Volume XXXIX, No. 6

PDA Letter

June 2003

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

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PDA/FDA Joint Regulatory Conference

Navigating Current GMPs: Catch the Compliance Wave

Omni Shoreham Hotel • Washington, DC

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

As the demand for timely and pertinent regulatory compliance information continues to grow, nothing can replace the important face-to-face interaction and information exchange with industry colleagues and representatives from the FDA and European health authorities. Make your plans now to join key industry and regulatory leaders at the conference that will get you updated on the latest compliance trends.

The 2003 PDA/FDA Joint Regulatory Conference — your one-stop shop to get the latest detailed information on current and evolving industry practices. Catch the wave!

Confirmed speakers from the Food and Drug Administration include Lester Crawford, Ph.D., DVM, Deputy Commissioner; Murray M. Lumpkin, M.D., Associate Deputy Commissioner; Helen Winkle, CDER, FDA; Ajaz Hussain, Ph.D., CDER, FDA; Joseph Famulare, CDER, FDA; Rick L. Friedman, CDER, FDA; Nick Buhay, CDER, FDA; Mary Kremzner, CDER, FDA; Warren Rumble, CDER Ombudsman, FDA; Yana Milley, CDER, FDA; Gary German, CBER, FDA; Seamus O'Boyle, CBER, FDA; Robert Coleman, ORA, FDA; Jean Blackstone Hill, ORA, FDA; Marie T. Falcone, ORA, FDA; Pat Lefler, ORA, FDA; and Mark Kramer, Office of Compliance (OC), FDA.

Conference Highlights

A wide variety of compliance-focused sessions will offer conference participants the opportunity to hear discussions on cutting-edge issues of importance to the industry, including FDA's new Aseptic Processing Guidance, corrective and preventative actions, inspection trends, legal issues and Part 11 compliance.

Several optional breakfast sessions will be offered to help enhance your knowledge and to provide interaction with the FDA.

A "Meet the FDA" luncheon will be offered to all full conference registrants, providing an additional opportunity to facilitate discussion on critical issues.

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PDA-TRI August Course Series to be Held in San Francisco

The Fairmont Hotel
San Francisco, CA
August 19–21, 2003

PDA-TRI is presenting a series of nine outstanding courses this August 19–21, 2003, in San Francisco, CA. Home to the Golden Gate Bridge, cable cars, Chinatown, and more, this venue is the perfect setting to expand both your cultural and professional development.

The three-day series offers choices of one-, two-, and three-day courses covering general and advanced compliance and regulatory topics. Learn the five values found in the Current Good Manufacturing Practices (CGMPs) in Jim Vesper's interactive "Good Manufacturing Practice (GMP) Fundamentals" course. In " CGMP and Compliance," discuss the elements of Quality Assurance/Quality Control (QA/QC) and CGMPs with Gayle Dolecek, formerly on staff at the Center for Drug Evaluation and Research's (CDER) Policy and Guidance Branch.

A. Samuel Clark and Jon Voss will present their program on "Computer-Related Systems Validation" to help you identify several ways to improve

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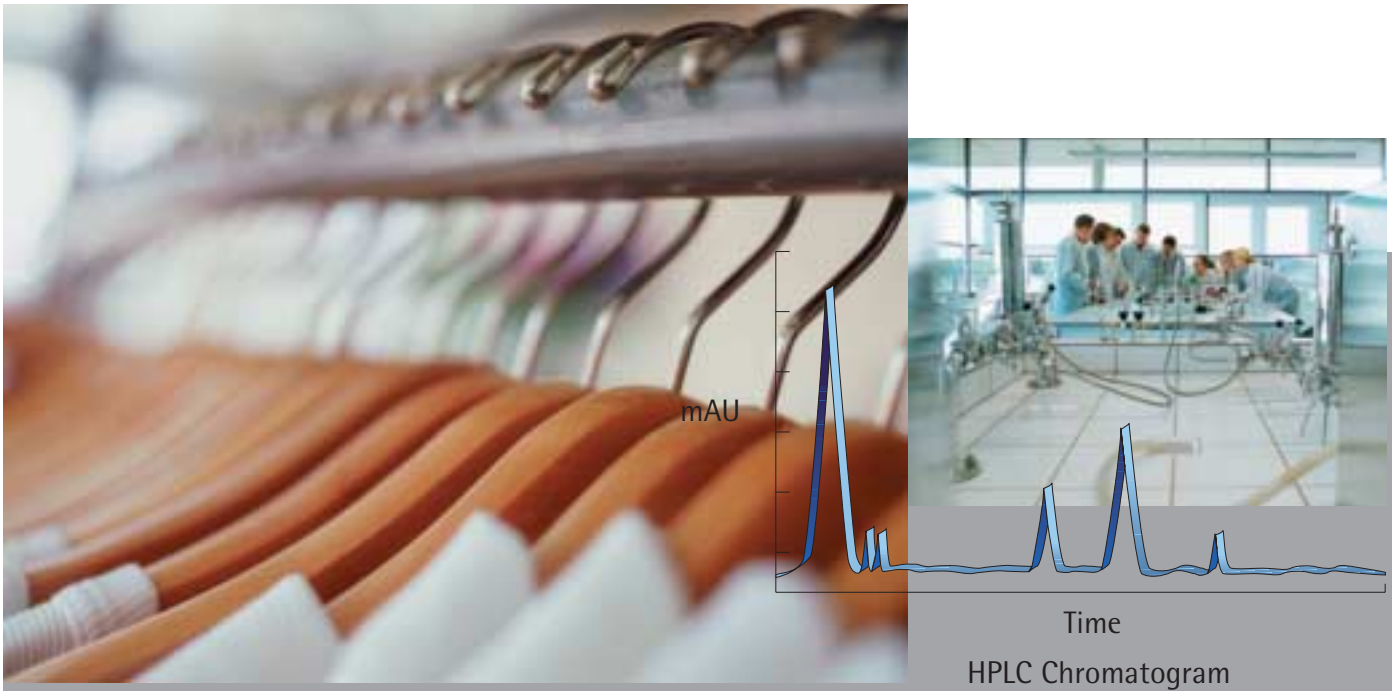

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Important Dates...

- **July 15th, 2003—deadline for submission for Call For Papers, 2004 PDA Training Conference—see page 30**
- **July 18th, 2003—deadline for submission for Call For Papers, 2004 PDA SciTech Summit™**
- **July 25th, 2003—deadline for submission for Call For Nominations—see page 4**

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Neal G. Koller
PDA President

Call for Nominations—
PDA Honor Awards

by Neal Koller

Now is the time to prepare nominations for PDA's 2003 Honor Awards. These prestigious awards are bestowed every year at PDA's Annual Meeting to members who are recognized by their peers and by the PDA Board of Directors as having exceptional ability and dedication to PDA. I encourage all PDA members to consider submitting nominations for these important awards.

Award recipients are selected from nominations assembled by an ad hoc Board subcommittee and ratified by the PDA Board. If you know of a worthy PDA member for one of the following categories of awards, please submit the information directly to me, and I will forward the nomination to the Awards subcommittee for consideration. You, the members, are the life blood of PDA, and the association is grateful to have such dedicated people contribute to the accomplishments and achievements that PDA has been able to realize.

Nominations should be submitted directly to me and should include:

- Nominee's name
- Company affiliation
- Identity of the specific award (Honorary Membership, Gordon Personeus, Frederick J. Carleton, or Distinguished Service)
- A paragraph describing why the individual is deserving of the award.

Nominations will be accepted by e-mail to macauley@pda.org, by fax to (301) 986-0296 or via the postal service to PDA Headquarters, 3 Bethesda Metro Center, Suite 1500, Bethesda, Maryland 20814. The deadline for submission is July 25, 2003.

Award Categories

Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award has usually been given in recognition of very long service, of a very significant nature, to PDA. The award requires unanimous approval of the PDA Board of Directors, and honorary members are not eligible for other awards in the same year.

Gordon Personeus Award

Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award is intended to honor a PDA member for long-term acts or contributions other than Board service that are of noteworthy or special importance to PDA. Past service on the Board of Directors is not a disqualifying factor, but the award is presented for service other than Board service.

Frederick J. Carleton Award

Presented as a tribute to lifetime contributor, past President, past Executive Director, and current Honorary Member Frederick J. Carleton, this award is designated for past or present Board members whose performance and service on the Board is recognized by his/her peers as worthy of recognition.

Distinguished Service Award

This award is given for special acts, contributions or services that have contributed to the success and strength of PDA.

There are other prestigious awards that do not lend themselves to at-large nominations. One is the Agalloco Award, which is presented to a PDA faculty member who exemplifies outstanding performance in education. It is named for James P. Agalloco in honor of his work in developing the PDA education program. Due to the nature of the honor, it stands to reason that the recipient should be decided among the many participants of our PDA courses, along with the PDA-TRI education staff.

Another is the Frederick D. Simon Best Paper Award, given to the author(s) of the best paper published in the *PDA Journal of Pharmaceutical Science and Technology* during the previous year. Judges are assembled from an ad hoc committee of scientists who review all of the papers. The award is named for the late Frederick D. Simon, a long-time PDA volunteer and staff member. The PDA Chapter Award recognizes the contributions of PDA members who participate at the chapter level.

Nominations will be accepted by e-mail to macauley@pda.org, by fax to (301) 986-0296 or via the postal service to:

PDA Headquarters
3 Bethesda Metro Center, Suite 1500
Bethesda, Maryland 20814.

The deadline for submission is July 25, 2003.

Past recipients of the awards are as follows:

Honorary Membership

1958 Arthur D. Herrick
1961 Joseph F. Greene
Hugo Schaefer
1969 Joseph W. Kouten
1973 William S. Bucke
1975 Hubert E. Boyden
1976 Harold Blumberg
1983 George H. Hopkins
1985 Joseph Ushkow
Robert E. King
1987 Nathan C. Kirsch
Bradshaw Mintener
Solomon C. Pflag
1988 Kenneth E. Avis
1990 Gordon R. Personeus
1991 Frederick J. Carleton
Frederick D. Simon
1995 Leon Lachman
1996 Robert G. Kieffer
Jack Cole
Theodore H. Meltzer
1997 Doris L. Conrad
1999 Irving J. Pflug
2000 Clarence A. Kemper
2001 Michael S. Korczynski, Ph.D.
2002 Joseph R. Robinson, Ph.D.
R. Michael Enzinger, Ph.D.

Gordon Personeus Award

1991 Timothy Leahy
1995 Edward J. Smith
1996 Frederick A. Gustafson
1997 James D. Wilson
1998 Kunio Kawamura
Toshinobu Aoyama
1999 Carol M. Lampe
Bernard Kronenberg
2000 Frank Bing
Robert A. Pazzano
2001 Regina McCairns
2002 Award not given

Frederick J. Carleton Award

1992 Regina C. McCairns
1993 Doris L. Conrad
1994 Robert G. Kieffer
Jack Cole
1995 James P. Agalloco
1996 Michael S. Korczynski
R. Michael Enzinger
1997 Clarence E. Kemper
1998 James E. Akers
1999 Floyd Benjamin
2000 Raymond Shaw, Jr.
2001 Joyce H. Aydlett
2002 Robert B. Myers

Distinguished Service Award

1993 Jeanne Devers White
1994 Willard Webster
1995 Joseph B. Schwartz
1996 Bengt C. Ljungqvist
Berit M. Reinmuller
Floyd Benjamin
Sol Motola
1997 Stanley Sklar
Daniel L. Gold
Donald E. Baker
1998 Robert L. Dana
Martin W. Henley
1999 Joyce L. DeYoung
2000 Julius Z. Knapp
Duncan E. McVean
Jeanne E. Moldenhauer
2001 Robert L. Garnick, Ph.D.
John Geigert, Ph.D.
Charles J. Cherundolo
Edmund J. Fitzgerald
2002 Raymond Gabler ■

U.S. Regulatory Briefs

FDA Office of Pharmaceutical Science Names Process Analytical Technologies (PAT) Policy Development Team "PATRIOT" members (PAT Review, Inspection and OPS [Office of Pharmaceutical Science] Policy Development Team) can be found at the recently updated Process Analytical Technologies Initiative Web page: www.fda.gov/cder/ops/pat.htm. PATRIOT members include Inspectors, Compliance Officers, Reviewers, the Policy Development Team and Training Coordinators.

CDER announces Drugs@FDA Web site This is a catalog of FDA-approved drug products, a pilot project that provides one place where you can search for official, up-to-date information about FDA-approved brand name and generic drugs, including approval letters, labels, and scientific reviews. All of this information can be found on the Internet at: http://www.accessdata.fda.gov/scripts/cder/drugcat.

FDA Re-opens Comment Period for the Draft Guidance Submitting Marketing Applications According to the ICH/CTD Format; General Considerations The Food and Drug Administration (FDA) is reopening until June 16, 2003, the comment period for the draft guidance for industry entitled "Submitting Marketing Applications According to the International Conference on Harmonization (ICH)/Common Technical Document (CTD) Format; General Considerations" that appeared in the *Federal Register* of September 5, 2001 (66 FR 46464). The agency is taking this action in response to several informal requests for an extension of the comment period.

For further information contact:

Randy Levin
Center for Drug Evaluation and Research (HFD-001)
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20857
(301) 594-5400

or

Robert Yetter
Center for Biologics Evaluation and Research (HFM-25)
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852
(301) 827-0373.

ICH: Guidance for Industry: M2 eCTD: Electronic Common Technical Document Specification FDA is announcing the availability of a guidance entitled "M2 eCTD: Electronic Common Technical Document Specification." The guidance was prepared under the auspices of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use. The guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The guidance is intended to assist industry in electronically transferring their marketing applications for human drug and biological products to a regulatory authority. This document is available on the Internet at: http://www.fda.gov/cber/guidelines.htm#m2ctd.

