Volume XXXVII, No.8

PDA Letter

August 2001

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

TSE Advisory Committee Meeting summary, see page 12

2001 PDA Annual Meeting, Courses and Exhibition

Compliance: Challenges and Pragmatic Solutions

December 3–7, 2001 • Marriott Wardman Park, Washington, DC

Brian R. Matthews, Ph.D., of Alcon Laboratories in the UK will present his cutting edge white paper, *BSE/TSE Risks Associated with APIs and Starting Materials: The Situation in Europe and the Global Implications for Healthcare Manufacturers* at the 2001 PDA Annual Meeting, Courses and Exhibition. Dr. Matthew's research has garnered much interest around the world and PDA's annual meeting will provide an excellent forum for discussion of the issues. Extend your stay in Washington, DC to attend a one-day forum on BSE/TSE issues on December 6, 2001. Details on the forum are forthcoming.

Conference Highlights:

- Participate in PDA's Interest Group meetings and presentations;
- Visit the sold out exhibit hall, offering one of the industry's most informative and educational displays of the latest in science in technology; and
- Choose from among a variety of training courses offered by PDA's Training and Research Institute (PDA-TRI). The courses will include offerings in Auditing, Computer Systems Validation, Change Control and an advanced course in Regulatory Compliance designed for new supervisors and

continues on page 23

Blend Uniformity Data Needed

The Product Quality Research Institute (PQRI) is requesting industry assistance in a data mining exercise to support a new Blend Uniformity proposal for powder blends, in-process dosage unit samples and finished dosage units. In August of 1999, the FDA issued the draft *Guidance for Industry, ANDAs: Blend Uniformity Analysis.* Both the generic and innovator companies raised a number of concerns following the issuance of this document. It is the intent of the PQRI Blend Uniformity Working Group (BUWG), to determine through scientific analysis, the appropriate degree of testing to assure consistency of content in finished dosage units.

Companies that must prove blend uniformity and content uniformity (to assure the FDA of the adequacy of the blending process) stand to benefit from this data mining exercise through reduced sampling and testing. All data will be treated in the strictest confidence, and any source data will be removed by the PQRI Executive Secretary prior to forwarding the data for analysis. Please participate in this process by visiting the PQRI Web site at http://www.pqri.org and downloading the data template which can be found

It is the intent of the PQRI...to determine ... the appropriate degree of testing to assure consistency of content in finished dosage units.

continues on page 5

A filter validation promise to customers all around the world:

Dreissig Tage
Trente jours
Dertig dagen
Trenta giorni
三十天
Trienta dias
Thirty days

No Excuses. Yes, We Can!

From vaccines and cell cultures to blood products– only Sartorius lets you validate with CONFIDENCE®

In matters of validation, Sartorius makes an extra effort to ensure quality in your process. And we do it all in 30 days or less. It's all part of our FACTS® program of Fully Advanced Customer Total Support. We take the time to do it right. We test your filters with your product under your process conditions. We run "worst-case" bacteria challenge tests and worst-case extraction. Our modern analytical validation labs include FT-IR, GC/MS, RPHPLC, UV-VIS, GPC, HPCE, SFC, NVR and TOC. No other filter manufacturer performs these validation procedures with more accuracy than Sartorius.

So when it comes down to deciding who the most viable filtration partner is to properly challenge your process, in 30 days or less, call us. Yes, we can!

Focus On Validation Support

sartorius

Sartorius AG, Germany: 49 551 308 0 • Sartorius S.A., France: +33 1 69 19 21 00 • Sartorius Ltd.,UK: +44 1 372 737100
Sartorius S.p.A., Italy: +39 055 505671 • Sartorius Corp., USA: +1 800 368 7178 • Sartorius K.K., Japan: +81 3 3329 5533

PDA
7500 Old Georgetown Road, Suite 620
Bethesda, MD 20814 USA
Tel: (301) 986-0293 Fax: (301) 986-0296
E-mail: *info@pda.org*
www.pda.org

PDA Training & Research Institute
c/o UMBC Technology Center
1450 S. Rolling Road
Baltimore, MD 21227 USA
Tel: (410) 455-5800 Fax: (410) 455-5802

PDA Europe Office
Postfach 620
CH-4144 Arlesheim, Switzerland
Tel: +41 61 703 1688 Fax: +41 61 703 1689
E-mail: *lyda@pda.org*

The ***PDA Letter*** is published monthly by PDA, exclusively for PDA members. Subscriptions are not available.

PDA President
Edmund M. Fry

Director, Communications & Marketing
Linda M. Williams

Editor/Web Editor
Joseph G. Bury

Manager, Publications & Production
Janet Raysick

PDA Letter

Important Dates...

- November 9, 2001—hotel cutoff for PDA Annual Meeting, see page 23

IN THIS ISSUE...

USP UPDATE

by Roger Dabbah, Ph.D., USP

USP plans to publish the USP-NF annually starting in 2002. The July–August 2001 Pharmacopeial Forum includes the Eleventh Interim Revision Announcement (IRA). Items under this IRA are Official August 1, 2002 unless otherwise indicated. This IRA includes: Amifostine and Amifostine for Injection; Prednisolone; and Sulfadimethoxine and Sulfadimethoxine Sodium. Also under this IRA are additions and or changes to <11> Reference Standards.

In the In-Process section of this PF we have a number of revisions to a number of monographs as well as proposals for new monographs. Among the new monographs proposed for the first Supplement of USP 25 are: Bupropion Hydrochloride; Choline Chloride; Desogestrel; Iodixanol; Isoflupredone Acetate and Isoflupredone Injectable Suspension; Paroxetine Hydrochloride; Perflutren protein-type A Microsphere for Injection; Propofol; Sunflower Oil; and many more. In the In-Process section of NF new monographs slated for the first Supplement are: USP 25 Acacia Syrup; Diluted Acetic Acid; Caraway; Caraway Oil; Cardamon Seed; Cardamon Oil; and many others. A new in-process proposal, also slated for the first Supplement of USP 25, is the information chapter <1146> Packaging Practice—Repackaging a single Solid Oral Drug Product into a Unit-Dose Container.

