Volume XXXIX, No. 5

PDA Letter

May 2003

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

PDA Forms Network Infrastructure Qualification Task Group, page 14

Advisory Committee for Pharmaceutical Science Update

FDA's Advisory Committee for Pharmaceutical Science (ACPS) met on March 12 and 13, 2003, in Rockville, MD, to provide subcommittee updates, to discuss future subcommittees, comparability protocols, and to provide an update on the GMPs for the 21st Century initiative.

Subcommittee Updates

Process Analytical Technologies (PAT) Subcommittee

Tom Layloff, Ph.D., Management Sciences for Health, provided a final report: PAT has finished its work. The PAT subcommittee met three times in 2002 to discuss the application and benefits of the technology; how to validate process and analytical technologies; PAT's applicability to product and process development activities; training and certification needs; and new analytical methods, such as rapid microbiological identification and analysis. PAT offers an integrated systems approach supported by science and risk evaluation and provides a framework for manufacturers to develop design controls. Layloff stressed the ad-

continues on page 14

PDA and CleanRooms Group Announce Industry Partnership

Organizations will Co-Locate PDA WEEK and CleanRooms East

March 8–12, 2004 • Orlando, FL

PDA and CleanRooms Group of PennWell Corp., publishers of *CleanRooms* magazine, have signed a multi-year contract to co-locate their industry events. This important alliance enables both organizations to provide a more value-added and well-rounded educational forum for their members and customers who are involved in the pharmaceutical, biotechnology, and life sciences industries.

The events, PDA WEEK and CleanRooms East, will be co-located at the Orlando County Convention Center in Orlando, Florida, beginning March 8, 2004. The five-day event will be a "one-stop shop" for life sciences professionals seeking cutting-edge expertise and state-of-the-art technology for phar-

continues on page 27

PDA-TRI Toronto Course Series Offered

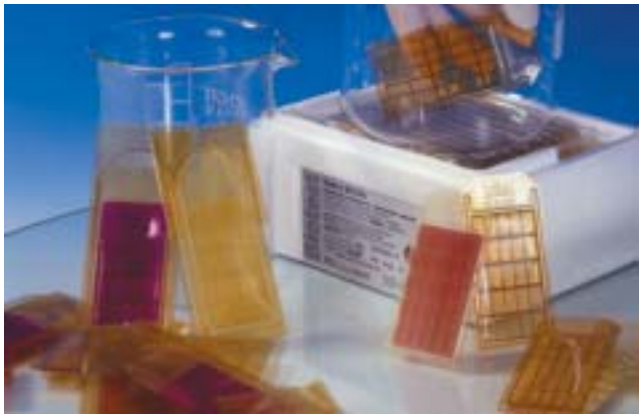
Join other PDA members on June 23–25, 2003, as the PDA Training and Research Institute (PDA-TRI) presents its Toronto Course series. The venue for this event is the Westin Harbor Castle in Toronto, Canada. Eleven courses will be offered covering an array of topics developed for manufacturing, engineering, QA/QC laboratory, and compliance groups. Topics offered in Toronto include:

- Cleaning and Cleaning Validation;
- Failures/Deviation/and Change Control;
- API Manufacture and Validation;
- Tablet Formulation and Manufacturing;
- Pharmaceutical Manufacturing Ventilation Systems;
- Radiation Processing—Dosimetry and Calibration;
- CGMP and Compliance;
- Knowledge and Skills for the QA/QC Manager;
- CGMP Compliance in Biotech Product Development;
- Z1.4 Attribute Inspection (formerly Mil. Std. 105E); and
- Assay Validation.

More information and a brochure on the Toronto Course series can be obtained on the PDA Web site (www.pda.org).

Mark your calendars and register early (fax, mail, online), because this is sure to be a popular series of courses. See you in Toronto! ■

—Robert J. Mello, Ph.D.



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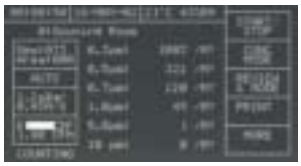

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Important Dates...

- **June 12**—deadline for written comments on Proposed Rule on Bar Code Label for Human Drug Products and Blood, page 5
- **July 14**—deadline for written comments on Proposal to Amend Safety Reporting Requirements for Human Drug and Biological Products, page 5

IN THIS ISSUE...

Executive Message

Neal G. Koller
PDA President

Neal G. Koller, President

Over the years PDA has successfully established its position as the premier source for the latest scientific, technical, educational, and regulatory information available in the pharmaceutical industry. In recent years PDA's mission statement has been expanded to include the biopharmaceutical industry, which is why many of our events now include biopharmaceutical subject matter. If you attended a recent PDA event, you know exactly what I mean. With a sharpening sense of the various comparability issues that are a part of the science and technology of biopharmaceutical manufacturing, an awareness of "hot" compliance issues (what regulators are looking for), and a knowledge of the impact that today's regulatory environment is having on biopharmaceutical product development and approval, the word "biopharmaceutical" is becoming as synonymous with PDA as "pharmaceutical" has been for over 50 years.

Held in March at the spectacular Paradise Point Resort & Spa in the biotech-rich region of San Diego, PDA's Spring Conference proved to be truly remarkable with its comprehensive biotechnology agenda focused on science, technology, education, and regulation. The theme of the conference, "Bridging the Gap from Science to Compliance," was as much a statement about the impact of changing regulatory trends on biotech product development and production as it was a forum and delivery platform for mutual industry issues that brought together a cross-section of pharmaceutical and biopharmaceutical PDA members. Together they took advantage of the many course offerings designed for R&D and QA/QC personnel, auditors, and engineers, as well as for those involved in areas such as Packaging Science, Toxicology, and Drug Formulation, to name a few. The tech-savvy tabletop exhibits were impressive. I noticed the usual opportunities for PDA members to network with industry and regulatory representatives. Quite a number of members asked about a new benefit of attending PDA events: a CD-ROM of all of the conference proceedings. Those who attended the PDA Spring Conference should already have received their complimentary CD-ROM, which includes all of the presentations given at the meeting.

Looking ahead, I hope to meet you at the PDA/FDA Joint Regulatory Conference in Washington, DC this September 8-12. You can register now at our Web site, www.pda.org. The PDA/FDA Joint Regulatory Conference will provide you with an information-packed program—information ready-to-use and immediately adaptable to your pharmaceutical and biopharmaceutical work. I look forward to seeing you at this and future PDA events. ■

U.S. Regulatory Briefs

Final Phase of Consolidating Certain Biologic and Drug Reviews Concluded FDA has completed the last phase of its consolidation of certain biological product reviews into the agency's Center for Drug Evaluation and Research (CDER), a move begun last year to produce a more efficient, effective and consistent review system for human drugs and biologics. Information can be found at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00880.html.

FDA Issues Proposed Rule on Bar Code Label for Human Drug Products and Blood *PDA posted this Federal Register Notice on its Web site, www.pda.org, on March 12, 2003.*

The FDA is proposing a new rule that would require certain human drug product labels and biological product labels to have bar codes. The bar code for human drug products and biological products (other than blood and blood components) would contain the National Drug Code (NDC) number in a linear bar code. The proposed rule would help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. The proposed rule would also require the use of machine-readable information on blood and blood component container labels to help reduce medication errors.

In 1999, the Institute of Medicine (IOM) issued a report entitled "To Err Is Human: Building a Safer Health System." The IOM is a private, nonprofit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences. The IOM report cited studies and articles to estimate that between 44,000 and 98,000 Americans may die each year due to a range of medical mistakes made by health care professionals. The IOM report estimated that, in 1993 alone, an estimated 7,000 deaths were attributable to medication errors.

The report defines medical errors as:

- Administering the wrong dose;
- Administering a drug to a patient who is known to be allergic;
- Administering the wrong drug to a patient or administering a drug to the wrong patient;
- Administering the drug incorrectly; and
- Administering the drug at the wrong time or missing doses.

Submit written comments by **June 12, 2003**, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to www.fda.gov/dockets/ecomments. Include Docket Number 02N-0204 with your comments. For further information contact: Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; (301) 827-3380.

The proposed rule can be found at: http://www.fda.gov/cber/rules/barcodelabel.htm.

FDA Proposal to Amend the Safety Reporting Requirements for Human Drug and Biological Products *PDA posted this Federal Register Notice on its Web site, www.pda.org, on March 12, 2003.*

The FDA is proposing to amend its pre- and post marketing safety reporting regulations for human drug and biological products to implement definitions and reporting formats and standards recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and by the World Health Organization's (WHO's) Council for International Organizations of Medical Sciences (CIOMS); codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and licensed biological products; require that certain information, such as domestic reports of medication errors, be submitted to the agency in an expedited manner; clarify certain requirements; and make other minor revisions. FDA is also proposing to amend its post marketing annual reporting regulations for human drug and licensed biological products by revising the content for these reports.