For further information contact:

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FDA Issues Guidance for Industry, FDA Staff and Third Parties on the Implementation of Inspections of Device Establishments by Accredited Persons On April 28, 2003, the FDA issued this guidance to implement the new section 704(g) of the Federal Food, Drug and Cosmetic Act, accrediting third parties (Accredited Persons) to conduct inspections of eligible manufactures of class II and class III medical devices. Inspections by Accredited Persons (AP) will be conducted in essentially the same manner as those conducted by FDA. The inspections by the Accredited Persons Program will be conducted independent of third party inspections performed under the US/EC Mutual Recognition Agreement (MRA), http://www.fda.gov/cdrh/mre/introduction.html,) that is currently in progress. However, some features of the program will be similar. This is a voluntary program. While all firms remain subject to inspections by FDA, eligible manufactures have the option of being inspected by an AP. This guidance can be found at: http://www.fda.gov/cdrh/mdufma/guidance/1200.pdf. ■

—William Stoedter

European Regulatory and GMP Briefs

What's new from the European Agency for the Evaluation of Medicinal Products (EMEA)? An updated version of Chapter 4 Centralized Procedures* in volume 6A Notice to Applicants April 2003 has been agreed in the Working Party on the Notice to Applicants. The chapter describes the procedures in detail and should provide useful guidance to applicants, including a regime for supply of translations of the product literature. An updated version of Chapter 7 General Information in volume 6A Notice to Applicants** April 2003 has also been produced, including updated tables on general requirements for the submission of applications for marketing authorization for veterinary medicinal products.

Commission Adopts a Modified Proposal on Traditional Herbal Medicines On April 9, 2003, the Commission adopted the amended proposal for a Directive on traditional herbal medicinal products. The Commission reacted to some amendments suggested by the European Parliament in its vote of November 2002. As compared to the original proposal, the amended text brings changes, in particular, with regard to the scope of the simplified procedure, to the minimum time of use within the EU, and to the competencies of the new scientific committee for herbal medicines.

Mutual Recognition Agreements (MRAs): An Update on Current Status, Key Elements and Product Coverage of GMP Sector From now on, regularly updated versions of the "Current Status of Mutual Recognition Agreements—Good Manufacturing Practice (GMP) Sector" and of the table "Mutual Recognition Agreements—Key Elements and Product Coverage (GMP sector)" are available in F2 unit activities (section "Mutual Recognition Agreements").

The Agreement between the European Community and the Swiss Confederation on Mutual Recognition in relation to conformity assessment entered into force on June 1st , 2002 Chapter 15 of this agreement concerns medicinal products, GMP inspections and batch certification and allows for the mutual recognition of the results of GMP inspections performed in the European Union (EU) and Switzerland. As of June 1, 2002, imports of medicinal products into the EU from Switzerland are not required to be recontrolled at import, provided they are imported in accordance with the provisions of Chapter 15. The legal references of the "explanatory notes" on the operation of this chapter were revised by the European Commission and the Swiss authorities in October 2002. New documents agreed by the Joint Committee have been published in the Official Journal as follows:

- Decision No 1/2003 (2003/128/EC) in OJ L 56, 01.03.2003, p. 1–213;
- Corrigendum to Decision No 1/2003 (2003/128/EC) in OJ L 66, 11.03.2003, p. 51;
- Decision No 2/2003 (2003/154/2003) in OJ L 68, 12.03.2003, p. 1–39 (including chapter 15.)

All language versions are available on http://europa.eu.int/eur-lex.

The actual versions of the Internationally Harmonized Requirements for Batch Certification and the EU Certificate of GMP Compliance of a manufacturer are available on the EMEA Web site, http://www.emea.eu.int/htms/technical/mra/mra.htm.

A Revised Version of the "Questions and Answers" Document Related to the CTD is Available The revision concerns: an update of the question 2—reformatting of dossiers; question 4—variations; question 6—line extensions; questions 7 and 8—generic applications;

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* The centralised procedure is mandatory for certain biotech-derived medicinal products and optional for other innovative products. For example: a pharmaceutical company established in the EU submits a marketing authorisation application to the European Agency for the Evaluation of Medicinal Products (EMEA). Drawing on scientific advice of the highest possible quality, the Agency coordinates, through the 15 Member States, a single scientific evaluation of the application. The applicant then obtains a single marketing authorisation, valid throughout the EU.

The mutual recognition procedure is the main route for non-biotech products: a pharmaceutical company established in the EU, which has obtained a marketing authorisation in one EU member state, applies to one or more other member states to recognise it, in accordance with the mutual recognition principle.

The national procedure is used to authorise medicinal products for local use in individual member states.

** Notice to Applicants: The data requirements for registration of human medicinal products in EU member states are detailed in Directive 75/318/EEC as amended and in guidelines, which are known as the "Notice to Applicants". The Notice, issued by the Commission of the European Communities, was prepared to facilitate the compilation of the registration dossier required by Article 4 of the Directive 65/65/EEC. It has no legal force but provides the harmonized view of the EU member states as to how to meet the legal requirements of the relevant directives as well as data requirements. The Notice details the format of the registration dossier and provides the guidance on the preparation of expert reports. The Notice to Applicants was first published in 1986.
VOLUME 2 of Notice to Applicants:
Pharmaceutical Legislation: Notice to Applicants
VOLUME 2A - Procedures for Marketing Authorisation
VOLUME 2B - Presentation and Content of the Dossier
VOLUME 2C - Regulatory Guidelines

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question 9—herbal medicinal products; question 10—Mutual Recognition; and question 13—bibliographic applications.

Updating the Notice to Applicants—Medicinal Products for Human Use—Volume 2B, Presentation and Content of the Dossier—Part 1: Summary of the Dossier-Part1A—1998 Edition or Common Technical Document-Module 1-Administrative Information: Application Form-2001 Edition The application form is updated in section 2.5.3, definition of final manufacturer, and section 2.6.2, with the request to include the number of the certificate of suitability for Transmissible Spongiform Encephalophathies (TSE.) This is available in a .PDF format and in a Word format. Details on the above-mentioned extracts can be obtained by visiting the following Web site: http://pharmacos.eudra.org/F2/pharmacos/docs.htm#news.

German Health Authority News The German Health Authority (BPharm, BfArM) in Bonn issued guidelines for bioavailability and bioequivalence. For further information please go to the Web site: http://www.bfarm.de/de/index.php. These guidelines will be discussed at the PDA Basel Pharmaceutical Forum on June 30, 2003.

EDQM (European Directorate for the Quality of Medicines) Foot and mouth disease and vaccines: where are we? Recently, the research group of the standing technical committee of the European Commission for the control of foot-and-mouth disease (FMD) of the Food and Agriculture (FAO-EUFMD) made proposals for a further revision of the monograph of the European Pharmacopoeia on the requirements of the FMD vaccines to adapt to current production standards and conditions of use. These proposals gave rise to a new draft issued for public comments.

At about the same time, an ad hoc group of the EMEA Committee on Veterinary Medicinal Products (CVMP) began drafting a guideline on the requirements for marketing authorization of FMD vaccines and also made proposals for the further revision of the monograph to ensure compatibility with the guidelines. The work on the guideline and on the revision of the monograph has been carried out as a collaborative project between the two groups involved against the background of recent FMD outbreaks in Europe.

The EDQM of the Council of Europe organized a symposium on March 17–18, 2003 in order to give the opportunity for debate on the provisions of the two documents, which can then go for approval and implementation. The two groups were made up of the representatives from the Immunological Working Party of the CVMP of the Commission of the European Communities, the World Organization for the Animal Health and the FAO-EUFMD. Representatives of manufacturers, the principal public and private research centers, universities, national authorities and the Official Medicines Control Laboratories (OMCLs) participated in the discussions. The symposium was attended by 43 participants from 16 countries (mostly European countries but also Bolivia, Colombia, Argentina, and the United States).

Further information (such as slides presented by the speakers) can be found on the Internet site: www.pheur.org. ■

—Gautam Maitra

PDA Journal of Pharmaceutical Science and Technology
Call for Papers

From Lee Kirsch, Ph.D., Editor

The *PDA Journal of Pharmaceutical Science and Technology* is one of a few peer-reviewed, widely recognized and respected journals dedicated to the scientific foundations of pharmaceutical product development, manufacturing and quality assurance. It has served to legitimize pharmaceutical product quality practices and to introduce new methods, concepts and technologies into the field.

The Journal has historically served both the PDA membership and their colleagues well for over 50 years. Its continued success depends on your participation by submitting research articles and relevant commentary, by encouraging your colleagues to submit their work and by your willingness to participate in the peer-review process.

As Editor of the PDA Journal, I am delighted to have the opportunity to serve the PDA membership by facilitating the publication of worthy contributions in their well-respected and oft-cited journal. I welcome the suggestions, comments and advice of the Journal's readers and contributors.

My editorial assistant, Madhushree Gokhale, and I can be contacted by phone: (319) 384-4408; facsimile: (319) 384-4409; or e-mail: pda-journal@uiowa.edu. Author's instructions for submitting manuscripts to the Journal appear on www.pda.org. Send manuscripts to:

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Regulators Meet Industry Face to Face on the CTD at the PDA Basel Pharmaceutical Forum

The first PDA Basel Pharmaceutical Forum was launched by the European Office on March 31, 2003. The aim of forums is to bring regulators and industry together to meet on a current burning subject.

This forum was attended by 20 participants who came from the pharmaceutical industry in Switzerland, Germany, France, and Austria. Mary Lyda (KMI, a division of PAREXEL International, LLC) delivered an impressive keynote address. Among other topics, she touched upon the new Food and Drug Administration (FDA) initiatives on pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st century.

The Common Technical Document (CTD) is the most important subject in Europe right now, as the CTD is mandatory for the European Union (EU) starting July 2003. The CTD is the common format agreed upon by the three regions (US, EU and Japan). The CTD does not cover all aspects of the content, however. There are many regional requirements that could affect the contents of the dossier in each region. This was emphasized by Dr. Christa Wirthumer-Hoche (Federal Ministry of Social Security and Generations). For the EU-CTD, no difference is expected where the International Conference on Harmonization (ICH) guidelines exist. The content needs to take into account the EU guidelines. The Pharmacopoeial Standards and Transmissible Spongiform Encephalopathies (TSE) guidelines must be respected. The European Certificate of Suitability Scheme or the European Drug Master File (EDMF) may be used. As a member of the Notice to Applicants and the ICH on CTD, Dr. Wirthumer-Hoche concluded that CTD implementation in the EU requires legislative adaptations. In the long term, the CTD gives better opportunities for sharing information in the interests of public health.

From the industry side, Dr. Hiltrud Horn (HORN Pharmaceutical Consulting) highlighted the structure of the CTD and advocated industry discussions with the authorities on structure and content. She also emphasized that the CTD is basically the structure, and that ICH and national requirements must be taken into consideration.

PDA Basel Pharmaceutical Forum, March 31, 2003—Dr. Thomas Hottiger, Swissmedic (speaking).

Dr. Thomas Hottiger (Swissmedic) gave an extensive and comprehensive presentation on the additional requirements of the CTD for sterile products. One key message from the Swiss Health Authority representative was that the microbial (endotoxin/particulate) contamination of sterile products was a frequent quality defect, and therefore sterile products deserve special attention. He also mentioned that there is still substantial disharmony about the European and the US requirements regarding the documentation for sterile products.

Dr. Fabien Peuvrelle (Novartis Pharma AG) spoke about the electronic version of the CTD (eCTD). The eCTD specification describes the means to create and transport the electronic submission that meets the definitions of the CTD. The eCTD is not a review tool; it is generated for transport. Agencies have to create their own review tools. The eCTD will reduce printing and courier costs. The record retention will be easier and will reduce review time. Implementation of the eCTD will take some time as new skill-sets are required. The current publishing environment may have to be upgraded (partly redesigned) to allow for a real eCTD implementation.

The late afternoon session was a presentation on filing changes in Europe by Dr. Hiltrud Horn. An overview of the current regulations in the EU was given. As of July 1, 2003, filing for variation should be in the CTD format. The presentation slides can be viewed on the PDA Web site: www.pda.org.

Following the Forum, the Central European Chapter held its annual general assembly, during which the committee members were elected. The following candidates have been elected. Please join me in welcoming the new committee:

– Erich Sturzengger (President)
– Georg Roessling (Vice President)
– Carlo Voellmy (Treasurer)
– Roger Seiler (Secretary)

Chairs of Committees:

– Dr. Hiltrud Horn (Regulatory);
– Mary Lyda (GMP);
– Klaus Haberer (Microbiology);
– Bernard Kronenberg/Dieter Witthauser (Steam Sterilization). ■

—Gautam Maitra

PDA Basel Pharmaceutical Forum, March 31, 2003—Dr. Hiltrud Horn, Horn Pharmaceutical Consulting gives a presentation on variations to marketed products in the EU.

Central European Chapter "Veterans"—(L to R) Finley Skinner (CEC Secretary), Novartis Pharma AG; Carlo Voellmy (CEC Treasurer), Novartis Pharma AG; Georg Roessling (CEC Vice President), SCHERING AG; Bernard Kronenberg (CEC outgoing President), Bakrona Basel AG.

Meet the Regulator

Dr. Christa Wirthumer-Hoche, Dipl.Ing.

PDA was honored to have Dr. Wirthumer-Hoche as one of the main speakers at the PDA Basel Pharmaceutical Forum on March 31, 2003. Dr. Christa Wirthumer-Hoche is the Head of the Licensing Division for Human Medicinal Products (except blood products and vaccines) in the Unit for Pharmaceutical Affairs. She graduated from the Technical University, Vienna, in 1981, and did her doctoral thesis at the Institute for Medical Physiology, graduating in 1983.

Since that time until May 1998 she joined the Austrian National Institute for Quality Control of Drugs, where she focussed her interest on quality items in the assessment of marketing authorization dossiers. Since 1994 she has been involved in different European committees and working groups.

From 1994–1997 she was a member of the Committee for Proprietary Medicinal Products (CPMP)/the Committee on Veterinary Medicinal Products (CVMP) Quality Working Party. From June 1997 until December 2000 she was one of the Austrian delegates in the CPMP. Since June 1997 she has been a member of the Mutual Recognition Facilitation Group (MRFG.) Under the Austrian European Union presidency (June–December 1998) she was the Chairperson of the MRFG.

Since October 1999 she has been the Austrian member of the Notice to Applicants Group. In December 1999 she was appointed by the European Commission as Coordinator for the Common Technical Document implementation in Europe, and since that time she has also participated in the International Conference on Harmonization CTD Implementation Group. Since the start of the Pan European Regulatory Forum (PERF) project in the summer of 1999, she was nominated as the Austrian expert for the priority action area "Implementation of the Acquis."