In the Harmonization section of this PF, a monograph on Benzyl Alcohol is proposed that represents the Consensus stage 5B2 Draft. In the absence of any adverse comments, an implementation date of the First Supplement of USP 25 is proposed.

In the PF, Pharmacopeial Previews section, the following monographs are proposed: Fexofenadine Hydrochloride; Insulin Lispro; and Insulin Lispro Injection. In the NF Previews section the following monographs are proposed: Black Kohosh; Powdered Black Cohosh; Powdered Blavck Kohosh Extract; and Black Kohosh Tablets.

A new information chapter is proposed under Previews, <1265> Written Prescription Drug Information-Guidelines. This guideline is based on relevant research literature, on patient interviews and laboratory cognitive research funded by USP and the Department of Health and Human Services Action Plan for the Provision of Useful Prescription Medicine Information.

An interesting Stimuli For the Revision Process Article, *Toward Standardization of an In Vitro Method of Drug Absorption,* by Donna A. Volpe et al. (from FDA-CDER) recommends a general protocol to evaluate in vitro drug permeability as described in a recent FDA-CDER Biopharmaceuticals Classification System Guidance for Industry. It allows for the use of other epithelial cell lines than the one proposed by USP (Caco-2 cells), provided that system suitability is demonstrated through the use of internal standards and model compounds.

USP is offering new courses on *USP-NF* and *Standard Development*. Contact Diana Lenehan at (301) 816-8530 or dpl@usp.org for more information or to register. Another course, *Fundamentals of Dissolution,* is also being offered.

A USP Open Conference on Excipients is planned for December 12–14, 2001 in Fort Myers, FL in collaboration with IPEC. For additional information, contact Dorothy Chaconas at USP at DMC@usp.org. ■

International Calendar

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

2001

SEPTEMBER

September 6-7, 2001
PDA/IABs Conference on Process Validation for Biologicals and Biological Products:
A State-of-the-Art Perspective
Berlin Hilton Hotel
Berlin, Germany

September 17-18, 2001
PDA Canada Chapter/ A3P International Conference and Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec, Canada

OCTOBER

October 24-26, 2001
A3P 14th International Congress
Espace Bellevue
Biarritz, France
INFORMATION AND REGISTRATION:
Frédéric Estassy
A3P Services – Le Gros Moulin – F-45200 Amilly – France
E-mail: info@a3pservices.com
Tel: +33 (0)2 38 071 – Fax: +33 (0)2 38 071 072
Web site: www.a3pservices.com

2002

FEBRUARY

February 11-13, 2002
Basel 2002: PDA International Congress, Courses and Exhibition
Adding Value to the Pharmaceutical Industry—Leveraging the Future
Basel Convention Center
Basel, Switzerland

European Pharmacopoeia — News and Updates

The European Directorate for the Quality of Medicines (EDQM), which publishes the European Pharmacopoeia, has announced the following events and updates.

EDQM advises of the following information available from their Web site. Publications and services available free of charge:

- Proceedings of the international symposium on Pestivirus contamination of bovine sera and other bovine sera contamination (Paris, March 29–30, 2001), www.pheur.org/Conferences/Pestivirus_Proceedings.pdf.
- Thirty-eight new or revised European Guidelines for the batch release of blood products and vaccines, see News/Download headings.
- Certification of Suitability: Updated lists of certificates of suitability granted (June 14, 2001), www.pheur.org/download/pdf_files/list_certificates_1406.pdf, www.pheur.org/download/pdf_files/list_certificates_TSE_1406.pdf.

Conference:

- The updated program of the international conference on "New developments of the procedure of certification of suitability of the European Pharmacopoeia's Monographs", November 8–9, 2001, Athens/Vouliagmeni, Greece, www.pheur.org/conferences/programme_athens.pdf.

Other publications and services:

- Pharmeuropa 13.3 (July 2001 issue) For the List of contents, prices and conditions for ordering, see Publications/Pharmeuropa headlines: www.pheur.org. ■

—James C. Lyda

Blend Uniformity Data Needed continued from cover

under "Blend Uniformity Stratified Sampling."

The Product Quality Research Institute is a collaborative process involving the FDA's Center for Drug Evaluation and Research (CDER), Industry and Academia. The mission of PQRI is to conduct research to generate scientific information to support regulatory policy. This initiative will help identify the types of product quality information that should be submitted in a regulatory filing to CDER. PQRI has been in development since January of 1996, guided by a Steering Committee composed of individuals representing the sponsoring organizations listed below.

PQRI Founding Member Organizations

AAPS ..... American Association of Pharmaceutical Scientists
CHPA ..... Consumer Healthcare Products Association
GPhA ..... Generic Pharmaceutical Association (formerly GPIA, NPA and NAPM)
PhRMA ..... Pharmaceutical Research and Manufacturers of America
FDA/CDER ..... US Food and Drug Administration
PDA ..... PDA

PQRI New Member Organizations

IPEC ..... International Pharmaceutical Excipients Council
ISPE ..... International Society for Pharmaceutical Engineering
USP ..... United States Pharmacopeia

The outcomes of PQRI will be focused on research projects whose results provide a continuing scientific basis for regulatory policy. The research may support reduction in the regulatory burden by decreasing the amount of information needed for a submission and/or regulatory filing. ■

—William Stoedter

The mission of PQRI is to conduct research to generate scientific information to support regulatory policy.

TR-32 UPDATE

by Harvey Greenawalt, Audit Repository Center

Since the issue of TR-32 in January of 2000, the audits are being scheduled and implemented at an average rate of two per month. This effort is made possible by contributions from Pharmaceutical Industry Subscribers and Participating Suppliers to PDA's licensed audit repository administered by Audit Repository Center (ARC).

Currently, 33 audits are either in process or on file for distribution by the repository. Since February of 2000, six pharmaceutical and biotechnology companies and four suppliers have joined the PDA Process Repository. Two pharmaceutical companies and one supplier have renewed their subscription for a second year.

