, Virginia, West Virginia
Contact: **Allen Burgenson**
Life Technologies, Inc.
Tel: (301) 610-8567
Fax: (301) 610-8768
E-mail: *aburgens@lifetech.com*

Delaware Valley Chapter
Areas Served: Delaware, New Jersey, Pennsylvania
Contact: **Mark Kaiser**
Lancaster Laboratories
Tel: (717) 656-2300 x1263
Fax: (717) 656-2681
E-mail: *Mwkaiser@lancasterlabs.com*
Website: ***www.pdadv.org***

European Chapter
Contact: **James Lyda**
PDA Europe Office
Switzerland
Tel: +41-61-703-1688
Fax: +41-61-703-1689
E-mail: *lyda@pda.org*

Israel Chapter
Contact: **Karen S. Ginsbury**
PCI–Pharmaceutical Consulting Israel Ltd.
Tel: +972-3-9214261
Fax: +972-3-9215127
E-mail: *kstaylor@netvision.net.il*

Italy Chapter
Contact: **Vincenzo Baselli**
Pall Italia
Tel: +39-02-477-961
Fax: +39-02-4122-985
E-mail: *vincenzo_baselli@pall.com*

Japan Chapter
Contact: **Hiroshi Harada**
Tel: +81-3-3815-1681
Fax: +81-3-3815-1942
E-mail: *hharada@bcasj.or.jp*

Korea Chapter
Contact: **Jong Hwa A. Park**
Tel: +82-2-538-9712
Fax: +82-2-569-9092
E-mail: *Jong_Hwa_Park@pall.com*

Metro Chapter
Areas Served: New Jersey, New York
Contact: **Felicia Manganiello**
Tel: (732) 521-8274
Fax: (732) 521-5933
E-mail: *fmanganiello@aol.com*

Midwest Chapter
Areas Served: Illinois, Indiana, Ohio, Wisconsin, Iowa, Minnesota
Contact: **Robert S. Murphy**
Searle
Tel: (847) 581-6118
Fax: (847) 581-6553
E-mail: *robert.s.murphy@monsanto.com*

Mountain States Chapter
Areas Served: Colorado, Wyoming, Utah, Idaho, Nebraska, Kansas, Oklahoma, Montana
Contact: **Jeff Beste**
Pendleton Resources
Tel: (303) 832-8100
Fax: (303) 832-9346
E-mail: *cmdjeff@aol.com*
Website: ***www.boulder.net/~rmpda/***

New England Chapter
Areas Served: Massachusetts, Connecticut, Rhode Island, New Hampshire, Vermont, Maine
Contact: **Robert A. Pazzano, P.D.**
Validation and Training Services
Tel: (508) 870-0007 x140
Fax: (508) 870-0224
E-mail: *robert_pazzano@vtsinc.net*

Southeast Chapter
Areas Served: North Carolina, South Carolina, Tennessee, Virginia, Florida, Georgia
Contact: **Mary Carver**
Eisai, Inc.
Tel: (919) 474-2149
Fax: (919) 941-6934
E-mail: *mary_carver@rocky.eisai.com*
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FDA Documents Available

For a full listing of documents available, please contact PDA or visit our website, www.pda.org.

Guide to Inspections of Pharmaceutical Quality Control Laboratories; July 1993; Office of Regulatory Affairs; 15 pp; $15 members/$30 nonmembers. FDA 28

Guide to Inspections of Validation of Cleaning Processes; July 1993; Office of Regulatory Affairs; 9 pp; $15 members/$30 nonmembers. FDA 29

Guide to Inspections of High Purity Water Systems; July 1993; Office of Regulatory Affairs; 13 pp; $15 members/$30 nonmembers. FDA 31

Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories; July 1993; Office of Regulatory Affairs; 8 pp; $15 members/$30 nonmembers. FDA 32

Guideline on Sterile Drug Products Produced by Aseptic Processing; June 1987; CDER, CBER, Office of Regulatory Affairs; 43 pp; $15 members/$30 nonmembers. FDA 33

Guideline on Validation of Analytical Methods: Definitions & Terminology (Q2A); March 1, 1994; CDER; 4 pp; ICH Step 5 Final Guideline. $15 members/$30 nonmembers. FDA 53

Review Guidance, Validation of Chromatographic Methods; November 1994; CDER; 33 pp; $25 members/$40 nonmembers FDA 108

Validation Documentation Inspection Guide; 1993; ORA; 27 pp; ***Not available on the Internet.*** $25 members/$40 nonmembers. FDA 110

Guideline on the Validation of Analytical Procedures: Methodology; May 19, 1997; ICH; 5 pp; ICH Step 5 Final Guideline. $15 members/$30 nonmembers. FDA 125 (revised)

Draft Guidance for Industry: Manufacturing, Processing or Holding of Active Pharmaceutical Ingredients; April 17, 1998; CDER/CBER/CVM; 57 pp; Revised draft of FDA GMP guidance for APIs originally released in September 1996. $35 members/$50 nonmembers. FDA 158