PDA received very positive feedback from the attendees at the Basel Pharmaceutical Forum regarding Dr. Wirthumer-Hoche's presentation on the Common Technical Document (CTD). The presentation can be found on the PDA Web site: www.pda.org. ■

—Gautam Maitra

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2003 INTERNATIONAL CALENDAR 2003

June 23–27, 2003
PDA Italy Chapter Presents
Sterile Manufacturing Practices in the Third Millennium: A Regulatory and Industry Perspective
Melia Milano Hotel, Milan, ITALY
Conference: June 23–25
Course: June 25–27
PDA-TRI Lecture Course:
June 25–27
Design, Engineering and Validation of Isolators for Pharmaceutical Applications

June 30, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

September 29, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

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-Institute
Frankfurt, GERMANY

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

October 13–14, 2003
2003 Taormina International Conference and Tabletop Exhibits for Senior Executives in the Pharmaceutical Industry
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

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

2004

February 16–18, 2004
2004 PDA International Congress, Courses and Exhibition—Basel
Messe Basel Congress Center,
Basel, SWITZERLAND

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

PDA
An International Association For Pharmaceutical Science And Technology

TR-32 UPDATE

by Sharon Schleuter, Serena Software; Steven Swartz, Julian Stevens Communications; and Harvey Greenawalt, Audit Repository Center

Serena Software, Inc. Becomes Participating Supplier of the Audit Repository Center

Serena Software, Inc. has completed a TR-32 audit for Serena™ ChangeMan® ZMF Software Change Manager (SCM) for z/OS and OS/390 Environments. The results of this audit, commissioned by a major pharmaceutical corporation, are posted to the Audit Repository Center (ARC) Web site, www.auditcenter.com. After realizing the tremendous value this audit brings to Food and Drug Administration (FDA) regulated industries, Serena joined ARC as a Participating Supplier and has scheduled another TR-32 audit for our entire product suite (planned for June 2003 completion).

Serena provides an elegantly architected enterprise solution designed to leverage existing investments, support emerging technologies, accommodate packaged applications, and integrate with the widest range of developer tools on all platforms. Serena's open architecture enables central enterprise application management with native platform support, comprehensive multi-platform integration, thorough and flexible security, complete audit capabilities and customizable Web access to development activity anywhere in the enterprise.

This ensures application availability and speeds time to market—while reducing development costs. According to a recent Yankee report, organizations, utilizing Serena's technology, realize a 28% reduction in application downtime, a 23% improvement in time to market, and an 18% reduction in development costs.

Utilizing Serena's ECM solution provides pharmaceutical and other FDA regulated companies with controls and processes necessary to meet FDA guidelines like 21 CFR Part 11. Serena's Enterprise Change Management Solution automates and enforces sound software development processes, ensuring application integrity, providing readily retrievable audit trails, restricting access to authorized individuals, providing easy rollback, restoring capability, and is completely scalable and flexible.

For over 22 years Serena has focused exclusively on providing application change management solutions to the world's leading enterprises, and today its products are in use at over 2,750 customer sites—including 42 of the Fortune 50. Headquartered in San Mateo, California, Serena serves customers worldwide through its local and international offices and an international network of distributors. More information is available on Serena's Web site at www.serena.com.

Auditor Training & Qualification

Currently there are 98 PDA Qualified Auditors. The PDA Qualified Auditors represent over 16 countries throughout the USA, Europe and Asia.

Information on applications for qualification and course registration is available on the PDA Web site at www.pda.org.

Availability of Audits

Currently 53 audits are either under consideration, in process, or are available for distribution.

Table 1.0 provides a summary of the 28 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
1	Access360, Inc.	enRole 4.0 (Provisioning Software)
2	Agilent Technologies	Cerity for Pharmaceutical QA/QC; Network data system for analytical laboratories
3	Alacris, Inc.	idNexus, Alacris products are designed to simplify identity management and maximize trust associated with Public Key Infrastructure (PKI) implementation and security technologies
4	Automation Tooling Systems, Inc.	Custom programming services for Process Control Software
5	Decision Management International, Inc. (DMI)	Regulus(tm) Document Authoring (DA), a member of the Regulus(tm) off-the-shelf solution set
6	Documentum, Inc.	Content Authentication Services (CAS), eContentServer, DocControlManager 7(DCM) and GMPharma
7	Entrust Technologies Ltd.	Digital security technology for enterprise resource systems; Public Key Infrastructure Technology (PKI)

Table 1 continues on next page.

Table 1, continued.

	Supplier Name	Supplier Product
8	Epicentric, Inc.	Foundation Enterprise Server 4.0, which is a tool for coordinating information from disparate sources and for disparate uses
9	First Consulting Group, Inc.	Custom information-based strategy Software, operations improvements, management and integration services
10	Fisher-Rosemount Systems, Inc.	Distributed Factory Automation, Delta V product line
11	Foss NIRSystems, Inc.	SLE Near-infrared analysis of chemical and physical properties
12	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
13	Innovatum, Inc.	DataThread™ - Data audit, workflow, 21 CFR Part 11 and e-signature solution for AS/400 applications, without programming changes
14	Interwoven, Inc.	Web Publication Management
15	Lexign Corporation	Lexign Flow™ EPR Software
16	LoftWare, Inc.	Loftware Print Server (LPS) Lable Printing System
17	MARC Global Systems	Warehouse Execution Systems
18	Merant	PVCS Dimensions and PVCS Replicator Software Configuration Management Tool
19	Mercury Interactive	Test Management Tools: - QuickTest Professional - Astra QuickTest - Astra LoadTest - Astra FastTrack - LoadRunner - LoadRunner TestCenter - TestDirector - WinRunner
20	Propack Data GmbH	Enterprise Production Management System, PMX 3.2 with Solutions MES and CTM
21	Rational Software Corporation	Rational Suite® Enterprise - Rational ClearQuest (for team-based change request and defect management) - Rational ClearCase LT (configuration management for smaller development teams)
22	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)
23	Schlumberger	Cyberflex Palmer Smart Card and Cyberflex Access Intergration Kit
24	Serena Software, Inc.	Serena ChangeMan Automating the Software Lifecycle
25	Sparta Systems, Inc.	TrackWise®Training, Configuration, Installation and Support for TrackWise®
26	SSA Global Technologies, Inc.	Mid-Range ERP software for manufacturing, supply chain and financial application domains
27	Supply Chain Logic, Inc.	COTS asset tracking/delivery systems for general use
28	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

PDA-Pharmaceutical Cold Chain Discussion Group (PCCDG) Meeting, March 18, 2003

by Rafik H. Bishara, Ph.D., Chair, PDA Pharmaceutical Cold Chain Discussion Group

Dr. Bishara can be reached at:
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The first session of the PDA-Pharmaceutical Cold Chain Discussion Group (PCCDG) at the PDA Spring Meeting in San Diego, CA was attended by 32 participants. The leader of the group, Rafik H. Bishara, Ph.D., Eli Lilly and Company presented an introduction of the newly formed PCCDG "History, Charter, and Goals." The current membership of the group is at 75 members representing 31 pharmaceutical and biotechnology companies. Secondary membership is offered to interested parties who are not from the previously mentioned companies. The group is developing a "Cold Chain Management Guideline" to provide guidance to the industry on the essential principles and practices of shipping temperature-sensitive pharmaceutical products through the transportation environment. Kevin O'Donnell, Abbott Laboratories, discussed the Cold Chain Training Modules, emphasizing "Cold Chain 101." This will help provide a thorough understanding of the nature and extent of the hazards.

The second session of the PCCDG was designed for an informal Round Table Discussion. It was attended by 16 participants and covered multiple Cold Chain Management topics, including:

- Differentiation between validation and qualification. Consensus was reached that validation is internal and is controlled by manufacturers. Qualification is external and needs cooperation between manufacturers and other parties involved in the cold chain distribution;
- Need of a glossary or a Lexicon;
- Need of a partnership with global regulatory agencies to determine their expectations for shipping validation;
- Need to establish cycle time profiles;
- Bringing the right team together to manage the cold chain is paramount to success. The team should include representation from: stability, validation, compliance, quality assurance, purchasing, packaging, distribution, and marketing.
- To monitor or not to monitor?
  - Regulatory requirements
  - Risks
  - Industry capabilities
  - Industry limitations
  - Trends
  - Future expectations, requirements, and regulations
- Labeling and marking of cold chain packages
- Product temperature requirements
  - Understanding and licensing product temperature requirements for storage vs. transportation
  - Linking stability studies to real world expectations
  - Discrepancy experiences
  - Regulatory experiences
- Qualification testing
  - Laboratory simulation—basics
  - Laboratory simulation—Operational Qualification (OQ)
  - Real world testing—basics
  - Real World Testing—Performance Qualification (PQ)
  - Simulation vs. real world testing
- Shipping cycle for testing
  - Shipping cycle—basics
  - Standard / Guidance to use—ISTA, maximum/minimum 'record' temperatures, maximum/minimum 'actual distribution' temperature
  - Summer vs. winter profile
  - Guidances to use (ISTA)
- Industry perception of regulatory requirements
  - FDA/CBER
  - EU/EMEA
  - Japanese (MHO)
  - Guidances
- Active vs. passive packaging
  - Envirotainer
  - Insulated Shipping Container (ISC) Shipper with gel packs.

A one-day session on Cold Chain Management will be offered November 11 at the 2003 PDA Annual Meeting in Atlanta. ■

Interest Group Updates from PDA Spring Conference, San Diego

Packaging Science Interest Group

Edward J. Smith, Ph.D., Wyeth Pharmaceuticals

Seventeen PDA meeting attendees were present at the Packaging Science Interest Group (PSIG) meeting.

The first item discussed was the proposed change of US Pharmacopeia (USP) <381> on Elastomeric Closures. The consensus opinion shared at the meeting was that these changes will reduce the testing burden on users and suppliers by harmonizing the USP and European Pharmacopoeia (EP) test protocols into one set of physicochemical tests and specifications. Attendees shared many of the suggested changes that were submitted to the USP. These included the following:

Biological Tests – The PF article specifies that the Agar Diffusion Test in USP<87> be utilized.

Suggest that this be changed to the Elution Test in USP<87>, since historically the Elution Test has been the method of choice for closure suppliers, pharmaceutical manufacturers, and contract testing laboratories. "Formulation Characteristics" data sheets distributed by rubber closure suppliers have most commonly contained toxicity data obtained by the Elution Test.

The current version of USP<381> does not specify which of the three test procedures described in USP<87> (Agar Diffusion, Direct Contact, or Elution) must be used. Since Elution is the most commonly used, there is no need now to specify another test.

INTRODUCTION—Omit all text starting in the third paragraph with "However, this specification is not intended…"

This text does not contribute to the correct performance or utilization of the test and merely summarizes previously published information contained in the FDA Packaging Guidance.

CHARACTERISTICS—See bullets.

- Change "relative density" to "specific gravity."
- Omit "determination of sulphated ash." The ash content is contained in Identification Test C – Residue on Ignition.
- Change "sulphur content" to "sulfur content" to conform to conventional US spelling.
- Omit "UV absorption…extract." This test is already included in the proposed USP revision.
- Omit "IR absorption…pyrolysate." This is Identification Test B.

Change the heading "IDENTIFICATION TESTS" to "Identification Tests" in order to harmonize with the other types of tests – Biological Tests and Physicochemical Tests.

TEST PROCEDURES—Pretest Preparation of Sample:

- Omit "If closure siliconization has been found to skew physicochemical analysis results, this process may be eliminated from the processing steps."
- It would be difficult to know if the results are "skewed." Which test results are correct—those with silicone or those without? Omit this sentence.

HEAVY METALS—Put text describing the complete procedure in USP<381> instead of just referring to USP<231>, Heavy Metals.

VOLATILE SULFIDES—Move "Note–For…dry." to a different position.

- Put a new header between the VOLATILE SULFIDES and PENETRABILITY test descriptions.

Thus, the section should appear as:

VOLATILE SULFIDES— Place closures…by the control solution.

Functional Tests

Note—for the following three functional tests, use a closure treated as described for the preparation of Solution S, and allowed to dry.

PENETRABILITY

This test is performed…for each closure.

FRAGMENTATION

This test is performed…determine their nature and size.

SELF-SEALING CAPACITY

This test is performed…trace of blue solution.

Thus, USP<381> will describe four types of tests: Identification, Biological, Physicochemical, and Functional.

A possible numerical error in the Opalescence test reference solutions should be reviewed by USP to make sure it corresponds exactly to EP. The USP solutions appear to be 10x less concentrated than the EP solutions.

The USP should review the definitions of Type I and Type II closures and compare to EP. There should be no differences.

Preparation of Samples: The USP proposal allows several options which are not permitted by EP. This section should be made uniform.

Preparation of solution S: USP specifies Water for Injection. Since sterility of the water will not affect results, change the water to Purified Water.

Reducing substances: The USP proposal calls for the addition of alkaline cupric citrate whereas the EP does not. The USP method should agree with EP.

PDA will submit written comments to USP regarding USP<381>. Several of the attending companies reported that they also have submitted comments to USP.

Other questions concerned when and how the USP will implement these new requirements. Will

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the new requirements apply to currently marketed drug products? Will all tests be required as incoming Quality Control (QC) tests on elastomeric closures?

The second item discussed was the interpretation and implementation of FDA's Packaging Guidance of 1999. Most attendees reported that their companies were making slow progress due to the uncertainty in the level of analysis and qualification required. Several companies reported that they are utilizing contract analytical labs to perform both extractables and leachables studies. Time and cost are factors of concern.

Finally, a brief announcement was made by Paul Harber of Eli Lilly and Company regarding the ongoing work of a group on Type III Drug Master Files (DMFs). The announcement is attached to the PSIG minutes posted on PDA's Web site, www.pda.org.

The next meeting will be held in Atlanta on either November 10, 11, or 12.

Inspection Trends/Regulatory Affairs Interest Group

Robert L. Dana, Elkhorn Associates, Inc.

The Inspection Trends/Regulatory Affairs Interest Group met on March 17, 2003, during the PDA Spring 2003 Meeting. Attendees discussed their experiences with the Systems Inspection approach, and concurred that there were still inconsistencies in how the program is being applied.

In addition, FDA's six-month milestone report on the progress of their "Good Manufacturing Practices (GMPs) for the 21st Century" program was discussed. A copy of the presentation used to facilitate that discussion follows.

GMPs for the 21st Century:

- FDA Initiative, August 2002
  - Reviews and inspections based on good science;
  - Encourage the adoption of new technologies by the industry;
  - Better integration of quality management techniques;
  - Risk-based approach;
  - Enhanced consistency; better coordination.
- Overseen by Steering Committee, Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), Chair;
- The Center for Biologics Evaluation and Research (CBER), CDER, the Center for Veterinary Medicine (CVM), the Office of Regulatory Affairs (ORA) and the Office of Commissioner (OC) were all represented;
- The Center for Food Safety and Nutrition (CFSAN) and the Center for Devices and Radiological Health (CDRH) were involved with the Part 11 implementation;
- 13 Working Groups.