First Year Performance

The results of the metrics from the first year of implementation, obtained from Suppliers who were audited using the PDA Process Model, indicate the Suppliers felt that audits were performed in an expedient, positive and professional manor by experienced personnel. This aspect is critical to suppliers in that it represents reduced impact on their development efforts and ensures accurate reporting of the quality of their products.

Suppliers also found the Data Collection Tool, contained in TR-32, to be a clear and thorough tool with which to probe the supplier's practices and to benchmark their practices against pharmaceutical industry expectations.

Results established that there is a good level of agreement between the Auditor and Suppliers and that the Process produces a consistent and reliable result no matter who uses it. Subscribers, who have used the data obtained from the repository, supported this.

All stakeholders indicated that the Process is a time-efficient method to reduce cost, satisfy regulatory requirements and provide shareable data. The Process promotes clarification and understanding of the objectives audits performed to meet system validation requirements.

Due to reductions in the up-front cost of procuring a particular supplier's product, subscribing pharmaceutical companies realized cost savings when using audits that were contributed by a Participating Supplier. Subscribers indicated that this was very important to them since it was a method of reducing the financial burden inherent with ensuring proper regulatory compliance, while maintaining the same degree of integrity required by their corporate commitments to quality and excellence.

The first year of implementation of TR-32 appears to have met industry expectations and provided a sound, reliable product which meets the needs of suppliers to industry and Pharmaceutical Industry Subscribers.

Auditor Training & Qualification

One hundred and eight auditors have been qualified under the purview of PDA to implement the process defined in TR-32. Representatives of pharmaceutical companies, suppliers and third party consultant groups have attended auditor training. Roughly 10 percent of the auditors who have been qualified reside in Europe. One auditor resides in Japan. Forty-eight percent of the auditors are from pharmaceutical industry companies with the balance coming from consultancy groups.

Suppliers seeking to place their audit information in the repository for use by their pharmaceutical clients have found the information obtained from the auditor training to be extremely beneficial in expediting the audit process and in the internal benchmarking of their quality systems.

Pharmaceutical company personnel seeking qualification to perform audits using TR-32, as well as management personnel responsible for the implementation of validation, quality management and corporate computer systems implementation have attended the auditor training.

Pharmaceutical companies have requested several special training sessions. These sessions have been delivered on the company's facility by PDA-TRI.

The next auditor training course is scheduled for October 11–12, 2001 at PDA-TRI in Baltimore, Maryland.

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

Availability of Audits

Currently, 45 audits are either available for distribution, in process or planned to be implemented within the next six months.

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

Table 1.0 provides a summary of the 13 audits that are currently available for distribution from the repository. ■

Table 1.0 Audits Currently Available in ARC

Supplier	Product
Accraply, Inc.	Label Applicators, Automatic Labeling Systems, & Custom Designed and Self Adhesive Material Application Systems
ActionPoint	Input Accel Document Imaging LIMS
Applied Biosystems	SQL*LIMS – Laboratory Information Management System including the QA Stability & Schedule Modules
Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set
Etrails.com, Inc.	Electronic Data Capture – EDC Electronic Patient Diaries – EPD Electronic Trail Management – ETM
Fanuc Robotics North America	Robotic Controllers & Communications
First Consulting Group, Inc.	Custom information based strategy software, operations improvements management and integration services
Infinity QS International (Lyle-Kearsley, Inc.)	Infinity QS Statistical Process Control Software
Merant, Inc.	PVCS Dimensions & PVCS Replicator Configuration Management Systems
Precision Solutions	Custom Development, SLE-Capture of check weight data Custom Software Programming
Qumas, Ltd (Participating Supplier)	Qumas-Doc: Electronic Records Document Management Systems
SSA Global Technologies, Inc.	Mid range ERP software for manufacturing, supply chain and financial application domains
Supply Chain Logic, Inc.	General use COTS Asset Tracking/Delivery Systems

FYI FYI FYI FYI FYI

Computer Products Supplier Auditing Process Model: Auditor Training,

October 11–12 and November 15–16, 2001 in Baltimore, Maryland

$950 PDA members/ $1,100 nonmembers.

For more information, vist our Web site, www.pda.org.

US Regulatory Briefs

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

The FDA has assumed the sole responsibility for Drug Quality Reporting. The Drug Quality Reporting System (DQRS), is a system of voluntary reporting through the MedWatch Program. The DQRS grew out of FDA's recognition that pharmacists and other health care professionals who regularly handle drugs can provide an invaluable service by reporting problems to the FDA which may not have been discovered by the manufacturer. Previously, Drug Quality Reports were made to either the US Pharmacopeia or the FDA. August, 2001 marks the first year that the FDA, under the MedWatch program, has been the sole conduit for drug quality problem reports.

Postmarketing surveillance, of which DQRS is a part, is essential for maintaining high-quality, safe and effective drug products in the US. In fiscal year 2000, FDA review of more than 2000 of these reports resulted in 11 recalls, one market withdrawal and 24 corrective actions.

Typical observations reported in this program include:

- Mislabeled drugs;
- Incorrect information on the labeling;
- Packaging problems;
- Bacterial contamination;
- Precipitation or particulates; and
- Odor or taste change.

MedWatch form 3500 is used for Drug Quality Reports as well as medication errors and adverse events. Reports can be submitted by telephone at 1 (800) 332-1088. This same number can be used to ask questions about the program. Reports can be sent by fax to 1 (800) 332-0178 or by mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787. Reporting can also be facilitated online at www.fda.gov/medwatch. Reporters can request anonymity, although only about 20 percent actually do.

On March 29, 2001 the FDA updated Investigations Operations Manual (IOM) was posted on the FDA Web site. The IOM is the primary source of guidance regarding Agency policy and procedures for field investigators and inspectors. This extends to all individuals who perform field investigational activities in support of the Agency's public mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency and efficiency in field operations. Although the IOM is the primary source of policy, the specific information in this manual is supplemented, not superseded, by other manuals and field guidance documents. Recognizing that this manual may not cover all situations or variables arising from field operations, any significant departures from IOM established procedures must have the concurrence of district management with appropriate documentation as needed.