General Principles of Software Validation Guidance for Industry; June 1, 1997; CDRH; 20 pp; $25 members/$40 nonmembers. FDA 187

Stability Testing of Drug Substances and Drug Products; June 1998; CDER/CBER; 114 pp; FDA's revised draft guidance for industry on stability testing. $35 members/$50 nonmembers. FDA 220

Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production; Draft Guidance; September 1998; CDER; 11 pp; $15 members/$30 nonmembers. FDA 229

PDA Technical Reports Available

Evaluation, Validation and Implementation of New Microbiological Testing Methods; This report is intended to provide a general approach to the introduction of new microbiology methods in a government-regulated environment. It is also intended to provide guidance for the successful evaluation, validation and implementation of new microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. These new methodologies offer significant improvements in terms of the speed, accuracy, precision and specificity with which testing can be performed. 2000; 37 pp; $75 members/$125 nonmembers. TR 33

Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations; Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; $90 members/$140 nonmembers (paper copy)**; TR 32**. $50 members/$75 nonmenbers (CD-ROM format) TR 32 CD.

Validation and Qualification of Computerized Laboratory Data Acquisition Systems; Prepared by the PhRMA CSVWG and the PDA Computer Related Systems-Laboratory Systems Task Group, TR 31 provides guidance to lab scientists, technicians and managers responsible for the implementation, testing, control and usage of Laboratory Data Acquisition Systems (LDAS) used within a GMP-, GLP- or GCP-regulated environment. Addresses computerized LDAS within a regulated environment; also applicable to systems critical to the operation of a company, department or function, regardless of the system's regulatory impact. 1999; 12 pp; $50 members/$75 nonmembers. TR 31

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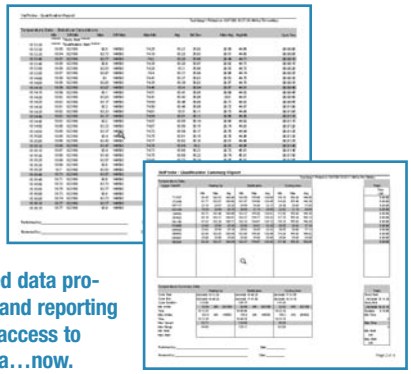

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Pharmaceutical Water: System Design & Validation
Stockholm, Sweden

FEBRUARY

February 5, 2001
PDA Information Workshop
Surviving System-based Inspections
New Brunswick. NJ

February 6, 2001
PDA-TRI Education Courses
- *Documentation Systems and Practices*
- *Design and Implementation of a World Class Quality System*

February 8, 2001
PDA Information Workshop
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Los Angeles area

February 9, 2001
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February 12–14, 2001
PDA-TRI Orlando Education Course Series
Grosvenor Resort, Downtown Disney
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February 12
- *Electronic Records, Electronic Signatures: Introductory Level*
- *Root Cause Analysis (1/2 day)*
- *Introduction to Process Validation (1/2 day)*
- *A Practical Guide to Change Control*

February 12–14 *(three-day course)*
- *Laboratory Statistics*

February 13–14 *(two-day courses)*
- *Computer Related Systems Validation*
- *Viable Environmental Monitoring - Introductory Level*
- *Auditing and Process Assessments*

February 15, 2001
PDA Information Workshop
Surviving System-based Inspections
San Juan, Puerto Rico

February 16, 2001
PDA-TRI Education Courses
- *Documentation Systems and Practices*
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February 19–23, 2001
PDA International Congress
In cooperation with PDA Japan Chapter
Bridging the Healthcare and Pharmaceutical World in the New Millennium
Kyoto International Conference Hall
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PDA-TRI Education Courses

February 22–23
- *Designing Training That Works*
- *Practical and Suitable Measures for FDA Inspections*

MARCH

March 12–16, 2001
PDA Spring Conference, Courses and Tabletop Exhibit
Modern Pharmaceutical Microbiology: Advancing the Science
Aladdin Resort & Casino
Las Vegas, NV
PDA-TRI Education Courses

March 15 *(half-day course)*
- *PDA Computer Products Supplier Audit Management Overview Training*

March 15–16 *(two-day courses)*
- *Cleanroom Management*
- *Environmental Surveillance and Control*
- *Introduction to Validation*

APRIL

April 2–5, 2001
PDA Good Electronic Records Management (GERM) Conference
Hyatt Regency Tampa
Tampa, Florida

April 5–6, 2001
PDA & PDA Italy Chapter Conference on
Maximizing Global Manufacturing Strategies for Pharmaceutical Production
Grand Hotel Timeo
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SEPTEMBER

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Hyatt Regency Washington, DC on Capitol Hill
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PDA/FDA Viral Clearance Forum and Tabletop Exhibit
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