FDA is taking this action to strengthen its ability to monitor the safety of human drugs and biological products. The intended effect of these changes is to further worldwide consistency in the collection of safety information and submission of safety reports, increase the quality of safety reports, expedite FDA's review of critical safety information, and enable the agency to protect and promote public health. These proposed changes would be an important step toward global harmonization of safety reporting requirements and additional efforts are underway within the Department of Health and Human Services (HHS) to harmonize the reporting requirements of U.S. Federal agencies (e.g., FDA and the National Institutes of Health (NIH) are continuing to work together to address the best ways to streamline information sharing and harmonize, to the extent possible, the safety reporting requirements of the two agencies).

Submit written comments by **July 14, 2003**, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov. Reference Docket Number 00N-1484. For information concerning human drug products: Audrey A. Thomas, Center for Drug Evaluation and Research (CDER) (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; (301) 594-5626. For information concerning human biological products contact Miles Braun, Center for Biologics Evalua-

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Job IDs: amge-00000583; amge-00000567; amge-00000533; amge-00000582

Pilot Plant Operator III – Process Development
Job ID: amge-00000076

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Job ID: amge-00000474

Research Scientist II – Analytical Sciences
Job ID: amge-00000596

Engineer II – Drug Product Process Development
Job ID: 03-0000348

Research Scientist III – Drug Product Process Development
Job ID: 03-0000240

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tion and Research (CBER) (HFM-220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; (301) 827-6079. The proposed rule can be found at: http://www.fda.gov/cber/rules/safereport.htm.

Revision to the General Safety Requirements for Biological Products, Final Rule Effective May 5, 2003 The final rule codifies, at Sec. 610.11(g) (2), an administrative procedure under which manufacturers of biological products may request and obtain exemptions from the General Safety Test (GST). Many biological products are currently manufactured, or will be manufactured in the future, under highly controlled and rigorously monitored conditions. Therefore, under Sec. 610.11(g) (2), FDA will permit biological product manufacturers who employ appropriate production, final filling controls, and quality assurance safeguards to apply for an exemption from the GST requirement. Manufacturers who request an exemption must provide supporting documentation to the Director, Center for Biologics Evaluation and Research (CBER), as to why a product should not be subject to the GST requirement. The request must include an explanation of why the GST is unnecessary or cannot be performed due to the mode of administration, the method of preparation, or the special nature of the product and must describe alternate procedures, if any, to be employed. The Director of CBER may grant an exemption if he/she finds that the manufacturer's submission justifies an exemption. Manufacturers wishing to obtain an exemption to the GST for a particular product should contact the appropriate CBER product division for specific information regarding how to apply and what information should be included in the application or supplemental application.

For further information contact: Stephen M. Ripley, Center for Biologics Evaluation and Research (CBER) (HFM-17), Food and Drug Administration, 1401Rockville Pike, Rockville, MD 20852-1448, (301) 827-6210. The full text of this final rule can be found at: http://www.fda.gov/cber/rules/gensafrev.htm.

CBER Compliance Program Guides Posted on CBER Web Site:

- 7341.002—Inspection of Tissue Establishments
- 7342.006—Inspection of Plasma Derivatives of Human Origin
- 7342.008—Inspection of Licensed Viral Marker Test Kits
- 7345.001—Inspection of Licensed Allergenic Products

Compliance Policy Guides (CPG) explain the FDA policy on regulatory issues related to the FDA laws or regulations. These include Current Good Manufacturing Practice (CGMP) regulations and application commitments. They advise the field inspection and compliance staffs as to the Agency's standards and procedures to be applied when determining industry compliance. Compliance Policy Guides may derive from a request for an advisory opinion, from a petition from outside the Agency, or from a perceived need for a policy clarification by FDA personnel.

The FDA Compliance Policy Guides Manual can be found at: http://www.fda.gov/ora/compliance_ref/cpg/.

Information on FDA Office of Pharmacoepidemiology and Statistical Science (OPaSS) The Office of Pharmacoepidemiology and Statistical Science plays a significant role in the Center's mission of assuring the availability of safe and effective drugs for the American people by:

- Providing leadership, direction, planning, and policy formulation for CDER's risk assessment, risk management, and risk communication programs;
- Working closely with the staff of CDER's other "super" offices, the Office of New Drugs and the Office of Pharmaceutical Science, to provide the statistical and computational aspects of drug review evaluation and research.

OPaSS, which includes the Office of Biostatistics and the Office of Drug Safety, was created as part of CDER reorganization in 2002, and has about 180 of CDER's 1,700 employees. Staff working in the Office of Biostatistics and the Office of Drug Safety have backgrounds in a variety of disciplines including medicine, epidemiology, pharmacology, pharmacy, statistics, regulatory science, health science, information technology, and administration and support services. The Director of the office is Dr. Paul Seligman.

FDA Issues "The Leveraging Handbook" for Guidance to FDA Staff On March 12, 2003, the FDA issued "The Leveraging Handbook" as guidance to FDA staff. Leveraging consists of partnerships, cooperative agreements, or any similar collaborative arrangement that is entered into by FDA and another organization, such as a corporation, educational institution, trade or consumer group, government agency, or foreign government. Leveraging is always cooperative and beneficial to all the parties involved, and advances FDA's mission to protect and promote the Nation's public health.

This Handbook is a compendium of information and tools to support leveraging. It was developed for Agency staff and managers who may be involved in leveraging project development and implementation. It is intended to provide the reader with an introduction to and an overview of key leveraging topics and issues. This guidance finalizes the draft guidance of the same title dated November 2001.

- FDA's mission to protect and promote the public health is not ours alone;
- academia, health providers, other government agencies, regulated industry, and consumers all have roles to play in advancing the public health;
- leveraging, collaboration, cooperation, or partnering are not new to the Agency;

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- resources from outside organizations and individuals that have shared interests have helped FDA accomplish its vital mission in the past and these efforts are on-going and will expand in the future;
- cooperative leveraging ventures are a means to maximize our intellect, time, money, and resources; and
- FDA, at all levels of the organization, should think of leveraging and other collaborative opportunities as primary strategies for achieving our mission.

The Leveraging Handbook can be found at: http://www.fda.gov/cber/gdlns/leverhnbk.htm.

International Regulatory Briefs

Australia, Therapeutic Goods Administration (TGA) Announces Fees for Assessment of Overseas Manufacturers GMP Compliance The 2002 Review of the TGA's Good Manufacturing Practice Audit and Licensing program proposed a set of fees for assessment of evidence of GMP compliance of overseas manufacturers ('pre-clearance'). The proposal was discussed with the industry organizations Medicines Australia, Australian Self-Medication Industry, Complementary Healthcare Council of Australia and Medical Industry Association of Australia, and the following set of fees have been agreed to.

1. A fee for assessment of evidence of GMP compliance of an overseas manufacturer ($240). This fee is payable every three years.
2. A fee for obtaining GMP evidence from an overseas regulatory authority ($210). This is in addition to the assessment fee of $240 and is applicable only if the TGA is requested to obtain GMP evidence of manufacture from European Mutual Recognition Agreement GMP inspectorates or the US FDA. The fee will apply to every application with such a request.
3. A reinstatement fee of $750—to apply to approval of an overseas manufacturer that has been allowed to expire and a subsequent application for assessment is made. It has been agreed that the TGA will notify manufacturers at least 3 months before expiry to allow time for the manufacturers to take appropriate action and provide further GMP evidence of manufacture for assessment.

It is anticipated that these fees will be effective from July 1, 2003. The TGA also anticipates that revision of the *Guidelines on Standard of Overseas Manufacturers* (12th Edition) will be finalized by July 2003.

If you have any questions regarding the fees outlined above, please contact Dr. Udomsri Low by phone (02) 6232 8622, fax (02) 6232 8785, or e-mail gmp@health.gov.au.

TGA Sterility Testing Guidelines *TGA Guidelines for Sterility Testing of Therapeutic Goods 2002* replaced the *TGA Guidelines for Sterility Testing of Therapeutic Goods 1998* on the TGA internet site (www.health.gov.au/tga). This revised document reflects changes to the Test for Sterility included in Appendix XVI of the *British Pharmacopoeia 2001* and adopted by the TGA on December 1, 2001.Most significant are the changes to Table 5 (Table 16A-1, BP), which include more specific requirements for growth promotion, validation and stasis tests.

The purpose of the *TGA Guidelines for Sterility Testing of Therapeutic Goods 2002* is to provide guidance to manufacturers and contract testing laboratories on the British Pharmacopoeia 2001, Test for Sterility. These guidelines are not mandatory.

Belgium Pharmaceutical Inspectorate Undergoes Name Changes In the context of the civil service reform initiated by the Belgium Federal Government, better known as the "Copernicus Reform," the traditional Departments or Ministries were transformed into "federal public services." The Department of Social Affairs, Public Health and the Environment, for example, split into the Federal Public Service of Social Security and the Federal Public Service of Health, Food Chain Safety and Environment. The Pharmacy Inspectorate, formerly a branch of the Health Protection Division, is now officially called the "Directorate General of Health Protection: Medicines." Visit http://afigp.fgov.be, for more information.

