Volume XXXIX, No. 8

PDA Letter

August 2003

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

Carnegie Mellon SEI Examines PDA Technical Report No. 32, page 6

2003 PDA/FDA Joint Regulatory Conference—be sure to attend this premier conference in the Nation's Capital.

Navigating Current GMPs: Catch the Compliance Wave

Senior FDA officials and international regulatory representatives will convene with PDA in September to discuss critical compliance and scientific issues. Don't miss your chance to sit at the table with these experts.

More than 25 FDA and international health authority representatives and over 30 industry experts will assemble in Washington, DC to participate in interactive sessions on a wide variety of compliance-focused sessions.

Highlights:

- Discuss FDA's new aseptic processing guidance, corrective and preventative actions, inspection trends, legal issues and the new Part 11 Guidance.
- Optional breakfast sessions will be offered to help enhance your knowledge and interaction with the FDA.
- "Meet the FDA" at a luncheon provided to all full conference registrants, providing an additional opportunity to facilitate discussion on critical issues.

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For a List of Confirmed FDA Speakers, turn to page 19

Omni Shoreham Hotel—
Washington, DC

Conference: **September 8–10**
Tabletop Exhibition: **September 8–9**
Courses: **September 11–12**

2003 PDA Annual Meeting, Courses and Exhibition

Building on Our Strengths: Quality, Science and Innovation

Janet Woodcock, M.D., FDA, Director, CDER, to provide update on FDA GMP Initiative

Register today for PDA's largest conference of the year, offering you a broad variety of opportunities to learn from industry experts, exchange ideas and gain new knowledge important to doing your job.

Overview

Discover the latest advances in pharmaceutical and biopharmaceutical science and technology and significantly expand your international scientific network in a multi-track format.

Highlights include:

- Scientific sessions;
- Interactive Interest Group discussions;
- Roundtable exchange breakfast (choose from a variety of topics);
- Interactive exhibit hall and poster session;
- Pre-conference: online access to speaker presentations that you can download in advance (contingent upon advance receipt of presentations from speakers);
- Post-conference: complimentary CD-ROM of all conference presentations, and
- "Midnight Train to Georgia" reception.

Three distinct session tracks—Compliance Issues, Manufacturing, and Science and Development—will feature case studies and presentations from over 50 industry experts.

- Discuss the importance of quality assurance and

continues on page 20

Downtown Hilton Atlanta
on Courtland NE, Atlanta, GA

Conference: **November 10–12**
Exhibition: **November 10–11**
Courses: **November 13–14**

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Sartorius North America Inc.
131 Heartland Blvd.
Edgewood, New York 11717
Phone +1.800.635.2906
Fax +1.631.254.4253

Sartorius AG
Weender Landstrasse 94–108
37075 Goettingen, Germany
Phone +49.551.308.0
Fax +49.551.308.3289

sartocheck@sartorius.com
www.sartorius.com

Visit us at the PDA/FDA Joint Regulatory Conference—Table #47

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

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

PDA Europe Office
Gautam Maitra
Director, Europe
R-1045.P.18
Postfach
CH-4002 Basel
Switzerland
Tel: +41 61 321 56 30 (Fixnet)
Mobile: +41 79 439 59 56
Fax: +41 61 321 83 48
E-mail: *maitra@pda.org*

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Neal G. Koller
President

Matthew Clark
Director of Marketing Services

Evelyn N. Heitman
Editor/Writer

Janet Raysick
Production Manager

Virginia Ventura
Membership Director

PDA Letter

Important Dates...

- September 1, 2003—registration deadline for the Taormina International Conference, page 23
- October 10, 2003—deadline to sign up for hosting a breakfast roundtable discussion at the 2003 PDA Annual Meeting, page 20
- January 31, 2004—2004 Trainer's Choice Award Call for Entries deadline, page 27

IN THIS ISSUE...

Neal G. Koller
PDA President

PDA Meets with Thomas Lönngren, Executive Director of EMEA

As part of a continuing effort to build PDA's scientific and technology-based relationships with global health authorities, I met with the Executive Director of EMEA, Thomas Lönngren, on July 2, 2003. The meeting was also attended by PDA Board member Georg Roessling, Ph.D., Schering AG; Gautam Maitra, PDA Director, Europe; and key senior managers from EMEA, including Tony Humphreys, Head of Sector, Regulatory Affairs and Organization Support Sector; Katrin Nodop, Principal Administrator, Scientific and Inspections Section; and Arielle North, Scientific Administrator for the Directorate.

Our presentation focused in particular on PDA's strong Science and Technology programs and the ongoing activities in Europe. We discussed the PDA Science Advisory Board (SAB) in purpose, function and activities in detail. We further presented the scientific base for the activities of the PDA Regulatory Affairs and Quality Committee (RAQC) and suggested the EMEA may have interest in participation in SAB and RAQC. Mr. Lönngren suggested that EMEA may explore the possibility of participating in PDA science activities.

One of the PDA projects of interest was the PDA-TRI training of the pharmaceutical and biopharmaceutical inspectors of the Italian Health Authority, which is currently being conducted in a series of six one-week-long modules in Italy. Mr. Lönngren was pleased to learn of this initiative and expressed strong interest in PDA providing GMP and regulatory training, especially to the EU candidate countries.

We also discussed the possibility of expanding on the PDA/EMEA Virus Safety Forum by holding a Pan European Regulatory Summit with EMEA and individual EU member health authorities in Europe once per year. The upcoming PDA/EMEA European Virus Safety Forum, to be held September 29–October 1, in Frankfurt, Germany, was cited as an important step in the collaborative efforts between PDA and EMEA.

Mr. Lönngren was interested in learning more about how PDA collaborates with FDA. Georg Roessling, Gautam Maitra and I agreed to provide EMEA with an understanding of how that important relationship has developed and strengthened over the years.

We all look forward to building a closer science-based relationship with EMEA. ■

PDA
An International Association For Pharmaceutical Science And Technology

Virus Safety Forum

September 29 to October 1, 2003
Paul-Ehrlich-Institut, Langen, Germany

emea

Virus safety is a key issue for biological and biotechnological medicinal products. This first joint PDA/EMEA European Virus Safety Forum will bring together an international panel of speakers from industry, regulatory authorities and research to present and discuss the most up-to-date scientific knowledge and regulatory aspects in the area of virus safety of recombinant proteins, monoclonal antibodies, plasma-derived medicinal products and advanced technology medicinal products. The conference aims to facilitate discussion between all parties on the various aspects related to the virus safety of medicinal products.

Session I: Regulatory Requirements
- EMEA Perspective; FDA Perspective
- Industry Perspective for Plasma-Derived and Biotech Products

Session II: Testing Source Material
- QPCR for Retrovirus Detection
- DNA Microarray Technology
- Developing New Infectivity Assays
- Qualification of Virus/Cell Systems for Their Intended Use
- MVM Testing of Recombinant Products: Rationale for Testing; West Nile Virus – Epidemiology & Testing
- Variants of B19

Session III a: Virus Validation, Virus Assay and Standardization
- Appropriateness of Virus Preparations for Virus Validation Studies; Plasmid DNA as a Tool for Validation
- Use of Quantitative PCR in Viral Clearance Studies
- Use of Bacteriophage as a Surrogate for Viruses

Session III b.: Virus Validation, Model Viruses
- Model Virus Approach for West Nile Virus
- Cell Culture-Based Assay of Parvovirus B19 and the Relevance of Animal Model Viruses
- Considerations for a Model Virus of HBV

Session IV: Virus Inactivation/Removal Technologies
- Matrix Approach to Evaluate Virus Removal and Inactivation
- Robustness Studies: Definition of Parameters/Generic Use
- Nanofiltration – PDA Virus Filter Task Force Status Report
- Gamma Irradiation; Irradiation of Human Albumin Solution at Manufacturing Scale

Session V: Virus Safety Aspects of Advanced Technology Medicinal Products
- Cell Therapy Medicinal Products; Gene Therapy
- Clinical Significance of Animal Viruses
- Products from Transgenic Animals
- Xenogeneic Cell Therapy Medicinal Products

Call for Poster Abstracts

Poster abstracts are welcome before **August 15th** for consideration by the organizing committee. Abstracts should be approximately 100 words in length and sent to maitra@pda.org in Microsoft Word or Rich Text format.

Full program and registration information will be posted to www.pda.org (scroll through Events on front page), or call the Registrar today to sign up for this limited attendance conference...+1-301-986-0293 ext. 131.

Recent Sci-Tech Discussions

EU GMPs and OOS Results

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

This month's posting …

Question

I know that the EU GMPs do not consider the OOS situation in the same way that the FDA does, but, can anyone assist me with some questions?

a. If an EU company does not investigate OOS's are they in breach of any EU-GMPs?
b. If an EU company does not investigate OOS's, will local inspection authorities be upset or do they not care?
c. Do most EU companies follow FDA's guidelines (and American GMP practices) on OOS's?

Response 1

According to ICH Q7A (GMPs for the APIs), "any out-of-specification result obtained should be investigated and documented according to a procedure. This procedure should require analysis of the data, assessment of whether a significant problem exists, allocation of the tasks for corrective actions, and conclusions. Any resampling and/or retesting after OOS results should be performed according to a documented procedure." This looks similar to the OOS investigation in the USA. However, it will be interesting to hear from Europe how it is practiced and/or enforced. I will also be interested to know of any similar guidance and/or regulation on finished drug products.

ICH Q7A was accepted as Annex 18 to the EU Guide to Good Manufacturing Practice.

Response 2

EU and therefore EU-GMP need not dance to the tunes of the US. In fact, OOS was the term used by Judge Wolin during the ruling in the landmark case of *US* v. *Barr Laboratories*. This ruling was made following the days of generic drug scandal in the US. Such deficiency was and is not felt in EU's GMP standards/rules/expectations. Most importantly, EU need not follow what the US does. A counter question that might be imagined is "Why are US companies not in compliance with EU-GMPs"? Not following OOS is not and cannot be a breach in EU as it is not applicable to EU countries.

Second, local EU inspection need not impose OOS on any firms, and hence the question of their getting upset does not arise. Third, EU companies need not follow any FDA guideline as long as they are in compliance to their own GMP requirements. But, some EU companies do hold USA registration for trading purposes, and they do follow the guidelines of FDA in addition to complying with EU GMPs.

Response 3

Thanks, but my question was: is there an equivalent EU requirement to FDA's OOS regulations?

Response 4

Does EU follow the ICH Q7A guidelines? You need take a look at ICH Q7A, which does include OOS.

Response 5

Although there is no direct reference to OOS in the EU Rules, except the previously mentioned Annex 18, or ICH Q7A, EU inspectors do expect basic good science to be followed. Should an inspector find a similar set of circumstances that resulted in *US* v. *Barr Laboratories*, I'm certain that it would result in regulatory action. The regulatory action would be unlikely to result in legal proceedings instituted by the company as the EU pharmaceutical laws are framed differently, and there is a well-defined dispute resolution procedure. It also helps that generally there are no Freedom of Information laws, and therefore problems between a company and a regulatory agency do not enter the public domain.

Response 6

I always avoid mixing politics with technology. With regard to inspectors, other than US-FDA inspectors, trying to question those companies who are not based in the USA and not having registration of US-FDA for non-implementation of OOS, then it is their own expectations and not a regulatory requirement. And everyone knows that what is not a regulatory requirement could be challenged to your advantage within the meaning and scope of regulatory requirements. ■

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. Visit PDA's Web site at **www.pda.org** to sign up via the Web or send an e-mail to *requests@www2.pharmweb.net*.

TR-32 Update

Software Engineering Institute Publishes Report on PDA Technical Report No. 32

by Harvey F. Greenawalt

Carnegie Mellon University's Software Engineering Institute (SEI) has completed their case study and issued Technical Report CMU/SEI-2003-TR-011 Case Study and Technical Report on PDA Technical Report No. 32 (TR-32): *Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations* as a method for organizational appraisals in COTS Evaluation Activities and as a model for sharing objective information about supplier practices. PDA and Carnegie Mellon University's SEI began their work on the report on April 10, 2001.

The SEI Case Study and Technical Report on PDA TR-32 was issued on May 23, 2003. The SEI Technical Report has been made available to DoD sponsors and to the software community.

SEI's conclusion states: "Failure to adopt the program could result in an inefficient use of valuable resources and lost time to build and calibrate a program specialized to a specific industry. Time and resources spent on such a task could now be redirected to integrate knowledge of a supplier's technology process into technology acquisition practices. Such knowledge, when buying COTS products from the marketplace, could reduce procurement, project, and technology risks."

The Case Study describes the development of an evaluation capability of computer and software suppliers for use by the pharmaceutical industry. The study describes the background of industry practice and the role of government regulation within the industry. The role of audits of computer and software suppliers is examined together with the need for a standardized audit practice.

The SEI Report analyzes the PDA process for audit practice that is based on a defined process model consisting of six steps: initiation, pre-work, auditing, observations and reporting, decision, and follow-up. Each of these steps is described in detail, as are several key enablers of the process: a data collection tool, an audit repository center (ARC), and extensive auditor training supervised by an industry-regulated oversight agency.

Finally, the SEI report describes the results to date of the audit process, the benefits to suppliers and end users together with a set of lessons learned from the experience of creating the PDA Process.

SEI concluded that the PDA Process has four unique features, which make it a valuable tool in performing evaluations of COTS products:

1. Domain independence;
2. A functional repository that meets the security concerns of all stakeholders;
3. A supporting infrastructure for continuous improvement (training and qualification of auditors, ensured refresh of assessment data, operational metrics, and oversight by an independent board); and
4. Deliberate separation of the audit process from data collection tools.

SEI findings indicate that the potential value of this program to prospective subscribers external to the FDA-regulated industry (e.g., government, defense, and other private industries) is quite high. The benefits of adopting the program should prove immediate, because:

1. There is little need to spend development time to create a program that is industry-specific;
2. One gains instant access to current report data in the repository holdings;
3. There is increasing cross-industry value of the program, thus increasing the repository holdings; and
4. By layering data collection needs on top of the common data-collection tools, the user can leverage program modularity for either industry-specific or even subscriber-specific issues.

The SEI Report can be reviewed online at http://www.sei.cmu.edu/publications/documents/03.reports/03tr011.html.

Training on PDA TR-32 and auditor qualification is conducted by the PDA Training and Research Institute. For details, see www.pda.org/courses/courses.

Membership

Fifty-four major pharmaceutical/chemical, biotechnology, OTC and medical device companies have become members of the Audit Repository since June of 2000.

Fifteen suppliers of computer products and services to the industry have become members of the Audit Repository to voluntarily place their audit data in the repository for distribution to their pharmaceutical industry clients.

Auditor Resources

Currently there are ninety-eight PDA Qualified Auditors. The PDA Qualified Auditors represent over sixteen countries throughout the USA, Canada, Europe, and Asia.

Information on applications for qualification and course registration is available on the PDA Web site at www.auditcenter.com/training.

Availability of Audits

Currently fifty-four audits are either under consideration, in process or available for distribution. Thirty audits are available for immediate distribution.

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

For more information about the Audit Repository, audits and their availability, visit ARC's Web site at www.auditcenter.com.

Table 1.0

Supplier Name	Supplier Product	Annual Refresh Available
Access360, Inc.	enRole 4.0 (Provisioning Software).	No
Agilent Technologies	Cerity for Pharmaceutical QA/QC. Network data system for analytical laboratories.	N.R.
Alacris, Inc.	idNexus, Alacris products are designed to simplify identity management and maximize trust associated with Public Key Infrastructure (PKI) implementation and security technologies.	N.R.
Applied Biosystems, Inc.	SQL*LIMS™ Software - Laboratory Information Management System.	N.R.
Automation Tooling Systems, Inc.	Custom programming services for Process Control Software.	N.R.
Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set.	Yes
Documentum, Inc.	• Content Authentication Services (CAS) • Document Control Manager (DCM) • Documentum eContent Server • GXPharma	Yes
Documentum, Inc.	• Document WebDAV Server • Documentum Digital Asset Manager • Document Media Services • Document Desktop for Macintosh	N.R.
Entrust Technologies Ltd.	Digital security technology for enterprise resource systems. Public Key Infrastructure Technology (PKI).	Yes
Epicentric, Inc.	Foundation Enterprise Server 4.0, which is a tool for coordinating information from disparate sources and for disparate uses.	N.R.
First Consulting Group, Inc.	Custom information-based strategy software, operations improvements, management and integration services.	Yes
Fisher-Rosemount Systems, Inc.	Distributed Factory Automation, Delta V product line.	No
Foss NIRSystems, Inc.	SLE Near-infrared analysis of chemical and physical properties.	No
Inktomi Corporation	Enterprise Search. Providing performance, scalability, and ease-of-use, Inktomi Enterprise Search is a comprehensive information retrieval platform that delivers access to content across the enterprise, regardless of location, language, or file format.	No
Innovatum, Inc.	DataThread™ - Data audit, workflow, 21 CFR Part 11 and E-signature solution for AS/400 applications, without programming changes.	N.R.
Interwoven, Inc.	Web Publication Management.	No
Lexign Corporation	Lexign Flow™ EPR Software.	N.R.
LoftWare, Inc.	Loftware Print Server (LPS) Lable Printing System.	Yes
MARC Global Systems	Warehouse Execution Systems.	No
Merant	PVCS Dimensions & PVCS Replicator Software Configuration Management Tool.	N.R.
Mercury Interactive	Test Management Tools: • QuickTest Professional • Astra QuickTest • Astra LoadTest • Astra FastTrack • LoadRunner • LoadRunner TestCenter • TestDirector • WinRunner	Yes
Propack Data GmbH	Enterprise Production Management System, PMX 3.2 with Solutions MES and CTM.	N.R.
Rational Software Corporation	Rational Suite® Enterprise • Rational ClearQuest (for team-based change request and defect management). • Rational ClearCase (configuration management for smaller development teams).	N.R.
SAP AG	mySAP.com E-business platform, specifically: aspects of Supply Chain Management, Product Lifecycle Management and Business Intelligence relevant to pharmaceutical manufacturing operations (Includes Product Lines: SAP R/3 4.5B and SAP R/3 4.6B/C).	No
Schlumberger	Cyberflex Palmer Smart Card and Cyberflex Access Intergration Kit.	No
Serena Software, Inc.	Serena ChangeMan Automating the Software Lifecycle.	N.R.
Sparta Systems, Inc.	TrackWise®. Training, Configuration, Installation and Support for TrackWise®.	Yes
SSA Global Technologies, Inc.	Mid-Range ERP software for manufacturing, supply chain and financial application domains.	Yes
The Sycamore Group	Custom IT Solutions. Integration suite of COTS products and services to bridge data across multiple internal computer systems, including E-Commerce, LIMS, ERP, enterprise databases, mainframes, and wireless and portable devices.	N.R.