There are many changes and additions to the Year 2001 IOM. The agency has modified the implementation of the medical device expansion pilot to make notification of inspections outside the medical device area optional or as directed by a specific program. Included are new guidances on the preparation of inspection reports. This additional information is compatible with TURBO EIR, being piloted in multiple Districts.

Since December 1996, the IOM has been posted to ORA's Internet Home Page, www.fda.gov/ora/inspect_ref/iom/iomtc.html. The entire IOM is available there, with all graphics included. Future updates to the IOM will be done periodically during the year to this on-line version. Hard copy publication will be done yearly. Remember, whether reviewing the "hard copy" or the "on line" version of the IOM, the most recent version is the document of record.

Draft Guidance for Industry - Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan. This is the second draft guidance document intended to assist industry when submitting information to the Clinical Trials Data Bank required by Section 113 of the *Food and Drug Administration Modernization Act of 1997 (Modernization Act*). The first draft guidance document was published on March 29, 2001. It addressed statutory requirements for submission of protocol information. This guidance document discusses procedural issues that were not included in the first document. A final combined guidance will be issued after consideration of any comments received. Until the final guidance document is available, sponsors submitting clinical trial information for inclusion in the AIDS Clinical Trials Information Service (ACTIS) data bank should continue to follow procedures currently in place.

Section 113 of the *Modernization Act* provides for the public availability of specified information on studies of drugs for serious or life-threatening diseases conducted under FDA's IND regulations (21 CFR part 312).

The Clinical Trials Data Bank is intended to be a central resource, providing current information on clinical trials to individuals with serious or life-threatening diseases, to other members of the public and to health care providers and researchers. Specifically, the Clinical Trials Data Bank will contain:

1. Information about clinical trials, both federally and privately funded, of experimental treatments (drugs, including biological products) for patients with serious or life-threatening diseases;

2. A description of the purpose of the experimental drug;
3. Patient eligibility criteria;
4. The location of clinical trials sites; and
5. A point of contact for patients wanting to enroll in the trial.

Section 113 of the *Modernization Act* specifies that information for the Clinical Trials Data Bank must be in a form that can be readily understood by the public. For more information go to www.fda.gov/cder/guidance/index.htm.

The FDA Center for Devices and Radiological Health (CDRH) has posted a list of sterilants on their Web page. This is a list of Sterilants and High Level Disinfectants cleared by FDA in a 510(k) as of June 29, 2001. The list can be found at www.fda.gov/cdrh/ode/germlab.html.

—William Stoedter

International Regulatory Briefs

Compliance with Pharmacovigilance Regulatory Obligations. In June, the EMEA released the draft *European Concept Paper on Compliance with Pharmcovigilance Regulatory Obligations* (CPMP/PhVWP/1618/01, June 27, 2001). This draft concept paper was prepared by the CPMP Pharmacovigilance Working Party following consultation with the competent authorities, the Good Clinical Practice and Good Manufacturing Practice inspectorates. The paper sets out the legal basis for pharmacovigilance obligations, how compliance should be monitored in Europe and the types of regulatory action that may be considered in the event of non-compliance. Topics include system requirements, qualified persons, change in risk/benefit assessment, expedited ADR reporting, periodic safety updates, submission of safety variations, pharmacovigilance inspections and regulatory actions. Deadline for comments is September 30, 2001.

Processing Renewals in the Centralized Procedure. In May, the EMEA adopted *Guideline on the Processing of Renewals in the Centralised Procedure* (EMA/CPMP/2990/00 rev. 2, May 31, 2001). This Guideline, developed following consultation of the CPMP and the European Commission, outlines the issues associated with the processing of renewals in the centralized procedure with an aim of giving procedural guidance to marketing authorization holders. The legal framework and the principles of submission and evaluation are addressed. Annexes regarding Definitions, Renewal Timetable and Documents Required for Submission are included. The effective date was June 2001.

Harmonization of Requirements for Influenza Vaccines. In May, the EMEA released *Concept Paper on the Revision of the CPMP/BWP Note for Guidance on Harmonisation of Requirements for Influenza Vaccines* (CPMP/EWP/1045/01, May 31, 2001). This paper describes changes to the criteria currently used for the evaluation of immunogenicity for influenza vaccines. Influenza vaccines are modified yearly to take into account the changes in the prevalent viruses using assessment criteria defined by the Note for Guidance. Due to questionable immunogenicity in the elderly, it is proposed that the EWP prepares a revision of the existing Note for guidance addressing the following issues: the relevance of the current requirements; the potential importance of each serological criterion as compared to the others; the choice of one or more of the 3 predefined serological criteria to assess immunogenicity and; the need to take into account the 95% ci and more specifically its limits when they are below the required limits. A revised document is expected to be available for submission to the CPMP prior to the forthcoming vaccine season.

Evaluation of Anticancer Medicinal Products in Man. In May, the EMEA issued *Note for Guidance on Evaluation of Anticancer Medicinal Products in Man* (CMPM/EWP/205/95 rev.1, May 31, 2001). This Note provides guidance for the clinical investigation of anticancer agents, cytotoxic/cytostatic agents in particular, from Phase I Initial Human Studies through the requirements for authorization. Those sections dealing with requirements for authorization and Phase II/III studies may also be applicable for other classes of anticancer agents. Clinical trial requirements for other compounds, such as chemoprotector agents and drug resistance modifiers used as part of chemotherapeutic regimens, are also given in the appropriate sections of this guideline. This Note will be updated as experience with other classes of anticancer agents becomes available at both the scientific and regulatory levels. The effective date is November 2001.