UK Medicines Control Agency (MCA) to Merge with Medical Devices Agency (MDA) On April 1, 2003, the Medicines Control Agency (MCA) merged with the Medical Devices Agency (MDA) to form the Medicines and Healthcare products Regulatory Agency (MHRA). Telephone and fax numbers for Market Towers and the regional offices did not change; the number for the Central Enquiry Point remains 020-7273 0000. E-mail addresses adopted the form: name.surname@mhra.gsi.gov.uk. However, for the foreseeable future, e-mails addressed to name.surname@mca.gsi.gov.uk will reach the intended recipient. The new Agency's Web site is http://www.mhra.gov.uk.

UK MCA Introduces Best Practice Guidance on the Labeling and Packaging of Medicines As part of a wider impetus to reduce medication errors, the Committee on Safety of Medicines (CSM) has reviewed how labeling and packaging impacts the safe use of the medicine. As a result of their work they have agreed on principles which should be applied when labeling medicines which are published in this Best Practice Guidance document. From March 1, 2003, all labeling received by the Agency associated with a new marketing authorization application will be considered against this guidance document. The document can be found at: www.mhra.gov.uk. ■

—William Stoedter

European News

European Pharmacopoeia Symposium on Standardization and Quality Control of Cell and Gene Therapy Products, Strasbourg, France, February 24–25, 2003 The European Directorate for the Quality of Medicines (EDQM)* of the Council of Europe organized this scientific symposium at the request of the European Pharmacopoeia Commission, with the close cooperation of the Commission of the European Communities and the European Agency for the Evaluation of Medicinal Products (EMEA). Representatives of manufacturers, the principal public, private research centres, universities, national licensing authorities and Official Medicines Control Laboratories (OMCLs) participated in the discussions. The aim of the symposium was to present the latest developments concerning these new therapies and the new quality and safety issues arising from these therapies.

The latest results of scientific research and current experimentation were presented (e.g., work on viral vectors, plasmids, autologous and heterologous cell therapies). The manufacturers of these products described their approach to quality control, to obtain the best possible quality with current knowledge and technologies. Proposals were made for future strategies adapted to these innovative and unusual products, in particular, with regard to control of starting materials, in-process controls (IPCs), control tests on the finished products, and GMP.

The European regulatory authorities exchanged views on appropriate regulations to be implemented, and they discussed their experiences acquired from current national projects. The manufacturers stressed the need for a common approach to be applied to all clinical trials in Europe, not only for the conduct of these trials but also for their evaluation; they also expressed their wish for a centralized European approach to the processing of marketing authorization applications.

The participants recognized that cooperation was essential to facilitate the introduction of suitable new analytical methods and test methods. New quality control approaches for cell and gene therapy products were discussed, in particular with regard to general methods for biological safety, new assay methods and the need for specific standards. Special needs were expressed regarding the tests for sterility, viral safety and mycoplasmas as well as general methods of analysis to be developed and standardized, such as the quantitative polymerase chain reaction (PCR). The need to develop suitable reference materials was also discussed.

This symposium marked the official opening of the European Pharmacopoeia Commission's work program in these areas, which will be undertaken by experts appointed to two working parties that will meet regularly: The Gene Therapy Products Working Party (GTP) and the Cell Therapy Products Working Party (CTP). The symposium was attended by 153 participants from 22 countries (mostly European countries but also Taiwan, South Korea, China, the USA, and Canada). Bringing together all the interested parties to exchange views in this way is part of an international consultative process to promote international harmonization and facilitate the use of cell and gene therapy products under conditions that ensure the protection of public health.

There was an impressive session on the regulatory aspects of Gene and Cell Therapy products. The presenters were Dr. Erik Tambuyzer, Genzyme, Chairperson EuroBio Health Care Board; Dr. Christine-Lise Julou from the European Federation of Pharmaceutical Industry Association (EFPIA); P. Zorzi; and S. Lucas from the French Health Authorities (AFSSAPS). The presentation slides can be viewed on www.pheur.org.

** EDQM is the publisher of the European Pharmacopoeia.*

WHERE/WHEN MEET THE EDQM/ EUROPEAN PHARMACOPOEIA?

- **CPHI, Shanghai Everbright**, Booth A 217, Exhibition, 17–19 June 2003, Shanghai, China
- **Training for Herbals**, 26–27 June 2003, Strasbourg, France
- **Training for Chemicals**, 4–5 December 2003, Strasbourg, France

Don't miss these opportunities to meet the EDQM/European Pharmacopoeia.

News from the EMEA:

Operational Phase of the EU-Canada Mutual Recognition Agreement Entered into Force on 1 February 2003 The Sectoral Annex on Good Manufacturing Practice started its operational phase on 1 February 2003. The Joint Sectoral Group met on 17 January 2003 and agreed that the transitional activities should end. The Joint Committee was informed and recorded at its 6th meeting on 13 March 2003 that this sector is operational now. The list of products covered under the Annex includes human and veterinary medicinal products. Veterinary immunological products are not included. The Annex is not in operation for pre-approval inspections and stable medicinal products derived from human blood or human plasma. The agreement is based on an exchange of certificates of GMP compliance for manufacturers and batch certificates. The contents of these certificates are available at www.emea.eu.int/htms/technical/mra/mra.htm.

Qualification and Validation

This document is the German version of the Annex 15 to the EU GMP Guide entitled "Qualification and Validation". The updated version has been provided by Germany (ZLG) and has been agreed by the German "Länder", the German Health Ministry, the German Working Group "Medicinal Gases" and also the Austrian Authorities. Visit http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm for details.

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European News from page 9

Certification by a Qualified Person and Batch Release This document is the German version of the Annex 16 to the EU GMP Guide entitled "Certification by a Qualified Person and Batch Release". This version has been provided by Germany (ZLG) and has been agreed by the German "Länder", the German Health Ministry, the German Working Group on "Inspections" and also the Austrian Authorities. Visit http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm for details.

Parametric Release This document is the German version of the Annex 17 to the EU GMP Guide with title "Parametric Release". The version has been provided by Germany (ZLG) and has been agreed by the German "Länder", the German Health Ministry, the German Working Group on "Inspections" and also the Austrian Authorities. Visit http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm for details.

New Directive on Human Blood and Blood Components Entered into Force On 8 February 2003, the new directive on quality and safety standards of human blood and blood components entered into force. The full title is Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, published in the Official Journal L 33 of 8 February 2003, p. 30. This directive is relevant for the pharmaceutical sector, as it lays down technical requirements for the collection and testing of all blood and blood components including starting materials for medicinal products. In this context, it amends Article 109 of Directive 2001/83 (see Article 31 of Directive 2002/98). For the text of the Directive, visit http://pharmacos.eudra.org/F2/eudralex/vol-1/27012003. ■

—Gautam Maitra

2003 INTERNATIONAL CALENDAR 2003

JUNE

June 2–4, 2003
The 34th Symposium of the R^3 Nordic Society
Turku Polytechnic
Turku, FINLAND

June 23–25, 2003
PDA-TRI Toronto Course Series
Westin Harbour Castle
Toronto, CANADA
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

SEPTEMBER

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

OCTOBER

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

December 15, 2003
PDA Presents *Basel Pharmaceutical Forums*
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PDA
An International Association For Pharmaceutical Science And Technology

USP Update

April 2003

by Roger Dabbah, Ph.D., USP

Pharmacopeial Previews is a section of Pharmacopeial Forum (PF) that contains potential revisions or additions of Monographs not yet targeted for official adoption. Each previewed revision includes a briefing that lists the reasons and rationale for the new Monographs or General Chapter and includes the name of the liaison that is to be contacted for further information. The decision to publish a Pharmacopeial Preview depends on a number of factors such as changes that would affect a large number of Monographs, or new or unusual technologies, or Monographs requesting additional data from manufacturers. This section allows for publication of proposed changes as early as possible to alert readers of incoming changes that might affect their products. Comments at this stage of the revision process can and do influence the final revised product. It is recommended that manufacturers pay close attention to the Pharmacopeial Previews. In the March–April 2003 PF there are three Monographs proposed under Previews: Mirtazapine, Mirtazapine Tablets, and Topiramate.

An update on harmonization indicates steady progress. There are 10 chapters at Stage 6 of the harmonization which is the Adoption Stage. These are: Sterility Tests, Residue on ignition, Protein Determination, Capillary Electrophoresis, Extractable Volume, Particulate Matter, Amino Acid Determination, Peptide Mapping, Polyacrylamide Gel Electrophoresis, and Isoelectric Focusing. Microbial Limit Tests is at stage 4, Official Inquiry, and will be published in all three forums in the near future for public comment.

Due to a number of unforeseen circumstances, USP has decided to postpone its Scientific Conference on Biotechnology and Biological Products from April 1 to the fall of 2003. ■

TR-32 Update

by Jan Ohman, Merant; Debbie Black, Sterling Communications; and Harvey Greenawalt, ARC

Merant's PVCS Dimensions™ Completes PDA Supplier Evaluation

HILLSBORO, Ore.—Merant (NASDAQ: MRNT; LSE: MRN), a leading provider of software and services that deliver flexible control of code, content, and other business-critical assets, announced that Merant's PVCS Dimensions recently passed the rigorous PDA Pharmaceutical Industry Software Supplier Quality Audit. The PDA audit verifies that (1) software vendors use documented quality management procedures during software development, (2) adequately test software before release, and (3) have sound support processes in place. By having participated in the PDA audit, Merant has eliminated the need for their life sciences customers to conduct individual audits. This results in a significant cost savings for Merant and each of its customers.