PDA Interest Group Leaders

Biotechnology
Frank Matarrese
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608
Tel: (510) 923-3128
Fax: (510) 923-3375
E-mail—
frank_matarrese@chiron.com

Computer Systems
Barbara L. Meserve
The Hollis Group Inc.
Station Square Two #109
Paoli, PA 19301
Tel: (610) 889-7350
Fax: (610) 296-2339
E-mail—
bmeserve@hollisgroup.com

Contract Manufacturing
Michael R. Porter
Eli Lilly & Company
DC 3852
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 277-2595
Fax: (317) 276-8116
E-mail—
porter_michael_r@lilly.com

Drug–Device Delivery Systems
Raymond A. Pritchard
Alkermes, Inc.
88 Sidney Street
Cambridge, MA 02139
Tel: (617) 250-1621
Fax: (617) 494-5504
E-mail—
ray.pritchard@alkermes.com

Filtration
Jack Cole
Jack Cole Associates
115 Turtle Cove Lane
Huntington, NY 11743
Tel: (631) 424-3658
Fax: (631) 424-3658
E-mail—
jvcole@aol.com

GMP Purchasing
Nancy M. Kochevar
Amgen, Inc.
MS 9-1-E
One Amgen Center
Thousand Oaks, CA 91320-1799
Tel: (805) 447-4813
Fax: (805) 447-1904
E-mail—
nancyk@amgen.com

Inspection Trends/ Regulatory Affairs
Robert L. Dana
Elkhorn Associates Inc.
4828 Patrick Place
Liverpool, NY 13088
Tel: (315) 457-3242
Fax: (315) 451-7363
E-mail—
elkhornassoc1@aol.com

Isolation Technology
Dimitri P. Wirchansky
Jacobs Engineering Group, Inc.
Three Tower Bridge
Two Ash Street, Ste. 3000
Conshohocken, PA 19428
Tel: (610) 567-4452
Fax: (610) 238-1100
E-mail—
dimitri.wirchansky@jacobs.com

Lyophilization
Edward H. Trappler
Lyophilization Techology
30 Indian Drive
Ivyland, PA 18974
Tel: (215) 396-8373
Fax: (215) 396-8375
E-mail—
frzdry@lyo-t.com

Microbiology/ Environmental Monitoring
Jeanne E. Moldenhauer, Ph.D.
Vectech Pharmaceutical Consulting, Inc.
16100 W. Port Clinton Rd.
Lincolnshire, IL 60069
Tel: (847) 478-1439
Fax: (847) 478-1745
E-mail—
jeannemoldenhauer@yahoo.com

Ophthalmics
Chris Danford
Alcon Laboratories Inc.
Mail Code Q-108
6201 South Freeway
Ft. Worth, TX 76134
Tel: (817) 551-4014
Fax: (817) 568-7004
E-mail—
chris.danford@alconlabs.com

Packaging Science
Edward J. Smith, Ph.D.
Wyeth Pharmaceuticals
2100 Renaissance Blvd.
King of Prussia, PA 19406
Tel: (610) 313-4338
Fax: (610) 313-4644
E-mail—
smithej@wyeth.com

Pharmaceutical Water
Theodore H. Meltzer, Ph.D.
Capitola Consulting Co.
8103 Hampden Lane
Bethesda, MD 20814-1124
Tel: (301) 986-8640
Fax: (301) 986-9085
E-mail—
theodorehmeltzer@hotmail.com

Production and Engineering
Frank Bing
Abbott Laboratories
D-968/AP4B
100 Abbott Park Road
Abbott Park, IL 60064-6076
Tel: (847) 937-8191
Fax: (847) 938-6569
E-mail—
frank.bing@abbott.com

Quality Assurance/ Quality Control
Don E. Elinski
Johnson & Johnson Merck
1734 Valette Drive
Lancaster, PA 17602
Tel: (717) 207-3858
Fax: (717) 207-3556
E-mail—
elinski@aol.com

Solid Dosage Forms
Pedro J. Jimenez, Ph.D.
Eli Lilly & Company
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 277-3618
Fax: (317) 276-3618
E-mail—
jimenez_pedro_j@lilly.com

Stability
Rafik H. Bishara, Ph.D
Eli Lilly & Company
DC 2623 Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 276-4116
Fax: (317) 276-1838
E-mail—
rhb@lilly.com

Sterilization/ Aseptic Processing
James P. Agalloco
Agalloco & Associates
2162 US Highway 206
Belle Mead, NJ 08502
Tel: (908) 874-7558
Fax: (908) 874-8161
E-mail—
jagalloco@aol.com

Training
Thomas W. Wilkin, Ed.D.
Schering-Plough Corp.
M/S R-40
2000 Galloping Hill Road
Kenilworth, NJ 07083-1328
Tel: (908) 298-5213
Fax: (908) 298-5120
E-mail—
thomas.wilkin@spcorp.com

Vaccines
Frank S. Kohn, Ph.D.
FSK Associate
1899 North Twins Lake Rd.
Manson, IA 50563
Tel: (712) 297-8074
Fax: (712) 297-8074
E-mail—
fsk@lowatelecom.net

Validation
Bohdan M. Ferenc
Qualification Services
116 Route 10
Succasunna, NJ 07876
Tel: (973) 927-9823
Fax: (973) 927-9823
E-mail—
biferenc@aol.com

Visual Inspection of Parenterals
John G. Shabushnig, Ph.D.
Pfizer Inc.
7171 Portage Road
MS 2043-41-104
Kalamazoo, MI 49001-0199
Tel: (269) 833-8906
Fax: (616) 833-9987
E-mail—
john.g.shabushnig@pfizer.com

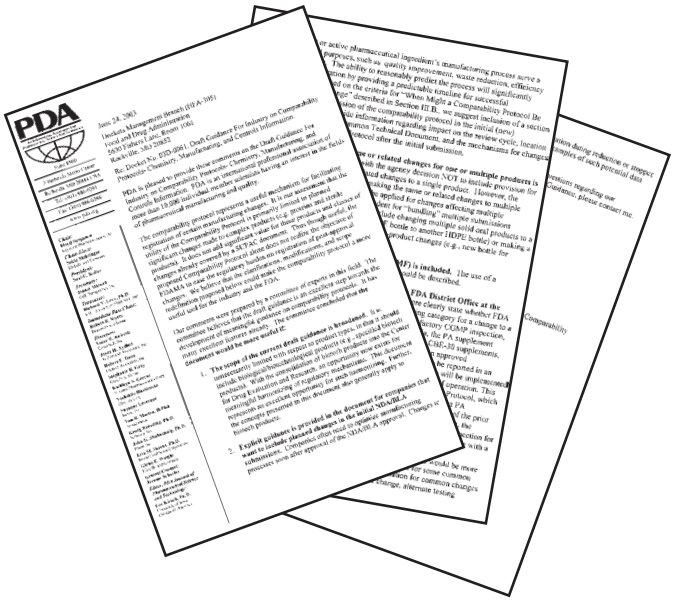
PDA Comments on FDA Draft Guidance for Industry on Comparability Protocols

FDA issued a Draft Guidance for Industry on Comparability Protocols covering Chemistry, Manufacturing and Controls (CMC) information on February 13, 2003. PDA formed a Task Group to comment on the draft and submitted these comments to FDA on June 24. Following is the full text of PDA's comments.

June 24, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Re: Docket No. 03D-0061, Draft Guidance For Industry on Comparability Protocols- Chemistry, Manufacturing, and Controls Information.

PDA is pleased to provide these comments on the Draft Guidance For Industry on Comparability Protocols- Chemistry, Manufacturing, and Controls Information. PDA is an international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical manufacturing and quality.



The comparability protocol represents a useful mechanism for facilitating registration of certain manufacturing changes. It is our assessment that the utility of the Comparability Protocol is primarily limited to planned significant changes made to complex products (e.g. proteins and sterile products). It does not add significant value for those products and classes of changes already covered by a SUPAC document. Thus though useful, the proposed Comparability Protocol alone does not realize the objective of FDAMA to ease the regulatory burden on registration of post-approval changes. We believe that the clarifications, modifications, and scope redefinition proposed below could make the comparability protocol a more useful tool for the industry and the FDA.

Our comments were prepared by a committee of experts in this field. The committee believes that the draft guidance is an excellent step towards the development of meaningful guidance on comparability protocols. It has many excellent features already. The committee concluded that **the document would be more useful if**:

1. **The scope of the current draft guidance is broadened**. It is unnecessarily limited with respect to product types, in that it should include biological/biotechnological products (e.g., specified biotech products). With the consolidation of biotech products into the Center for Drug Evaluation and Research, an opportunity now exists for meaningful harmonizing of regulatory mechanisms. This document represents an excellent opportunity for such harmonizing. Further, the concepts presented in this document also generally apply to biotech products.
2. **Explicit guidance is provided in the document for companies that want to include planned changes in the initial NDA/BLA submissions.** Companies often need to optimize manufacturing processes soon after approval of the NDA/BLA approval. Changes to a drug product or active pharmaceutical ingredient's manufacturing process serve a variety of useful purposes, such as quality improvement, waste reduction, efficiency enhancement, etc. The ability to reasonably predict the process will significantly improve implementation by providing a predictable timeline for successful implementation. Based on the criteria for "When Might a Comparability Protocol Be Useful for a CMC Change" described in Section III.B., we suggest inclusion of a section that discusses the submission of the comparability protocol in the initial (new) submission. It could provide information regarding impact on the review cycle, location of the information in the Common Technical Document, and the mechanisms for changes to approve a Comparability Protocol after the initial submission.

continues on page 10

Comparability Protocols, from page 9

3. **The ability to "bundle" the same or related changes for one or multiple products is explicitly provided.** We concur with the agency decision NOT to include provision for general protocols for multiple unrelated changes to a single product. However, the guidance should explicitly allow for making the same or related changes to multiple products, i.e., bundling, which should be applied for changes affecting multiple regulatory files. In such cases, the precedent for "bundling" multiple submissions together is well established. Examples include changing multiple solid oral products to a new packaging system (e.g., from one HDPE bottle to another HDPE bottle) or making a change to allow technology-specific multiple-product changes (e.g., new bottle for several solid orals).
4. **Information related to Drug Master Filings (DMF) is included.** The use of a Comparability Protocol when a DMF is involved should be described.
5. **Inspection timing could be coordinated through the FDA District Office at the request of the Manufacturer.** The Guidance should more clearly state whether FDA would permit a supplement in a non-prior-approval reporting category for a change to a new site that has not been inspected or does not have a satisfactory CGMP inspection, because an inspection is usually prompted by, or requested via, the PA supplement process. For instance, standard packaging site changes require CBE-30 supplements, unless the site does not have a satisfactory CGMP inspection. An approved Comparability Protocol could allow for a packaging site change to be reported in an annual report, along with a statement (Lines 570–573) that the move will be implemented only when the site has a satisfactory CGMP inspection for that type of operation. This Guidance, as written, does not provide for use of such a Comparability Protocol, which requires insuring completion of a satisfactory CGMP inspection without a PA supplement. We propose language such as (line 579): "If the submission of the prior approval Comparability Protocol supplement would require a site inspection, the applicant is responsible for insuring that the site has a satisfactory CGMP inspection for the type of operation prior to commercial distribution of a change in accordance with a commitment to the approved Comparability Protocol."
6. **Data requirements for common changes.** Comparability Protocols would be more useful to manufacturers if FDA could provide data requirements for some common changes. Data requirements capturing the expected information for common changes such as alternate API supplier, API manufacturing site change, alternate testing laboratory, product line extension (a new fill size), expiration dating reduction or stopper changes could be very useful. We have attached three examples of such potential data requirements in Attachment 2.

More specific comments are in the attachment. If you have any questions regarding our comments, or how we may assist with further development of the Guidance, please contact me.

Sincerely,

William Stoedter, RAC
Director Regulatory Affairs
stoedter@pda.org

Attachment: PDA comments on the FDA Draft Guidance for Industry on Comparability Protocols- Chemistry, Manufacturing, and Controls Information
Common Data Requirements for Common Changes

Please Note: The Attachment containing additional PDA comments can be found on the PDA Web site at www.pda.org under "Regulatory Comments." ■

Meet the Regulator
Rebeca Rodríguez


Rebeca Rodríguez

Contact Information:
National Drug Expert Investigator
DFI/ORO/ORA/FDA
466 Fernández Juncos Avenue
San Juan, P.R. 00901-3223

E-mail:
Rebeca.Rodriguez@fda.gov

Work History

Rebeca Rodríguez started her career in 1981 as an Analyst for a pharmaceutical company in Puerto Rico. Her job responsibilities included conducting raw materials and finished product testing and calibration of Nuclear Magnetic Resonance (NMR) equipment. She joined the San Juan District of the Food and Drug Administration (FDA) in 1989 as a Chemist. In this position, she analyzed food and drug samples, conducted method validations, performed check analysis of violative samples, and reviewed analytical worksheets of other chemists. She also worked on GMP and pre-approval inspections with Investigators. She participated in a criminal investigation evaluating the integrity of test data and presented evidence obtained during the investigation in an ad hoc meeting at FDA headquarters. The ad hoc meeting resulted in the application of a data integrity policy, a consent decree of injunction and a criminal investigation of the company.

In May of 1992, Rodríguez was transferred to the San Juan District Investigations Branch as an Investigator; she joined FDA's Foreign Inspection Cadre in 1993. In July of 1995 she was promoted to a GS-12 Drug Specialist and in March 1999 to a GS-13 Drug Specialist. As an FDA Investigator, she conducted GMP and pre-approval inspections of domestic and foreign bulk pharmaceutical drug manufacturers, as well as validity assessment inspections under the Application Integrity Policy (AIP), congressional inquiry investigations, tampering investigations, criminal investigations, and complaint and recall follow-up investigations. She has also provided instruction and training in the techniques of inspections and investigations for lower grade trainees and journeymen investigators. She has conducted inspections of domestic and foreign medical device manufacturers, as well.

Rodríguez has represented FDA as an instructor and a speaker in the drug and medical device areas for private industry. As a District Drug Specialist, she served as an advisor for issues related to drug GMP and pre-approval inspections, and she assisted FDA in the development of inspectional and regulatory strategies and recommendations for the disposition of cases. She has served as the Supervisor's back-up in drug program areas and has often served as Acting Supervisory Investigator and Acting Compliance Officer. Rodríguez has received numerous local and national FDA awards for outstanding performance.

Current Job Responsibilities

In February of 2003, Rodríguez was selected as an FDA National Expert Investigator for drug program areas. Her current job responsibilities include:

- Conducting inspections of applications that include Process Analytical Technologies (PAT) as a member of FDA's Process Analytical Technology Review, Inspection, and Office of Pharmaceutical Science Team (PATRIOT);
- Representing FDA by developing and providing formal instruction and delivering key presentations to private industry in drug program areas;
- Developing and implementing formal training for Agency personnel and state and local officials;
- Supporting critical FDA activities, such as international harmonization, partnerships, and training;
- Serving as a liaison and providing guidance concerning drug programs for regulated industries, state agencies, other federal agencies, and FDA management;
- Offering advice and guidance on new advances in technology related to drug products, programs, laws and regulations, court decisions, trends, and scientific findings;
- Meeting with industry representatives to discuss any identified deficiencies and to obtain critical information;
- Serving as an expert witness in court cases;
- Planning, coordinating, and evaluating programs and activities for the professional regulatory field.

Education

Rodríguez earned a Bachelor of Science degree in Chemistry, Magna Cum Laude, from the University of Puerto Rico in 1981 and was approved by the American Society for Quality (ASQ) as a Certified Quality Engineer in 1991.