Assessment of Anti-HIV Medicinal Products. The EMEA released in May, the draft *Points to Consider on the Assessment of Anti-HIV Medicinal Products* (CPMP/602/95 rev.3, May 31, 2001). Originally adopted in 1996 by the CPMP, the document was revised in 1997 to include further elaboration on the regulatory implications of pharmacokinetics, virus resistance and data requirements in patients failing therapy. The current revision includes an Appendix III, which sets out general principles on the clinical development of dual protease inhibitors as the use of dual or boosted protease inhibitors has evolved from an investigational concept to widespread use. Appendix III provides guidance on the requirements for data on the use of dual or boosted protease inhibitors to be included into the Summary of Product Characteristics. The deadline for comments relating to Appendix III only is August 2001 and the effective date is September 2001.

Applications with Meta-Analyses and One Pivotal Study. A draft of *Points to Consider on Application with 1. Meta-Analyses; 2. One Pivotal Study* (CPMP/EWP/2330/99, May 31, 2001) was issued in May by the EMEA. This PtC discusses the validity and interpretation of this methodology when meta-analytic techniques are applied to the studies included in a drug application. Though the guidelines (ICH E9) recognize that there are circumstances when meta-analysis can be sufficient for approval, these guidelines are not specific about the circumstances when this applies. This document provides clarification regarding the selection of studies, the need for pre-specification of the meta-analysis, the outcome of individual studies in relation to the pooled result and the clinical relevance and external validity of the pooled result. Also included in this PtC is a discussion on the use of only a single pivotal study in Phase III clinical development. Though there is no formal requirement to include two or more pivotal studies in the Phase III program, in most cases, it is the most or perhaps only feasible way to provide the variety of data needed to confirm the usefulness of a product in the intended population. This document presents a number of reasons why it is usually prudent to plan for more than one study in the phase III program.

—James C. Lyda

The International Conference on Harmonization (ICH) has a new Web page for the ICH Global Cooperation Group (GCG). The ICH GCG is a subcommittee of the ICH Steering Committee. Its purpose is to make information available on ICH, ICH activities and ICH guidelines to any country or company that requests the information. The GCG is made up of one representative from each of the six parties on the ICH Steering Committee plus the ICH Secretariat. Two Observers, the World Health Organization (WHO) and Canada are also part of the GCG. Some of the Guiding Principles of the GCG are:

- The ICH will not seek to impose its views on any country, region or company, but will serve as a resource for information and data;
- ICH will provide non-ICH member countries or companies with any document related to the GCG initiative without charge; and
- While some non-ICH countries are not in a position to utilize ICH guidelines at present, these guidelines will be used as the basis of ICH's response whenever information is requested.

More information about the ICH GCG can be found at: www.ifpma.org/ich1.html.

The Pharmaceutical Inspection Cooperation Scheme (PIC/S). PIC/S is the abbreviation and logo used to describe both the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Cooperation Scheme (PIC Scheme) operating together in parallel.

The PIC Scheme commenced operating on November 2, 1995 in conjunction with PIC, which had already been operating since 1970. The need to form the PIC Scheme became necessary when it was realized that an incompatibility between PIC and European law did not permit individual EU countries that were members of PIC to sign agreements with other countries seeking to join PIC. Only the European Commission was permitted to sign agreements with countries outside Europe, and the Commission itself was not a member of PIC.

Therefore, a less formal and more flexible cooperation scheme was developed to continue and

enhance the work of PIC. Instead of being a legal treaty between countries (i.e. like PIC), the PIC Scheme is a cooperative arrangement between health authorities.

PIC and the PIC Scheme, operating together as PIC/S, provide an active and constructive cooperation in the field of GMP (Good Manufacturing Practice). The purpose of PIC/S is to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of GMP inspectors.

The main differences between the PIC Scheme and PIC are:

PIC Scheme	PIC
A Program	An Agreement
An Informal Arrangement	A Formal Treaty
Has No Legal Status Between Health Authorities	Has Legal Status Between Countries
Exchange Of Information	Mutual Recognition Of Inspections

The purpose of the PIC Scheme with regard to public health is to:

- Pursue and strengthen the cooperation established between the participating authorities in the field of inspection and related areas with a view to maintaining the mutual confidence and promoting quality assurance of inspections;
- Provide the framework for all necessary exchange of information and experience;
- Coordinate mutual training for inspectors and for other technical experts in related fields;
- Continue common efforts towards the improvement and harmonization of technical standards and procedures regarding the inspection of the manufacture of medicinal products and the testing of medicinal products by official control laboratories;
- Continue common efforts for the development, harmonization and maintenance of Good Manufacturing Practice (GMP); and
- Extend the cooperation to other competent authorities having the national arrangements necessary to apply equivalent standards and procedures with a view to contributing to global harmonization.

For more information on PIC/S and a list of member countries visit www.picscheme.org.

In a letter dated June 19, 2001, the Canadian Health Products and Food Branch Inspectorate issued the draft version of the Good Manufacturing Practices (GMP) Guidelines, 2002 Edition. The draft GMPs are available on the Therapeutic Products Program (now the Therapeutic Program Directorate) Web site at: www.hc-sc.gc.ca/hpb-dgps/therapeut.

This version has been developed by the GMP Committee as part of a process that includes consultation with the stakeholders. Changes from the previous edition are highlighted. The guidance given in this document has been written with a view to harmonization with GMP standards from other countries and those of the World Health Organization (WHO) and the International Conference on Harmonization (ICH). The 2002 Edition also reflects Mutual Recognition Agreements and Canadian acceptance as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

Comments about this document can be submitted to Ms. France Dansereau, Head of the Inspection Unit, National Coordination Center, Health Products and Food Branch Inspectorate, until August 31, 2001. Comments may be sent by email to france_dansereau@hc-sc.gc.ca or by fax to (613) 952-9805. ■

—William Stoedter

Transmissible Spongiform Encephalopathies (TSE) Advisory Committee Meeting

Issues in the processing of blood, plasma and gelatin

The Food and Drug Administration Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) meeting took place on June 28–29, 2001 in Bethesda, Maryland. Three topics were addressed:

1. The suitability of blood donors who have lived or traveled in various countries;
2. Safety of FDA-regulated plasma derivatives prepared in establishments using the same manufacturing equipment to process European and US plasma; and
3. A report on the interim results of a new study on the inactivation of the TSE agent by the manufacturing process of gelatin.