PVCS Dimensions is a field-proven solution particularly suited to addressing critical issues such as GxP compliance, computer systems validation (CSV), and change control, and is part of an aggressive effort by Merant to deliver a number of change control solutions for the life sciences industry. In combination with PVCS' broader benefits of increased systems and process efficiency, faster time to market and reduced operational costs, Merant's solutions help life sciences companies both reduce risk and increase the overall return on asset investments.

"The life sciences industry is not only confronted with the same challenges faced by most businesses today, namely how to better control and improve efficiency of asset usage, but has the added burden of regulatory compliance," noted Alan Jezek, Merant's Segment Manager for life sciences. "As these companies adopt technology to automate business processes, they need to also control and reduce the associated risks, making GxP compliance and CSV a critical issue. Merant has helped more than 200 life sciences organizations bridge the gap between GxP compliance and profitability with comprehensive enterprise change management solutions such as PVCS Dimensions."

GxP compliance can help mitigate risk in an industry that is highly regulated by the FDA. Life sciences companies must respond to published FDA guidelines regarding software validation and computer regulations, such as 21 CFR Part 11, which mandates specific controls around the use of electronic records. Failure to comply with FDA regulations can result in fines, and even products being removed from the market.

Merant's life sciences solutions help companies identify, track, and control changes to their business-critical assets, including code, content, processes, systems, etc., thus reducing risk by helping to ensure regulatory compliance. Moreover, this change control enables companies to improve efficiency, better secure their assets, minimize errors and costs, and ultimately speed products to market. Change-control components enable companies to proactively define and document their processes, preventing unauthorized changes and creating an audit trail. System Development Lifecycle (SDLC) components provide secure permissions-based system access and manages the software validation process, as well as delivering snapshots of baseline systems and enabling rollback of implemented changes. The integration of this change control and SDLC helps automate workflow, increase auditability and traceability and provide risk-based change assessment.

About PVCS Dimensions

Delivering unsurpassed scalability and flexibility, Merant's PVCS Dimensions is the industry's first comprehensive change management platform for automating development processes, business rules and asset change practices. Dimensions provides, in a single change management framework, comprehensive process control, versioning, baseline management, issue management, release management, build management, and workflow management. Scalable enough to address the needs of teams of all sizes, Dimensions can be rapidly implemented, ensuring the protection and management of all enterprise assets. With process control that can be easily customized to fit agile or traditional methodologies, or modeled on specific needs, Dimensions quickly simplifies change management across an entire organization.

About Merant

Merant delivers the industry's most flexible and comprehensive enterprise change management solutions. Already in use at more than 16,000 organizations across the globe, including 90 of the Fortune 100s, Merant's products and services dramatically enhance the productivity, quality, and ROI of customers' technology initiatives by allowing them to quickly and cost-effectively track, manage, and control modifications in business-critical information assets. For more information, please visit www.merant.com.

For more information contact: Jan Ohman of Merant at (503) 617-2766 or at jan.ohman@merant.com, or Debbie Black of Sterling Communications, Inc. at (253) 853-5030 or at dblack@sterlingpr.com.

Auditor Training & Qualification

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

Availability of Audits

Currently, 54 audits are either under consideration, in process, or available for distribution.

Table 1.0 provides a summary of the 27 audits that are currently available for distribution from the Repository.

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

TABLE 1.0 Audits Currently Available from ARC

	SUPPLIER	PRODUCT
1	Access 360, 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 (DMI) International, Inc.	Regulus™ Document Authoring (DA), a member of the Regulus™ off-the-shelf solution set
6	Documentum, Inc.	Content Authentication Services (CAS), eContentServer, DocControlManager (DCM) and GMPharama
7	Entrust Technologies Ltd.	Public Key Infrastructure Technology (PKI). Digital Security technology for enterprise resource systems
8	Epicentric, Inc.	Foundation Enterprise Server 4.0, tool for coordinating information from disparate sources and for disparate users
9	First Consulting Group	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 Software (information retrieval solutions)
13	Innovatum, Inc.	Data Thread™ 21 CFR Part 11 compliance solution for the AS/400
14	Interwoven, Inc.	Web Publication management
15	Lexign Corporation	Lexign Flow EPR Software
16	Loftware, Inc.	Loftware print server (LPS) Label printing system
17	MARC Global Systems	Warehouse Execution Systems
18	Merant, Inc.	PVCS Dimensions & PVCS Replicator Configuration Management Systems
19	Mercury Interactive	Test management Tools: • QuickTest Professional • Astra Fast Track • Astra LoadTest • Astra Quick Test • Test Director • LoadRunner • LoadRunner TestCenter • WinRunner
20	Propack Data GmbH	Enterprise production Management System, PMX 3.2 with Solutions MES and CTM
21	SAP AG	MySAP.com e-business platform, specifically aspects of Supply Chain management, Product Lifecycle Management and Business Intelligence relevant to manufacturing operations. (Includes Product Lines: SAP R/3 4.5B and SAP R/3 4.6B/C)
22	Schlumberger	Secure ID Card
23	Serena Software, Inc.	Serena ChangeMan Automating the Software Lifecycle
24	Sparta Systems, Inc.	Track Wise Software
25	SSA Global Technologies, Inc.	Mid range ERP software for manufacturing, supply chain and financial application domains
26	Supply Chain Logic, Inc.	General use COTS Asset Tracking/Delivery Systems
27	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 database, mainframe and wireless portable devices

PDA Forms Network Infrastructure Qualification Task Group

PDA is pleased to announce the formation of a *Network Infrastructure Qualification Task Group*. The purpose of the Task Group is to publish a technical report which presents a practical approach for bringing an organization's information technology (IT) infrastructure into compliance with regulatory requirements. It is the qualification of this IT infrastructure, e.g., data center facilities, servers, network systems and services, networking equipment, network configuration, monitoring software and desktop computers, that are the primary focus of the Task Group.

The Task Group's practical approach for qualification of network infrastructure will be based on published IT standards and business practices. The network infrastructure issues, discussed since the publication of the "Network Management in an FDA-Regulated Environment" commentary in the *PDA Journal of Pharmaceutical Science and Technology* (Vol. 53, No.6 / November–December 1999) and the recent PDA/ISPE *Good Electronic Records Management (GERM)* series, form the basis for establishing this Task Group.

The PDA Task Group will have regular teleconference and face-to-face meetings at PDA headquarters in Bethesda, MD. The Task Group mandate is to draft a paper suitable for publication as a PDA Technical Report.

For further information, please contact the Task Group leader:

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campbellmw@acm.org

—Russell E. Madsen

Advisory Committee from cover

vantages of developing PAT systems gradually so that they might be fully integrated into a firm's process control and quality management systems.

Manufacturing Subcommittee

This new committee, which was established to replace PAT, according to Ajaz Hussain, Ph.D., Deputy Director Office of Pharmaceutical Science, will be chaired by Judy Boehlert, Ph.D., Boehlert Associates, Inc. The subcommittee will work on a broad range of topics and will provide a mechanism for partnering with ORA and OPS where coordination would be beneficial. The first meeting of the subcommittee will be held May 21–22, 2003, in Rockville, MD.

Future Subcommittees

Microbiology

This new subcommittee will provide advice for scientific and regulatory decisions related to microbiology issues, according to Peter Cooney, Ph.D., Associate Director for New Drug Microbiology. Topics to be addressed include parametric release of sterile products, development of VHP decontamination cycles for isolators, the advisability of an adverse event report review from a microbiological perspective, evaluation, validation and filing strategies for rapid microbiological methods, and evaluation of new sterilization and sterile product manufacturing technologies. ■

—Russell E. Madsen

Verification of Compendial Test Methods

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 1

My question is related to the required validation a testing site should perform when using a USP/EP or other compendial test for the first time in their laboratory. We primarily test raw materials using these compendial methods, and not drug products. We are leaning toward verifying only chromatograph type procedures, some potentiometric procedures, and not verifying basic wet chemistry procedures. I would appreciate any information to help me with this question.

Response 1.1

I am a bit confused. Compendial methods, be they what they may be, are considered validated methods. In the hands of properly trained personnel they need no validation.

Do you have problems with your lab people and their ability to perform these tests?

Response 1.2

As stated by USP, those using methodology described in the USP and the NF are not required to validate the accuracy and reliability of these methods, but merely verify their suitability under actual conditions of use. Verification depends on your definition of the word. Many companies merely carry out the analysis by either one or more analysts and document the successful (accurate) completion of the analysis. This is especially true for API and raw materials in which the monographs are followed verbatim. Some companies go as far as performing several basic validation studies such as precision, linearity and accuracy both to gather experience with the method and to assure that expected results can be obtained. As to question about only using verification for chromatographic methods, I would not place an exception on any particular type of method, but would carry out a simple verification on all compendial methods used in the lab for the first time (wet methods included).

Response 1.3

If the method has been studied in a collaborative trial, the new laboratory has to verify that it is capable of achieving the published performance characteristics of the method or that it is otherwise able to fulfill the requirements of the analytical task.