Personal Interests

Rodríguez says, "I have immensely enjoyed my 13-year career with FDA, and while my work is a very important part of my life, I also have other activities and hobbies that add variety and enjoyment to my life. One of my favorite activities is sharing time with friends at restaurants or during weekends at the beach. I like to go to the beach, not to swim, but mainly to sit in the shade just watching and listening to the sights and sounds of the sea, listening to music, or reading a book. My favorite hobby has always been reading books; the books I enjoy most are those written by great Latin-American and Spanish female writers, such as Isabel Allende, Marcela Serrano, Almudena Grandes, Rosario Ferré, Rosa Montero, and others. I also enjoy Gabriel García Márquez novels. In addition, I like going to the movies, practicing yoga, and playing a friendly match of tennis with relatives and friends. And, one of my great passions is cats: I own three beautiful cats: a Himalayan, a Persian and a mixed-breed." ■

—compiled by Evelyn N. Heitman

U.S. Regulatory Briefs

FDA Announces Draft Guidance on Providing Regulatory Submissions in Electronic Format — Postmarketing Periodic Adverse Drug Experience Reports This is one in a series of Guidance documents intended to assist applicants making regulatory submissions in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA). Agency Guidance documents on electronic submissions will be updated regularly to reflect the evolving nature of the technology and the experience of those using this technology.

This guidance discusses general issues related to the electronic submission of postmarketing periodic adverse drug experience reports for (1) drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs) and (2) therapeutic and blood products marketed for human use with biologics license applications (BLAs). This guidance does not apply to vaccines, whole blood, or components of whole blood.

Submit written comments on the draft guidance by August 25, 2003, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Reference Docket No. 2003D-0231. Submit electronic comments to: http://www.fda.gov/dockets/ecomments. For questions regarding this draft document, send an e-mail (CDER and CBER) to aersesub@cder.fda.gov, or telephone (CDER) Randy Levin, (301) 594-5411, or (CBER) Michael Fauntleroy, (301) 827-5132. The document can be found at: http://www.fda.gov/cder/guidance/4781dft.doc.

FDA Announces Pilot Program for Posting Warning Letter Responses on FDA's Web Site FDA traditionally receives many requests under the Freedom of Information Act (FOIA) (5 U.S.C. 552) for warning letters issued to FDA-regulated entities. In compliance with the Electronic Freedom of Information Act Amendments of 1996 (EFOIA), FDA will post on the FDA Web site warning letters that are, or are likely to be, frequently requested documents under FOIA.

The pilot program is part of the agency's ongoing efforts to keep the public informed regarding agency activities and to make information available in a manner that is accessible and fair. Accordingly, FDA plans to test a pilot program for 6 months that provides warning letter recipients the opportunity to have their responses to warning letters posted on the Web site. For purposes of this pilot only, the agency will consider warning letter recipients to be the addressee and any other individuals or entities specifically named in a warning letter.

FDA will post a warning letter recipient's response on the Web site if the recipient: (1) requests that the response be posted, and (2) submits a copy of the response in a word processing format on a disk or CD-ROM. (The disk or CD-ROM should be submitted to the FDA office that issued the warning letter and should be submitted with the response.) FDA will review the response and redact certain information to ensure that the response complies with protections available under FOIA. The pilot program will begin on September 22, 2003. For further information, contact Philip L. Chao, Office of Policy and Planning, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 827-0587. The announcement can be found at: http://www.fda.gov/OHRMS/DOCKETS/98fr/03-15732.html.

Transfer of Product Oversight from CBER to CDER FDA is transferring certain product oversight responsibilities from CBER to CDER. As of June 30, 2003, responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines) will have transferred from the Office of Therapeutics Research and Review (OTRR), CBER, to the Office of New Drugs (OND) and the Office of Pharmaceutical Science (OPS), CDER. This transfer will take place as the divisions of OTRR within CBER are moved to offices within CDER.

- The Division of Therapeutic Proteins and the Division of Monoclonal Antibodies of OTRR, CBER will be moved to OPS, CDER.
- The Division of Clinical Trial Design and Analysis, the Division of Application Review and Policy, and the immediate office of the Director, OTRR, CBER will be moved to OND, CDER.

FDA anticipates that as of October 1, 2003, the start of the fiscal year 2004, the offices detailed to CBER will be incorporated into CDER's organizational structure, including the creation of a new Office of Drug Evaluation (ODE) in OND, CDER.

A Web site has been created listing the identification numbers of the IND's, BLA's, investigational device exemptions, and NDA's in CBER that are being transferred to CDER. Holders of all CBER applications are encouraged to check this Web site to determine which, if any, of their applications are being transferred and to find new contact information. Until notified by CDER, submitters should continue to send submissions to the CBER Document Control Center. The Web site address is: www.fda.gov/cber/transfer/transfer.htm. The agency is in the process of

making technical amendments to its regulations affected by this reorganization and anticipates these revisions will be completed by October 1, 2003, or shortly thereafter.

FDA Announces Two Pilot Programs for Continuous Marketing Applications (CMA)—*as posted on PDA's Web site in June of 2003* Pilot 1 provides for the review of a limited number of presubmitted portions of an applicant's marketing application (reviewable units) based on the terms and conditions agreed upon by the applicant and FDA. Pilot 1 applies only to certain new drug or biological products that have been designated as Fast Track products pursuant to Section 112 of the Food and Drug Administration Modernization Act of 1997. Pilot 1 will be effective October 1, 2003 through September 30, 2007, and will include an evaluation component to determine the added value and costs of the program and its impact on the efficiency of the review process. The Pilot 1 program can be found at: http://www.fda.gov/cber/gdlns/pdufa1.htm. Pilot 2 will test the CMA concept during the investigational (IND) phase of new drug and biological product development. It will also provide for frequent scientific feedback and interaction between FDA and applicants. Pilot 2 will be effective October 1, 2003 through September 30, 2007, and will include an evaluation component to determine the added value and costs of the program and its impact on the efficiency of the development process. The Pilot 2 program can be found at: http://www.fda.gov/cber/gdlns/pdufa2.pdf. ■

—William Stoedter

Regulatory News

European Regulatory and GMP Briefs

EMEA News

In its judgment of June 12, 2003, the European Court of Justice has ruled that the Republic of Finland has failed to fulfill its obligations under Directive 89/105/EEC (the so-called "Transparency Directive", which applies to any national measure to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by the national sickness insurance systems). In particular, decisions adopted pursuant to the Finnish legislation as to the inclusion of a medicinal product in a category qualifying for higher-rate insurance coverage did not comply with the requirements of Article 6 of the Directive, since: they were not amenable to judicial review, they did not have to contain a statement of reasons, and the persons concerned did not have a right to be heard.

The revision of Annex 1 to the EU GMP Guide has been adopted by the ad hoc GMP inspectors Working Group at their meeting on April 28–29, 2003. The amendments concern only section 3 harmonizing where appropriate, the environmental standards for cleanrooms laid down in the GMP Guide with those laid down in international standards (e.g., EN/ISO 14644-1) together with a minor change to section 20. The remainder of the Annex is unchanged. The Pharmaceutical Committee has adopted the revised version at its meeting on May 15, 2003 setting September 1, 2003 as the date for coming into operation.

PIC/S

PIC/S Committee Meeting & PIC/S Seminar in Bratislava, Slovak Republic

A joint meeting of the Committee of Officials, established under the terms of the Pharmaceutical Inspection Convention (PIC), and the Committee set up under the Pharmaceutical Inspection Cooperation Scheme (jointly referred to as PIC/S) took place in Bratislava, Slovak Republic on June 2–3, 2003 under the chairmanship of Lilian Hamilton, Sweden/Medical Products Agency. With the exception of Singapore, unable to attend due to SARS, all PIC/S members were represented. The EMEA, Estonia, Latvia, Poland, South Africa and WHO also participated in the meeting. All in all, 40 delegates from 30 Inspectorates and two Agencies took part in the meeting.

International Medicinal Inspectorates Database

The Committee adopted the statute of the International Medicinal Inspectorates Database (IMID), which aims at establishing—on a voluntary basis—a database containing information on GMP inspections carried out (or to be carried out) by IMID participating Regulatory Authorities. The IMID exclusively targets medicinal products [finished products, active pharmaceutical ingredients (APIs) and investigational medicinal products] which have been manufactured in non-PIC/S countries. The main aim of the IMID is to alleviate the workload of PIC/S members with regard to third-country inspections. This is to be achieved by sharing information on the GMP compliance status of manufacturing sites. The IMID will result in a reduction in the number of inspections, in particular of duplicative inspections (for more information on the IMID, see http://www.picscheme.org/IMID/imid.htm).

The IMID started operating on July 1, 2003. With the exception of Germany and the United Kingdom, all other PIC/S Participating Authorities have expressed an interest in the IMID.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme are two international agreements between countries and pharmaceutical inspection authorities which together provide an active and constructive cooperation in the field of GMP. Their purpose is the networking between competent authorities, the development and maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of inspectors.

There are currently 26 Participating Authorities in the PIC/S (Convention and Scheme taken together). All countries which are parties to the Convention (*) are members of the Scheme. The PIC/S Participating Authorities are: Australia*, Austria*, Belgium*, Canada, Czech Republic, Denmark*, Finland*, France*, Germany*, Greece, Hungary*, Iceland*, Ireland*, Italy*, Liechtenstein*, Malaysia, Netherlands, Norway*, Portugal*, Romania*, Singapore, Slovak Republic, Spain, Sweden*, Switzerland*, and the United Kingdom*.

Joint Reassessment Programme

The Committee decided to conclude the pilot phase of the PIC/S Joint Reassessment Programme (JRP) following the positive experience made during the reassessment of Romania and Sweden (in the second half of 2002) as well as Australia (in the first half of 2003). It also revised and simplified the procedure for the JRP, allowing auditors to make use of other evaluation reports (e.g., under a Mutual Recognition Agreement). It selected the next Authorities to be reassessed and their respective auditors. Finally, the Committee also supported the proposal to merge the JRP with the Joint Audit Programme launched by the EU Heads of Agencies in order to avoid unnecessary duplications between the two programmes.

Evaluation of Membership Applications

A follow-up visit by a PIC/S delegation to Latvia took place in March 2003. On the basis of the delegation's recommendations, the Committee agreed

to invite Latvia's National Inspection System to accede to PIC/S by January 1, 2004. However, Latvia will have to report beforehand on changes to the licensing system, its ability to honor membership obligations, and the GMP compliance of industry.

A follow-up visit by a PIC/S delegation to Estonia was postponed for the second time, thus prompting the Committee to request a progress report by Estonia's State Agency of Medicines before the next Committee meeting. The Committee reviewed the membership application made by Poland's Main Pharmaceutical Inspectorate. It decided to give Poland sufficient time to implement the recent legislative changes before sending a delegation to assess the Polish GMP inspection system.

The Committee examined the membership application made by the Czech Institute for State Control of Veterinary Biologicals and Medicaments and decided to proceed with an evaluation visit in autumn of 2003, possibly in conjunction with a similar visit to be carried out by the EU in the context of a PECA Agreement with the Czech Republic. The Czech Institute is the first veterinary agency to apply for PIC/S membership (the Czech State Institute for Drug Control, responsible for medicines for human use, is already a PIC/S member).

Some progress was reported on the application by the National Laboratories for Foods and Drugs (NLFD). However, a number of important questions still need to be addressed, in particular why a three to five year-long transitional period is needed by the NLFD to adopt the PIC/S GMP Guide (or equivalent)—a basic requirement for any PIC/S membership applicant. South Africa's Medicines Regulatory Authority reported that it would update its membership application shortly, thus resuming with the interrupted application process.

New Membership Applications—Lithuania, Oman, Russia, Ukraine

A preliminary assessment of the application made by Lithuania's Department of Pharmacy was given to the Committee. Three new but incomplete applications were received by the Secretariat: one from Oman's Ministry of Health, one from the Ministry of Health of the Russian Federation, and one from the Ukrainian Ministry of Health. The representatives of Oman, Russia and the Ukraine were also met in the margin of the PIC/S 2003 Seminar (see Annex).

Training for Inspectors

The Committee was informed of PIC/S seminars for GMP inspectors, in particular: the 2003 seminar on the Inspection of Quality Control Laboratories (Bratislava, June 4–6, 2003), organized by the Slovak State Institute for Drug Control (SIDC) (see Annex), and the 2004 seminar on the Inspection of Active Pharmaceutical Ingredients, organized by the Spanish "Agencia Española del Medicamento" (AEM), which will take place near Barcelona, Spain on June 16–18, 2004.

Information was also provided on PIC/S Expert Circles:

- The 4th meeting of the Expert Circle on Medicinal Gases, organized by Finland's National Agency for Medicines, will be held in Hämeenlinna, Finland on June 9–11, 2003.
- The 10th meeting of the Expert Circle on Human Blood and Tissue, organized by the Hungarian National Institute of Pharmacy, will take place in Visegrad, Hungary from September 8–11, 2003.
- The 6th meeting of the Expert Circle on Hospital Pharmacy, organized by the Medicines and Healthcare Products Regulatory Agency, in London, UK will be held on October 21–22, 2002.
- The 2nd meeting of the Expert Circle on Computerized Systems, organized by Australia's Therapeutic Goods Administration, will occur in Canberra, Australia, on February 17–18, 2003.
- The 2nd meeting of the Working Group on Biotechnology, organized by the Danish Medicines Agency, will be held in Brønshøj, Denmark on August 29, 2003.

continues on page 16

European Regulatory and GMP Briefs, from page 15

New/Revised PIC/S Guidance Documents

The Committee adopted the following documents: Guide to Inspections of Source Plasma Establishments and Plasma Warehouses (PI 008-1); Site Master File for Source Plasma Establishments (PI 019-1); and Site Master File for Plasma Warehouses (PI 020-1). These documents will enter into force on July 15, 2003. The PIC/S Guidance on Best Practices for Computerized Systems in Regulated "GxP" Environments (PI 011-1) will enter into force on September 1, 2003; Annex 1 to the PIC/S GMP Guide (revision in parallel with the EU) will be adopted by a written procedure and will enter into force at the same time as in the EU; Annex 13 to the PIC/S GMP Guide (revision in parallel with the EU) will enter into force at the same time as in the EU.

PIC/S Online

The Committee was informed of the initial draft of a "Questions & Answers" document with regard to the interpretation of the PIC/S GMP Guide, which will be posted on the PIC/S Web site (http://www.picscheme.org) once completed. The Committee agreed to meet in Geneva, Switzerland on November 11–12, 2003 (a one-and-a-half day meeting).

2003 PIC/S Seminar—Bratislava, Slovak Republic

The joint meeting of the PIC/S Committee was followed by a seminar on "The Inspection of Quality Control Laboratories" (June 4–6, 2003), organized by SIDC. The PIC/S seminar was attended by 95 participants from 36 countries. This number also includes invited inspectors and speakers from a number of non-PIC/S countries or agencies such as: Cyprus, EMEA, Estonia, FDA, Latvia, Lithuania, Macedonia, New Zealand, Oman, Poland, Russia, Serbia, South Africa, Ukraine, UNICEF, and WHO.

The seminar focused on:

- Expert discussions on current regulatory issues related to GMP in pharmaceutical quality control laboratories;
- The harmonization of inspection standards and practices; and
- The drafting of guidance documents, in particular an Aide Memoire on the inspection of pharmaceutical quality control laboratories.

The collected papers presented at the seminar will be made available on a CD-ROM. ■

—Gautam Maitra

PDA
An International Association For Pharmaceutical Science And Technology

2003–2004 International Calendar

2003

September 29–October 1, 2003
PDA/EMEA European Virus Safety Forum
Hosted by the PDA Central Europe Chapter in collaboration with EMEA and the Paul-Ehrlich-Institut
Langen—Metro Frankfurt, GERMANY

October 2, 2003
EC GMP Annex 1 Sterile Products Forum
Langen-Metro Frankfurt, GERMANY

October 13–14, 2003
2003 Taormina International Conference
A Conference for Decision-Makers Responsible for Strategy, Implementation and Management of Quality Assurance and Regulatory Compliance—***Managing for Quality in a Cost-Focused Environment***
Conference: October 13–14
Tabletop Exhibits: October 13–14
Grand Hotel Timeo & Villa Flora
Taormina, Sicily, ITALY

October 21–23, 2003
A3P 16th International Congress
Congress: October 21–23
Exhibits: October 21–23
Bellevue Congress Hall
Biarritz, FRANCE

December 15, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

2004

February 16–20, 2004
2004 PDA International Congress—Basel
Messe Basel Convention Center
Basel, SWITZERLAND

May 17–21, 2004
2004 PDA Pacific Rim Congress—Singapore
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
The Ritz Carlton Millenia, SINGAPORE

June 7–8, 2004
PDA/R3 Nordic
Scientific, Industrial, and Regulatory Aspects of Clean Products and Devices
Stockholm, SWEDEN

Stay tuned to
www.pda.org
for the most up-to-date calendar information.

PDA is the preeminent science and technology organization that provides state-of-the-art training for the pharmaceutical and biopharmaceutical manufacturing industry.

PDA SciTech Summit™

March 8–12, 2004 • Orlando County Convention Center • Orlando, FL

A week-long series of conferences and training courses is now being planned for the spring of 2004. The PDA SciTech Summit™ will provide the industry with a one-stop "shop" for all training and education needs on the most critical issues facing industry in production and manufacturing, science and technology, QA/QC, regulatory compliance, and biopharmaceuticals.

Special sessions will focus on cold chain management, Part 11 issues and GMPs in development. International regulatory and health authority participation is expected.

With the strategic co-location of the 2004 SciTech Summit™ with the CleanRooms East Exposition, professionals will discover cutting-edge expertise and state-of-the-art technology for contamination control and drug manufacturing.

Contact PDA if you are interested in exhibit or speaking opportunities. Watch the PDA Web site at www.pda.org for updated information on the PDA 2004 SciTech Summit™. Budget now to attend this important industry summit. ■

—Leslie Zeck

PQRI Blend Uniformity Workshop

September 22–23, 2003 • Bethesda, Maryland

The Product Quality Research Institute (PQRI) is conducting a workshop to discuss the recommendations developed on Blend Uniformity.