GMPs for the 21st Century – Working Groups

- Contracts Management
- Part 11
- Warning Letter Review
- Changes without Prior Review
- Work Planning and Risk Management
- Manufacturing Science
- Quality Systems
- International Activities
- Dispute Resolution
- 483 Communications
- Product Specialists on Inspection Teams
- Pharmaceutical Inspectorate
- Evaluation of the Initiative

GMPs for the 21st Century – Six-Month Milestones

- Part 11
  - February 20, 2003 Draft Guidance
    - Reexamining applicability, may revise;
    - Exercising enforcement discretion for legacy systems;
  - Withdrawing Compliance Policy Guide 7153.17; Enforcement Policy for 21CFR Part 11
  - Withdrawing guidance documents on validation, glossary of terms, time stamps and maintenance of electronic records.
- Encouraging Changes Within the Existing Framework
  - New draft guidance "Comparability Protocols-Chemistry and Manufacturing Controls (CMC) Information";
    - Applies to non-protein pharmaceuticals and veterinary drugs;
    - Provides for change implementation without prior approval in certain circumstances;
    - Facilitates continuous improvement and innovation;
  - Related guidances under development.
- Warning Letter Reviews
  - Center review prior to issue, beginning March 1;
  - Aimed at reducing inconsistency.
- Dispute Resolution Process (Inspections)
  - Progress report issued
    - Three levels; one informal (investigator) and two formal (District, Center);
    - Dispute resolution panel;
    - 12-month pilot proposed.
- FDA483 Communications
  - New language to be added:

"This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objec-

tion or action with the FDA representative(s) during the inspection or submit the information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above."
  - Clarify purpose and effect of FDA483
- Scientific Workshops with Stakeholders
  - Scheduled April 22–24, 2003;
  - Will address:
    - Risk-based Current Good Manufacturing Practice (CGMP);
    - Integrated systems approach to CMC review and GMP inspections;
    - Post-approval manufacturing changes;
    - Manufacturing science.
- Risk-Based Approach to Planning Process
  - FY 2003 inspection priorities
    - Sterile drug manufacturers;
    - Rx drug manufacturers;
    - New registrants not previously inspected.
  - More detailed model for 2004
  - CDER Division of Compliance Risk Management and Surveillance
- Team Biologics
  - Ongoing improvements include:
    - Internal quality management system;
    - Metrics to assess impact of Team Biologics;
    - Standardized training and qualifications;
    - Risk-based work planning;
    - Increased communications between Center and field.
- Product Specialists on Inspection Teams
  - Have been used in the past;
  - Use has added value;
  - Need to better formalize program;
  - Progress report issued.
- Enhancing Expertise in Pharmaceutical Technology
  - Some experts have been hired;
  - Collaborating with academia and industry.
- International Collaboration
- Pharmaceutical Inspectorate
- Process Analytical Technologies (PAT) Initiative
- Effective Business Practices
- Quality Management System

GMPs for the 21st Century – PDA Activities

- Regulatory Affairs Quality Committee (RAQC) Working Group to Define Risk-Based Management and Science-Based Regulation;
- RAQC Working Group to Review FDA's Progress Report;
- Working Groups Developing Comments on Part 11 and Comparability Protocol Draft Guidances;
- Agency Feedback to be Provided.

Quality Assurance/Quality Control Interest Group

Don Elinski, Eli Lilly and Company (moderated by Jim Fernandez, Fernandez and Associates)

The Quality Assurance/Quality Control (QA/QC) Interest Group met in San Diego in March 2003 and discussed the following topics.

- System-Based Inspections;
- Media Fills
  - Bovine Spongiform Encephalopathy (BSE) risk from media;
  - Freeze dryer simulations;
  - Size/shift treatments;
  - Annual or biannual.
- Foreign Matter
  - Tablets
- Acceptable Size/Types
  - Glass inspection standards
- Environmental Monitoring
  - Inside freeze dryers;
  - Alert/action levels general.
- Validation
  - How do you qualify QA signatories on validation?
- QA/QC Forum Issues 2003;
- Total Organic Carbon (TOC) testing of Water for Injection (WFI);
  - Should limit be 500 ppb or limit response of sucrose standard?
- Cleaning Processes;
- Document Control Software;
- Change Control Practices;
- Pipet Calibration;
- Is QA Doing its Job?
  - Why or why not?
  - What can we do better?
- Potable Water Alert Limits;
- What is the Best Organizational Structure for a QA Unit?;
- Investigations/Deviations;
- Part 11—Laboratory Equipment
  - What if my vendor does not have a Part 11 solution yet?
- Topics of Interest or Concern for Future Discussion or Research.

PDA Pharmaceutical Water Interest Group

Theodore H. Meltzer, Ph.D., Consultant

Agenda

The Task Force members present were informed that a questionnaire directed to the pharmaceutical industry regarding selected facets of Pharmaceutical Water preparation and usage had been drawn up by Bill Stoedter and Ted Meltzer from several lists collected from various contributors since our first meeting. Reviews of the selected questions were made by Frank Bing and by Russ Madsen prior to submittal to the Board. Its approval by the Board is now pending.

Although established at an earlier date, the Task Force, in effect, was at its first working session. The purpose was to determine the Task Force's priorities regarding the water topics of interest to the group. The topics were advanced by

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the participants, who then assigned priorities, as made manifest by vote. It was hoped that volunteer committees would then constitute themselves to undertake the elucidation of the topics considered most urgently in need of resolution.

Prioritized Topics

The attendees identified six topics considered as now in need of useful resolution or clarification. The Task Force constituted itself into self-appointed sub-committees to collect whatever enlightenment is to be found relative to these subjects, whether from the literature, participation in actual work, from FDA origins, from knowledgeable colleagues, or other sources. Following which, longer range, each sub-committee will arrange and reconcile the material it procured. The eventual goal is to solve, or at least to make better known, the existing information about topics that are now insufficiently organized to permit their practical application.

# Committee	Topics	# Votes
1	FDA regulations and/or views pertaining to the use of membrane filters in the storage, distribution, and points-of-use areas of pharmaceutical water systems.	9
2	Biofilms. Collect, organize, and, if possible, unify the existing information.	8
3	Sampling. Where, When, How. Comparison of FDA and European requirements.	7
4	Microbiological Issues. Media selections, Incubation Methods.	6
5	Rouging/Passivation. Collect, reconcile, and unify, if possible, the views of metallurgists, passivation-practitioners, corrosion experts, and microbiologists.	3
6	Production of Water for Injection. Comparison of Distillation and Reverse Osmosis.	3

Sub-committee	Chairperson	Topic	Other Members
1	J. Martin	FDA rulings on Filter usage	T.H. Meltzer
2	H.G. Schroeder	Biofilms	Allen Leduc
3	B. Conley	Sampling	
4	M.Bullard	Microbiological Issues	H.G. Schroeder, Paul McVeigh
5	T.H. Meltzer	Passivation, Rouging	
6	Allen Leduc	WFI Production	H.G. Schroeder

Follow-Up

The Task Force will next convene at the PDA Annual Meeting in Atlanta the week of November 9th. It is planned to contact the sub-committee Chairpersons in mid-July to ascertain the progress being made in the voluntarily assumed tasks.

The high enthusiasm evident at the meeting will undoubtedly abate somewhat when the participants return to their work stations. Too much may be expected. Please note the disparity between the numbers attending the meeting, the number voting for the investigation of a given topic, and the number volunteering to work on the selected topics.

Regardless of the delayed beginning and of the daily work priority at a pace yet to be demonstrated, the PDA Task Force on Pharmaceutical Water will persist in the pursuit of the stated goals. ■

Highlights from the

FDA/PQRI Workshop entitled, "A Drug Quality System for the 21st Century"

On May 22–24, 2003, industry, FDA and academia came together in Washington, DC to discuss the implementation of FDA's "Current Good Manufacturing Practices (CGMPs) for the 21st Century" initiative. The workshop provided opportunities to discuss the initiative with FDA relative to four topic areas:

- Risk-Based CGMPs: Defining Risk and Quality;
- Integrating Chemistry and Manufacturing (CMC) Review and Inspection;
- Changes Without Prior Approval;
- Manufacturing Science.

Workshop sessions on these four topics were preceded by presentations by industry and FDA designed to stimulate discussion.

Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research (CDER), described the desired future state of manufacturing envisioned in the drug quality initiative as "reliability and availability of high-quality, efficiently produced drugs." She said that barriers to the desired state included product complexity, future smaller target populations, and cost pressures.

Regarding the desired state of manufacturing, Woodcock said it would be characterized by effective, efficient manufacturing processes, specifications based on mechanistic (predictive) product understanding, continuous improvement and the use of new technology.

The desired state of regulation, according to Woodcock, is an understanding of manufacturing and quality systems, the use of a risk management framework, and the avoidance of "one size fits all" regulation.

Woodcock explained the reasons for the GMP initiative. She said the regulatory system was outdated: the GMP regulations date from 1978. There also are more approved drugs than ever, and there have been advances in pharmaceutical science, manufacturing technologies, and quality management concepts. Biotechnology and the globalization of the industries are drivers, also.

It is important for the Agency to understand the relationship between CMC and CGMP. She said that while it is intuitively simple, drug product quality is difficult to define. Is it "fitness for use," attributes ensuring safety and efficacy, manufacturing according to CGMP, availability, or design attributes linked to safety and efficacy? Might it also be thought of in terms of patient risk linked to quality attributes? Woodcock said that the "integration of CMC review and inspections is critical" to the success of the GMP initiative.

Gordon Munro, Director of Inspection and Enforcement, MCA [the newly named Medicines and Healthcare products Regulatory Agency (MHRA) as of April 1, 2003], provided an international perspective as he discussed the roles and functions of the European Agency for the Evaluation of Medicinal Products (EMEA) and MCA. MCA's main functions are: to license products, conduct surveillance, pharmacovigilance, inspection, enforcement (criminal), standards, and policy.

Munro described "through life" inspections, in which the same inspectors are involved throughout the product life cycle, from development to clinical studies through production and on into generic introduction.

Some key differences between MCA and FDA regulatory programs include MCA's use of industry-experienced inspectors, of risk-based inspections, and of the assessment of deficiencies as "critical," "major," and "minor." There are five levels of notification letters ranging from "everything's OK" to notification of serious problems. Deficiencies are evaluated by an "inspections action group."

Speaking on a personal level, Munro said that GMPs might eventually need to be changed, but not yet. The real problem with harmonization lies in interpretation rather than in differences in the regulations themselves. There are really only a few real differences, such as the requirement in the United Kingdom for a "qualified person." The focus should be on a small number of internationally harmonized guidelines such as process capability, assessing new measuring and manufacturing technology, and the required principles of a quality systems approach.

During her presentation on integrating CMC and inspection, Christine Mundkur, Barr Laboratories, emphasized the need to enhance the consistency and predictability of FDA's approach among Districts and Centers. In her view, the purpose of CMC submissions is to provide information on specifications and production processes to enable the reviewers to evaluate those factors. Compliance, on the other hand, uses the submitted information during Pre-approval Inspections (PAIs) to evaluate validation and other operational aspects that cannot be adequately reviewed on paper.

Mundker said that industry's role is to ensure good quality systems and to ensure that the development processes are in place to produce "well-characterized" products. Continuous im-

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FDA/PQRI Workshop from page 19

provement systems should also be in place to support the submission of additional data as indicated in the Common Technical Document (CTD). She said that the reviewer's and investigator's roles are blurred, in her view, and there is a need to clarify those roles. Also, if reviewers accompany investigators on inspections under a new system, are PAIs still relevant, and how might this relate to inspections based on quality systems?

Gerry Migliaccio, Pfizer's Vice President of Quality, in discussing manufacturing science, said that industry and FDA agree conceptually but may differ on "mechanics." Industry desires flexibility and innovation. There is a need to define FDA's required data set and to develop agreement between FDA and industry on the use of technology to mitigate risk. Current manufacturing and control processes, while they can be optimized from an efficiency standpoint, yield products for which the "status quo from a patient safety perspective is acceptable."

Breakout sessions, which were held to discuss the four topic areas, were summarized on the last day of the workshop. Highlights of the summaries follow.

Risk-based CGMPs: Defining Risk and Quality

Consensus was not achieved on what constitutes risk, since there are different types of risk. Definitions may need to be product-related. It was agreed that risk changes throughout the product life cycle. Categories or types of risk are patient risk, business risk, and regulatory risk, among others. Points to consider for defining risk include benefit, quality system, acceptable levels, and exposure.

Quality can be defined in many ways: fitness for use, effectiveness, availability, in addition to "meets specifications."

Benefits of risk-based quality systems include the potential increased product availability (more products, lower cost) and faster approval. FDA gains more product and process knowledge, which can lead to better resource allocation and increased trust and understanding, while the benefits accruing to industry are fewer/better inspections, faster, more consistent reviews, reduced regulatory burden, and the ability to focus resources on critical issues. Should something be done just because it can be done? Risk-based quality systems say no.

Challenges to implementing risk-based systems include: cultural change, trust, risk assessment and management training, perceived risk of Development Report review, and communication within FDA. Existing models for risk-based systems such as the Quality System Inspection Technique (QSIT) and the Hazard Analysis and Critical Control Point (HACCP) can be useful.

The next steps are to evaluate systems, define risk and quality in the context of risk-based GMP, expand global harmonization and explore the feasibility of self-regulation.

Integrating CMC Review and Inspection

Development data should include information about critical process control parameters, and this can lead to a reduction in regulatory burden; however, concern was expressed that detailed information of this type in development reports could increase the level of FDA questions resulting in extended approval times. Because of this, submission of additional development data should not be mandatory.

PAIs should be eliminated in their current form since they tend to be inconsistent, and investigators are sometimes not adequately briefed or prepared.

Inspections should focus on high-risk processes and products. GMP inspections should focus on quality systems, and as indicated in the Manufacturing Science discussions, inspectors should have industry experience. The role and need for specialists should be discussed at an application pre-submission meeting. If specialists are necessary during the inspection, they could also be used to support CMC review. It is also important to clarify and coordinate the roles of inspectors and reviewers.

Suggested next steps include a workshop on setting interim specifications, the International Conference on Harmonization (ICH) guidance on pharmaceutical development, a more thorough analysis of lessons learned with the Team Bio approach, and pre-license inspections. There was agreement that FDA should work to standardize pre-approval and pre-license review.