My opinion: the laboratory should undertake precision and matrix effect in a real sample.

Response 1.4

None of the compendial test methods are required to be validated. The user is only required to undertake verification of suitability and reproducibility under actual conditions of use. This statement is true and works well with APIs, but might pose problems in products. Compendial tests for products are based on certain non-disclosed and most common excipients, which need not be the same with all the manufacturers. The excipient effects play a roll on the success of prescribed tests. Sometimes (in fact, most of the time) the user needs to alter some of the conditions to get promising results. "Altering any conditions requires revalidation"; based on this principle it is advisable to undertake limited validation of the compendial test methods, based on the degree of, alterations made, for adapting the tests to users specific product. This good practice is followed by advancing pharmaceutical companies.

Response 1.5

Recently we had an FDA inspection and one of the 483s was directly related to the company not performing a mini-validation on compendial methods used to test a grandfather product.

Response 1.6

Whatever you do, it needs to be supported by a written justification that is scientifically sound.

The first hurdle a lab faces is that the specific details of the monograph testing (outlined in the USP and the EP) are neither published nor available.

Second, the USP/EP test outlines published in these compendia are, strictly speaking, not "methods" because they lack the often critical details as to exactly how an action is to be performed.

Moreover, as written, the test outlines published in the individual monographs for the components (and drug products) are often not even scientifically sound. Having observed different analysts in the same lab "follow" simple instruc-

continues on page 16

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*.

Compendial Test Methods from page 15

tions like "shake"—on different apparatus (wrist shaker and table shaker) for different times (in different ways (intermittently and continuously), I know that methods filled with such simplistic instructions are not scientifically sound.

A scientifically sound method should spell out in detail exactly how each step in the method is to be done; the latitude, if any, permitted in the performance of the step and the variability (in terms of range or limits) acceptable in any variable that is controlled.

Thus, the instruction "shake" would, for example, become, "using a Mfg Model No nnn, or equivalent, wrist shaker, set the speed to 10 to 12 cycles per minute, secure the flasks to the shaker, and shake the secured flasks for 10 to 15 minutes."

Obviously, each lab must translate all such compendial "test outlines" into written, scientifically sound methods and establish that said methods produce scientifically sound results when the appropriate set of routine and challenge samples are tested. However, as you know, there are many ways to translate each step.

The result is that there are wide differences in the "implementation" of most compendial methods among the labs using a given compendial test outline.

Labs that simply parrot the compendial test outline in their write-up of the test procedure often find different analysts doing things differently. In general, this leads to increased result uncertainty and, in some cases, results that are inaccurate (passing materials fail the testing or, worse, failing materials pass) simply because the written test procedure used is too general.

My favorite example is the wide range of values that some get for "assay" aliquots when the compendial instruction simply states, "weigh and finely powder not less than 20 tablets" and the multiple-film-coated (base coat, color coat, and seal coat) tablets are from a formulation that contains significant levels of ingredients whose phase transitions (from solid to semi-solid) are close to room temperature or components that are hygroscopic when the humidity exceeds 50% RH.

In fact, such products are the ones I use in teaching analysts how to properly convert 20 such tablets into a homogeneous fine powder having the texture of ground nutmeg. Yet this USP/EP instruction does not: a) specify the type of equipment used to "finely powder" the 20 or more tablets weighed, b) define what is a "fine powder," or c) even include any of the critical terms (e.g. homogeneous, uniform, or even "well mixed").

The USP relies on the analysts' having carefully read, understood, and followed the appropriate section in the General Notices.

I could go on, but you should have grasped the obvious by now.

The scientifically sound, appropriate, written, quality control unit-approved, detailed test method developed and used in your lab must have proofs that it is suited for the material that you test from the sources you get them.

If your firm is a drug manufacturer, then you should use the limited guidance provided in 21 CFR 211 as your starting point. The overarching requirements for "test procedures" (which include methods as a subset) are set forth in 21 CFR 211.160(b) which states: "Laboratory controls shall include the establishment of scientifically sound and appropriate … test procedures designed to assure … Laboratory controls shall include: (1) Determination of conformance to appropriate written specifications for the acceptance of … components, drug product containers, closures, and labeling used … The specifications shall include a description of the sampling and testing procedures used … (2) Determination of conformance to … specifications and a description of … testing procedures for in-process materials … (3) Determination of conformance to written descriptions of sampling procedures and … specifications for drug products (4) … "Based on 21 CFR 211.160(b), your firm must establish (prove) that the test procedures used for incoming and in-process materials are scientifically sound and appropriate.

Looking further, you should note that under the heading "Testing and release for distribution," 21 CFR 211.165(e) states: The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with Sec. 211.194(a)(2)."

In this subsection, validation of a test method is equated to establishing the accuracy, sensitivity, specificity, and reproducibility of a test method.

With respect to "documentation," 21 CFR 211.194 has much to say:

> (a) Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:
> (1) A description of the sample received for testing with identification of source (that is, location from where the sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.
> (2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, Association of Official Analytical Chemists, Book of Methods, or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice) …
> (b) Complete records shall be maintained of any modification of an established method employed in testing. Based on the preceding, it is clear that 21 CFR 211.194 focuses on records.

This is as it should be since 21 CFR 211.194 is a subsection of 21 CFR 211 Subpart J—Records and Reports.

With respect to "validation," 21 CFR 211.194 contains less information.

> "(a)(2) … The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested … The suitability of all testing methods used shall be verified under actual conditions of use.
> (b) … Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method."

Ironically, if one carefully reads the language in 21 CFR 211.194(a), all it really does is permit, but not require, the citation of the method's name and source to be used in place of "A statement of each method used in the testing of the sample."

If: A) a compendial method, not a testing outline, or other recognized method exists and B) your firm's examination and suitability testing under actual conditions of use verifies that the method is valid for use in its laboratory for testing the samples it tests, then that verification data is the data that establishes that the method meets "proper standards of accuracy and reliability as applied to the product tested."

Moreover, the minimum proper standards of accuracy & reliability are those delineated in 21 CFR 211.165(e)—accuracy, sensitivity, specificity, and reproducibility.

Thus, each CGMP-compliant laboratory is required to maintain data and records that establish (prove) that each method that they use is suitable (valid) for all of its permitted uses. Those labs are not permitted to just cite the source and use the method because any lab (other than the lab that developed and/or participated in the initial interlaboratory studies performed to ensure that the method was reliable) using compendial methods lacks the detailed description of exactly how to follow said methods.

Lacking the details, the implementation by each lab is an a priori modification of the "method" that was submitted to the compendial body. Thus, in reality, each lab uses the compendial testing outline and develops its own method.

Given the aforementioned, all labs must prove the validity of their implementation of the method.

The preceding clearly establishes what a CGMP-complying lab must initially do to:

A) Convert the testing outlines provided in compendia into the lab's written scientifically sound, appropriate, method.
B) Verify the validity of the "exact" methods that it uses in testing the samples submitted to the lab.
C) Establish the data and records required to satisfy the recordkeeping requirements of 21 CFR 211.194.

More may be required to be done, but the preceding is a logical, scientifically sound answer to your "first use" question from a classically trained Ph.D., Analytical Chemist.

Response 1.7

The draft guidance (Aug 2000): "Analytical procedures and method validation" states the following under "Compendial analytical procedures": The suitability of a compendial analytical procedure must be verified under actual conditions of use (21 CFR 211.194(a)(2)) … Information on the specificity, intermediate precision, and stability of the sample solution should be included.

Response 1.8

Please note that my previous remarks about compendial methods still remain valid. Your example, however, is also correct in the 483 citation. Why? Your example is correct because all formulations differ in the ingredients and/or the color(s) used. You are required to prove that your preparation can be analyzed by the USP method if it is labeled USP. If the method is updated, then you should revalidate. ■

—compiled by Russell E. Madsen

Company, Colleague & Product Announcements

Cambrex has announced that **Gary L. Mossman** was appointed President of Cambrex Pharma Business Unit with overall responsibility for accelerating growth of products and services sold to pharmaceutical customers. Mossman previously held the position of President of Dixie Chemical for 14 years. Cambrex is a global, diversified life science company dedicated to providing high quality products and services to accelerate drug discovery, development, and manufacturing processes for customers focused on health and the prevention of disease. For more information, contact Anne-Marie Hess, Director Investor Relations & Corporate Communications at Cambrex at (201) 804-3062 or annemarie.hess@cambrex.com.

The **United States Pharmacopeia (USP)** announced that **Dr. Gary Allmaier** has been appointed Director of its Research & Development Laboratory (RDL). USP's RDL conducts analytical development and other activities in support of official USP Reference Standards. These reference standards are used to assess the strength, quality, and purity of drugs, including biologics, dietary supplements, and healthcare devices. To date, USP's RDL has helped support the availability of more than 1,400 official USP Reference Standards. These have been provided to more than 2,000 pharmaceutical companies in 86 countries. As the new director of RDL, Allmaier will provide leadership for the laboratory and advance its initiatives to support the development of new analytical methods for USP monographs and reference standards. Allmaier comes to USP from Bristol-Myers Squibb where he was responsible for managing the development of several novel drugs from discovery to new drug approval (NDA). Prior to this role, Allmaier spent 22 years in the pharmaceutical industry as an analytical research and development manager and chemist. For more information, contact Sherrie Borden at (301) 816-8268 or at slb@usp.org.