In response to concerns expressed by applicants regarding inconsistent policies in establishing blend uniformity acceptance criteria to demonstrate adequacy of mix, the FDA Office of Generic Drugs (OGD) issued the draft document *Guidance for Industry, ANDAs: Blend Uniformity Analysis* (August 1999). Both generic and innovator pharmaceutical companies raised a number of concerns following the publication of this document. The PQRI Blend Uniformity Working Group (BUWG) was established in February 2000.

One of the primary goals of this group was to draft a scientifically-based alternative to the OGD document. The resulting recommendation addresses both FDA and industry concerns by substantially enhancing product quality assurance without increasing regulatory burden. The PQRI BUWG recommends that these blend and dosage unit uniformity requirements be administered uniformly throughout the industry. PQRI submitted the recommendation to the FDA on December 31, 2002, providing the Agency with an alternative strategy to consider when drafting future regulatory policy to assess blend and dosage unit uniformity.

This project provided both industry and FDA with proof of principle that the PQRI concept is viable and that FDA would indeed accept and act on a PQRI recommendation.

The recommendation addresses both FDA and industry concerns by substantially enhancing product quality assurance without increasing regulatory burden.

Blend Uniformity Working Group

Under the leadership of Dr. Tom Garcia, Pfizer, Inc., the PQRI Blend Uniformity Working Group labored to articulate the specific industry and FDA issues with the FDA draft *Guidance for Industry, ANDA's: Blend Uniformity Analysis*, developed a work plan to address each issue, evaluated data provided by industry and available in the literature and jointly agreed upon a recommendation that was submitted to FDA for consideration. The Agency reviewed the initial recommendation and raised several issues for the working group to address before it could be accepted. The group met with the FDA reviewers and successfully responded to their concerns. The final recommendation has been accepted by the Agency and the guidance is incorporating the points made therein. It should also be noted that the PQRI recommendation was reviewed and accepted by the Pharmaceutical Sciences Advisory Committee. PQRI is proud to provide this unique forum to address product quality issues and invite all interested parties to participate in the Blend Uniformity Working Group Workshop.

PQRI is a non-profit corporation, established for education and scientific purposes. PQRI represents a unique collaboration and commitment to pharmaceutical excellence between academia, government (primarily through the Food and Drug Administration), and industry, including trade organizations and associations representing its various segments. The primary goal of PQRI is to serve as a neutral forum for academia, government and industry to cooperatively conduct pharmaceutical product quality research with the ultimate objective of reducing unnecessary regulatory burden through the provision of sound scientific evidence.

Registration for this conference is being handled by PDA. Details will be available on our Web site at www.pda.org. ■

—Leslie Zeck

PDA/FDA Joint Regulatory Conference, from cover

- Meet the FDA Ombudsman in a special luncheon session (previously scheduled as a breakfast session, this session has been enhanced and moved to a later time on the agenda.)
- The Capitol Steps, a troupe of current and former Congressional staffers who claim to be the only group in America that attempts to be "funnier than the Congress."

—Someone from your company should attend—

This conference has something to offer everyone. Individuals of all expertise levels who are involved in pharmaceutical and biopharmaceutical product development, regulatory approval, production and quality assurance, including those associated with drug product manufacture, service providers, contract services and US and international regulatory authorities will benefit from participation in this important conference.

Register online at www.pda.org/PDF/03PDA-FDA-RegForm.pdf. ■

—Leslie Zeck

Confirmed FDA participants include:

Lester C. Crawford, DVM, Ph.D., Deputy Commissioner
Murray M. Lumpkin, M.D., Principal Associate Commissioner
Helen Winkle, CDER
Ajaz Hussain, Ph.D., CDER
Richard L. Friedman, CDER
Nick Buhay, CDER
Mary Kremzner, CDER
Warren F. Rumble, CDER
Yana R. Mille, CDER
Gary German, CBER
Seamus O'Boyle, CBER
Sheryl Lard Whiteford, CBER
Robert Coleman, ORA
Jean Blackston Hill, ORA
Marie T. Falcone, ORA
Mark Kramer, Office of the Ombudsman

PDA-TRI Lecture Courses during PDA/FDA Conference:

September 11

Biopharmaceutical QA/QC for Senior Management

September 11–12

Cleanroom Management

CGMP & Compliance

Preparing for an FDA Pre-Approval Inspection

Validation of Sterilization Processes

September 12

Application of CIP to the Pharmaceutical Process

2003 PDA/FDA Joint Regulatory Conference
Exhibitor Listing

Alphabetical by company name, with tabletop location.

As of 7/30/03

2003 PDA Annual Meeting, from cover

GMP in drug development;

- Discuss the new FDA Part 11 Guidance;
- Identify issues and technologies in environmental monitoring;
- Identify approaches for improving quality systems;
- Discuss new technologies for manufacturing, and
- Discuss issues related to cold chain management.

Volunteer to facilitate a roundtable discussion on a topic of interest to the industry including aseptic processing, cleaning validation, environmental monitoring, GMPs, 21 CFR Part 11, changes to the USP, isolator technology, PAT, quality auditing, rapid methods in microbiology, stability, sterilization, sterility, LAL testing, and more.

E-mail zeck@pda.org by October 10 if you are interested in hosting a breakfast roundtable discussion on these or other topics.

Register today at www.pda.org/PDF/03AnnMtgRegForm.pdf. ■

—Leslie Zeck

To Register, see form on **page 28**.

PDA-TRI Lecture Courses:

November 13

Designing, Monitoring & Validation of Pharmaceutical Manufacturing Ventilation Systems

Auditing Techniques for CGMP Compliance

November 13–14

Basic Concepts in Cleaning and Cleaning Validation

Computer-Related Systems Validation

A Practical Approach to Aseptic Processing and Contamination Control

November 14

Managing in a GMP Environment

Change Control & Documentation

2003 PDA Annual Meeting Exhibitors

Alphabetical by company, with booth location. (As of 7/30/03.)

EXHIBITORS

AAI	510
Abbott Laboratories, OEM Group.	726
Abbott One 2 One	724
Accugenix	422
Afton Scientific Corp.	707
Akorn, Inc.	727
American Pharmaceutical Partners, Inc	629
American Plastics Technology, Inc.	507
American Stelmi Corporation	621
Applied Biosystems	605
Associates of Cape Cod, Inc.	310, 312
Baxter Pharmaceutical Solutions, LLC	512
BD Diagnostic Systems	225, 227
Ben Venue Laboratories, Inc.	624
Biolog, Inc.	116
bioMerieux, Inc.	529, 531
BioMondex, Ltd.	405
BioPort Corporation	919
Bioscience International, Inc.	719
BioScreen Testing Services	610
Biotest Diagnostics Corp.	329
BOC Edwards Pharmaceutical Systems	622
Cambrex Bio Science Walkersville, Inc.	720
Cambridge AccuSense, Inc.	606
Carlisle Life Sciences	224
Celsis Laboratory Group	226
Charles River Laboratories	630
Chesapeake Biological Labs, Inc.	211
Clarkston Consulting	802
Clordisys Solutions, Inc.	202
Comar, Inc.	735
Commissioning Agents, Inc.	611
Compliance Software Solutions Corp.	204
Compli, LLC	819
CompuVal, Inc.	114
Contec, Inc	607
Covance	205
CRB Consulting Engineers, Inc.	613
CRC Press	506
Cryovac Sealed Air Corporation	504
CUNO, Inc.	708
Dabrico, Inc.	711
Dresser-ebro Instruments	304
DSM Pharmaceuticals, Inc.	508
Duoject Medical Systems, Inc.	513
DuPont Contamination Control	305
DuPont Qualicon	125
Ecolab	511
Eisai USA, Inc.	308
EMD Chemicals, Inc.	828
Envirocooler	917
FBN Validation Associates, Inc.	404
Gavin Pharmaceutical Services	627
GE Kaye Instruments, Inc.	324, 326
Genesis Machinery Products	712
Getinge/Castle, Inc.	713
Grace Engineering & Validation, LLC	218
Hach Ultra Analytics	721, 723

Around the Corner...

The 2003 PDA Annual Meeting, Courses and Exhibition

Downtown Hilton Atlanta on Courtland NE • Atlanta, GA

November 10–14, 2003

Annual Meeting:
November 10–12

Courses:
November 13–14

Exhibition:
November 10–11

The fall season is approaching quickly, and so is PDA's largest meeting of the year—the 2003 PDA Annual Meeting, Courses and Exhibition. You will want to showcase your products and services at this conference, which is offering a variety of opportunities to learn from experts, exchange ideas, and network with customers and health authorities.

If you already have reserved your space, now is the time to plan for your exhibition; please check the deadline for submittal of your company description, category listing and booth personnel registration at www.pda.org/PDF/03AnnMtg-Sponsorship.pdf. Also, please note that:

- Your company description will be posted on the PDA Web site for 90 days;
- Your company description and category listing will be printed in the Exhibit Guide, which will be distributed to all the attendees at the show.

If you have not reserved your space, this is your chance to meet new prospects and build upon existing customers. PDA offers opportunities designed to achieve your company's budget goals. Sponsoring an event or advertising in the Exhibit Guide will build your company's recognition throughout the pharmaceutical and biopharmaceutical industries.

As a sponsor you would gain the following benefits, which will provide maximum exposure and increase your booth traffic:

- Recognition in the Exhibit Guide;
- Recognition on Directional Signs throughout the conference;
- Sponsor ribbons for all company personnel attending the event;
- Recognition in the *PDA Letter* show issue;
- Additional priority points toward selection of your future space.

Take advantage of this proven PDA vehicle to maximize the return on your budget!

Also, remember that the 2003 PDA Taormina International Conference and Tabletop Exhibits will convene October 13–14 in Taormina, Sicily, Italy. The overarching theme will be: Managing for Quality in a Cost-Focused Environment. This conference will provide an excellent opportunity to brand your company name and products and to advertise your company message. Plan now to attend!

To reserve your space and/or sign up for sponsorship and advertising, please contact Nahid Kiani at (301) 656-5900 or kiani@pda.org. ■

—Nahid Kiani

2003 PDA Annual Meeting Exhibitors

(continued from page 20)

EXHIBITORS

PDA/EMEA Virus Safety Forum

Hosted by PDA and EMEA • September 29–October 1, 2003

Paul-Ehrlich Institut, Langen, Germany

Limited seating is available at the PDA/EMEA joint conference. Register today.

The conference will provide a forum for discussion of current issues relating to the virus safety of recombinant proteins, monoclonal antibodies and plasma-derived medicinal products.

Virus safety is a key issue for biological and biotechnological medicinal products. This first joint PDA/EMEA European Virus Safety Forum will bring together an international panel of speakers from industry, regulatory authorities and research to present and discuss the most up-to-date scientific knowledge and regulatory aspects in the area of virus safety of recombinant proteins, monoclonal antibodies, plasma derived medicinal products and advanced technology medicinal products. The conference aims to facilitate discussion between all parties on the various aspects related to the virus safety of medicinal products.

Conference Highlights:

- Two-and-a-half day conference;
- Extensive health authority participation from Europe and the US;
- Five interactive sessions addressing scientific, technical and regulatory issues;
- Two networking receptions;
- Proceedings to be published by the International Association for Biologicals (IABs).

The conference aims to facilitate discussion between all parties on the various aspects related to the virus safety of medicinal products.

Speakers include:

Johannes Blümel, Ph.D., Paul-Ehrlich-Institut, Germany
Kurt Brorson, Ph.D., FDA, CBER, USA
Kevin Brown, Ph.D., National Heart, Lung and Blood Institute, USA
Patrick Celis, Ph.D., EMEA, UK
Klaus Cichutek, Ph.D., Paul-Ehrlich-Institut, Germany
Albert Farrugia, Ph.D., Therapeutic Goods Administration, Australia
Mahmood Farshid, Ph.D., FDA, CBER, USA
Paula Korhola, Ph.D., National Agency for Medicines, Finland
Johannes Löwer, Ph.D., Paul-Ehrlich-Institut, Germany
Philip Minor, Ph.D., National Institute for Biological Standards and Control, UK
James S. Robertson, Ph.D., National Institute for Biological Standards and Control, UK
John Saldanha, Canadian Blood Service, Canada
Glenda Silvester, EMEA, UK
Ralf Toenjes, Ph.D., Paul-Ehrlich-Institut, Germany

The first PDA European Biotechnology Interest Group meeting will take place in conjunction with this forum. Influence this PDA Interest Group and increase your networking horizon by attending this meeting. This interactive session will facilitate in-depth information exchange and will feature lively discussion among participants. The Interest Group session is open to all full registrants of the conference.

To register, visit www.pda.org/PDF/PDA-EMEA-VirusSafety-RegForm.pdf. ■

—Leslie Zeck

To download brochure, go to www.pda.org/PDF/PDA-EMEA-VirusSafety-Bro.pdf.

PDA Audio Conferences

Delivering Timely Information to You in a Cost-Saving Manner

PDA audio conferences offer you the opportunity to stay informed about the latest hot topics in the pharmaceutical and biopharmaceutical industry without even leaving your office! With an enhanced Web component, it's even easier for you and your colleagues to benefit from presentations by industry and regulatory speakers. Audio conferences save you time, money, and provide an excellent return on your investment!

Registration fees for PDA audio conferences are $325 for each site. Your entire department can participate from a speaker phone and an LCD projector set up in your company's conference room. You can distribute photocopies of the presentations or even request an audio tape for future training purposes.

The next featured topic will be: Combination Products: Understanding the Unique Issues. Check the PDA Web site, www.pda.org for details on this and future audio conferences. ■

—Andrea Agalloco

2003 Taormina International Conference

Managing for Quality in a Cost-Focused Environment

A must-attend event for decision-makers

Effective compliance and quality management are critical to a company's success. PDA invites the participation of key decision-makers in a prestigious international conference for those responsible for strategy, implementation and management of global quality assurance and regulatory compliance.

A limited number of industry executives are invited to participate with expert leaders from the pharmaceutical and biopharmaceutical manufacturing industry to convene at the exclusive **Grand Timeo Hotel & Villa Flora** in Taormina, Sicily on **October 13–14, 2003**. At this conference, we will discuss critical issues and challenges related to **"Managing for Quality in a Cost-Focused Environment."** Representatives from FDA, EMEA and industry will lead these important discussions. Participants will interact with such featured presenters as:

- John Mitchell, Vice President for Global Quality for Pfizer, Inc.;
- Helen Winkle, FDA, CDER, Acting Director, Office of Pharmaceutical Science;
- Jean-Louis Robert, EMEA, CPMP;
- Michael Beatrice, Vice President, Abbott Laboratories;
- Eric Blumberg, FDA, Deputy Chief Counsel;
- Ronald F. Tetzlaff, Ph.D., President, KMI, a division of PAREXEL International, LLC;
- William Vodra, J.D., Arnold & Porter law firm.

The conference will provide a forum for discussion of practical information relevant to effective compliance and quality management. Participants will gain important new knowledge on developing and implementing new quality systems and how to rebuild quality within an organization. The design of the conference, including formal presentations, roundtable discussions, tabletop exhibits, and social events, is specifically structured to enhance interaction among a select and limited number of delegates and world renowned experts.

Don't miss the opportunity to participate in this worldwide networking and strategy conference in an intimate setting. Full registration includes *two complimentary nights* at the first-class Grand Timeo Hotel (single room accommodation based on availability, for a limited time on a first-come, first-served basis to the first 50 paid registrants).

To ensure your participation please visit www.pda.org/calendar/index.html#taormina to download the brochure or **register online by September 1, 2003**. Upon confirmation of your participation or that of representatives from your company, PDA will provide you with additional details about the conference and your accommodations in Taormina. ■

—Leslie Zeck

Conference:
October 13–14

Tabletop Exhibits:
October 13–14

Grand Hotel Timeo & Villa Flora
Taormina, Sicily
ITALY

Sponsored by the PDA Italy Chapter.

See registration form on page 31.

2004 PDA International Congress—Basel

Product Life Cycle Management for the 21st Century

Messe Basel Convention Center • Basel, Switzerland

Congress and Tabletop Exhibition
February 16–18, 2004

PDA-TRI Courses
February 19–20, 2004

February 19
Clinical Trials Directive & MP for Investigational Medicinal Products
Risk Estimation in Aseptic Processing

February 19–20
CGMPs for Bioprocesses
Ventilation & Airborne Contamination in Cleanrooms
Pragmatic Cleaning Validation

The program for this conference is still in development. Visit our Web site at www.pda.org for up-to-date information.

Mark A. Elengold, Deputy Director of CBER will discuss Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach/CBER Perspective.

Convene with FDA presenters from CDER and CBER along with industry during PDA's premier International Congress in scenic Basel, Switzerland for discussions on risk assessment, corrective and preventative action programs and further developments in the "Pharmaceutical Manufacturing in the 21st Century" initiatives. Both the European and US perspectives will be openly discussed.

Confirmed FDA Speakers include:
Ajaz Hussain, Ph.D., CDER
Mark Elengold, CDER

Roundtable Discussion

Start off your morning by joining colleagues for lively roundtable discussions on topics such as: European and U.S Inspection Trends, Regulatory Training, GMP Initiatives, and much more. Please visit PDA's Web site at www.pda.org for additional topics being offered or e-mail neal@pda.org to suggest or facilitate a specific topic.