Changes without Prior Approval

Risk can be considered in various contexts: cost, market availability, and approvability. In terms of influencing the ability to make changes without approval, risk can be defined in terms of "is the current product different from the product used to generate the clinical data?"

Industry concerns and suggestions included the need for a decision tree, the economic impact of making some changes, the need for harmonization and the development of a system to identify low-risk changes.

The use of Comparability Protocols (CPs) generated mixed reviews. The biotech industry has used CPs more extensively than the pharmaceuti-

cal industry. CP advantages include consistent timing and early FDA input. Problems with CPs are that the time involved is not always worth the effort; they are not useful for unplanned changes; and the draft CP guidance has too many exclusions. Suggestions included the use of one CP guidance for all types of products and the use of experiences with CPs to expand SUPACs.

With respect to development reports, the summary indicated that they were useful as a basis to support future changes and could be used to give FDA confidence that the product and process are fully understood. Development report disadvantages were said to be: inapplicability to older products, additional work without much advantage, lack of understanding about how DRs would be used by FDA, and the potential for delaying approval.

Some innovative approaches that were discussed included a suggestion that FDA develop a rating system for firms based on the compliance history and robustness of a firm's quality system. Firms with a good record might be able to implement changes without approval. It would be helpful to have CP templates. FDA was urged to consider the European system for Type I and II variations.

Under "next steps," more information is needed on the content and uses of development reports, and more guidance documents would be useful. A workshop on risk assessment of aseptic processing changes was suggested.

Manufacturing Science

The desired state is a culture that embraces change. There needs to be a shift in culture from "change is bad" to "change is good."

Manufacturing science is more than just technology; it is knowledge, technology, quality systems and training.

Documentation is important, since it captures data which leads to knowledge about process and product and serves as a basis for continuous improvement—hence "change."

There is general agreement between industry and FDA on what level of quality is appropriate.

Open communication and trust is mandatory and there needs to be a new mechanism for sharing knowledge between industry and FDA.

Process analytical technologies (PAT) can be used for the closed-loop control of manufacturing processes.

In terms of getting from "here" to "there," the use of "Super Supplements" during the first year of product production could capture multiple process and specification changes. INDs and INADs could also be useful instruments for sharing process development knowledge.

Inspectors need more training and experience. In this regard, the European (MCA) model of using inspectors with five years of industrial experience might be useful. Scheduled inspections might be more efficient than ones that are unannounced, allowing the necessary company individuals to be present to fully explain processes, manufacturing and control systems. Inspectional focus should change from documentation review to quality systems.

The use of PAT should not be mandatory. PAT might require different specifications, since today's specifications were generally developed with relatively small sample sizes, and therefore may need adjustment. The use of interim specifications, developed using failure mode analysis, would be appropriate. ■

—Russell Madsen

Rinse Volumes for Cleaning Validation Studies

The following remarks are taken from an exchange in the Pharmaceutical Sci-Tech Discussion Group, a PDA-sponsored Online Forum held on the Internet 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

Can anyone send me a reference as to the "standard" rinse volumes which are used during cleaning validation studies?

Response 1

There are no such things as standard rinse volumes. If you intend to test rinse samples because it is not practical to swab the surfaces being cleaned, it makes sense to use the smallest practical volume. The smaller the volume the higher the concentration of the analyte—when the solvent has been selected, one does not normally have to consider solubility during cleaning validation as residues are, or should be very low. Basically carry out some development work and ascertain the smallest volume that will adequately wet all the surfaces to be cleaned. Vessels with a spray ball can normally be rinsed with much lower volumes than vessels without.

Response 2

The question is somewhat confusing. Do you mean rinse "sample" volumes? Rinse volumes for cleaning are established through development and are equipment and process-dependent.

Response 3

Sorry for the confusion and yes, I do mean rinse sample volumes. In answer to your question, I am wondering what volume of a rinse I should use, for instance, when "sampling" a 5 L pressure can or a 10 cc Cozzoli needle? In my current SOP for "Cleaning Verification for the Removal of Active Pharmaceutical Ingredients from Manufacturing Equipment and Surfaces," I have arbitrarily assigned these values: vessel size less than 100 mL, rinse volume is 5 mL; vessel size 100–500 mL, rinse volume is 10 mL; vessel size 501–5000 mL, rinse volume sample is 100 mL. My QA department has come back to me to ask for a reference for the assigned rinse sample volumes, and I can't find any references to my numbers. I know that I need to do recovery studies even with the rinse samples, but I would like to hear what you have to suggest for this rinse sample volume question. Hopefully I have made sense here.

Response 4

As far as I know, there is no "standard" rinsate volume for CV trials. The volume used depends on several factors: (1) the size and configuration of the equipment to be rinsed (need all product contact surfaces to be covered); (2) the limit of detection of the analyte of interest in the rinse solvent (too much solvent would render the analyte level undetectable); (3) acceptance criterion for the analyte under study; and (4) whether the analyte is stable in the rinse solvent over time.

Response 5

Unfortunately, there are no "standard" rinse volumes used in cleaning validation. I will say this though - as a rule, try to use the smallest volume you can legitimately get away with. This will increase the effective "sensitivity" of the sample.

Before you do any sampling, you need to do some quick calculations to make sure your sample is legitimate. For instance, let's say the maximum allowable residue on my surface is 1 microgram/cm2 and the LOQ of my analytical method is 1ppm. If I am sampling an entire piece of equipment and its total surface area is 100,000 cm2, then the largest volume I can legitimately use is something less than 100L. That is, if the actual residue is 1 micrograms/cm2, then the final concentration in my sample would be 1ppm. (1 micrograms/cm2 X 100,000 cm2 / 100L = 1ppm). That puts a failing result just at my limit of quantitation. Someone could argue that this is OK, but I would probably go with no more than 50L. If my volume was over 100L, I could not legitimately say that I met my criteria. At the acceptance criteria my sample would not meet the LOQ of the method.

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*.

So, you need to adjust and set the rinse volume ahead of time to best meet both your manufacturing and analytical situations. That will vary based primarily on your limits, the surface area sampled, and your method of LOQ/recovery. So I think you can see that there cannot be a "standard rinse volume."

Response 6

For small containers or filling needles we use swabs to obtain cleaning validation samples. The rinse samples have not produced repeatable or robust recovery values.

Response 7

If I were writing your SOP, I would add instructions based on what I wrote earlier about pre-determining the appropriate rinse volume based on: what size the surface area was being sampled, the acceptance criteria used, and the method of LOQ/recovery. I would then give a couple of examples of how to calculate the maximum volume you could use (anything less is fine). Then you don't need any outside references for sample volumes.

I wrote a CV Policy some years ago which had the calculations and examples and this kind of guidance, which I subsequently broke out into an SOP.

Response 8

The sample size (rinse volume) for cleaning verification depends on many factors, such as: the configuration of the equipment, the number of tests required to be done on the rinse solution, and the quantity required for each test.

There is no standard volume specified nor could there be any specified by any authority. What all authorities believe is that the smaller the volumes, the better the sensitivity, which greatly depends also on the sensitivity of the method used for detection.

Study your requirements on above line or arrive at conclusions based on your retrospective data and fix the volume specific to each equipment.

Response 9

I don't believe that you can successfully assign fixed rinsed volumes by looking exclusively at the equipment's volume capacity. Other factors must be considered, such as: the total product contact surface area of the equipment or equipment train; the actual cleaning limit generated using either the pharmacological approach (Fourman and Mullin) or the Toxicological approach (Conine, Larson and Stara); and finally the LOQ of the analytical method which has been properly validated for its function or use. As suggested by A. Walsh, one must take several factors into consideration to ensure the rinse volume is sufficiently small that the resulting rinsate residue concentration is at least 2–3-times greater than the method's LOQ for the same species. ■

—Russell Madsen

Company, Colleague & Product Announcements

PharmaSys Inc. has announced that **Chris Haskett** has been promoted to Vice President of Operations. In his new capacity, he will oversee all contract validation operations for both domestic and international markets. With PharmaSys since 2000, Haskett has experience in a wide variety of compliance-related functions, including validation planning, audits, cleaning validation, process validation, equipment validation, computer validation and commissioning. He has previously held positions with Glaxo Wellcome and Mallinckrodt. For more information about PharmaSys Inc., please visit their Web site at www.pharma-sys.com.

BioInformatics, LLC recently named **Jim Brady, Ph.D.** as the firm's Senior Science Analyst. Brady supports clients with his in-depth knowledge of modern biological laboratory techniques. His areas of expertise include cellular and molecular biology, genomics, gene therapy and virology. He has previously held research positions at the National Institutes of Health, MetaMorphix, Inc. and Genetic Therapy, Inc. He received his Ph.D. from Indiana University and a B.S. in Biology from the College of William and Mary.

The United States Pharmacopeia (USP) is pleased to announce that the 2003 edition of the *USP Dictionary of USAN and International Drug Names* (*USP Dictionary*) is now available in both a hardcover print and a new online format. For further information, please visit www.usp.org or e-mail your questions to custsvc@usp.org.

Malvern Instruments will be launching a major new product range at the end of May called the Zetasizer Nano series, which combines the best technologies to simplify the measurement of particle size, zeta potential and molecular weight of molecules and nano-sized particles. Features include the ability to measure high concentrations and particle sizes below 1 nm in diameter. It encompasses the recommendations of the ISO 13321 standard and allows users to meet FDA requirements for 21 CFR Part 11 compliance. The Zetasizer Nano series is ideal for quality control and process optimization and uses standard operating procedures (SOP's) to control the measurement process, which ensures optimum performance and excellent repeatability between operators. For more information, visit www.malvern.co.uk.

Malvern Zetasizer Nano series

Rockwell Automation recently announced that it has been selected by Laboratoires ROCHE Nicholas S.A., Gaillard, France, to implement global manufacturing solutions at the company's planned manufacturing locations in Turkey, Spain, and Switzerland. ROCHE has decided that the upgrade will include the Propack Data PMX™ from Rockwell Automation. Says Mr. Michel Doucet, Production Manager at Laboratoires ROCHE Nicholas S.A., "The new system has improved our workflow considerably. Management of user access, general planning, and the traceability of actions have become much easier. The project had to take into account the switch from our existing MES system to PMX™." The Propack Data PMX™ solution replaces five individual systems, a set-up that did not always provide optimum performance. For further information, contact Nadine Heier at nah@propack-data.com or visit www.propack-data.com.

Kendro has developed three new incubators: the new REVCO®, Ultima™ II, and Elite™ water-jacketed CO2 incubators incorporate sophisticated control functionality to make set-up, start-up and operation easier. The Ultima II models are carefully engineered to provide an optimal, stable growing environment for cultures. The REVCO CO2 incubators feature automated start-up. The fully-equipped Elite II models have a welded interior and provide repeatable and reliable performance for routine culture work. For more information, please visit www.kendro.com.

Stelex-TVG, a firm providing enterprise wide compliance solutions to FDA-regulated industries, announced the opening of a new office in Woburn, Massachusetts. This office will provide local support to its growing client base in the New England region, and builds on the company's previous expansion to Puerto Rico. **Leon Heredia** will be the District Manager of the New England region. He states "the Regional office will provide the full spectrum of validation, technology, regulatory, and business solutions we offer to all our clients." **Heredia** brings over 20 years of experience to Stelex-TVG. He held positions of increasing responsibility at major pharmaceutical, medical device and process controls companies, in management, technology and validation. ■

—compiled by Evelyn N. Heitman

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. . . to Joe Bury via e-mail at bury@pda.org or mail a hard copy to PDA headquarters at 3 Bethesda Metro Center, Suite 1500, Bethesda, MD 20814.

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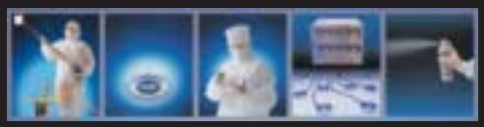

INNOVATIVE CLEAN ROOM PRODUCTS

2003 PDA Annual Meeting, Courses and Exhibition

Building on Our Strengths: Quality, Science and Innovation

November 10–14, 2003 • Atlanta Hilton Hotel

Conference:
November 10–12

Exhibits:
November 10–11

Courses:
November 13–14

This year's event, **Building on Our Strengths: Quality, Science and Innovation**, will chart the progress of pharmaceutical research, technology, manufacturing and compliance over the past decade, identify emerging trends, and discuss how to effectively and efficiently respond to the growing demand on pharmaceutical production in an evolving regulatory environment.

Keynote and plenary sessions presentations will feature:

- An update on the Food and Drug Administration (FDA) (in particular, the Center for Drug Evaluation and Research [CDER]) initiatives and activities;
- A dialogue on the impact of the Severe Acute Respiratory Syndrome (SARS) and emerging diseases on the pharmaceutical industry as well as an exploration of industry's response to these crises;
- A five-year forecast of the industry.

2003 PDA Annual Meeting, Courses and Exhibition

Exhibitor List

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as of 5/15/03

The conference program will consist of three distinct session tracks: Compliance Issues, Manufacturing, and Science and Development. Case studies and presentations within the Compliance track include: Part 11: the new guidance, quality systems, and the Aseptic Processing Guidance Document. Five sessions will discuss clinical, biotech and disposable manufacturing, outsourcing, and visual inspections. Presentations on environmental monitoring, process development and cleaning validation are some of the topics featured in the Science and Development track.

Also featured are the popular PDA Interest Group meetings, facilitating dialogue on a focused variety of topics and issues. An interactive exhibition will provide information on new concepts, products and services in pharmaceutical science and technology. Social and networking events are tentatively scheduled.

Don't miss this unique opportunity to network with colleagues and health authorities. Learn how to effectively respond to changing regulatory expectations, and become better-equipped to embrace the future of the industry. Visit PDA's Web site, www.pda.org, for further information.