Veltek Associates, Inc. recently introduced SimpleMIX® System, a newly developed way to eliminate filter sterilizing of disinfectants and sporicides. SimpleMIX® System features a sealed multi-chamber container that when activated mixes the two solutions. The top part of the container holds the sterile concentrate disinfectant and the bottom part contains the sterile USP WFI Quality Water. The system assures the appropriate dilution is made each time in a closed sterile system, insuring that the concentrate solutions are never handled. For more information, contact Veltek Associates, Inc. at (610) 983-4949 or visit www.sterile.com.

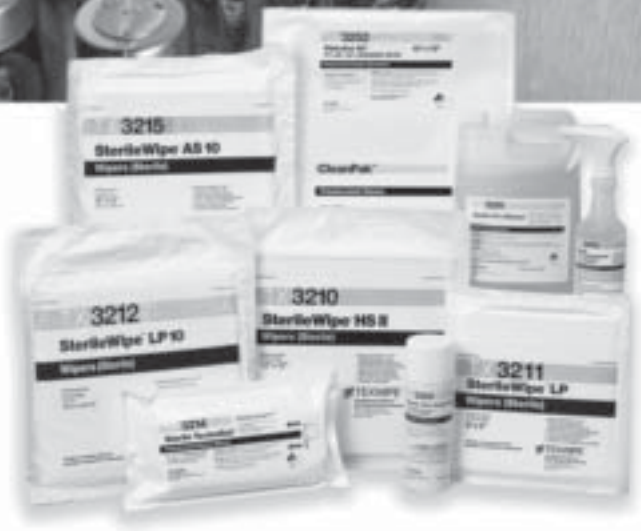
Millipore announced the availability of QuikScale™ columns, a full line of scaleable chromatography columns that deliver high purity, reproducible separations of fast linear velocities. QuikScale™ columns accommodate all media types and handle high operating pressures (up to 7 bar) necessary with smaller-particle-size, high resolution media, making the columns suitable for use in nearly every application. To improve productivity, the new column design minimizes maintenance and allows clean-in-place (CIP) procedures for sanitary operation. In addition, tool-free column setup and a spring-loaded, air actuated flow distributor ensure packing, processing, and unpacking are performed faster and with less effort than with traditional columns. Millipore is a multinational, high technology bioscience company that provides technologies, tools, and service for the development and production of new therapeutic drugs. It serves the life science, biotechnology, and pharmaceutical industries. For more information, contact Millipore Tech Service at 1 (800) MILLIPORE or visit http://www.millipore.com/biopharm/downstream.nsf/home.

Envirco has developed a terminal filter for use in t-bar drop ceilings with central air. The Enviro Ducted Ceiling Module (EDCM) is a disposable unit that is ideal for cleanrooms in the semiconductor, aerospace, laboratory, medical device manufacturing, photographic processing, pharmaceutical manufacturing, and hospital pharmacy sectors. Jill Neu, Envirco's General Manager said, "… it is an HEPA filter, it is 99.99 percent efficient in removing particles 0.3 microns and larger, and its main housing is made of anonized extruded aluminum for improved wear." For more information, contact Greg Steiger, Envirco at (919) 777-6205, gsteiger@fedders.com, or visit www.envirco.com.

Cardinal Health, Inc. announced it will provide alternative drug formulation development and delivery capabilities for the biotechnology and pharmaceutical industries, enabling its customers to establish alternative dose routes and plan for potential line extensions much earlier in the drug development process. The expanded capabilities, which include the prediction of buccal (mouth) absorption for a drug, reflect Cardinal Health's dedication to offering pharmaceutical outsourcing resources worldwide. For more information, contact Jennifer Latimer at (919) 277-1157 or at jlatimer@fwv-us.com. ■

Send announcements on personnel changes and new products . . .

. . . 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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2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits

Navigating Current GMPs: Catch the Compliance Wave

Omni Shoreham Hotel • Washington, DC

Conference:
September 8–10

Courses:
September 11–12

Tabletop Exhibits:
September 8–9

PDA is pleased to announce that Dr. Doug Dean, Partner, Pharmaceutical & Life Sciences for IBM Business Consulting Services, will deliver the closing keynote address on the IBM/Price Waterhouse Coopers report on Future Industry Manufacturing Models at the PDA/FDA Joint Regulatory Conference on Wednesday, September 10 in Washington, DC.

A multi-tracked conference format will offer conference participants the opportunity to hear a variety of discussions on cutting-edge issues of importance to the industry. Sample topics include:

- Navigating Legal Waters & Compliance Currents
- Laboratory Issues: Case Studies
- Riding the Changing Compliance Tides
- Inspection Trends
- Quality Regulatory Submissions
- Validation: Maintaining a State of Control
- Biopharmaceutical Process Validation Issues
- Part 11: What Is Current? Where is it Going?

Confirmed industry speakers include:

David Dimmick, *Connetics*;
Stewart Green, *Wyeth*;
Nancy Karaszkiewicz, *Dynport Vaccines Company*;
Raymond Kieffer, Ph.D., *BioReliance*;
Janeen Kincaid, *Pfizer, Inc.*;
Gerry Migliaccio, *Pfizer*;
Alan G. Minsk, *Arnall Golden Gregory LLP*;
Kelly O'Hare, *Cambrex BioScience*;
Leslie Osmera, *Wyeth BioPharma*;
Joseph A. Rogalewicz, *GlaxoSmithKline*;
Steven Ruhl, *IDEC*;
Sue Schniepp, *Abbott Laboratories*;
Lisa Skeens, Ph.D., *Baxter Health Care*;
Anders Vinther, Ph.D., *CMC Biopharmaceuticals A/S*;
Karen Walker, *Genitope*; and
Paula Wilkerson, *Applied Genetic Technologies Corporation*.

The goals for the conference are to:

- Discuss emerging and dynamic perspectives and interpretations of cGMPs;
- Identify today's global industry trends with case studies and real life examples;
- Describe how to anticipate continuous looming new trends; and
- Identify new technologies and their applications.

As an added benefit, all full, paid conference registrants will receive a complimentary ticket to see **The Capitol Steps**, a troupe of current and former Congressional staffers who monitor events and personalities on Capitol Hill, in the Oval Office, and in other centers of power and prestige around the world, with a humorous look at serious issues.

Discounts for early registration will be offered, so plan now to attend this important industry event. 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. Visit the PDA Web site at www.pda.org for current information and details as they become available. ■

—Leslie Zeck

2003 PDA/FDA Joint Regulatory Conference
Washington, DC • September 8 – 10, 2003

Exhibitor Booth List

For a listing of the PDA-TRI Courses being offered at the 2003 PDA/FDA Joint Regulatory Conference, please refer to the Calendar on the back cover.

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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

In 2001, PDA produced its groundbreaking conference on Good Electronic Records Management (GERM). Much more than the typical pharmaceutical "Part 11" Conference, GERM 2001 showcased leaders on the forefront of digital records issues from technology, legal, and regulatory backgrounds. Conference delegates were presented with a comprehensive view of the future of digital record issues within, and well beyond, FDA-regulated industries.

GERM 2003, rescheduled for June 22–25, 2003, will build on the strong foundation laid earlier, with an even greater emphasis on the critical needs of those responsible for managing all aspects of electronic record and signature environments. Several sessions will address topics from the recently-published GERM Guide—Part 1 of the PDA-ISPE Series on Good Practice for Electronic Records and Electronic Signatures. Additional sessions will highlight selected topics from Parts 2 and 3 in the PDA-ISPE trilogy of Good Practice Guides. The focus will be on concepts and principles to consider when building, maintaining, managing, and transitioning electronic record environments. The Conference will provide a forum for information exchange based on practical experiences, building on lessons learned from real-life electronic records management.

Major Topics Covered

Risk Management (record policies, practices, and QA of record processes)
Information Technology (implementing, validating, and maintaining operating computing environments, and storage media management)
Project Management (legacy remediation, managing outsourced EDC systems, new computing solutions, revising record strategies, and management buy-in)
Records Management (creating records, record content management, signing records, coexistence of paper and electronic worlds)
Digital Preservation (record retention, archival and retrieval, processability)
Education (training and education in e-records)
Legal (critical considerations beyond the technical and regulatory boundaries)

Faculty for this multi-track program of lectures, panels, forums and tutorials will speak on topics that represent a broader view of the legal, regulatory, and strategic issues facing the electronic record and electronic signature world today. These leaders are on the cutting edge of this digital information age, actively involved in establishing the groundwork for the future of electronic records and electronic signatures. Featured faculty are from FDA, FDA-regulated establishments, Judiciary, consultancies for records management, and technology research organizations.

Some of the Guest Speakers

Charles M. Dollar, Ph.D., Senior Consultant with Cohasset Associates, Inc. Dollar has extensive experience in dealing with the impact of digital technology issues on archives and records management. From 1974 to 1994 he was on the staff of the National Archives and Records Administration where he specialized in electronic storage media issues.