Congress Highlights

21st Century FDA Initiatives: Improving the Control and Effectiveness of Drugs

- GMP Changes
- Regulatory Changes
- Inspections
- Clinical Trials Development

From Current to Future Manufacturing & Technology Trends

- PAT Initiatives
- Contract Manufacturing
- Biotechnology
- Isolation Technology or What?
- Membrane Absorbing Technology
- Standardization of Nano (Virus) Filters
- New Drug Delivery Technologies—Combination Products
- Rapid Development of Vaccines vs. Emerging Global Diseases

Future Trends of Information and Control System Technology in the Pharmaceutical Industry

- Interpretation of Evolving Regulations
- Electronic Common Technical Documents (eCTDs)
- Electronic Process Assurance and Control

Who Should Attend

All individuals interested in the future of pharmaceutical and biopharmaceutical science and technology, including those engaged in manufacturing, production, quality assurance/quality control, engineering and maintenance operations, facility design, product and process development, scale-up, validation, compliance and regulatory affairs, and research and development will derive significant value from participation.

PDA Interest Groups

Take advantage of the informal discussion groups to meet with colleagues to discuss your specific questions and ideas. Interest Groups will be offered each day in the morning or afternoon in conjunction with the scheduled program.

Exhibits

This Congress will provide a great opportunity to see the latest in pharmaceutical and biopharmaceutical scientific and technological products and services at the Tabletop Exhibition. The Exhibition will be strategically located in the foyer area outside the main meeting rooms. Three receptions, two lunches and daily refreshments breaks are scheduled in the exhibit area. Exhibitors are encouraged to invite prospective clients—including those who are not attending the conference—to attend the exhibits without charge on Wednesday, February 18, 2004 from 8:30 am to 12:00 pm. For more information on exhibiting, contact Nahid Kiani at (301) 656-5900 or via e-mail at: kiani@pda.org.

Educational Courses

The PDA Training and Research Institute (PDA-TRI) provides unprecedented education, training, and applied research in pharmaceutical and biopharmaceutical sciences and associated technologies. Courses providing in-depth education on technology topics relating to the Congress will be held on February 19–20 following the Congress.

About Basel

Basel, a city of nearly 200,000 people and 2,000 years of history, is located at the elbow of the Rhine on the borders of France and Germany. It is the center of the pharmaceutical industry and the site of major trade fairs. A block of rooms are being held for Congress delegates at the Swissotel Basel, the Hotel Three Kings and the Hotel Europe, which are all conveniently located near the Messe Basel Convention Center. These three hotels are also accessible by tram, bus, and train. Detailed reservation information will be available in future announcements. ■

—Wanda Neal

Eliminate Filter Sterilizing

Disinfectants & Sporicides

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What is SimpleMIX?

The convenient, patent pending SimpleMIX System provides a sealed multi-chamber container that when activated mixes the two solutions. The top part contains the sterile concentrate disinfectant or sporicide and the bottom part contains the sterile USP WFI Quality Water. Just pull the tab and they instantly mix together.

US and Foreign Patents Pending

Features of SimpleMIX:

- All chemical agents and the WFI Quality Water are filtered at 0.2 microns and manufactured in a Class 100 filling operation.
- Eliminates regulatory concerns for mixing and sterility of the solution.
- No more concerns for mixing concentrate phenolics, quaternary ammoniums or peracetic acid & H2O2 with sterile water in aseptic manufacturing operations.
- The contents of the double bag package are sterilized through a validated gamma radiation cycle.
- Lot sterility tested per current USP compendium.
- The system assures the appropriate dilution is made each time in a closed, sterile system.
- Concentrate solutions are never handled.

Made for Veltek's DECON-PHENE®, DECON-PHASE®, DECON-CYCLE®, DECON-QUAT100®, DECON-Clean® and DECON-SPORE 200 Plus®

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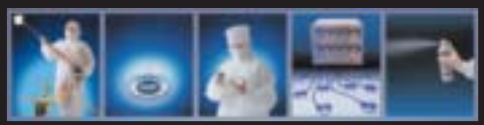
Phoenixville, PA 19460-4218 USA
(610) 983-4949 • Fax (610) 983-9494



INNOVATIVE CLEAN ROOM PRODUCTS

Visit us at the PDA/FDA Joint Regulatory Conference—Table #29

Possessing all but super hero powers,

the Environmental Monitoring Software System™ (EMSS™) is here to transform the way you handle environmental and water sampling data. EMSS can collect, document and trend data effortlessly, plus give you complete control of all your sampling and testing.

You may not be able to leap tall buildings in a single bound with EMSS, but you'll feel like the hero when you can comply with regulatory requirements ***and*** exceed industry guidelines.

For a copy of your 21CFR Part11 assessment, contact your local BD representative today.

Visit Booth #31 at the PDA / FDA Joint Conference, September 8-9, 2003, to learn how EMSS can bring the future of data management to your microbiology lab!

BD

BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152-0999 USA
800.638.8663
www.bd.com/industrial

Visit us at the PDA/FDA Joint Regulatory Conference—Table #31

PDA Web Seminars Archive—Available Now, On Demand

Did you miss the Puerto Rico conference on Current Issues in Pharmaceutical Manufacturing? Did your schedule or your time zone prevent you from listening to the May 29th audio conference on CAPA Programs?

PDA Web Seminars—on-demand Web-based presentations—offer interactive, inexpensive access to comprehensive information from leading industry and regulatory experts. PDA reaches thousands with the live audio conferences and in-person meetings. Available now are selected presentations from recent conferences, on demand, for review at your convenience. Schedule an in-house Web Seminar in your company, or view alone at your own desktop. The choice is yours.

PDA Web Seminars—on-demand Web-based presentations offer interactive, inexpensive access to comprehensive information from leading industry and regulatory experts.

The following presentations are now available:

Rapid Microbial Methods: A Regulatory Viewpoint—*Presented by*: Bryan Riley, Ph.D., CDER, FDA and Scott Sutton, Ph.D., Alcon Laboratories.

Designing a Cleaning and Disinfection Program in GMP-Controlled Environments—*Presented by*: Art Vellutato, Jr., Veltek Associates, Inc.

GMP Training Overview and Job Skills Training Requirements in an Aseptic Environment, or What Does the FDA Have to Say About That?—*Presented by*: Richard T. Sands, RTS Training Services.

How to Build an Effective CAPA Program—*Presented by*: Paula Shadle, Ph.D., Shadle Consulting; Daniel Aparicio, Tefen USA; and Paula Wilkerson, RAC, Applied Genetic Technologies Corporation.

Each archived Web Seminar is $150 for PDA members, $300 for nonmembers, and $60 for government personnel (you must be an employee of an official government agency).

Download the presentation of your choice at www.pda.org/webinars/index.html. ■

—Lisa Wade

2004 PDA Trainers' Choice Awards

PDA Biennial Trainers' Conference

May 16–19, 2004 • Puerto Rico

Do you have an innovative method of delivering CGMP training? Share your techniques with your peers and get the recognition you deserve. The 2004 Trainers' Choice Award is presented to trainers by their peers for outstanding achievement in the design, development and delivery of CGMP and technical training programs or materials. Submissions are now being accepted in the following categories:

- Best Multimedia Presentation (can be: video, slide show, or PowerPoint presentation);
- Best Classroom/Training Manual (course design and materials from classroom training – participant handouts and Trainers' Guide);
- Best e-learning program/Web page design (can be interactive computer-based program, Web page, or Web program);
- Best Experiential/Interactive Training (game, simulation, exercise, magic trick, etc.).

E-mail wade@pda.org to obtain an application for the Call for Entries.

Deadline for submissions is January 31, 2004. The recognition ceremony will take place at the 2004 Trainers' Conference at the Westin Rio Mar, Puerto Rico, on Wednesday, May 19, 2004. ■

—Lisa Wade

CORRECTION—The list of recipients of the PDA Distinguished Service Awards that was published in the June *PDA Letter* omitted the names of two recipients: **Simon Rusmin, Ph.D.** and **Richard T. Wood, Ph.D.** PDA sincerely apologizes for this omission.

Registration Form

THIS FORM MUST BE MAILED OR FAXED TO PDA

R

2003 PDA Annual Meeting, Courses and Exhibition • November 10-14, 2003 • Hilton Atlanta • Atlanta, Georgia

1. PLEASE TYPE OR CLEARL Y PRINT YOUR CONT ACT INFORMA TION.

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

Job Title | Membership Number

Company (indicate full company name)

Business Address

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

Business Phone | Fax | E-mail

☐ Substituting for

LTR0803

(Check here 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. PAYMENT OPTIONS (PLEASE CHECK ONE)

A **Wire Transfer Payments/By bank-to-bank transfer to: (required if paying in foreign currency; prevailing exchange rate at date of submission will apply)**

UBS AG Basel
Swift Code: UBSWCHZH40M
Account Number (please specify correct account number for currency being remitted):

- ☐ CHF: Account No. 292-568-280-02T
- ☐ EUR: Account No. 292-568-280-64B
- ☐ GBP: Account No. 292-568-280-65E
- ☐ USD: Account No. 292-568-280-66M
- ☐ YEN: Account No. 292-568-280-67C

Please reference code 1-1-1010

Bank Address:
UBS AG Basel, Postfach, Aeschenplatz 6, 4002 Basel, Switzerland

☐ **B** **By a bankers' draft forwarded together with the registration form PAYABLE IN US DOLLARS ONLY to:**

PDA, Inc.
P.O. Box 79465
Baltimore, MD 21279-0465

☐ **C** **By credit card (Visa, MasterCard/EuroCard, American Express), clearly indicating account number and expiration date. Proceed to Item 4 below.**

☐ **D** **Please mark here to request an invoice from PDA.**[1]

Important: When making a bank transfer it is most important that the name of the delegate is clearly stated, and a copy of this form is provided. **Please note:** All banking fees must be settled by the remitter.

[1] You are not considered registered for a PDA conference or course until payment is received and a formal confirmation letter is issued by PDA. Should you attend a conference without a formal confirmation or receipt of payment you will be required to provide a credit card as guarantee of payment.

3. FEES

Not a member of PDA? JOIN TODAY and you may register at the r educed member rate. This is just one of the many benefits of membership in PDA! Detailed information on PDA membership can be found at www .pda.org.

☐ **Process my PDA membership today (US $195) so that I may register at the member rate!**

Membership dues are non-refundable and non-transferable.

FULL CONFERENCE REGISTRATION

PDA Member	Nonmember	Government
☐ US $1,200	☐ US $2,400	☐ US $480

MONDAY ONLY (includes lunch and reception)

PDA Member	Nonmember	Government
☐ US $650	☐ US $1,300	☐ US $260

TUESDAY ONLY (includes lunch)

PDA Member	Nonmember	Government
☐ US $600	☐ US $1,200	☐ US $240

GUEST TICKET TO RECEPTION

PDA Member	Nonmember	Government
☐ US $55	☐ US $55	☐ US $55

GOVERNMENT: You must be an employee of an official government agency to qualify for this discounted rate.

COURSE REGISTRATION

	PDA Member	Nonmember	Government
PDA #496 (11/13)	☐ US $900	☐ US $1800	☐ US $360
PDA #127 (11/13)	☐ US $900	☐ US $1800	☐ US $360
PDA #110 (11/13-14)	☐ US $1350	☐ US $2700	☐ US $540
PDA #381 (11/13-14)	☐ US $1350	☐ US $2700	☐ US $540
PDA #651 (11/13-14)	☐ US $1350	☐ US $2700	☐ US $540
PDA #115 (11/14)	☐ US $900	☐ US $1800	☐ US $360
PDA #370 (11/14)	☐ US $900	☐ US $1800	☐ US $360

TOTAL FEES

$_____ $_____ $_____

PDA Federal Tax I.D.: 52-1906152

4. PLEASE CHECK THE APPROPRIA TE BOX.

☐ Wire Transfer ☐ Check Enclosed *Charge to:* ☐ MasterCard/EuroCard ☐ VISA ☐ AMEX

Account Number _____ Exp. Date _____

Name Exactly as on Card _____

Signature _____ Date _____

Wire Transfer confirmation number: _____

(insert your confirmation of receipt by UBS Bank here)

5. MAIL OR F AX THIS FORM ALONG WITH WIRE TRANSFER CONFIRMA TION, CHECK OR CREDIT CARD P AYMENTS TO:

PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA OR Fax: (301) 986-1093 (Credit Cards Only)

Please tell us how you learned about this event

- ☐ I'm a PDA member
- ☐ Advertisement
- ☐ Direct Mail
- ☐ Fax
- ☐ Internet
- ☐ Colleague
- ☐ Other_____

Business Environment (check one)

- ☐ Academic
- ☐ Consultant
- ☐ Engineering and Construction
- ☐ Government Regulatory Agency
- ☐ Industry Supplier
- ☐ Medical Device Manufacturing
- ☐ Pharmaceutical Manufacturing
- ☐ Pharmacy
- ☐ Recruiter
- ☐ Other_____

Professional Interest (check all that apply)

- ☐ Aerosols
- ☐ Analytical Chemistry
- ☐ Biologicals
- ☐ Biotechnology
- ☐ Computers
- ☐ Engineering
- ☐ Formulation Development
- ☐ GMP Compliance/ Inspection Trends
- ☐ Liquids
- ☐ Maintenance
- ☐ Manufacturing/Production
- ☐ Microbiology
- ☐ Ointments
- ☐ Ophthalmics
- ☐ Packaging
- ☐ Parenterals
- ☐ Quality Assurance/ Quality Control
- ☐ Regulatory Affairs
- ☐ Research
- ☐ Solid Dosage Forms
- ☐ Sterilization/ Aseptic Processing
- ☐ Training
- ☐ Validation

See general Information on page 17 for important confirmation, substitution, refund and Event Postponement or Cancellation information.

PDA Use: Date:_____ Check #:_____ Amount:_____ Account:_____

Company, Colleague & Product Announcements

Medicis recently announced the promotion of **Robert Curwin** from Executive Director, Operations Planning & Management to Vice President, Operations Planning & Management. Curwin joined Medicis in May, 1992. Prior to joining Medicis, he served as Assistant Vice President in the Technology Group for Nikko Securities, New York in their Fixed Income Division. Curwin earned a bachelor's degree in computer science from New York University in 1984. To find out more about Medicis, visit www.medicis.com.

Second Supplement to the 2003 USP-NF Now Available The United States Pharmacopeia (USP) is pleased to announce that the second *Supplement* to its official standards publication, the *United States Pharmacopeia and National Formulary (NF) (USP 26-NF 21)* is now available. *Supplement 2* is included in a subscription to the *USP 26-NF 21* and became official on August 1, 2003. The second *Supplement* to the *USP 26-NF 21* contains 21 new monographs, a new General Information Chapter <1196>, *Pharmacopeial Harmonization,* and a number of revisions to the USP Reference Standards Chapter <11>. *Supplement 2* is organized in the same manner as the *USP-NF;* it is a continuation of the compendia and contains revisions and additions to the publication, keeping the compendia up-to-date. It is available in print, CD, Intranet, and online formats as part of an annual *USP-NF 21* subscription.

The book contains two separate official compendia, the *USP* and the *NF. USP-NF* monographs contain specifications (tests, procedures, and acceptance criteria) that help ensure the strength, quality, and purity of named items. The *USP-NF* also contains monographs and general approaches to ensure the quality of compounded preparations. *USP-NF* monographs, which are recognized worldwide, may be enforceable by the US Food and Drug Administration (FDA) and also by state agencies in the United States.

The United States Pharmacopeia, established in 1820, contains legally recognized standards of identity, strength, quality, purity, packaging, and labeling for drug substances, dosage forms, and other therapeutic products, including nutritionals and dietary supplements. The National Formulary, established in 1888 by the American Pharmaceutical Association, includes standards for excipients, botanicals, and other similar products. USP purchased NF in 1975, combining the two publications under one cover, creating the *USP-NF.*

For more information about the new *Supplement*, visit the USP Web site at www.usp.org, or e-mail your questions to custsvc@usp.org. To order the *USP 26-NF 21*, please call 1-800-227-8772, (301) 881-0666, or order online at www.usp.org.

Baxa Corporation recently announced the launch of the Rapid-Fill ™ Automated Syringe Filling (AFS) system. Designed for speed and accuracy, the Rapid-Fill ASF automates the process of sterile syringe filling, capping and labeling in a pharmacy hood. The Rapid-Fill was designed to meet a market need of 360 million small volume parenteral doses administered each year in the US. "The Rapid-Fill Automated Syringe Filler eliminates the risk of touch contamination in the filling process," says Market Manager Mark Thrasher, "while reducing waste through utilization of all of the drug in source containers. And, its integrated disposable combines the syringe, cap and label in a single unit, facilitating the process while minimizing raw material inventories." Accurate to within +/- 0.2 mL, the Rapid-Fill ASF is a safe and cost-effective alternative to minibags and pre-filled syringes." Further information is available at www.baxa.com.