The estimated impact of this proposal is a 4.6 to 5.3% loss of donors, a 72% reduction of the current risk of infection and a 91% reduction of the total risk of infection.

Regarding topic number one, the committee voted 10 to seven to recommend that blood donors be excluded who:

- Spent a total of three months or more in the UK from 1980 through the end of 1996;
- Were US military personnel or dependents who have spent six months or more on a base in Europe from 1980 through the end of 1996 (or 1980 through 1990 if all exposure after 1990 was on a base North of the Alps);
- Spent a cumulative of five years or more living or traveling in any European country other than the UK from 1980 to the present; or
- Have received blood transfusions in the UK since 1980.

While the FDA is not obliged to follow committee recommendations, most are adopted. A great deal of testimony was heard about the need for balance in protecting the public from potentially infectious blood and the very real potential of a reduction in available blood donors leading to blood shortages in the US. The estimated impact of this proposal is a 4.6 to 5.3% loss of donors, a 72% reduction of the current risk of infection and a 91% reduction of the total risk of infection.

Regarding topic number two (the safety of FDA regulated plasma derivatives prepared in establishments using the same manufacturing equipment to process European and US plasma) there was much discussion on the lack of data by which a risk assessment can be determined. Following are the questions asked of the Committee and their answers:

Q. What is the risk of variant Creutzfeldt-Jakob disease (vCJD) from campaigned manufacturing involving exposure to European plasma?

A. The risk of vCJD is unknown but probably low.

Q. Does the Committee believe that additional steps should be taken to address the use of common manufacturing lines for European and US plasma?

A. The Committee feels that segregation of manufacturing is a complex issue and it requires further FDA study.

Q. Should FDA consider labeling plasma to identify manufacturing operations that may involve exposure to European plasma?

A. Additional labeling should be considered, but a vote was not taken on this matter.

Q. Should FDA consider requiring additional decontamination procedures?

A. Advanced cleaning is a worthwhile endeavor but the subject needs additional research relevant to the facilities in question. Validation methods would need to be developed.

Q. Should FDA consider requiring the use of dedicated lines?

A. The opinion was that dedicated lines should not be mandated.

While topics one and two dealt with policy, topic number three (a report on the interim results of a new study on the inactivation of the TSE agent by the manufacturing process of gelatin) dealt with science. Michel Schoentjes, Ph.D. Vice President of the Gelatin Manufacturers of Europe (GME) presented a global overview of gelatin manufacturing. See side story, *How Gelatin Is Made From Bone*, on the facing page.

The GME association represents 11 member companies operating 27 gelatin plants (21 plants in Europe, three plants in the US and three plants outside Europe and the US). GME plants produce 45% of the world's gelatin. The US requires 10,000 metric tons of gelatin a year for the capsule industry, yet the available gelatin production from the US is only 5,000 metric tons. This requires the need for an additional 5,000 metric tons which must be imported.

In Europe, the safety of the raw materials used for gelatin production is assured by:

- Raw materials being taken from only healthy animals;
- Animals only being slaughtered in slaughterhouses;
- The animals being declared as fit for human consumption after anti and post mortem inspection;
- The animals being certified by official veterinary authorities;
- A documented traceability of the animals; and
- The slaughterhouses being audited by veterinary authorities and by the gelatin manufacturers.

The major European regulations for preventing TSE risk are:

- A total ban on using animal meat and bone meal as feed material and also a selective ban of animal fats as feed material;
- BSE testing of at-risk animals and all animals above 30 months of age;
- Mandatory destruction of affected animals or herds;
- Removal and destruction of specified risk materials;
- A ban of ruminant by-products as fertilizers;
- A classification according to geographical BSE risk status; and
- A ban of ruminant derived gelatin and by-products in animal feed.

Robert Rohwer, Ph.D. presented an overview and preliminary report on the status of validating the inactivation of the TSE agent by heat and pressure. The validation study was carried out to determine the safety of gelatin manufactured from bovine bones by a novel heat and pressure process with regard to the transmissible agent that causes bovine spongiform encephalopathy (BSE) in cattle. In this process the raw bone material is autoclaved at 133°C for 20 minutes. Starting with bone that was artificially contaminated with BSE infected mouse brain, gelatin was manufactured in a laboratory scale model of the process. The infective titre of the obtained gelatin was determined by mouse bioassay. Until now, more than 400 days past injection, none of the mice inoculated with the extracted gelatin has shown signs of TSE. ■

—William Stoedter

How Gelatin Is Made From Bone

The industrial process of producing gelatin starts with bones of animals fit for human consumption being obtained from the slaughterhouse. The skull and spinal column are used in the US process but not used in the European process. The bones are finely crushed and stirred for 20 minutes with 90° C hot water to remove grease and tissue. The wet crushed bone is dried in a stream of hot air such that the bone does not exceed a temperature of 85° C. The dried bone is then mechanically sorted to remove small pieces and the fraction below economic usability.

The bone material is then de-mineralized by soaking in a Hydrochloric Acid solution (the minerals can be removed from the acid solution and are used in the making of "bone china"). The resulting bone or "ossein" looks like bone but is porous and elastic. The ossein is then soaked for 2–3 weeks in a weak alkaline solution. After the solution is neutralized, the crude gelatin is heated to 60° C, then 70° C, then 80° C and the different grades of gelatin are extracted at each temperature with the better grades being extracted at the higher temperatures.

The gelatin extract is then filtered though diatomaceous earth to remove particles and impurities. Ion exchange with cation and anion resins is then used to remove salts from the extract. Using Ultra High Temperature (UHT), the extract is sterilized for at least four seconds at 130 to 140° C. Finally the water content is evaporated to produce solid gelatin.

Did You Get the News?