Raymond Lorie, Research Staff Member at the IBM Almaden Research Center and ACM Fellow. Lorie is conducting groundbreaking research in the development of the Universal Virtual Computer (UVC), a Digital Preservation Solution for long-term storage and retrieval of electronic records.

Gordon B. Richman, Chem. Eng., J.D. Richman is Vice President, Strategic Compliance Consulting and General Counsel of EduQuest. Previously he was Director of Worldwide Quality Strategy in GlaxoSmithKline's (GSK's) Global Manufacturing and Supply operations. Prior to GSK, he spent several years in FDA regulatory practice with law firms in Washington, DC.

Jeffrey Rothenberg, Ph.D., Senior Computer Scientist in the Social Policy Department of the RAND Corporation. Rothenberg is the author of the landmark Scientific American article, "Ensuring the Longevity of Digital Documents," in which he called for immediate action to prevent future loss of today's electronic documents.

Gary W. Secrest, M.S., National Security Strategy. Secrest is Director of Worldwide Information Security at Johnson & Johnson (J&J). Prior to joining J&J he held senior executive positions with the National Security Agency, including head of the Network Security Group and Director of the Department of Defense (DoD) Public Key Infrastructure Program.

Pre-Conference Tutorials Offered

1. Electronic Records Management on Trial—Ken Winters, Esq., Federal Judicial Center, United States Courts

Responding to court-ordered electronic records discovery requests is an increasingly important component of electronic records management. In this multifaceted, role playing tutorial, a hypothetical electronic records management program will be developed. The participants will then defend (or challenge) that program in a mock court case be-

GERM Chicago, IL

fore a real judge. The key concepts of records management law, discovery procedure, and courtroom evidence addressed in this tutorial are applicable in all government and business electronic records management planning. This will be truly a unique and incisive event that will help you get prepared.

2. Managing Electronic Records: A Practical Approach—Laurie Fisher, Cohasset Associates, Inc.

This popular, information-packed tutorial will provide an overview of the challenges facing all organizations in the management of their electronic records. It presents a tested practical model for incorporating e-records into a records management program—an approach based on solid project management methodologies (risk management, quality management, and resource management) as well as well-established techniques. Throughout this interactive tutorial, common pitfalls and shortcomings will be highlighted – to help you avoid making similar mistakes. Participants also will have the opportunity to "test" the concepts and methodologies presented in the tutorial—via worksheets and key concept tables.

3. What is Part 11?—John McKenney, SEC Associates, Inc.

This comprehensive tutorial is designed to provide participants with an in-depth understanding of the 21 CFR Part 11 Electronic Records Electronic Signatures Rule. It will also address the implications on the predicate rule record-keeping requirements for FDA-regulated activities. Participants will evaluate each section of the rule as it relates to their specific job roles. This widely acclaimed tutorial is intended for individuals who need a thorough understanding of the basic concepts and principles embodied in Part 11. Its easy-to-understand presentation format is ideal for those who are new to the subject.

4. Digital Preservation; Examination of Migration and Emulation Options—Dick Fisher and Charles Dollar, Cohasset Associates, Inc.

This tutorial will be presented by two of the nation's foremost experts on digital preservation. They will begin with their insights on the problem of digital preservation and its impending consequences when information is lost or inaccessible. They then will analyze the available options and detail their advantages as well as disadvantages. The focus of this tutorial will be a comprehensive examination of the two primary digital preservation options: migration and emulation. Participants will take away a clear understanding of the issues and options of an increasingly important problem. Avoid major future problems by preparing now! ■

—Leslie Zeck

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PDA Basel Pharmaceutical Forum

Biopharmaceutical Classification System (BCS) and In Vivo-In Vitro Correlation (IVIVC): Applications and Opportunities

Monday
June 30, 2003
UBS Ausbildungs-und Konferenzzentrum

The regulatory guidance addressing either the Biopharmaceutical Classification System (BCS) or the *in vivo-in vitro* Correlation (IVIVC) were created with the purpose of reducing the regulatory requirements during the development of drug products or when modifying marketed products. The underlying principles and conditions for BCS and IVIVC were generated by scientists from FDA, academia, and industry. They were published by FDA first and have since been adopted "in principle" by the European Health Authorities.

The BCS guidance classifies drug substances according to their therapeutic permeability and solubility, and for drug products the dissolution rate plays an additional important role. A high solubility is assigned when the total dose is soluble in 250 ml of aqueous buffer in the physiologic pH range. A high permeability is assigned when the drug's bioavailability is above 90%; *in vitro* data oriented at internal standards and marker substances can equally serve as characterization for the permeability. The dissolution rate is preferably determined in compendial apparatus and media. During the course of the drug's development or the product's modification the BCS can streamline the *in vitro* and *in vivo* experiments up to and including a biowaiver.

The IVIVC is a mathematical relationship between *in vitro* and *in vivo* data. In the case of product development normally *in vitro* dissolution data are related to plasma concentration data. Because the plasma concentration data cannot be directly correlated to *in vitro* dissolution data, the *in vivo* data need to be translated at first into *in vivo* dissolution or absorption data before a mathematical correlation can be established. Of regulatory relevance are correlations which reflect the entire *in vitro* and *in vivo* behavior (profile) of the drug product. An IVIVC should be possible once the rate for the dissolution from the product is determined for the subsequent absorption process. The IVIVC is considered robust when it has an acceptable prediction power. The predictive power allows one to single out the discriminating dissolution method, to set therapeutically meaningful release specifications, and to justify biowaivers in certain cases.

Utilizing the BCS or IVIVC tool during product development to their full extent depends on the properties of the drug substance and its formulation. Not all substances can benefit from the opportunity, but it is prudent to establish the BSC during the course of the development path as early as possible, likewise for establishing the IVIVC, if possible.

The PDA Basel Forum will review the principles of these two tools, as well as its limitations, illustrated by numerous examples. The speakers are selected on purpose from industry and from a regulatory agency to cover their application from both angles.

Both the BCS and the IVIVC are built on reliable *in vitro* data, i.e., the solubility of the active substance and dissolution rate of it from the pharmaceutical product. The topic will therefore be complimented with all aspects leading to such a trustworthy *in vitro* data base.

Following is the Preliminary Program for the June 30th PDA Basel Pharmaceutical Forum:

Presentations in the morning

- Biopharmaceutical Classification System (BCS), *in vitro* dissolution, and *in vivo-in vitro* Correlation (IVIVC) from regulators standpoint
  European Health Authority expert (invited)
- Biopharmaceutical Classification System, *in vitro* dissolution, and IVIVC from the industry standpoint
  Dr. Harald Rettig, BioVista, Basel

Presentation in the afternoon

- State-of-the-Art Dissolution Testing
  Dr. Johannes Krämer, PHAST GmbH Gesellschaft für Pharmazeutische, Qualitätsstandards mbH ■

—Gautam Maitra

Basel Pharmaceutical Forum

Vancouver Conference on Current Issues in Pharmaceutical Manufacturing

June 9–10, 2003 • Hyatt Regency Vancouver

Tabletop Exhibition
Monday, June 9
For details, contact:
Patrick Bronsard
Project Manager
SNC-Lavalin Pharma
8000 Decarie Blvd., 3rd Fl.
Montreal, Quebec
Canada, H4P 2S4
Tel: (514) 735-5651 ext. 2270
Fax: (514) 737-7988
e-mail: patrick.bronsard@snclavalin.com

Monday, June 9

8:00 am Registration and Continental Breakfast
9:00 am **FDA Systems Based Inspections Issues**
Bob Coleman, ORA, FDA
10:00 am **GMP Compliance Issues for Marketed Products**
Sherry Warren Nagy, Health Canada
11:00 am Exhibit Break
11:30 am **Part 11 Compliance: FDA Expectations**
Daniel Kordi, Wyeth Pharmaceuticals
12:30 pm Lunch
1:30 pm **PQRI Recommendations to the FDA on their Preliminary Concept Paper on Sterile Drug Products Produced by Aseptic Processing**
Jeanne Moldenhauer, Ph.D., Vectech Pharmaceutical, Inc.; John Lindsay, Aseptic Solutions, Inc.; Carol Lampe, Baxter Healthcare
3:30 pm PM Exhibit Break
4:00 pm **Aseptic Processing**, continued
6:00 pm Reception in Exhibit Hall

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May 16

Tuesday, June 10

8:00 am Registration and Continental Breakfast
9:00 am **Training**
Gregg Sherman, Watson Pharmaceuticals
10:00 am **Team Biologics**
11:00 am Refreshment Break
11:30 am **Process Validation for Biologics**
Harold Rode, Ph.D., Health Canada
12:30 pm Lunch
1:30 pm **Inspection of Biotech Facilities**
2:30 pm **Preparing for an FDA Pre-Approval Inspection**
Ron Tetzlaff, Ph.D., KMI
3:30 pm Refreshment Break
3:45 pm **Hot Topics Panel**
4:30 pm Adjourn

The program and speakers for this conference are subject to change. Please refer to the PDA Web site (www.pda.org) for the most updated information.

Vancouver

maceutical manufacturing and contamination control.

PDA will offer a five-day, multi-track series of scientific sessions and education courses. CleanRooms Group conferences will expand from the standard two days to a three-day program.