Rapid-Fill ™ Automated Syringe Filling (AFS) system

Millipore announced the availability of its Lynx ST (Steam-To) connector, a disposable valve that connects fluid paths in a sterile manner. Ideally designed for a broad range of applications, including sterile liquid transfer and process sampling, the Lynx ST connector ensures secure connections between pre-sterilized single use disposable assemblies and stainless steel systems. Unlike conventional aseptic connections where sterility is operator- and procedure-dependent, the Lynx ST connector is pre-assembled to the disposable fluid path and gamma sterilized. The risk of process sterility failure associated with aseptic connection techniques is eliminated by steam-in-place (SIP) procedures, which sterilize the stainless-steel equipment/piping and the connector interface before any fluid is transferred or sampled. The simplicity of the connector's construction allows flexibility of use and compatibility with many disposable fluid-path configurations. In addition, the Lynx ST connector consists of high-temperature resistant PEI (polyetherimide) with a locking cam action for reliable operation. The Lynx ST

Lynx ST (Steam-To) connector

continues on page 30

Send announcements on personnel changes and new products . . .

. . . to **Evelyn Heitman** via e-mail at heitman@pda.org or mail a hard copy to PDA headquarters at 3 Bethesda Metro Center, Suite 1500, Bethesda, MD 20814.

Industry News, from page 29

connector is available in packages of 1 and 10. For more information, please contact Millipore Tech Service at 1-800-MILLIPORE or visit www.millipore.com/lynxst.

Ernst & Young Biotechnology Reports Foresee an Industry Poised for Profitability *Challenges Continue as Global Industry Undergoes Extraordinary Changes*

Ernst & Young has released two reports, entitled "Beyond Borders: The Global Biotechnology Report 2003", and "Resilience: America's Biotechnology Report 2003", depicting an industry that is simultaneously struggling and succeeding. The reports indicate the industry may achieve profitability by 2010 if regulatory and reimbursement issues can be dealt with effectively over the next few years. Michael Hildreth, Ernst & Young's Biotechnology Director, said, "Based on the industry's revenue growth, robust pipeline, more efficient product development, and belt-tightening in the face of the current cash crunch, the biotech industry as a whole could reach a major milestone within five years: its first profitable year overall since the industry began more than 25 years ago."

Jürg Zücher, Ernst and Young's Biotechnology leader in Switzerland, said, "The biotech industry is proving it can succeed as an economic enterprise. The industry is at the beginning of its technology curve, and innovation is accelerating. Biotechnology is the driver of innovation not only in healthcare, but also agriculture, industrial production, and environmental management. Over the past five years, revenues in Europe have soared 845 percent, nearly 200 percent in Canada, and more than 80 percent in the US."

Overall, global biotech revenues increased 15 percent to more that $41 billion. For further information, contact Samantha Thomson at samantha.thomson@uk.ey.com.

Cambrex to Expand CGMP Cell Therapy Capacity Cambrex Corporation, a leading provider of cell therapy services, has announced that it is constructing a new facility to accommodate four CGMP suites dedicated to cell therapy manufacturing. The expansion will increase the company's manufacturing capacity by 100%. The facility and the first two suites are expected to be completed and validated by December 2003. The Cambrex Board of Directors approved the capital expansion in support of the Company's continued commitment to the rapidly growing cell therapy market. Cambrex is a global, diversified life science company dedicated to providing high quality products and services to accelerate drug discovery, development, and manufacturing processes for customers focused on health and the prevention of disease. For more information, visit their Web site at www.cambrex.com.

continues on page 36

registration*form*

THIS FORM MUST BE MAILED OR FAXED TO PDA

R

2003 PDA Taormina Conference • 13-14 October 2003 • Grand Hotel Timeo • Taormina, Sicily, Italy

1. PLEASE TYPE OR CLEARLY PRINT YOUR CONTACT INFORMATION.

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

Job Title | Membership Number

Company (indicate full company name)

Business Address

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

Business Phone | Fax | E-mail

☐ Substituting for LTR0803

(Check here 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.)

For advance roundtrip airport transfer reservations, please advise of your dates of arrival/departure: _____ _____

2. PAYMENT OPTIONS (PLEASE CHECK ONE)

☐ **A Wire Transfer Payments/By bank-to-bank transfer to:**
UBS AG Basel
Swift Code: UBSWCHZH40M
Account Number (please specify correct account number for currency being remitted):
- CHF: Account No. 292-568-280-2T
- EUR: Account No. 292-568-280-64B
- GBP: Account No. 292-568-280-65E
- USD: Account No. 292-568-280-66M
- YEN: Account No. 292-568-280-67C

Please reference code 1-1-1057

Bank Address:
UBS AG Basel, Postfach, Aeschenplatz 6, 4002 Basel, Switzerland

☐ **B By a bankers' draft forwarded together with the registration form payable in $US to:**

PDA, Inc.
P.O. Box 79465
Baltimore, MD 21279-0465

☐ **C By credit card (Visa, MasterCard/EuroCard, American Express), clearly indicating account number and expiration date. Proceed to Item 4 below.**

Important: When making a bank transfer it is most important that the name of the delegate is clearly stated, and a copy of this form is provided.
Please note: All banking fees must be settled by the remitter.

3. FEES

CONFERENCE REGISTRATION FEES

PDA Member	Nonmember
☐ CHF 2900	☐ CHF 3300
☐ €2000	☐ €2200
☐ £1500	☐ £1600
☐ US$2250	☐ US$2500
☐ ¥270,000	☐ ¥300,000

If you are not currently a PDA member, you must pay the nonmember fee. Nonmembers will receive one year of full membership in PDA. Membership dues are non-refundable and non-transferable.

GOVERNMENT: Call PDA to confirm your discounted government rate. You must be an employee of an official government agency to qualify for this discounted rate.

PDA Federal Tax I.D.: 52-1906152

4. PLEASE CHECK THE APPROPRIATE BOX.

☐ Check Enclosed Charge to: ☐ MasterCard/EuroCard ☐ VISA ☐ AMEX ☐ Wire Transfer

Account Number _____ Exp. Date _____

Name Exactly as on Card _____

Signature _____ Date _____

Wire Transfer confirmation number: _____

(insert your confirmation of receipt by UBS Bank here)

5. MAIL OR FAX THIS FORM ALONG WITH WIRE TRANSFER CONFIRMATION, CHECK OR CREDIT CARD PAYMENTS TO:

PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA
Fax: (301) 986-1093 (Credit Cards Only)

Please tell us how you learned about this event
- ☐ I'm a PDA member
- ☐ Advertisement
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- ☐ Other_____

Business Environment (check one)
- ☐ Academic
- ☐ Consultant
- ☐ Engineering and Construction
- ☐ Government Regulatory Agency
- ☐ Industry Supplier
- ☐ Medical Device Manufacturing
- ☐ Pharmaceutical Manufacturing
- ☐ Pharmacy
- ☐ Recruiter
- ☐ Other_____

Professional Interest (check all that apply)
- ☐ Aerosols
- ☐ Analytical Chemistry
- ☐ Biologicals
- ☐ Biotechnology
- ☐ Computers
- ☐ Engineering
- ☐ Formulation Development
- ☐ GMP Compliance/ Inspection Trends
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- ☐ Microbiology
- ☐ Ointments
- ☐ Ophthalmics
- ☐ Packaging
- ☐ Parenterals
- ☐ Quality Assurance/ Quality Control
- ☐ Regulatory Affairs
- ☐ Research
- ☐ Solid Dosage Forms
- ☐ Sterilization/ Aseptic Processing
- ☐ Training
- ☐ Validation

Confirmation: Written confirmation will be sent to you once payment is received. You must have 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. If you are pre-registering as a substitute attendee, indicate this on the registration form. A non-member substituting for a member must pay the additional fee. **Refunds:** Refund requests must be made in writing. Registrants whose written requests for refunds are received at PDA on or before **September 15** will receive a full refund less a US$55 (US) processing fee. Registrants whose written requests for refunds are received after **September 15** and on or before **September 30** will receive 50% of the registration fee. After that, no refunds can be made.
SEE REGISTRATION INFORMATION FOR IMPORTANT EVENT POSTPONEMENT OR CANCELLATION INFORMATION.

PDA Use: Date:_____ Check #:_____ Amount:_____ Account:_____

ITW Texwipe is dedicated to understanding the unique requirements for cleaning and contamination control in sterile suites and aseptic fill environments. Our new **TexBleach**™ is an aseptically filled 5.25% Sodium Hypochlorite and USP Purified Water solution. The solution is 0.22 µm filtered into pre-sterilized, one gallon bottles. Each lot is USP 26 <71> sterility tested. TexBleach™ is **EPA registered** as a surface cleaner and is ideal for sanitizing surfaces, walls, floors and ceilings in aseptic fill environments.

Because your reputation relies on **consistent performance**, contact ITW Texwipe for more information. Call 1-800-839-9473, ext. 120 or visit our website.

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Better solutions, together.

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PDA-TRI Director's Message

Networking, Sponges and Higher Life Forms

Bob Mello, Ph.D.

With all due respect to Willie Nelson, I'm "on the road again" at 37,000 feet over the Atlantic. Therefore, it is only natural that I find myself writing this month's article for the *PDA Letter*.

Before starting this month's commentary, I shall, as is my custom, begin by acknowledging those companies and individuals who make possible the continued success of the PDA Training and Research Institute (PDA-TRI) through their continuing donations of materials and services. This month our thanks go out to:

- **Lyophilization Technologies, Inc.**, for their service and repair of the facility's Virtis freeze dryer that is used in our Aseptic Processing course. We are happy to report that the unit is functioning within all performance specifications.
- **Schott Glass Company**, for their much-needed donation of 20,000 vials for use in the Media Fill Validation portion of the Aseptic Processing course.
- **National Instruments**, for their continued maintenance support on the monobloc fill/stopper/seal machine that is a cornerstone of the Aseptic Processing course.

We recently had a "vial crisis" at PDA-TRI, and I was especially grateful to Schott Glass and National Instruments for the speed in which they responded to our rather urgent requests. Within a two-day period, Schott responded to our request, shipped samples to us for machinability trials and began processing the shipping paperwork. The vials arrived within a week. Meanwhile, National Instruments responded immediately to our request for a service call. Their service technician was at PDA-TRI the next morning to make the necessary adjustments to accommodate the Schott vials and to perform the machinability trials. So ended the "vial crisis."

Now, on with my commentary: networking, sponges and higher life forms. Sounds like a strange theme for a PDA-TRI article. Perhaps, but there is a thread here.

All of us know what networking is. We all do it, in one form or another, almost every day. We ask friends for their recommendations for doctors, dentists, lawyers, etc. When I had a problem with bees at my home, I asked my neighbor whom he had used in a similar situation. That's one form of networking. Many of us associate networking with a job search or career change. It is still, by the way, the best avenue for that effort.

I was recently asked why I joined PDA. My answer today is as it was many years ago—for the networking and training opportunities. Networking can be used as a tool for your professional development—through conferences and courses. When you attend a training course at PDA-TRI, you have the unique opportunity to network with a small group of individuals who share your objectives, that is, to learn more about that particular subject to enable you to be more effective in your workplace. What better way than to discuss your issues in the classroom or one-on-one with expert faculty or other attendees.

However, you have to take the networking initiative, expend some effort, interact and ask questions. It is through that exchange of ideas that understanding (learning) occurs. If you simply sit back, quietly taking notes, and absorb information—like a sponge—well, you are missing out on the chance to address *your* most important issues. I studied developmental biology many, many years ago, and I still remember that a sponge does not rank high among the more "intelligent" or "advanced" life forms on this planet.

> "When you attend a training course at PDA-TRI, you have the unique opportunity to network with a small group of individuals who share your objectives..."

I encourage you to exercise your abilities as a higher life form and interact, network and ask questions. One of the best ways to maximize your professional networking efforts is by attending PDA-TRI laboratory and lecture courses. When you do, remember, don't go as a sponge. You will miss out on the chance to learn more than you might expect from your peers.

So, networking, sponges and higher life forms. Still a strange topic? Maybe so. But of these three concepts, start by implementing the first, and see if you don't become the last. ■

—Bob Mello, Ph.D.

PDA-B/F/S Joint Workshop on Blow/Fill/Seal Processing

Join PDA and the Blow/Fill/Seal (B/F/S) International Operators Association (IOA) for an informative workshop on the theory and practice of this unique and expanding technology. This lecture-lab workshop will be held at the Cardinal Health B/F/S facility in Woodstock, IL (Metro Chicago) on September 18–19, 2003.

Aseptically produced B/F/S products have not gone unnoticed by FDA, as demonstrated by the inclusion of a section in the Agency's Aseptic Processing Concept Paper that specifically addresses B/F/S issues. Due to the hands-on nature of the workshop's laboratory component, attendance must be limited. Do not delay your registration. Course details and registration information can be obtained at www.pda.org/PDF/TRI-BlowFillSeal-Bro.pdf and www.pda.org/PDF/TRI-BlowFillSeal-RegForm.pdf.

Reserve your spot today! ■

—Bob Mello, Ph.D.

2004 Aseptic Processing Course Dates

The 2004 dates for the PDA Training and Research Institute (PDA-TRI) laboratory course on Aseptic Processing have been established. Due to the intensive hands-on nature of this course, class registration must be limited to 20 students per offering (or Option, as it is called). In response to the overwhelming registration requests for the four Option dates in 2003, PDA-TRI has added a fifth Option date to this series in 2004. This extremely popular 2-week course sells out rapidly, so we urge you to register early. Check our Web site at www.pda.org; the registration information will be available soon.

The 2004 dates are as follows:

Option I

Week 1 January 26–30, 2004
Week 2 February 23–27, 2004

Option II

Week 1 March 22–26, 2004
Week 2 April 26–30, 2004

Option III

Week 1 May 24–28, 2004
Week 2 June 14–18, 2004

Option IV

Week 1 August 16–20, 2004
Week 2 September 13–17, 2004

Option V

Week 1 October 4–8, 2004
Week 2 November 1–5, 2004 ■

——Bob Mello, Ph.D.

PDA-TRI Thanks the Following...

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Upcoming PDA-TRI Education Courses

Courses listed in alphabetical order

Aseptic Processing 2003 Training Program—Lab Option 4: October 27–31, 2003 and November 17–21, 2003; $7,500 members/$7,695 nonmembers; *Faculty:* John Lindsay and David Matsuhiro **SOLD OUT**

CGMP Trainer's Qualification Program—Lecture October 20–24, 2003; $3,450 members/$3,645 nonmembers; *Faculty*: Rick Rogers

Cleaning Validation—Lab October 13–15, 2003; $3,000 members/$3,195 nonmembers; *Faculty:* Jon Voss and Bob O'Brien

Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance—Lab October 8–10, 2003; $2,500 members/$2,695 nonmembers; *Faculty:* Bob Livingston

Ensuring Measurement Integrity in the Validation of Thermal Processes—Lab November 6–7, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* Göran Bringert

Environmental Mycology Identification Workshop—Lab October 2–3, 2003; December 4–5, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* John Brecker

Rapid Microbiological Methods December 8–12, 2003; $4,500 members/$4,695 nonmembers; *Faculty:* Jeanne Moldenhauer ■

These courses will be held at PDA-TRI in Baltimore, MD unless otherwise noted.

For course content information, call PDA-TRI directly at **(410) 455-5800**.

For registration information, call PDA headquarters in Bethesda, MD at **(301) 656-5900**.

PDA-TRI Location/Lodging Information

Unless otherwise noted, PDA-TRI courses are held at: PDA Training and Research Institute, 1450 South Rolling Road, Baltimore, MD 21227, Tel: (410) 455-5800; Fax: (410) 455-5802.

PDA has not secured any specific room blocks for participants attending courses at the Training and Research Institute. There are several hotels in the Inner Harbor (downtown Baltimore) and BWI airport areas. These include, but are not limited to:

Baltimore Hilton & Towers Inner Harbor
(410) 539-8400
(410) 625-1060 - fax

Courtyard by Marriott–BWI
(410) 859-8855
(410) 859-5068 – fax

Baltimore Marriott Inner Harbor
(410) 962-0202
(410) 625-7892 - fax

Embassy Suites BWI
(410) 850-0747
(410) 850-0816 – fax

Homewood Suites BWI*
(410) 684-6100
(410) 684-6810 – fax

Holiday Inn Inner Harbor **
(*Special Rates for our course attendees*)
(410) 685-3500
(410) 727-6169 – fax

Hyatt Regency Baltimore Inner Harbor
(410) 528-1234
(410) 605-2870 – fax

Sheraton International Hotel BWI
(410) 859-3300
(410) 859-0565 - fax

Courtyard Baltimore Downtown/Inner Harbor
(443) 923-4000
(443) 923-9970 – fax

Holiday Inn—BWI ***
(410) 859-8400
(410) 684-6778 – fax

For additional hotel information, please visit ww.baltconvstr.com, the Baltimore Convention and Visitors Bureau's Web site.

Transportation to PDA-TRI: All listed hotels are no more than a 15–20 minute taxi ride to the Training and Research Institute. All hotels can assist you with taxi arrangements. Registrants may prefer to rent a car for easier access to and from the Institute.

***** no on-site restaurant

**** A discounted rate** is available for **Holiday Inn Inner Harbor of $99.** To receive this rate call the number above and mention the PDA-TRI Corporate Rate (ID# 100196574) when making your reservations. **Rooms are based on availability.**

***** A discounted room rate** is also available from the **Holiday Inn—BWI**. You must call the number above and mention the PDA Corporate Rate (3-PDA) when making your reservations.

Industry News, from page 30

Patheon, Inc. has announced that its Italian subsidiary has entered into a new manufacturing services agreement with Roche S.p.A. to continue to supply Roche with solid, liquid and sterile products for the European market. The new agreement will commence on January 1, 2004 for an initial term of three years, with annual renewal provisions thereafter. The new agreement will replace, at that time, the existing supply agreement which was signed as part of Patheon's acquisition of its facility in Monza, Italy from the Roche Group in December 1998.