As a new member service, monthly PDA e-Updates will be sent to keep members apprised of activities, deadlines and other important issues. However, more than 30% of the PDA membership does not have an e-mail address on file. Members may add or update their e-mail addresses (as well as other contact information) by completing the form on page 29, or by sending this information by e-mail to info@pda.org.

E-mail updates on time-senstive issues will be released as needed. Be assured that we are taking every measure to use this communication vehicle judiciously (we won't bury you in e-mails). And, if you do not wish to receive the PDA e-Update, you may exercise an "opt out" at any time (opt out must be performed by direct link from the e-mail). ■

EU Revises Media Fill Requirements

Annex 1 Change

In a small but notable change, the European Commission (EC) has released a revision of paragraph 42 of Annex 1, "Manufacture of Sterile Medicinal Products". Revised paragraph 42 falls under the section on aseptic processing and addresses validation requirements, process simulation and media fills. According to the EC Web site, the changes were made following discussion in the EU inspectors working group in order to take account of current practices. Changes affect media fill acceptance criteria and the connection of validation to production shifts. These changes have necessitated three additional entries in the glossary of the Annex: Action Limit, Alert Limit and Media Fill.

It is unclear if there was any industry or public consultation/comment before the changes were made. It is also unclear of the impact of the changes across the affected industry, and how quickly the changes may be implemented by inspectors.

In order to aid readers in identifying the actual changes, a 'document compare' version of paragraph 42 follows. The strikeout text is deleted; the underlined text is the new wording. For copies of the change and the complete version of Annex 1, visit the EC Web site, http://pharmacos.eudra.org/F2/pharmacos/docs.htm#news. (Note: this is the 'News' section of the Web site, not the GMP section.) ■

—James C. Lyda

Guide to Good Pharmaceutical Manufacturing Practice
Annex 1
Paragraph 42

Strike through version showing amendments from initial version

42. Validation of aseptic processing should include a process simulation test ~~simulating the process~~ using a nutrient medium (medium fill). Selection of the nutrient medium should be based on dosage form of the product and selectivity, clarity, concentration and suitability for sterilisation of the nutrient medium. ~~The form of the nutrient medium should generally be equivalent to the dosage form of the product.~~ The process simulation test should imitate~~,~~ as closely as possible the routine aseptic manufacturing process and include all the critical subsequent manufacturing steps. It should also take into account various interventions known to occur during normal production as well as worst case situations. Process simulation should be performed as initial validation with three consecutive satisfactory simulation tests per shift and repeated at defined intervals and after any significant modification to the HVAC-system, equipment, process and number of shifts.~~-~~ ~~equipment and process~~. Normally process simulation tests should be repeated twice a year per shift and process. The number of containers used for ~~a medium fill~~ media fills should be sufficient to enable a valid evaluation. For small batches, the number of containers for the medium fill should at least equal the size of the product batch. ~~The contamination rate should be less than 0.1% with 95% confidence level.~~ The target should be zero growth but a contamination rate of less than 0.1% with 95% confidence limit is acceptable. The manufacturer should establish alert and action limits. Any contamination should be investigated.

A_3P 14th Congress

Biarritz, France
October 24–26, 2001

The Association Pour les Produits Propres et Steriles (Association for Clean and Sterile Products or A_3P), a PDA ally in Europe, is hosting their 14th International Congress in Biarritz, France in late October. The three-day program begins with plenary sessions on the first day, including a presentation by PDA's Russell Madsen on current validation concepts. Day 2 features 10 workshops on various technical topics. The final day concludes with reports on the workshop outcomes and a series of plenary presentations, with adjournment at 1:00 pm. As with past A_3P conferences, there will be a gala dinner on the 2nd night. The food and hospitality promise a memorable experience.

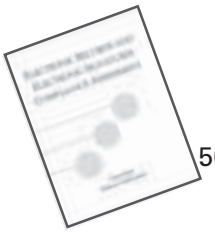
The plenary portions of the program are presented in French and English. There will be simultaneous interpretation into French, English and German. The workshops on day two are all in French except Nr. 3 on validation of cleaning processes and Nr. 8 on process isolators, both of which will be conducted in English. For more information contact Frederic Estassy, A_3P Services, Le Gros Moulin, F-45200 Amilly, France, email info@a3pservices.com, tel +33 (0) 238 071 071, fax +33 (0) 238 071 072. You can also visit the A_3P Web site, www.a3pservices.com. ■

—James C. Lyda

New Books
New Books
New Books

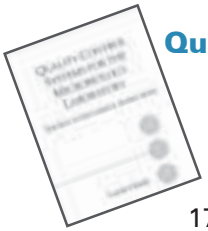
PDA
An International Association For Pharmaceutical Science And Technology

from PDA and Davis Horwood International Publishing, Ltd.



Electronic Records and Electronic Signatures
by Chris Reid and Barbara Mullendor
50 Pages | $99.00 | Item No. 17177

Understanding GMP: An Expert's View on Merging Global Regulatory and Manufacturing Perspectives
by Martyn Becker
224 Pages | $119.00 | Item No. 17174

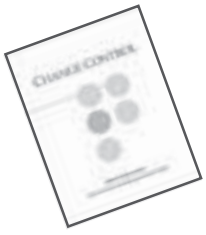


Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections
by Lucia Clontz
175 Pages | $119.00 | Item No. 17176

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry
by James Vesper
224 Pages | $119.00 | Item No. 17191

The Internal Quality Audit
by Monica Grimaldi and Janet Gough
100 Pages | $119.00 | Item No. 17179

Microbiology for Pharmaceutical Manufacturing
Edited by Richard Prince
900 Pages | $279.00 | Item No. 17185



Change Control
by Sören Schwartze
40 Pages | $80.00 | Item No. 17189

New Books
New Books

For additional information, or to place an order, please contact PDA.

Tel: (301) 986-0293 • Fax: (301) 986-1093 • E-mail: info@pda.org • Web site: www.pda.org

PDA Science and Technology Activity Update

GMP Audit Repository

PDA's Science Advisory Board (SAB) discussed expanding the PDA TR 32 program to GMP auditing of raw material and packaging component suppliers and contract manufacturers. SAB believes the concept deserves further study and will do this at future meetings. It can be based on the process model for computer and software suppliers (PDA TR 32).