"We are very sensitive to the ever increasing demands on our members," stated PDA President Neal G. Koller. "By marrying our traditional PDA Spring and Annual Meetings into a single event to be co-located with CleanRooms East, we can deliver a broader spectrum, content enriched opportunity for industry professionals resulting in less time away from the company."

"We are thrilled to partner with PDA—an established, well-respected industry organization," said James Enos, Vice President and Group Publishing Director of the CleanRooms Group. "This agreement allows PDA and the CleanRooms Group to not only maintain our respective identities, but it also provides attendees of both events the chance to participate in a forum that embraces two distinct, yet harmonious technologies."

Enos adds, "Co-locating broadens the spectrum of marketing and access for end users, members, and exhibitors who (in the past) had to plan to attend two separate events. Now they can attend one content-rich event, in a convenient and accessible format."

"This is just the beginning of what we can build together," said Adam Japko, President of the Advanced Technology Division of PennWell Corp. "This co-location, a cornerstone of the agreement, will undoubtedly grow and prosper into other industry ventures internationally to further benefit life sciences professionals worldwide."

PennWell (www.pennwell.com) is a diversified media company providing 45 authoritative print and online publications, 50 conferences and exhibitions, research, databases, Internet-based services and other information products to strategic global markets.

Contact PDA if you are interested in exhibit or speaking opportunities. Watch the PDA Web site at www.pda.org for updates on this exciting venture. ■

—Leslie Zeck

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As of 4/7/03

San Diego

2003 PDA Spring Conference Highlights

Mark Elengold, FDA, CBER delivers the closing keynote presentation on the status of the compliance environment.

A panel of FDA experts including Christopher Joneckis, Ph.D., CBER, Peter Cooney, Ph.D., CDER, and David Hussong, Ph.D., CDER, field questions.

Tom Handel, Meridian Technologies, PDA Exhibits Committee Chair, relaxes with a colleague at the Networking Reception.

Conference Co-Chair, Rhona O'Leary, Ph.D., Genentech, facilitates a question-and-answer session following presentations by Dr. Lance Gordon, VaxGen, and Dr. Ken Seamon, Amgen.

Conference participants discuss the presentations.

Prague

2003 PDA/IABs Conference on the Comparability of Biopharmaceuticals

Presenters at the February 2003 PDA/IABs Conference on the Comparability of Biopharmaceuticals in Prague include (from left) Toru Kawanishi, Ph.D., Division of Biological Chemistry and Bioligicals, National Institute of Health Sciences, Japan; Cindy Wong, MPA, Sweden; Anthony Lubiniecki, Sc.D., GlaxoSmithKline, USA; Emily Shacter, Ph.D., CBER, FDA, USA; Barry Cherney, Ph.D., CDER, FDA, OPS, USA; Karin Sewerin, Ph.D., Biologics Consulting Group, Sweden; and Anthony Ridgway, Ph.D., Health Canada.

Director's Message

International Course Program Development

My article for the April *PDA Letter* was written at 39,000 feet, somewhere over the Atlantic, while en route to the PDA International Congress & Courses held in Prague, Czech Republic. This month's article was written at 33,000 feet, above U.S. territory, while en route to the PDA Spring Conference & Courses in San Diego. For some, writing comes easy. For me, it appears I have to get "up" for it!

This month, I call your attention to PDA-TRI plans to expand course offerings in Europe and Asia. As our Association grows, a greater proportion of its membership falls outside the U.S. "home base." Therefore, it is imperative that PDA-TRI provide more educational content to our international membership, preferably at convenient locations for those members. To that end, this summer (June 23–25, 2003) we will be offering a series of 11 lecture courses in Toronto, Canada. (See the article on the cover page for more details.)

During my trip to Prague, I spoke with several European PDA members. Each had the same basic request—more course offerings in Europe, preferably with European faculty familiar with the day-to-day issues confronting European industry and regulatory agencies. PDA European members: I heard your message clearly! I am now actively recruiting faculty in and for the European training programs. Readers: if you reside in Europe and would like to contribute as a PDA-TRI instructor, I encourage you to contact me at mello@pda.org. We can begin the evaluation process.

This June, we are offering a course in Milan, Italy, on the design, validation, and use of isolators in pharmaceutical applications. The course is being offered in conjunction with a conference on sterile manufacturing issues sponsored by the PDA Italy Chapter (see the PDA Web site at www.pda.org for details). Also, as mentioned in the March *PDA Letter*, PDA is producing a GMP course series for the Italian Inspectorate. We hope to offer similar GMP program modules to other inspectorates, as well as to industry, throughout Europe.

From Asia, I have received several inquiries concerning the availability in Japan and Taiwan of our auditor training course entitled, "Computer Products Supplier Auditing Process Model: Auditor Training." We are making plans to offer this course in Asia, hopefully in 2003 and certainly in 2004. Such input coming from our membership and the area Chapters is invaluable to us in our planning and selection of course offerings in this region. We intend to offer a minimum of four or five different courses in Asia in 2004. Please let us know your areas of greatest interest. We exist for you—the membership. What courses or subjects would you like to see? Our plans for additional courses in Asia during 2003 and 2004 are evolving and I hope to report more details in subsequent messages. To our colleagues in Asia: I extend a request for instructors. Please contact me if you wish to be a part of the PDA-TRI Asia faculty.

We will be proceeding slowly with these new international training initiatives, while we establish faculty and a logistic infrastructure. We will add more courses with time.

This is a sampling of my thoughts and plans for the future of PDA-TRI from 33,000 feet. The seatbelt sign has come on and we have begun our landing approach. It's time to put these plans into action. ■

—Robert J. Mello, Ph.D.

Upcoming Course Series

PDA-TRI Toronto Course Series

Westin Harbour Castle, Toronto, CANADA
June 23–25, 2003
PDA-TRI Lecture Courses
June 23
Failures/Deviations and Change Control
Achieving CGMP Compliance during the 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

PDA-TRI San Francisco Course Series

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

Upcoming PDA-TRI Education Courses

Courses listed in alphabetical order

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

Cleaning Validation—Lab May 19–21, 2003; October 13–15, 2003; $3,000 members/$3,195 nonmembers; *Faculty:* Jon Voss and Bob O'Brien

Compliance Auditing of Cleanrooms and Controlled Environments—Lecture August 14–15, 2003

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 May 15–16, 2003; 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 ■

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:

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* no on-site restaurant

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

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

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.

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LTR 05/03

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 ❑).

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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.

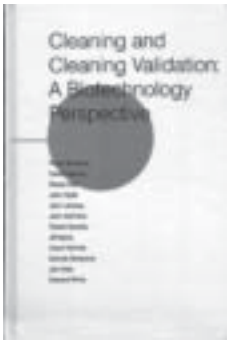
This document was produced through the collaboration of several industry groups (FDA regulated companies, system suppliers, legal experts, and consultants). It represents a compendium of current thinking on good electronic record management from an FDA-regulated industry perspective. GERM attempts to 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

Change Control Soren Schwartz; This manual provides a well-organized, practical process for the management of changes to the Information and Control Systems used in GxP-related operations. 25 pp; $90members/$109 nonmembers **Item # 17189**

Commercial Off-The-Shelf Software Validation for 21 CFR Part 11 David Nettleton and Janet Gough; Validation clearly is a requirement for regulatory compliance. Every indication is that the regulations will focus more and more on the electronic generation of data, data control, and data transfer. The goal of this book is to provide guidance for validating commercial, off-the-shelf (COTS) computer software that generates data or controls information about products and processes subject to binding regulations. 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**

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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**

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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**

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Understanding Active Pharmaceutical Ingredients Seigfried Schmitt; Written by a Chartered Chemist and Member of the Royal Society of Chemistry, and edited by Trevor Deeks, this succinct document provides an overview of API use, including regulatory and validation details. 44 pp; $80 members/$109 nonmembers **Item # 17188**

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 Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; 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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2003 Calendar from back cover

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

OCTOBER

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

October 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
Hilton Atlanta, Atlanta, GA
PDA-TRI Lecture Courses:
November 13
Designing, Monitoring & Validation of Pharmaceutical Manufacturing Ventilation Systems
Auditing Techniques for CGMP Compliance
November 13–14
Basic Concepts in Cleaning and Cleaning Validation
Computer-Related Systems Validation
A Practical Approach to Aseptic Processing and Contamination Control
November 14
Managing in a GMP Environment
Change Control & Documentation

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

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

DECEMBER

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

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

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!

www.pda.org

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For a complete PDA Calendar beyond December 2003, please visit **www.pda.org**.

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Calendar of Events

JUNE

June 2–4, 2003
The 34th Symposium of the R^3 Nordic Society
Turku Polytechnic, Turku, FINLAND

June 6, 2003
PDA Southeast Chapter Golf Outing
Location TBA

June 9–10, 2003
PDA Canada Conference on Current Issues in Pharmaceutical Manufacturing
Hyatt Vancouver, Vancouver, British Columbia

June 22–25, 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 Toronto Course Series
Westin Harbour Castle, Toronto, CANADA
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, 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 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
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

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Be sure to watch
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