The new agreement covers all of the products which are currently manufactured by Patheon for Roche at the Monza facility. The contract contemplates that Roche will rationalize certain of its products or transfer them to a facility within its network. Revenues are estimated to be approximately C $40 million in the first year and C $60 million over the next two years of the initial term of the agreement. Patheon is a leading global provider of drug development and manufacturing services in the pharmaceutical outsourcing sector.

For more information about Patheon, please visit their Web site at www.patheon.com.

Artel USA, specialist in performance measurement of liquid delivery instrumentation, presents the Pipette Tracker™ calibration data management program. The Pipette Tracker™ provides a total management system for quality control and proper maintenance of any pipette population. It facilitates the collection, analysis, documentation and management of pipette calibration information. Fully integrated with the Artel PCS®, it is user-friendly and provides the operator with step-by-step, easy-to-understand prompts while walking the user through the entire calibration process.

The Pipette Tracker™ meets GLP and ISO 9000 requirements and conforms to ISO 8655 DIN Standard 12650 and National Committee for Clinical Laboratory Standards (NCCLS). The program includes password protection features, 21 CFR Part 11-compliant electronic signature usage, and audit trail logging. To learn more, visit www.artel-usa.com. ■

—compiled by Evelyn N. Heitman

R

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+4/Postal Code

Telephone 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.)

LTR 08/03

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)	PRICE (govt. member or govt. nonmember)
				TOTAL :	$

3. Please check the appropriate box:

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

Account Number_____ Exp. Date _____

Name _____
(exactly as it appears on credit card; please print clearly)

Signature_____ Date _____

Payments must be made to PDA in US dollars by a check drawn on a US bank, or by American Express, MasterCard, EuroCard, or VISA.

Payment must be included to be considered registered.

4. Return completed form with payment made to:

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

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. Please allow one week for receipt of confirmation letter.*
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 the start of an event (course series, conference, etc.), a full refund, minus a $55.00 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 an 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:_____

Chapter News Update

Australia

The PDA Australia Chapter meetings have been very successful this year. In June, the Chapter met to discuss a variety of concerns, one of them being how to accommodate interest in the Chapter by having more meetings in a year. The Australia Chapter was also highlighted in the July issue of the *PDA Chapter News* electronic newsletter. They have two upcoming meetings: September 18 and November 27, 2003. For more information, please contact Ken Dibble at ken_dibble@millipore.com.

Canada

Canadian Chapter members participated with the Program Planning Committee for the June PDA Canada Conference on "Current Issues in Pharmaceutical Manufacturing" in Vancouver, British Columbia. Members worked with PDA to provide a Canadian perspective; tabletop exhibits were also presented. Individuals interested in helping out within the Canadian Chapter may contact one of the Chapter Board members below.

President
Grace Chin
Telephone: (416) 422-4056, ext. 230
E-mail: grace.chin@snclavalin.com

Vice President
Ameera Al-Jobore
Telephone: (905) 819-1380
E-mail: aaljobore@brocksolutions.com

Treasurer
Hein Wick
Telephone: (416) 762-4572
E-mail: hwick@hwmr.ca

Secretary
Patrick Bronsard
Telephone: (514) 735-5651, ext. 2270
E-mail: patrick.bronsard@snclavalin.com

Capital Area

In June, the Capital Area Chapter's popular annual Dinner Meeting welcomed speaker H. Gregg Claycamp, Ph.D., C.H.P, FDA, to speak on "Risk Assessment Principles for the Product Quality Initiatives." For more information about the Chapter, please contact Bob Mello, Ph.D. at rjmello1@aol.com.

Delaware Valley

The PDA Delaware Valley Chapter met in June, and Mitch Garber, Delaware Valley Chapter Chairperson, reported that the meeting was a great success. At this meeting, the Chapter presented awards to school children who had conducted worthy science research studies which were presented at the Delaware Valley Science Fairs, Inc. Each student received a plaque and a check for $250. The Chapter has two meetings scheduled this fall: September 17 and November 19, 2003. For more information, contact Art Vellutato, Jr. at Artjr@sterile.com.

Central Europe

For more information about the PDA Central Europe Chapter, please contact Erich Sturzenegger at erich.sturzenegger@pharma.novartis.com.

Israel

PDA Israel Chapter has been extremely active. Two seminars were held in February that were attended by over 200 delegates representing 40 companies. A discussion group on the topic of change control was held at the beginning of May with participation of over 60 people. On June 2, the Chapter held a one-day seminar on Stability Indicating Methods and Analytical Methods Development Related to Stability. Currently this Chapter's plans include: holding a one-day meeting on microbiological issues in September and holding their annual meeting in December. For more information, please contact Karen S. Ginsbury at kstaylor@netvision.net.il.

Italy

The PDA Italy Chapter held a Chapter Congress on "Sterile Manufacturing Practices in the Third Millennium: A Regulatory and Industry Perspective" on June 23–25 in Milan. A PDA-TRI Course was held in conjunction with this Congress, covering "Design, Engineering and Validation of Isolators for Pharmaceutical Applications." For more information, please contact Vincenzo Baselli at vincenzo_baselli@pall.com.

Japan

The PDA Japan Chapter Secretariat, Hiroshi Harada, reported the following information regarding upcoming meetings: the Japan Chapter Board Meeting is scheduled for August 27, 2003, and a presentation on "How to Receive an FDA Inspection" will occur on September 30, 2003. The PDA Japan Chapter Annual Meeting will be held on October 28–29, 2003. For more information, please contact Hiroshi Harada at van@bcasj.or.jp.

Membership News

Commemorative Pins

Special membership pins will be issued this month to commemorate those individuals who have been longtime PDA members. The pins will be awarded to members who have reached 10-, 20- and 30-year milestones, in recognition of their years of support. Be sure to wear your pin to PDA and industry events, Chapter meetings or anywhere else you wish to proclaim your PDA membership!

Korea

For more information about the PDA Korea Chapter, please contact Kuk Kim at jong_kuk_kim@pall.com.

Metro

The PDA Metro Chapter held their June Meeting, which featured Debra Pagano of IHL Consulting Group, who spoke on "Managing Contracted Services." Natale Manco, Metro Chapter Secretary, reported 23 attendees; she also noted that the Chapter had received a survey response rate of 50 percent. For more information, contact Frank R. Settineri at frank_settineri@chiron.com.

Midwest

The PDA Midwest Chapter President, Amy Gotham, reported that the Chapter is interested in hearing from other Chapters about volunteerism, speakers, generating feedback, and Web site suggestions. Their next meetings are scheduled for September 18 and November 20, 2003. For more information, contact Amy Gotham at PDAMidwest@northviewlabs.com.

Mountain States

The PDA Mountain States Chapter has scheduled a Vendor Night for September 11 and a Speaker Dinner for November 13, 2003. These will be the last two events of the year for the Chapter. The September 11th event will be held in conjunction with the local chapter of the Colorado Biotech Association. The speaker for the November dinner will be a former Denver FDA Director. For more information, please contact Jeff Beste at cmdjeff@aol.com.

New England

For more information about the PDA New England Chapter, please contact Robert A. Pazzano at robert_pazzano@vtsinc.net.

Southeast

The PDA Southeast Chapter held a very successful Spring Meeting on April 17, 2003, as reported by Chapter President Mary Carver. The meeting featured presentations and round table discussions on validation, environmental monitoring, and compliance issues. The Chapter also held a Golf Social on June 6, 2003. The next meeting will be held on September 23, 2003. The Southeast Chapter will hold elections this fall for the following offices: President, Vice President, Treasurer, and Secretary. (Reminder: only PDA members may serve as Chapter Officers.) For more information, contact Mary Carver at mary_carver@eisai.com.

Southeast Asia

For more information about the PDA Southeast Asia Chapter, please contact K.P.P. Prasad at Prasadk@labs.wyeth.com.

Southern California

For more information about the PDA Southern California Chapter, please contact John Spoden at spoden_john@allergan.com.

Taiwan

The PDA Taiwan Chapter Secretary General, Tuan-Tuan Su, presented a full report to PDA in June regarding the Chapter's activities. The PDA Chapter in Taiwan has been in operation since 1997 and has 483 members, 80 percent of whom are from the pharmaceutical industry sector. The PDA Taiwan Chapter has worked closely with the Industrial Development Bureau Ministry of Economic Affairs & Bureau of Pharmaceutical Affairs of the Taiwan government to implement CGMP validation. For more information, please contact Tuan-Tuan Su at pdatc@ms17.hinet.net.

UK & Ireland

Tony Waring, Promotions Officer of the PDA UK & Ireland Chapter, reported that the Chapter has been extremely busy with their UK & Ireland Training Special Interest Group (UKITSIG). To be attended by operational, quality, and training management professionals from both the Chapter and Europe, the Interest Group's meeting objective is to tackle training at the highest possible level starting with the development of meaningful documentation for Best Training Practice leading to performance evaluation and ROI criteria. Their first public meeting is scheduled for September 3, 2003. The meeting will feature four key presenters, each handling the four core areas of training: Training Policy; Training Audits, Needs and Inventory; The Training Plan; and Management and Assessment. For more information, contact John Moys at john.moys@sartorius.com.

West Coast

The PDA West Coast Chapter held a dinner meeting on June 17 about the "Design of Experiments for Validation," presented by Lynn Torbeck, of Torbeck and Associates. The PDA West Coast Chapter has been active for many years, and welcomes participation from all people in the San Francisco Bay biotech community. The Chapter targets professionals involved in the biotechnology, pharmaceutical, academic, and government organizations with a desire to learn more about issues facing the industry and provide networking opportunities. For more information, please contact Randall Tedder at randallt@istep.com. ■

—compiled by KiKi Coffman

Upcoming Chapter Events...

September 3, 2003
UK & Ireland Chapter Meeting—*Training Strategies*
Royal Pharmaceutical Society, UK

September 25–26, 2003
UK & Ireland Chapter Meeting—*What to Do When Things Go Wrong*
Britannia International, Canary Wharf, UK

October 28–29, 2003
PDA Japan Chapter—*Annual Meeting*
Location: TBA

November 20, 2003
UK & Ireland Chapter Meeting—*Impact of FDA's Revised Guidelines on Aseptic Manufacture*
Keele University Management Centre, UK

New member contact information is forwarded to chapters on an ongoing basis. For immediate notification of chapter events, please contact your local representative and ask to be placed on the chapter mailing list.

International Chapters

Australia Chapter
Contact: Ken Dibble
Millipore Australia
Tel: 61-4-1835-0455
Fax: 61-3-9563-2605
E-mail: ken_dibble@millipore.com

Canadian Chapter
Contact: Grace Chin
Pellemon, Inc.
Tel: (416) 422-4056 x230
Fax: (416) 422-4638
E-mail: grace.chin@snclavalin.com

Central Europe Chapter
Contact: Dr. Erich Sturzenegger
Novartis Pharma AG
Tel: +41-61-324-5572
Fax: +41-61-324-2089
E-mail: erich.sturzenegger@pharma.novartis.com

Israel Chapter
Contact: Karen S. Ginsbury
PCI-Pharmaceutical Consulting Israel Ltd.
Tel: +972-3-921-4261
Fax: +972-3-921-5127
E-mail: kstaylor@netvision.net.il

Italy Chapter
Contact: Vincenzo Baselli
Pall Italia
Tel: +39-02-477-96217
Fax: +39-02-423-6908
E-mail: vincenzo_baselli@pall.com
Web site: http://www.pda-it.org

Japan Chapter
Contact: Hiroshi Harada
Tel: +81-3-3815-1681
Fax: +81-3-3815-1691
E-mail: van@bcasj.or.jp
Web site: http://www.j-pda.jp/index.html

Korea Chapter
Contact: Kuk Kim
Tel: 82-2-560-7831
Fax: 82-2-569-9092
E-mail: jong_kuk_kim@pall.com

Southeast Asia Chapter
Contact: K. P. P. Prasad
Wyeth Pharmaceuticals
Tel: +65-6415-2000
Fax: +65-6415-2008
E-mail: Prasadk@labs.wyeth.com

Taiwan Chapter
Contact: Tuan-Tuan Su
Tel: +8862-2550-9301
Fax: +8862-2555-4707
E-mail: pdatc@ms17.hinet.net

United Kingdom and Ireland Chapter
Contact: John Moys
Sartorius
Tel: +44-1372-737-140
Fax: +44-1372-726-171
E-mail: john.moys@sartorius.com

US Chapters

Capital Area Chapter
Areas Served: MD, DC, VA, WV
Contact: Robert Mello, Ph.D.
PDA-TRI
Tel: (410) 804-2284
Fax: (410) 455-5802
E-mail: rjmello1@aol.com
Web site: www.pdacapitalchapter.org

Delaware Valley Chapter
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Veltek Associates, Inc.
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Fax: (610) 983-9494
E-mail: artjr@sterile.com
Web site: www.pdadv.org

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Chiron Corporation
Tel: (908) 730-1222
Fax: (908) 730-1217
E-mail: frank_settineri@chiron.com

Midwest Chapter
Areas Served: IL, IN, OH, WI, IA, MN
Contact: Amy Gotham
Northview Labs
Tel: (847) 564-8181 x263
E-mail: PDAMidwest@northviewlabs.com

Mountain States Chapter
Areas Served: CO, WY, UT, ID, NE, KS, OK, MT
Contact: Jeff Beste
Pendelton Resources
Tel: (303) 832-8100
Fax: (303) 832-9346
E-mail: cmdjeff@aol.com
Web site: www.mspda.org

New England Chapter
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Contact: Robert A. Pazzano, P.D.
VTS Consultants
Tel: (508) 870-0007 x140
Fax: (508) 870-0224
E-mail: robert_pazzano@vtsinc.net

Southeast Chapter
Areas Served: NC, SC, TN, VA, FL, GA
Contact: Mary Carver
Eisai, Inc.
Tel: (919) 474-2149
Fax: (919) 941-6934
E-mail: mary_carver@eisai.com
Web site: www.pdase.org

Southern California Chapter
Areas Served: Southern California
Contact: John Spoden
Allergan
Tel: (714) 246-5834
Fax: (714) 246-4272
E-mail: spoden_john@allergan.com
Web site: http://www.pda.org/chapters/Web-site-SoCal/SoCal-index.html

West Coast Chapter
Areas Served: Northern California
Contact: Randall Tedder
Tel: (415) 841-0373
Fax: (415) 841-1961
E-mail: randallt@istep.com

PDA
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NEW BOOKS

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NEW **Laboratory Validation: A Practitioner's Guide** edited by Jeanne Moldenhauer; In recent years, regulatory inspections have focused on laboratory testing performed to assess the quality attributes of a product. In many cases, the testing is so specialized or complex, that the entire responsibility for validation has been transferred to the laboratory personnel. This excellent guide and reference provides an overview of validation from a laboratory perspective.

Divided into three parts, Part 1 includes an overview of many of the laboratory support systems and equipment common to both microbiology and chemistry laboratories. Part 2 is dedicated to systems applicable specifically to the chemistry laboratory, and Part 3 covers the systems applicable to microbiology laboratories. Where the laboratory predominantly performs the test, for example, cleaning and disinfection, requirements are included within the text. While the book offer validation details representative of the most common types of laboratory systems, should you have a system that is not included, the information in these 38 chapters will likely be of great assistance in providing resources for compilation of requirements for other systems. 1224 pp; $250 member/$309 nonmember; hardcover **Item No. 17201**

PDA Technical Archive on CD-ROM

The PDA Archive will give you easy access to more than 50 years of research papers written by highly qualified research scientists in the pharmaceutical and biopharmaceutical industries. All *PDA Journal* articles, Technical Reports and Monographs, and selected Meeting Proceedings are available on this fully searchable CD-ROM.

The archive is updated each year adding six issues of the *PDA Journal*, all PDA Technical Reports and Monographs, and selected PDA Meeting Proceedings. The archive is a 4-CD set. Archive (contains data through the year 2002); $395 member/$1,200 nonmember **Item No. 01101**

2002 Update (only for those who already have an earlier version of the PDA Archive); $95 member $725 nonmember **Item No. 01002**

Pocket Code of Federal Regulations GMP Guide—2003 Edition 21 CFR Part 210-CGMP in Manufacturing, Processing, Packing, or holding of drugs; general. 21 CFR Part 211—CGMP for Finished Pharmaceuticals. Reproduced in pocket size by PDA. April, 2003. 56 pp; $4 members/$10 nonmembers **Item No. 13004**

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PDA-DHI Press Best Sellers

Change Control Soren Schwartze; This manual is one of the documents in the Serentec Press series: *Computer Systems Validation; A Life Cycle Approach*, edited by Chris Reid. It provides a well-organized, practical process for the management of changes to the Information and Control Systems used in GXP-related operations. Contents include process definitions for system changes to databases, operating systems, standard software, application software, and recommendations for ways to handle changes in hardware, process and the environment. It provides a complete example change control process, details about planned and unplanned changes, sample report forms for errors/changes, change requests, logs of change-related actions, logs of maintenance actions, recommended actions in case of changes to the hardware, software, users, and much more. A very valuable reference. 25 pp; 2001; $75 members/$90 nonmembers **Item No. 17189**

Commercial Off-The-Shelf Software Validation for 21 CFR Part 11 David Nettleton and Janet Gough; Validation clearly is a requirement for regulatory compliance. Every indication is that the regulations will focus more and more on the electronic generation of data, data control, and data transfer. The goal of this book is to provide guidance for validating commercial, off-the-shelf (COTS) computer software that generates data or controls information about products and processes subject to binding regulations. This book provides the practical information needed to ensure an understanding of the FDA-issued guidance as they develop systems that will enable them to go partially or fully electronic; hardcover; 118 pp; $185 members/$229 nonmembers **Item No. 17200**

JUST RELEASED

The Essence of GMPs: A Concise Practitioner's Guide U.G. Barad; This book is a compilation of more than 20 years of experience working with multinational pharmaceutical manufacturing companies and with various regulatory authorities. It incorporates and addresses the essence of GMPs prevailing around the world. It is organized in four sections. The principal section, entitled *Essentials*, covers policies that are expected to prevail in any pharmaceutical industry. The second section covers policies (prevention of contamination) that are the requirements of non-sterile pharmaceuticals. This section is followed by complete coverage of sterile products, and the book culminates with a complete glossary in part four.