To reserve an exhibit booth, contact Nahid Kiani at (301) 656-5900 ext. 128 or via e-mail at kiani@pda.org. ■

— Leslie Zeck and Chris Goldberg

PDA-TRI Lecture Courses at the 2003 PDA Annual Meeting:

November 13

Designing, Monitoring & Validation of Pharmaceutical Manufacturing Ventilation Systems

Auditing Techniques for CGMP Compliance

November 13–14

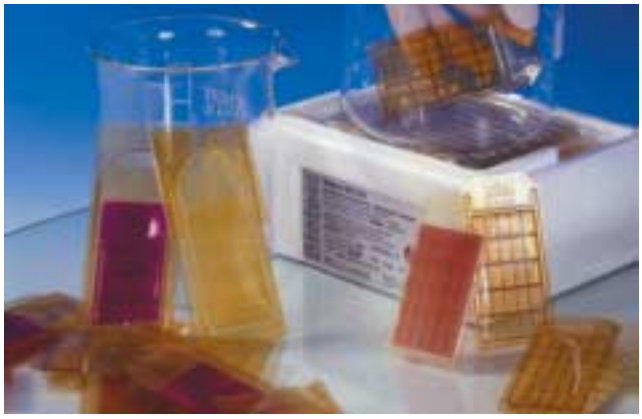
Basic Concepts in Cleaning and Cleaning Validation

Computer-Related Systems Validation

A Practical Approach to Aseptic Processing and Contamination Control

November 14

Managing in a GMP Environment Change Control & Documentation



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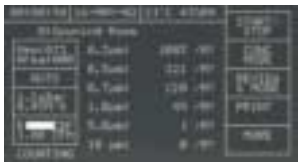

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RESCHEDULED—NEW DATES

2003 Taormina International Conference and Tabletop Exhibits for Senior Executives in the Pharmaceutical Industry

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

With the impact of global events, senior executives in quality assurance/control, global manufacturing, and regulatory affairs will now have even more reason to convene in Taormina to participate in an exclusive conference focusing on Managing for Quality in a Cost-Focused Environment. Key regulatory representatives and industry experts from around the world will present information relevant to effective compliance and quality management.

The design of the conference, including formal presentations, informal discussions and social events, is specifically developed to enhance interaction among attendees and speakers.

Highlights include:

- Expert executives from leading pharmaceutical firms, presenting industry experiences, perspectives and solutions;
- Outside technical experts;
- Legal and regulatory perspectives on consent decrees and other consequences, and how to avoid them;
- Discussion on the development, implementation and execution of a new quality management system;
- Identification of key elements of building an effective quality system;
- Discussion on supply chain management and strategic contracting.

Space at the conference is very limited. Please review the official brochure and registration information for this conference, now available online at www.pda.org. ■

—Leslie Zeck

PDA Audio Conferences: "Meeting the Needs of Our Members"

PDA continues to bring the quality education you've come to expect. Due to the economic, political and health climate around the world, PDA is creating new methods of delivery to minimize the time and financial impact quality education can demand.

Beginning in April 2002, PDA held six very successful audio conferences featuring industry and regulatory experts:

- An FDA presentation on Process Analytical Technologies (PAT)—John Shabushnig, Ph.D., Pfizer, Inc. and Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science, CDER, FDA;
- A summary of the PDA/USP Joint Conference on Sterile Product Manufacturing—Michael (Mike) Korczynski, Ph.D., founder and Senior Vice President of MIKKOR™ Enterprises, Inc. and David A. Porter, Ph.D., Senior Scientist at the US Pharmacopeia;
- FDA's Aseptic Processing Concept Paper—Carol Lampe, Baxter Healthcare; Richard Johnson, Abbott Laboratories; Rick Friedman, Ph.D., FDA; and Brenda Uratani, Ph.D., FDA;
- Emerging Rapid Microbial Methods Technology—Bryan Riley, Ph.D., CDER, FDA; Peter Cooney, Ph.D., FDA; Jeanne Moldenhauer, Ph.D., Vectech; and Roger Dabbah, Ph.D., US Pharmacopeia;
- Quality Contracts as Seen From Both Sides of the Table—Kelly O'Hare and Allen Burgenson, Cambrex;
- How to Build an Effective Corrective and Preventative Actions (CAPA) Program—Paula Wilkerson, Applied Genetic Technologies Corporation and Marc Puich, Tefen.

PDA has reached more than 3,000 listeners with these audio conferences and more individuals are participating with each conference.

Future audio conferences will address:

- Navigating Legal Waters
- The 10 Commandments of Writing Out of Specification (OOS) Reports
- Part 11: The New FDA Guidance
- Combination Products: Understanding the Unique Issues
- Internal Audits: Your Company's Defense (Qualifying Vendors)

Audio conferences are scheduled approximately every six weeks; check the PDA Web site at www.pda.org for details. ■

—Lisa Wade

2004 PDA Training Conference and Courses

"No Trainer is an Island—Developing and Leveraging Your Training Network for Success"

by Bill O'Connor, Conference Chair

Plans are underway for the 5th biennial PDA Training Conference: No Trainer is an Island—Developing and Leveraging Your Training Network for Success. The conference will be held May 16–19, 2004 at the award-winning Westin Rio Mar Beach Resort in Puerto Rico, the Caribbean's most comprehensive beachfront meeting and incentive destination.

The conference is targeted to current Good Manufacturing Practice (CGMP) and technical trainers in the pharmaceutical, biotech, medical device, and related industries. The conference format has been expanded to three full days of activities followed by two days of optional PDA-TRI courses targeted to training.

The last conference in Tampa attracted over 200 trainers from around the world. Conference attendees had over 20 concurrent sessions to choose from, which included basic presentations for new trainers, as well as an advanced track for the more experienced. These sessions were largely presented by peers and covered such topics as curriculum design, classroom techniques, developing e-learning, writing training manuals, and management training, to name a few. The general sessions featured presentations and a panel discussion by the Food and Drug Administration (FDA), "Testing Triage" by Indiana State University professors and authors Bill Cosscarelli and Sharon Schrock, as well as a full day of "Creative Training Techniques," presented by Dave Arch of The Bob Pike Group. Participants were also provided many opportunities for networking and time to attend the vendor exhibits, with 20 different vendors displaying training materials and services. Conference attendees also witnessed the creativity of some of their peers and selected the winners of the 2002 Trainer's Choice Award.

This year's conference promises to be another success. The conference committee is working hard to assemble an aggressive agenda, once again including speakers from the FDA, the training community at large, and trainers charged with CGMP and technical training. The "Call for Papers" has been posted, and we're seeking presentations on:

- Training Management Systems
- Career Development & Succession Planning
- Trainer Qualification
- Measuring Training Effectiveness
- Training Curriculum
- Competency-Based Training Methods
- Management Training
- Part 11 Training
- Compliance Training
- Obtaining Training Grant Funds
- Activities and Assessments
- Train the Trainer
- New Training Methods
- SOP Training
- Case Studies
- Technical Training

True to our conference theme, we will provide numerous opportunities to interact with peers, as well as more vendors with training materials and services, so that participants can truly develop and leverage their training network. We'll also feature all of our finalists for the 2004 Trainer's Choice Award and provide ample opportunity to "hobnob," benchmark, and be inspired by these very creative individuals. We're currently seeking submissions for this award in the following categories:

Best Multimedia Presentation Video	(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	(Can be: game, simulation, exercise, magic trick, etc.)

If you are interested in presenting at the 2004 conference or in submitting an entry for papers, go to www.pda.org and download the "Call for Papers." **The deadline for submission is July 15, 2003**. Information about the "2004 Trainer's Choice Award" will be available soon at www.pda.org: **deadline for submission of Trainer's Choice Award entries is January 31, 2004**. ■

2004 PDA International Congress, Courses and Exhibition

Product Life Cycle Management for the 21st Century

Mark your calendar to attend this prestigious three-day Congress in Basel, Switzerland. This event will attract at least 500 international professionals and scientists in the parenteral, sterile products, biotechnology and related fields for high-level education and dialogue among industry and regulatory experts. It is the eighth International Congress PDA has hosted in Europe since 1992.

All individuals interested in the future of pharmaceutical 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.

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 (ECTD)
- Electronic Process Assurance and Control

Educational Courses

The PDA Training and Research Institute (PDA-TRI) provides unprecedented education, training, and applied research in pharmaceutical 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.

Exhibits

Anticipated attendance of 500 scientists from Europe, US, Asia and other regions make this a premier event for pharmaceutical science and technology suppliers to meet key contacts. For information on exhibiting and/or sponsoring this event, contact Nahid Kiani.

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. Attendees of this Congress will be staying at the Swissotel Basel, which is conveniently located adjacent to the Messe Basel Convention Center and is accessible by tram, bus, and train. Detailed reservation information will be furnished in future announcements.

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

—Wanda Neal

Messe Basel Convention Center

Congress and Exhibition—February 16–18, 2004

Courses—February 19–20, 2004

PDA International Congress, Courses and Tabletop Exhibits

Due to travel warnings imposed by the World Health Organization and the Centers for Disease Control, PDA has agreed to postpone the Singapore Congress until 2004. Please save the dates of May 17–21, 2004. The advantage to you is that you can build this important networking and educational opportunity into your budget early and benefit from the same quality experience, same great location!

The Singapore Congress will feature presentations by industry and health authority experts on critical issues in pharmaceutical industry manufacturing. A variety of educational courses will provide additional opportunities for unprecedented worldwide education, training and applied research in pharmaceutical sciences and associated technologies. An interactive exhibition will feature the latest advances in technology and services in the industry.

Advise your colleagues who are 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, that they will derive significant value from participating in this unique opportunity.

Opportunities for tabletop exhibits are being offered to a limited number of companies. Please contact Nahid Kiani at (301) 656-5900 or via E-mail at Kiani@pda.org for details.

PDA looks forward to your participation in 2004! ■

—Leslie Zeck

May 17–21, 2004

The Ritz Carlton Millenia Singapore

Conference and Tabletop Exhibits:
May 17–19, 2004

Courses:
May 19–21, 2004

ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

August 20–22, 2003

San Francisco, CA • The Historic Fairmont Hotel

New Training Session Just Added! Get the Quality Training on this Guidance Directly from the Members of the Expert Working Group!

This exclusive training workshop has sold out in four locations in North America and Europe. Register today to ensure that you can benefit from training by the members of the International Conference on Harmonization (ICH) Expert Working Group. After this session, the training workshop will move to Asia.

The Food and Drug Administration (FDA), in collaboration with PDA, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA) developed a workshop training series on the ICH Q7A Guidance. The ICH Q7A document, the first Good Manufacturing Practice (GMP) guidance jointly developed between regulators and industry, is intended for use worldwide. It impacts any manufacturer who manufactures in, or intends to supply into the ICH regions (US, Europe, and Japan).

This three-day workshop will provide training of regulatory personnel alongside industry participants. The faculty is comprised of both regulators and industry representatives who served as members of the ICH Q7A Expert Working Group that developed the document. Substantial time has been allotted for question-and-answer sessions.

Highlights

- This is one of the only ICH Q7A trainings currently being conducted by members of the Expert Working Group that developed the Guidance; and
- The joint industry/regulatory/faculty participation will facilitate a mutual exchange of discussion issues on the ICH Q7A document.

The ICH Q7A Guidance Document can be found on the following Web sites:

- http://www.fda.gov/cder/guidance/index.htm
- http://www.emea.eu.int/pdfs/human/ich/410600en.pdf
- www.ifpma.org/ich5q.html#gmp

Who Should Attend

This document covers all aspects of the manufacturing, controlling and regulating of Active Pharmaceutical Ingredients (APIs). The following professionals will benefit from this training:

- Auditors of API Manufacturing Operations;
- Agents, Brokers, Traders, Distributors, Repackers and Relabellers of APIs;
- GMP Compliance Officials;
- Process Engineers;
- Production Engineers;
- Regulatory Investigators and Compliance Officers;
- Reviewing Chemists;
- Quality Assurance/Quality Control and Regulatory Affairs Professionals; and
- Consultants to the Pharmaceutical Industry.

Learning Objectives

- Understand the intent of the Expert Working Group that developed the ICH Q7A Guidance Document;
- Minimize variation in interpretation among industry and regulatory bodies worldwide;
- Address how the concepts of the ICH Q7A Guidance should be applied;
- Understand inspectional issues through side-by-side training of industry and regulators; and
- Understand how to interpret all 19 chapters of the ICH Q7A Guidance, including special sections on APIs manufactured by cell culture/fermentation, and APIs for use in clinical trials.

To register, visit PDA's Web site at www.pda.org. ■

—Leslie Zeck

PDA/FDA from cover

Enjoy a private performance by 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." The Capitol Steps monitor events and personalities on Capitol Hill, in the Oval Office, and in other centers of power and prestige around the world and then take a humorous look at serious issues while providing laughs for the entire audience.

Whether new to the industry or a seasoned veteran, individuals involved in pharmaceutical, 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.

Please note that this conference sells out each year. Register early on the PDA Web site at www.pda.org to guarantee your participation in this popular and important regulatory conference. ■

—Leslie Zeck

PDA/EMEA
European Virus Safety Forum

Hosted by the Central Europe Chapter of PDA in collaboration with EMEA and the Paul Ehrlich-Institute

Frankfurt, Germany

September 29–October 1, 2003

by Georg Roessling

This joint PDA/EMEA (European Agency for the Evaluation of Medicinal Products) conference will discuss current issues relating to the viral safety of recombinant proteins, monoclonal antibodies and plasma-derived medicinal products.

The conference will cover regulatory requirements for these products, aspects of testing source materials for viruses, several aspects of virus validation such as the model virus approach, as well as virus assays and their standardization. Virus inactivation/removal technologies and special aspects of their validation will be discussed.

A separate session will focus on the virus safety aspects of advanced technology medicinal products (gene therapy, cell therapy, xenogeneic cell therapy and products from transgenic animals) and will summarize the current knowledge.

The conference is intended for participants from regulatory authorities, industry, and academia.

Watch the PDA Web site, www.pda.org, for additional information on this important conference. ■

Reserve Your Space Today!
Showcase Your New Products!

We all know the value of face-to-face interaction between attendees and exhibitors. The attendees become aware of new products, evaluate vendors, renew relationships with existing vendors and often find new vendors to meet their needs.

PDA offers high quality scientific conferences and exhibitions that provide an opportunity to showcase your product/services and to build customer relationships with individuals involved in the pharmaceutical and biopharmaceutical industries.

The 2003 PDA/FDA Joint Regulatory Conference is a must-attend event. More than 550 attendees in product development, regulatory approval, production and quality assurance—including US and international regulatory authorities are attending. Lester Crawford, Ph. D., DVM, Deputy Director, FDA has confirmed his appearance.