The purpose of the book is to enable novices, busy executives, and hard-pressed colleagues to quickly gain access to excellent global GMP practice and expectations. Beginners will find that it provides a solid prescription in preparation for the constantly expanding global GMPs. Experienced readers will find this book invaluable as a tool for assistance in the preparation and design of common practices worldwide by enabling them to speak on common quality language regardless of location. 280 pp; $185 members/$229 nonmembers; hardcover **Item No. 17203**

For complete descriptions, visit our Web site, www.pda.org.

PDA-DHI Press Best Sellers, continued

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Introduction to Environmental Monitoring in Pharmaceutical Areas Michael Jahnke; Topics discussed include all aspects of cleanrooms, air handling systems, HAACP and risk analysis along with numerous useful charts, tables and figures. 104 pp; $90 members/$109 nonmembers **Item No. 17182**

Microbiology in Pharmaceutical Manufacturing Richard Prince, Editor; Providing valuable knowledge for the novice and the expert alike, many of the world's greatest pharmaceutical microbiologists and engineers, as well as other prestigious thought leaders, have invested their considerable talents in developing this comprehensive collection of timely information on this critically important subject. This book encapsulates current knowledge in a truly wide array of microbiological applications for the reader. It is hoped that this book will demystify the field of microbiology by describing it plainly and systematically from various scientific, technical, and functional perspectives. 900 pp; $240 members/$299 nonmembers; hardcover **Item No. 17185**

Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections Lucia Clontz; This text addresses the main quality control systems that should be implemented in a microbiology laboratory with a focus on current issues and inspection trends. It will help you produce timely, compliant results through each phase of laboratory work from development through the stability and batch release data needed after getting your product to market. Written by an experienced microbiologist, this manual contains chapters covering: current inspection trends; chemical and biological reference standards; laboratory equipment and facilities; preparation of media, buffers, and reagents; environmental monitoring; water systems for laboratory use; data trending and statistical process control; use of disinfectants and sanitizers; training of laboratory personnel; and the quality assurance program for the laboratory. 175 pp; 2001; $170 members/$209 nonmembers; hardcover **Item No. 17176**

Rapid Analytical Microbiology: The Chemistry and Physics of Microbial Identification Wayne P. Olson, Editor; The old, dendritic methods of identifying microbes can be found in the most recent edition of Bergey's Manual (Holt 1993). The issues with this approach to microbial identification (ID) include the time required to make a critical ID and the accuracy and reliability of IDs. Hence, the introduction and success of automated, rapid methods. This book focuses on the numerous new, efficient, and effective methods currently available and serves as both guide and reference to readers interested in improving performance and accuracy in a timely manner. 2003; 354 pp; ISBN 1-930114-36-2; $195 members/$239 nonmembers; hardcover **Item No. 17184**

Steam Sterilization—A Practitioner's Guide Jeanne Moldenhauer, Editor; Contains pragmatic details on how to accomplish the tasks necessary for a sterility assurance program for steam sterilization processes. Each chapter author is a subject matter expert and has a minimum of 10 years of hands-on experience in the topics discussed. The authors use this experience to identify practical ways to perform research, development, validation, and production activities associated with steam sterilization. Many of the chapters include sample standard procedures or protocols that may be used as templates to generate documents for your facility. Other chapters outline and explain the requirements. The book also provides guidance for those individuals who are responsible for the oversight of these processes or those who wish to update their knowledge. While written primarily for the pharmaceutical industry, much of the content may be applicable to the food and cosmetic industries as well. While this book does not specifically address the bulk drug industry, certain information may be applicable to bulk drug manufacturers. Whether your organization is small or large, this book contains insights and techniques that will prove invaluable in your effort to develop and maintain a sterility assurance program for steam sterilization processes. 740 pp; $215 members/$269 nonmembers; hardcover **Item No. 17183**

Supply of Chemicals in the Pharmaceutical Industry: Regulatory Guidelines and Rulings Mark Selby; This informative guide highlights the areas of legislation that suppliers of all chemicals involved in the synthesis and supply of healthcare products should be aware of, and offers details and comparisons of current issues in Europe, the United States, Canada, Australia, Japan and other countries worldwide. Topics include help in deciding how the legislation may apply to you if you manufacture chemicals, pharmaceuticals, or medical devices or are engaged in R & D related to these efforts. The book describes the chemical supply in global terms, discusses supply of new substances, offers specific cases such as export only, R & D, and clinical trials, provides information about worker health, communication of hazard, and control of pollution, and provides details about lab testing complete with examples of test guidelines. The book contains a useful glossary. If you supply any type of healthcare product, it is very likely that at some stage chemical supply legislation has an impact; failure to recognize the importance of such legislation may delay or prevent supply. 160 pp; $185 members/$229 nonmembers; hardcover **Item No. 17204**

Understanding GMP: A Practical Guide Martyn Becker; Now at Merck, Sharp, and Dohme Ltd., Martyn Becker is an ex-UK MCA Manager and Senior Medicines Inspector. In this book, he shares his expertise and perspectives on GMP regulations, legislation, applications, and practical challenges and solutions to applying GMP to the manufacturing environment. Anyone concerned with quality and GMP should have this book on a shelf nearby; it is a must-read offering an insider's view that is at once helpful and insightful. 237 pp; 2001; $170 members/$209 nonmembers; hardcover **Item No. 17174**

Good Practice and Compliance for Electronic Records

Published jointly with ISPE

Part 1—Good Electronic Records Management (GERM): Electronic Information Assurance for the Regulated Industry—Guide to Current Good Practice for Electronic Records and Signatures 2002; 104 pages; $95 PDA members/$190 nonmembers **Item No. 19003**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures 80 pages; $95 members/$190 nonmembers (English) **Item No. 19001**
Also available in German and Spanish. For more information, visit www.pda.org.

Selected PDA Technical Reports

Points to Consider for Aseptic Processing Volume 57 Number 2 Supplement This document represents over 18 months of dedicated work by the Task Force members. It presents the issues framed as problem statements with both a recommendation and a rationale for the recommendation provided. Some of the topics included in this 72-page report are: airflow velocity and patterns; critical area environments; differential pressures; HEPA filter testing and patching; setting environmental monitoring alert and action levels; the relationship of environmental monitoring results to batch release; investigation of environmental monitoring excursions; critical surfaces; process simulation acceptance criteria; incubation of normally excluded units; interventions; duration of process simulation tests; and number of media-filled units. 2003; 72 pp; $75 members/$125 nonmembers **Item No. 03004**

Technical Report No. 36 Current Practices in the Validation of Aseptic Processing—2001 The validation of aseptic processing continues to be a major area of interest within the pharmaceutical industry. Five years have passed since the last PDA survey on this subject. While there have been no new broadly applicable regulations or regulatory guidance since that time, there has been continued controversy over the details of aseptic processing and process simulation practice. Industry practices largely adhere to current regulations and guidelines on aseptic processing by the European Union, ISO, and FDA. The impact of PDA's Technical Report No. 22 on *Process Simulation Testing for Aseptically Filled Products* is also apparent.

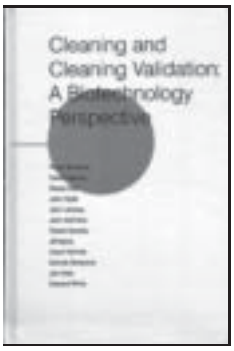
The Pharmaceutical Manufacturers Association (now PhRMA) in 1979 and PDA in 1986, 1992, and 1996 conducted surveys on this subject that have provided a clearer understanding of contemporary industry practice. This survey addresses the continuing need to track industry practices in the validation of aseptic processing as it evolves. 2002; 34 pp; $75 members/$125 nonmembers **Item No. 01036**

Technical Report No. 13 (REVISED 2001) Fundamentals of a Microbiological Environmental Monitoring Program The purpose of this document is to identify microbiological and particulate control concepts and principles as they relate to the manufacture of sterile pharmaceutical products. It expands substantially upon the first edition of Technical Report No. 13, *Fundamentals of a Microbiological Environmental Monitoring Program*, published by PDA in 1990. While this publication cannot possibly supplant the wealth of information published on this subject, it provides summary information and appropriate references for the reader to consult, if necessary. The objective was to contemporize the first edition through the utilization of current definitions, recognition of improved environmental monitoring procedures, and equipment. This document serves as a source on cleanroom environmental test methods, and although some non-viable particulate and endotoxin testing data are included, its primary focus is microbiological control. The concepts for sterile product manufacturing are the most stringent application, but these concepts can also be applied to non-sterile product manufacture. The focus is environmental monitoring as it relates to facility control and compliance. This document was compiled to aid in setting up a program that is meaningful, manageable, and defendable. 2001; 37 pp; $75 members/$125 nonmembers **Item No. 01013**

Technical Report No. 32 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 (SA & Q) Task Group, 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; 277 pp; $90 members/$140 nonmembers (paper copy **Item No. 01032**); CD-ROM—$50 members/$75 nonmembers (CD-ROM format **Item No. 01132**).

PDA Books

Cleaning & Cleaning Validation: A Biotechnology Perspective Authors: Roger Brunkow, David DeLucia, George Green, Shane Haft, John Hyde, John Lindsay, Jill Myers, Robert Murphy, John McEntire, Karen Nichols, Ray Prasad, Brenda Terranova, Jon Voss, Caroline Weil, and Edward White; This book is intended to serve as a source of practical technical information for those persons in the biotechnology industry. Case studies and/or actual industry examples are used to support the text wherever possible. While much of the material contained within this text is equally applicable to non-biopharmaceutical processes, the emphasis has been focused directly upon biopharmaceutical manufacturing.



Section I provides an in-depth analysis of the design concepts that lead to cleanable equipment. Also covered are cleaning mechanisms and cleaning systems. The first section is particularly useful to those persons faced with the task of designing systems that will be cleaned and also provides the biochemical background of the mechanisms associated with the removal of common biotechnology soils.

Section II focuses on cleaning validation concepts. While the material is equally useful for single product cleaning, emphasis is placed upon multi-product cleaning validation. Included are general validation principles as they apply to cleaning validation, detailed analysis of cleaning process validation, sampling techniques, analytical methods and acceptance criteria. The material in Section II will be useful to anyone responsible for the development of a cleaning validation program. Section III provides an overview of multi-product biotechnology manufacturing procedures. Included is an analysis of the risk-to-benefit scenarios associated with the various forms of product manufacturing, analysis of changeover programs, equipment considerations and material transport as they are affected by multi-product manufacturing strategies. 1995; 190 pp; $125 members/$145 nonmembers **Item No. 13002**

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PDA Publication Order Form

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- ❑ Pharmaceutical Manufacturing
- ❑ Pharmacy
- ❑ Recruiter
- ❑ Other

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- ❑ GMP Compliance/Inspection Trends
- ❑ Liquids
- ❑ Maintenance
- ❑ Manufacturing/Production
- ❑ Microbiology
- ❑ Ointments
- ❑ Ophthalmics
- ❑ Packaging
- ❑ Parenterals
- ❑ Quality Assurance/Quality Control
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Calendar of Events, from back cover

November 10–14, 2003
2003 PDA Annual Meeting, Courses and Exhibition
Building on Our Strengths: Quality, Science and Innovation
Annual Meeting: November 10–12
Courses: November 13–14
Exhibition: November 10–11
Downtown Hilton Atlanta on Courtland NE, Atlanta, GA
PDA-TRI Lecture Courses:
November 13
Designing, Monitoring & Validation of Pharmaceutical Manufacturing Ventilation Systems
Auditing Techniques for CGMP Compliance
November 13–14
Basic Concepts in Cleaning and Cleaning Validation
Computer-Related Systems Validation
A Practical Approach to Aseptic Processing and Contamination Control
November 14
Managing in a GMP Environment
Change Control & Documentation

November 17–21, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

November 20, 2003
UK & Ireland Chapter Meeting
Impact of FDA's Revised Guidelines on Aseptic Manufacture
Keele University Management Centre, UK

DECEMBER

December 4–5, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

December 8–12, 2003
PDA-TRI Laboratory Course:
Rapid Microbiological Methods
PDA-TRI Baltimore, MD

December 15, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

2004
JANUARY

January 26–30, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

FEBRUARY

February 16–20, 2004
2004 PDA International Congress—Basel
Messe Basel Convention Center, Basel, SWITZERLAND

February 23–27, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

MARCH

March 8–12, 2004
PDA SciTech Summit™
Orlando County Convention Center, Orlando, FL

March 22–26, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

APRIL

April 26–30, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

MAY

May 17–21, 2004
2004 PDA Biennial Training Conference, Courses and Vendor Exhibit
The Westin Rio Mar Beach Resort & Golf Club, Puerto Rico

May 17–21, 2004
2004 PDA Pacific Rim Congress—Singapore
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
The Ritz Carlton Millenia, SINGAPORE

May 24-28, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

JUNE

June 14–18, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

AUGUST

August 16–20, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

SEPTEMBER

September 13–17, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

OCTOBER

October 4–8, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

NOVEMBER

November 1–5, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

Information on these conferences and courses will be posted on the PDA Web site as it becomes available.

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Calendar of Events

2003

SEPTEMBER

September 3, 2003
UK & Ireland Chapter Meeting
Training Strategies
Royal Pharmaceutical Society, UK

September 8–12, 2003
2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits
Navigating Current GMPs: Catch the Compliance Wave
Conference: September 8–10
Courses: September 11–12
Tabletop Exhibits: September 8–9
Omni Shoreham Hotel, Washington, DC
PDA-TRI Lecture Courses:
September 11
Biopharmaceutical QA/QC for Senior Management
September 11–12
Cleanroom Management
CGMP & Compliance
Preparing for an FDA Pre-Approval Inspection
Validation of Sterilization Processes
September 12
Application of CIP to the Pharmaceutical Process

September 18–19, 2003
PDA-TRI Laboratory Course:
PDA-BFS Joint Workshop on Blow/Fill/Seal Processing
Cardinal Health Facility, Woodstock, IL–Metro Chicago

September 22–23, 2003
PQRI Blend Uniformity Workshop
Bethesda, MD

September 22–26, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

September 25–26, 2003
UK & Ireland Chapter Meeting
What to Do When Things Go Wrong
Britannia International, Canary Wharf, London, UK

September 29–October 1, 2003
PDA/EMEA European Virus Safety Forum
Hosted by the PDA Central Europe Chapter in collaboration with EMEA at the Paul-Ehrlich-Institut
Langen, GERMANY—Metro Frankfurt

September 30–October 1, 2003
PDA-TRI Lecture Course:
PDA Computer Products Supplier Auditor Process Model: Auditor Training
PDA-TRI Baltimore, MD

OCTOBER

October 2–3, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

October 8–10, 2003
PDA-TRI Laboratory Course:
Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance
PDA-TRI Baltimore, MD

October 13–14, 2003
2003 Taormina International Conference—a Conference for Decision-Makers Responsible for Strategy, Implementation and Management of Quality Assurance and Regulatory Compliance
Managing for Quality in a Cost-Focused Environment
Conference: October 13–14
Tabletop Exhibits: October 13–14
Grand Hotel Timeo & Villa Flora, Taormina, Sicily, ITALY

October 13–15, 2003
PDA-TRI Laboratory Course:
Cleaning Validation
PDA-TRI Baltimore, MD

October 20–22, 2003
PDA-TRI Boston Course Series
Radisson Hotel Boston, Boston, MA
PDA-TRI Lecture Courses:
October 20
Beyond the GMP/ISO Basics—Practical Strategies for Everyday Compliance
Bioassay Development & Validation
October 20–21
Parenteral Packaging: Rubber, Glass, Plastic and Metal Seals
Everything you Wanted to Know about Environmental Monitoring, but Were Afraid to Ask
October 20–22
GMP Training Manager Workshop
October 21
Maximizing SOPs—An Untapped Resource of Training
Assay Validation
October 22
Achieving CGMP Compliance during Development of a Biotechnology Product
Z1.4 Attribute Inspection Sampling in a CGMP Environment
Analytical Problem Solving for CAPA Systems
Annual Product Reviews: How to Comply with FDA & ICH Requirements

October 20–24, 2003
PDA-TRI Lecture Course:
CGMP Trainer's Qualification Program
PDA-TRI Baltimore, MD

October 21–23, 2003
A3P 16th International Congress
Congress: October 21–23
Exhibits: October 21–23
Bellevue Congress Hall, Biarritz, FRANCE

October 27–31, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

October 28–29, 2003
PDA Japan Chapter
Annual Meeting
Location: TBA

NOVEMBER

November 6–7, 2003
PDA-TRI Laboratory Course:
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA-TRI Baltimore, MD

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Be sure to watch
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for conference and course updates!