The exhibit space for this very important regulatory conference has been sold out for the past three years. Due to the demand from exhibitors, we have tripled the available tabletops and already 50% of them are sold out. The PDA/FDA Joint Regulatory Conference is *the* place to broaden your visibility and distinguish yourself from the competition. Following are some of the benefits of exhibiting at this show:

- Your company description will appear in the attendee portfolio and on a post-show CD
- Your company description will be posted on the PDA Web site for 90 days with a link to your site
- Recognition in *PDA Letter*
- If you are advertising in the *PDA Letter* pre-show and show issue (July and August) or the PDA Journal show issue (July/August), you will receive a tagline on your ad free.
- Exhibiting will add to your priority points

Also mark your calendar for our 2003 PDA Annual Meeting, Courses and Exhibition, November 10–12, 2003 in Atlanta, GA.

Please contact me at (301) 656-5900 ext. 128 or at kiani@pda.org if you have any questions or to reserve your space. ■

—Nabid Kiani

2003 PDA/FDA Joint Regulatory Conference Exhibitors Listing

Accugenix 21
BD Diagnostic Systems 31
bioMérieux, Inc. 24
BioReliance 41
Bioscience International, Inc. 30
Brock Solutions 45
Cambridge AccuSense, Inc. 40
Carlisle Life Sciences 34
Charles River Laboratories, Biopharmaceutical Services 26
Charles River Laboratories, Endotoxin Testing Services 25
CIMCON Software 20
CimQuest Inc. 38
Document Control Systems 14
DVT 44
Eli Lilly & Company 19
FOSS NIRsystems 32
Genesis Machinery Products, Inc. 28
Getinge USA 8
Grace Engineering Validation, LLC 37
INTELITEC CORPORATION 5
la Calhene, Inc. 7
Lansmont Corporation 36
LearnWright, Inc. 1
Millipore Corporation 39
Novatek International 58
Pall Life Sciences 15
Phoenix Imperative, Inc. 56
PML Microbiologicals, Inc. 4
ProPack Data Corporation 33
RCM Technologies, Inc. 27
Sparta Systems, Inc. 3
Vectech Pharmaceutical Consultants, Inc. 22
Veltek Associates, Inc. 29
Veriteq Instruments 35
West Pharmaceutical Services, Inc. 6
Working Words, Inc. 2

as of 5/15/03

Visit the Exhibit Hall at the 2003 PDA/FDA Conference for FREE!

Just provide a business card and receive your badge. You may purchase tickets to social events.

Exhibit Hours

Monday, September 8th
10:00 am – 7:00 pm

Tuesday, September 9th
10:30 am – 4:15 pm

Hall is closed for lunch both days
from 12:30 pm – 2:00 pm

Director's Message:
Update from PDA-TRI

PDA members who have followed the history of the PDA Training and Research Institute (PDA-TRI) know that some of the equipment and supplies used in our laboratory courses were (and still are) donations and loans from generous industry contributors. When you visit PDA-TRI, or attend classes here, they are readily visible. Other donations and contributions, such as goods and services, are less obvious—but no less important. I want to take this moment to thank some of our recent—less obvious—contributors:

- **Veltek**, for their continuing supplies of sanitization solutions and for supplies used throughout the PDA-TRI facility;
- **Millipore Corporation**, for a full maintenance service call for the PDA-TRI MilliQ water system;
- **Remel**, for numerous Cultiloops of yeast and mold species and specific growth media, which are especially useful in conducting our Mycology Identification classes;
- **Atlantic Technical Services**, for their maintenance service in the installation and certification of HEPA filters in PDA-TRI's Aseptic Processing Laboratory;
- **Lyophilization Technology, Inc.**, for their repair and maintenance of the freeze-dryer used in the Aseptic Processing courses;
- **Cardinal Health**, for their continuing donations of sterile, disposable garments and sterile gloves for use in the Aseptic Processing courses.

Such generosity from within our industry helps sustain PDA-TRI, permitting us to offer the highest quality professional training. We are truly grateful for their support.

Turning now to new initiatives, as mentioned in last month's *PDA Letter*, PDA-TRI plans to expand course offerings in Europe. While my original intent was to initiate this in 2004, European support for this program has been extremely encouraging. With the assistance of Gautam Maitra, PDA Director, Europe, I hope to have PDA-TRI produce several courses in Europe later this year. After that, I hope to produce course offerings on a regular basis throughout Europe, much as we do in the US. Plans are being formulated at this time, so watch for the announcements on the PDA Web site, www.pda.org.

There is still time to register for the July 15–16, 2003 course on "Computer Products Supplier Auditor Process Model: Auditor Training." This comprehensive course will train pre-qualified applicants in auditing suppliers of computer products according to the standardized model developed by PDA and published as PDA Technical Report #32. Formal training is required to become a certified auditor in the TR-32 process model. The course brochure can be obtained at www.pda.org/pdf/TRI-Auditor_Training03-BRO.pdf.

Such generosity from within our industry helps sustain PDA-TRI, permitting us to offer the highest quality professional training. We are truly grateful for their support.

PDA-TRI is also offering two courses in August at the PDA-TRI facility. A course on "Compliance Auditing of Cleanrooms and Controlled Environments" will be held August 14–15, 2003. Anne Marie Dixon, a recognized expert in cleanrooms and controlled environments, will teach this course. Don't miss this opportunity to learn and interact closely with one of the preeminent leaders in this field. On August 11–15, 2003, we will be offering the "Current Good Manufacturing Practice (CGMP) Trainer's Qualification Program." PDA-TRI faculty member (and former PDA-TRI Director) Rick Rogers will conduct this highly interactive five-day program for industry trainers. Learn what motivates students, how to "reach" them, and participate in actual "trainer" demonstrations. Register early for an exceptional training course designed for the trainer!

Also in August (8/19–21/2003), the San Francisco Lecture Course Series will take place. A total of nine courses will be offered, covering basic CGMP fundamentals and compliance, sterile dosage form basics, competency-based training issues, documentation practices, risk analysis, Corrective and Preventative Action (CAPA) systems, and annual product reviews. Visit the PDA Web site for the brochure and for more details on these and other courses offered through the PDA Training and Research Institute. ■

—Robert Mello, Ph.D.

PDA-BFS Joint Workshop on Blow/Fill/Seal Processing

PDA, in conjunction with the Blow/Fill/Seal International Operators Association (BFS-IOA), is pleased to announce that a hands-on training workshop on BFS processing will be offered September 18–19, 2003. Through both lecture and hands-on participation, attendees will learn the basics of blow/fill/seal processing in an actual production facility setting. Because of the need for specialized equipment, this combination lecture/lab course will be held at the blow/fill/seal facilities of Cardinal Health, located in Woodstock, IL in metropolitan Chicago. Due to the hands-on nature of the Day-2 session, class size must be restricted to 15 attendees. Members of PDA and BFS-IOA will receive a discounted registration fee. Details of the course content as well as registration forms will be available on the PDA Web site, www.pda.org. Register early—remember, class size is limited. ■

—Robert Mello, Ph.D.

San Francisco Courses from cover

your validation efficiency. Mike Akers and John Ludwig team up to bring you "Sterile Pharmaceutical Dosage Forms: Basic Principals" where an overview of sterile manufacturing, formulation development, microbiology and compliance training topics will be addressed. There will be specific time devoted in this course to participatory problem-solving exercises.

Corporate trainers developing internal training programs for multi-disciplined personnel will benefit greatly from "Introduction to Competency-Based Training" taught by David Gallup and Richard Sands. The importance of the role training plays in meeting regulatory requirements is but a part of this offering. "Managing in a GMP Environment" with Jim Vesper will present a workshop-style course for pharmaceutical industry managers who are responsible for GMP implementation in their organization.

Ken Peterson will be teaching the course on "Analytical Problem-Solving for Corrective and Preventative Action (CAPA) Systems." Designed for individuals who must quickly resolve problems, this course provides you with advanced skills in root cause analysis and problem prevention.

Dr. Alan Smith combines lecture, workshop and question/answer sessions during his course on "Annual Product Review (APRs): How to Comply with Food and Drug Administration (FDA) and International Conference on Harmonization (ICH) Requirements." Learn how to comply with regulatory requirements for APRs for drug products and active pharmaceutical ingredients (APIs).

How many times have you heard "If it's not documented, then you didn't do it!" Attend Jeff Masten's course on "Good Documentation Practices in the Pharmaceutical Industry" and be introduced to the fundamental documentation principles and industry standards that are required to produce high-quality records to support the manufacture and testing of pharmaceutical products.

As you can see, the lineup is packed with content to assist all areas of pharmaceutical professional development. AND, it's being held in a great venue. More details and registration information can be found on the PDA Web site, www.pda.org. Come for the training and save time to explore an outstanding city.

See you there! ■

—Bob Mello

PDA-TRI San Francisco Course Series
The Fairmont Hotel, San Francisco, CA

August 19
GMP Fundamentals

August 19–20
Sterile Pharmaceutical Dosage Forms: Basic Principles
Computer-Related Systems Validation
CGMP & Compliance

August 19–21
Introduction to Competency Based Training

August 20
Managing in a GMP Environment

August 21
Good Documentation Practices in the Pharmaceutical Industry
Analytical Problem Solving for CAPA Systems
Annual Product Reviews: How to Comply with FDA & ICH Requirements

2004 Aseptic Processing Course Dates Announced

The 2004 dates for the PDA Training and Research Institute (PDA-TRI) laboratory course on Aseptic Processing have been established. This extremely popular 2-week course sells out rapidly, so we urge you to register early. 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 in order to accommodate our members' requests. 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

—Robert Mello, Ph.D.

Upcoming PDA-TRI Education Courses

Aseptic Processing 2003 Training Program—Lab **Option 3**: August 25–29, 2003 and September 22–26, 2003; **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

SOLD OUT

CGMP Trainer's Qualification Program—Lecture August 11–15, 2003; October 20–24, 2003; $3,450 members/$3,645 nonmembers; *Faculty*: Rick Rogers

Compliance Auditing of Cleanrooms and Controlled Environments—Lecture August 14–15, 2003; $1,350 members/$1,545 nonmembers; *Faculty*: Anne Marie Dixon

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

Fundamentals of D, F, and Z Value Analysis—Lab August 21–22, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* John Shirtz

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

Courses listed in alphabetical order

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 the **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.

PDA-TRI Thanks the Following...

Sponsors

Abbott Laboratories
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Berkshire Corporation
bioMerieux Vitek, Inc.
Biotest Diagnostics Corporation
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Nalge Co.
Pacific Scientific Instruments
Pall Corporation
Particle Measuring Systems, Inc.
PML Microbiologicals
Raven Biologicals, Inc.
Research Equipment Services
Rhone-Poulenc Rorer
Sartorius AG
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SGM Biotech, Inc.
STERIS Corporation
Veltek Associates, Inc.
VWR Scientific Products
West Pharmaceutical Services
Wilco AG
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Contributors

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Contec, Inc.
Corning, Inc.
Cotter Corp.
DuPont Tyvek
Eli Lilly and Co.
Fedegari
Kaye Instruments, Inc.
Kimberly Clark, Corp.
National Instrument Co., Inc.
Neslo, Inc.
Perfex Corporation
Pfizer, Inc.
Sievers Instruments, Inc.
Technovation

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 06/03

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 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:_____

The PDA Delaware Valley Chapter: Meeting Members' Needs

With over 2,500 on their mailing list and four "special interest groups" that meet every one to two months, the Delaware Valley Chapter of PDA is a success story. Chapter President Art Vellutato, Jr., said he continues to watch the Chapter expand.

"We went from having 60 to 80 people per meeting to having 170 to 200 people per meeting," Vellutato said. "This Chapter just keeps on growing."

On April 16, 2003, 171 people attended a meeting of the Delaware Valley Chapter at the Desmond Hotel and Convention Center in Malvern, PA. The meeting included exhibits, a reception and dinner, followed by a presentation on "Sterile Manufacturing Compliance Issues" by Debbie Pagano, IHL Consulting.

> "People like PDA because they are protected from commercialism and they get great technical presentations."
> —Art Vellutato, Jr.

Debra Pagano, IHL Consulting, speaks to a full house at the April Delaware Valley Chapter meeting.

Pagano, a former FDA Investigator from the Philadelphia District Office, kept the audience riveted and helped achieve yet another successful meeting for the Chapter.

The Delaware Valley Chapter of PDA focuses its efforts on providing local events targeted at scientists involved in the development, manufacture, quality control, and regulation of pharmaceuticals, biopharmaceuticals and related products.

"I think the most important thing I've learned in being a leader of the Chapter is that the relationship between the local drug companies is critical to success," Vellutato said.

The Chapter organizes four dinner meetings annually. The focus of the meetings is to provide industry professionals the ability to converse in an educational environment while enjoying presentations from top industry professionals.

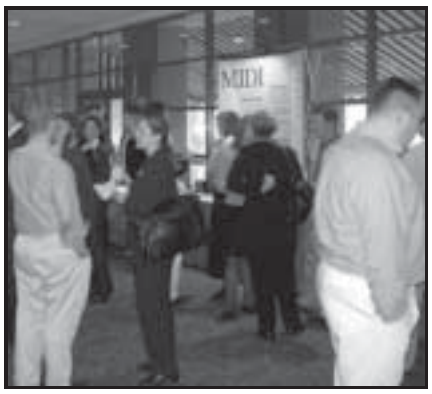
The dinner meetings are always held at the Desmond Hotel in Malvern, PA and include a cocktail hour, dinner and a featured presentation from 5:00 pm until 9:30 pm. The Delaware Valley Chapter aspires to be an integral link in education and is always looking for new volunteers who may assist in their efforts.

"People like PDA because they are protected from commercialism and they get great technical presentations," Vellutato said.

PDA Chapters exist to provide a local forum for PDA members to share information on scientific and technical topics related to the pharmaceutical industry. The Delaware Valley Chapter officers are: Art Vellutato, Jr., President; Marlene Raschiatore, Vice President; Jim Hallman, Treasurer; and Stephen Trombetta, Secretary.

If you would like more information about the Delaware Valley Chapter of PDA and its upcoming Chapter meetings, please contact Art Vellutato, Jr. at (610) 983-4949, E-mail: Artjr@sterile.com; or Kiki Coffman, Chapter Coordinator, at (301) 656-5900, ext. 149, E-mail: Coffman@pda.org. ■

—KiKi L. Coffman



Chapter members mingle outside meeting hall.

Attendees visit exhibits.

For PDA Chapter Contacts, turn to page 47.

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Wednesday only (9/10) *(does not include optional breakfast)*	☐ $ 350	☐ $ 450	☐ $ 500	☐ $ 150	☐ $ 230

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PDA Books

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 What you need to know about positioning regulated establishments for achieving electronic information assurance—the concepts and principles that need to be considered when building, maintaining, managing and transitioning electronic environments—can be found in Good Electronic Records Management (GERM), Part 1 of the PDA–ISPE series on Good Practice and Compliance for Electronic Records and Electronic Signatures. Focusing on requirements and concepts rather than technical implementation details, this resource document is a valuable tool for the architects of electronic records environments. Whether your mission is to define the requirements, policies and procedures or to construct the physical environment, you will find that Good Electronic Records Management (GERM) is a must for your bookshelf. Key elements of the document include: prerequisites; electronic records; organizational controls; operations and infrastructure; transactions; records retention; personnel qualification and training; hybrid systems and controls; legal; glossary; and further reading.

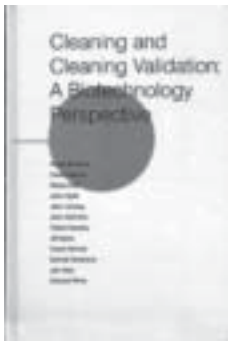
This document was produced through the collaboration of several industry groups (FDA regulated companies, system suppliers, legal experts, and consultants). It represents a compendium of current thinking on good electronic record management from an FDA-regulated industry perspective. GERM attempts to present these practices at an abstraction level that is descriptive. The stated practices and concepts are meant to educate the reader when considering options for electronic records management. No endorsement of specific technologies is made, nor are there any specifics that direct a standard for the implementation of concepts. Current thinking on the topics presented means that this compendium is intended to evolve as experience with electronic recordkeeping grows. Application of concepts may require a paradigm shift in some organizations with regard to the treatment of electronic records. Such changes are a conscious business decision and not an intentional prerequisite for implementation of any of the concepts presented. 2002; 104 pages; $95 PDA members/$190 nonmembers **Item # 19003**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures This document has been produced by a Special Interest Group of the GAMP Forum (pharmaceutical companies, suppliers, consultants and the Medicines Control Agency in the UK) in order to promote a better understanding of 21 CFR Part 11. It aims to provide industry and its suppliers with practical guidance on how to comply with the rule, while highlighting and addressing common issues of concern. The manuscript provides a management process for achieving and maintaining compliance with 21 CFR Part 11 in manufacturing environments. Specific guidance is provided for both new and existing systems in addition to the role of suppliers in supporting this approach. Appendices provide information, examples, templates, checklists, and a lifecycle for the management of electronic documents that are useful when implementing 21 CFR Part 11 compliance programs. A glossary and references list are also included.

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; 80 pages; $95 members/$190 nonmembers **(English) Item # 19001**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; 80 pages, $95 PDA members/$190 nonmembers **(German) Item # 19002**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures; 80 pages, $95 PDA members/$190 nonmembers **(Spanish)**—*The Spanish version must be ordered directly from:* Ediciones VR, Av. Belgrano 3786, Of. #2, (1210) Buenos Aires, Argentina, Attn: Ms. Florencia Viscaino; E-mail: subscripciones@edicionesvr.com; Fax: 54 11 4931 4861



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, 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, a 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; an analysis of changeover programs; and equipment considerations and material transport as they are affected by multi-product manufacturing strategies. 1995; 190 pages; $125 members/$145 nonmembers **Item # 13002**

Books from PDA-DHI Press

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. Drawing upon the authors' extensive 21 CFR Part 11 experience, this book offers a systematic approach to validation, from the determination to validate COTS computer software to assessing the outcome of the process. It also tells what measures companies must take to ensure that systems remain compliant with the binding regulations. It is designed to help readers save countless hours and dollars in pursuit of compliance. Making the transition from manual record-keeping to the electronic, paperless arena is not effortless. This book provides the practical information needed to ensure understanding of the FDA- issued guidance as they develop systems that will enable them to go partially or fully electronic. Intrinsic in the FDA guidance is that electronic systems that control the research, development, manufacturing, packaging, and distribution of products undergo validation and this book offers the information you need to proceed with confidence. Hardcover; 118 pp; $185 members/$229 nonmembers **Item # 17200**

Electronic Records and Electronic Signatures Compliance Assessment Chris Reid and Barbara Mullendore; *ERES* provides practical guidance on the interpretation of 21 CFR Part 11 and the steps you need to take to address current and future compliance issues. 58 pp; $90 members/$109 nonmembers **Item # 17177**

External Quality Audit, The Janet Gough and Monica Grimaldi; This book will help you to effectively evaluate suppliers to determine reliability, quality and value. 100 pp; $120 members/$149 nonmembers **Item # 17180**

Filtration Handbook—Integrity Testing Maik W. Jornitz and Theodore H. Meltzer; This complete guide explains the proper performance of filter integrity testing by clarifying its relationship to bioburden concerns and assessing its role in filter validation. It offers practical approaches to the appropriate use of integrity testing, wetting and temperature requirements, the Bubble Point test, diffusive airflow testing and much more. Numerous regulatory citations and references complete this invaluable book. 150 pp; $185 members/$229 nonmembers **Item # 17197**

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, 3rd edition James Vesper; A quick guide to GMP, designed to simplify and enhance understanding of most of the current GMP expectations and how they apply to ongoing tasks in any given pharmaceutical manufacturing situation. 224 pp; $105 members/$129 nonmembers **Item # 17199**

Hosting a Compliance Inspection Janet Gough; This is the guidance you need to host a compliance inspection. 106 pp; $120 members/$149 nonmembers **Item # 17192**

Internal Quality Audit, The Janet Gough and Monica Grimaldi; This book provides guidance for performing a systematic internal quality audit with guidelines and a common-sense approach to an often difficult task. 100 pp; $120 members/$149 nonmembers **Item # 17179**

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 # 17182**

Laboratory Systems Validation Testing and Practice Paul Coombes; This book aims to provide advice on the thinking and practice found to be successful and valuable in the validation of laboratory systems used in the pharmaceutical and related industries. 113 pp; $120 members/$149 nonmembers **Item # 17196**

Media Fill Validation Environmental Monitoring During Aseptic Processing Michael Jahnke; The second in this series of four books. This edition provides current, practical techniques that focus on considerations in the preparation and monitoring of aseptic manufacturing, taking into account the national and international requirements as well as guidelines concerning the validation of aseptic processing. Topics include: Risk analysis, HAACP, Documentation and qualification; Qualification and training of personnel; Scope of validation; Overall requirements; Release requirements; Documentation; and Authorization. The guide also includes an excellent Manufacturing and Testing Master Batch Record, and 25 extremely valuable charts, graphs, and figures. 108 pp; $90 members/$109 nonmembers **Item # 17181**

Microbiological Monitoring of Pharmaceutical Process Water Michael Jahnke; This quick guide discusses effective microbiological monitoring strategies for testing the quality of process water used in the pharmaceutical industry. 70 pp; $90 members/$109 nonmembers **Item # 17193**

Microbiological Risk Assessment in Pharmaceutical Clean Rooms Bengt Ljungqvist and Berit Reinmuller; This monograph clearly explains the Limitation of Risk Method (LR-Method). 17 pp; $75 members/$90 nonmembers **Item # 17175**

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 **Item # 17185**

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

To Order, Use Form on Page 46

Books from PDA-DHI Press *(continued)*

Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections Lucia Clontz; Addresses the main quality control systems that should be implemented in a microbiology laboratory with a focus on current issues and inspection trends. 175 pp; $135 members/$169 nonmembers **Item # 17176**

New Book!

Rapid Analytical Microbiology: The Chemistry and Physics of Microbial Indentification Wayne Olson; 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 avaliable and serves as both guide and reference to readers interested in improving performance and accuracy in a timely manner. 354 pp; $195 members/$239 nonmembers **Item # 17184**

Best Seller

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 **Item # 17183**

Understanding GMP: A Practical Guide Martyn Becker; This ex-MCA inspector, now at Merck, shares his expertise and perspectives on GMP regulations, legislation, applications, and practical challenges and solutions to applying GMP to the manufacturing environment. 237 pp; $130 member/$159 nonmember **Item # 17174**

Selected PDA Technical Reports

TR 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 TR 22: Process Simulation Testing for Aseptically Filled Products, is also apparent. Over time industry methods, practices and limits have been modified to adapt to the changing circumstances. 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 practice in the validation of aseptic processing as it evolves. Questionnaires were sent to 88 firms that specifically agreed to participate with PDA in this effort. Forty-three responses were received representing both US and overseas locations. The results were tabulated to provide both raw numerical and a percentage of total respondents. The respondents provided comments, either solicited or voluntarily, after the question. Where more than one respondent provided essentially the same response selection and comment, they have been consolidated and a number appears next to the response indicating the number of comments of that type. The nature and extent of the comments received were extensive, and for this reason the authors have chosen to combine similar responses. One of the major benefits of surveying on a regular basis is the opportunity to follow the evolution of concepts and practices over time. To that end, this survey instrument used many questions that were nearly identical to those asked in 1992 and 1996. 2001; 34 pages; $75 members/$125 nonmembers. Item No. 01036

TR 35 **A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry;** Many firms today have separate departments with different training requirements. Employees associated with the Microbiological Function do not always receive consistent training. This can lead to varying microbiological control practices within a manufacturing facility. This Technical Report was produced by the PDA Subcommittee on Microbiology Training, formed in January 2001, to develop an industry vision and guidance for instituting a step-wise, competency-based training program for the microbio-

Selected PDA Technical Reports *(continued)*

logical training of individuals engaged in work activities connected to the contamination control and microbiological testing of pharmaceutical articles. 2001; 24 pages; $75 members/$125 nonmembers. **Item No. 01035**

TR 34 Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products; This technical report addresses essential user requirements for the application of isolator technology to a broad range of manufacturing, development and testing applications in the health care product manufacturing industry. It covers not only product sterility assurance, but also the use of isolators for the containment of hazardous materials. 2001; 25 pages; $75 member/$125 nonmember. **Item No. 01034**

TR 13 Revised Fundamentals of an 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 (Revised), *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, and the recognition of improved environmental monitoring procedures and equipment. This document serves as a source on clean room 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 pages; $75 member/$125 nonmember. **Item No. 01013**

TR 33 Evaluation, Validation and Implementation of New Microbiological Testing Methods; This report is intended to provide a general approach to the introduction of new microbiology methods in a government-regulated environment. It is also intended to provide guidance for the successful evaluation, validation and implementation of new microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. These new methodologies offer significant improvements in terms of the speed, accuracy, precision and specificity with which testing can be performed. 2000; 37 pp; $75 members/$125 nonmembers. **Item No. 01033**

TR 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**).

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New England Chapter
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Southeast Chapter
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LTR 06/03

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- ❑ 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
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2003 Calendar from back cover

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

September 24–25, 2003
UK & Ireland Chapter Meeting
What to Do When Things Go Wrong
Britannia International, Canary Wharf, London, UK

September 29, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

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-Institute
Frankfurt, GERMANY

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

For a complete PDA Calendar please visit **www.pda.org**.

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

Visit often to get the latest information!

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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 and Tabletop Exhibits for Senior Executives in the Pharmaceutical Industry
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 27–31, 2003 —**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

NOVEMBER

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

November 10–14, 2003
2003 PDA Annual Meeting, Courses and Exhibition
Annual Meeting: November 10–12
Courses: November 13–14
Exhibition: November 10–11
Atlanta Hilton Hotel, 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

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Calendar of Events

2003

JUNE

June 22–25, 2003 — **RESCHEDULED FROM MAY 2003**
PDA Good Electronic Records Management Conference
Achieving FDA Part 11 Compliance with GERM
Conference: June 23–25
Courses/Tutorials: June 22
Westin Hotel, Chicago, IL
Pre-Conference Courses/Tutorials:
June 22
Electronic Records Management on Trial
Managing Electronic Records: A Practical Approach
What is Part 11?
Digital Preservation; Examination of Migration and Emulation Options

June 23–25, 2003
PDA-TRI Charleston Course Series — **MOVED FROM TORONTO**
Charleston Place Hotel — **SAME COURSE CONTENT**
Charleston, SC
PDA-TRI Lecture Courses:
June 23
Failures/Deviations and Change Control
Achieving CGMP Compliance during Development of a Biotechnology Product
June 23–24
Basic Concepts in Cleaning and Cleaning Validation
Active Pharmaceutical Ingredients: Manufacture & Validation
CGMP & Compliance
June 23–25
Tablet Formulation
June 24
Z1.4 Attribute Inspection Sampling in a CGMP Environment
June 24–25
Knowledge & Skills of the Successful QA/QC Manager in the Pharmaceutical Industry
June 25
Assay Validation
Designing, Monitoring and Validation of Pharmaceutical Manufacturing Ventilation Systems
Radiation Dosimetry & Calibration

June 23–27, 2003
PDA Italy Chapter Presents
Sterile Manufacturing Practices in the Third Millennium: A Regulatory and Industry Perspective
Melia Milano Hotel, Milan, ITALY
Conference: June 23–25
Course: June 25–27
PDA-TRI Lecture Course:
June 25–27
Design, Engineering and Validation of Isolators for Pharmaceutical Applications

June 30, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

JULY

July 15–16, 2003
PDA-TRI Lecture Course:
PDA Computer Products Supplier Auditor Process Model: Auditor Training
PDA-TRI Baltimore, MD

AUGUST

August 11–15, 2003
PDA-TRI Lecture Course:
CGMP Trainer's Qualification Program
PDA-TRI Baltimore, MD

August 14–15, 2003
PDA-TRI Lecture Course:
Compliance Auditing of Cleanrooms and Controlled Environments
PDA-TRI Baltimore, MD

August 19–21, 2003
PDA-TRI San Francisco Course Series
The Fairmont Hotel, San Francisco, CA
PDA-TRI Lecture Courses:
August 19
GMP Fundamentals
August 19–20
Sterile Pharmaceutical Dosage Forms: Basic Principles
Computer-Related Systems Validation
CGMP & Compliance
August 19–21
Introduction to Competency Based Training
August 20
Managing in a GMP Environment
August 21
Good Documentation Practices in the Pharmaceutical Industry
Analytical Problem Solving for CAPA Systems
Annual Product Reviews: How to Comply with FDA & ICH Requirements

August 20–22, 2003
ICH Q7A Workshop
Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
The Fairmont Hotel, San Francisco, CA

August 21–22, 2003
PDA-TRI Laboratory Course:
Fundamentals of D, F, and Z Value Analysis
PDA-TRI Baltimore, MD

August 25–29, 2003 — **SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

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

Be sure to watch
www.pda.org
for conference and course updates!

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