ISO/DIS14644-7

PDA Isolation Technology Task Force submitted comments to the ISO/DIS14644-7 Cleanrooms and Associated Controlled Environments – Part 7: Separative enclosures (clean air hoods, gloveboxes, isolators and minienvironments) Date 2001-02-22 on June 29, 2001. The comments are available on the PDA Web site.

PIC/S PE 004-1 (Draft 2)

PDA's Isolation Technology Task Force is developing comments to the PIC/S PE 004-1 (Draft 3), 12 June 2001, "Recommendation on Isolators Used for Aseptic Processing and Sterility Testing." Comments on the document, which are available on the PIC/S Web site at http://www.picscheme.org, are due September 30, 2001.

Aseptic Processing Survey

This survey is intended to update the PDA survey on aseptic processing practice. Previous PDA surveys on this subject were conducted in 1992 and 1996 and published in the following years. The survey instrument is in final stages of revision and the survey should go out in August, once the distribution list is finalized. The results of the survey should be available to the membership by the end of the year.

Aseptic Processing Task Group

This task group plans to develop a PDA technical report focusing on the key issues addressed at the Environmental Monitoring Aseptic Processing Forum (August 21, 2000) as well as other sections of the FDA 1987 Aseptic Processing Guideline which may no longer be appropriate with current technology. The task group has met several times and the draft is being finalized.

Part 11 Task Group

The primary objective of the task group is to endorse, for the pharmaceutical industry, electronic record keeping practices, including signatures, which make sense for regulated pharmaceutical and device manufacturers and which are compliant with 21 CFR Part 11. The secondary objective of the task group is to propose two models for achieving compliance with best practice and regulations resulting in a win-win for all stakeholders (one specific to existing systems and the other model specific for new systems). A full schedule of task group meetings has been established and the group estimates completion of the technical report by the end of 2001.

Revision of Technical Monograph No. 13

PDA's Environmental Monitoring Task Force has completed work on the revision of Technical Monograph No. 13, "Fundamentals of a Microbiological Environmental Monitoring Program." The extensively revised report replaces the current edition, which was originally published in 1990. The report is scheduled for publication as a supplement to the *PDA Journal of Pharmaceutical Science and Technology* and will be available free of charge to all PDA members.

Revision of Technical Report No. 18

A PDA task group under the leadership of Ed Crosson and Michele Pontinen is revising PDA Technical Report No. 18, "Validation of Computer-Related Systems," to ensure it is consistent with Part 11 and other recent technical publications. The task group plans to complete the project by the end of 2001.

Validation of Isolation Technology, TR 34

PDA's Isolation Technology Task Force representing US pharmaceutical companies and members of the Parenteral Society, A3P, R3-Nordic and PDA's Japan Chapter has completed work on PDA Technical Report No. 34, "Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products." TR 34 is scheduled for publication as a supplement to the *PDA Journal of Pharmaceutical Science and Technology* and will be available free of charge to all PDA members.

Validation of Steam Sterilization Cycles (Revision of)

The PDA Steam Sterilization Validation Task Force is revising Technical Monograph No. 1. This revision will provide comprehensive information on the validation of moist heat sterilization processes and will attempt to resolve the differences in approach that have developed between Europe and the US. Target for completion is the end of 2001. ■

—Russell E. Madsen

Stopper Inoculation and Biological Indicators

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 and join.

This month's posting…

Dear Forum,

Recently I have been discussing the methods of validating stoppers. One of the principle questions that is being asked is, "Do you inoculate your stoppers or use BI's?"

Response 1

For a previous company I worked with, we inoculated the stoppers with spore suspension aliquots and let it air dry.

Response 2

I have seen both methods used for validating the sterilization of stoppers. When the stoppers were placed in autoclave pouches, a BI was placed in various pouches based upon the load configuration. This was used for validating the autoclave cycle. An inoculated stopper can be used, however, it might be best to use a stopper of a different color (same material) so it can easily be identified. The inoculated stopper method was also used to validate the large type stopper washer/siliconizer/sterilizer units. Again, a different color stopper used to be able easily identify the stopper in a large load of stoppers.

Response 3

From experience in working with many companies, direct inoculation of the stopper is common practice. Your choice of bacterial spore to use and validate is of major importance. A dual inoculation with moist heat resistance spores and also dry heat resistance in spore selection should be considered. B. stearothermophilus with a lower D_{121} could be used or an alternative such as subtilis 5230.

Response 4

If you are talking about sterilization of stoppers, yes, the stoppers need to be inoculated with at least 1,000,000 cells/stopper of B. stearothermophillus to challenge the sterilization process. If you are talking about the washing process for stoppers, we validated the stopper washing process by spiking the stoppers with 10,000 EU of endotoxin per stopper.

Response 5

The substrate material has a significant effect on biological indicator resistance, so I would not suggest using a different color stopper. We thread fishing line or other suitable material through the stopper to make it easy to identify and recover. This works for stopper washers, but I can't testify as to how the fishing line holds up in autoclaves. Stainless steel wire certainly serves as an alternative for autoclave cycles.

Response 6

Has anyone carried out a comparative study on direct inoculation vs. spore strips? Although "many companies" validate by directly inoculating stoppers with spores, has anyone who does this established whether it is truly worst case?

Response 7

There is a published article in the *PDA Journal* that shows that it is dependent upon the stopper formulation. For some stoppers, it is a significantly more stringent test.

Response 8

There is no contest; direct inoculation is significantly more "worst case." Validation is simple. Verify the D-value of a lot of spore strips. Inoculate the stoppers with a known amount, then determine the D-value of the spores on the stoppers. You will notice that the carrier makes a significant difference and that the rubber insulates the spores much more than paper.

Response 9

We have seen D-values jump by a factor of 2 when spores from a batch are inoculated onto a paper carrier (strip) and compared to the same batch inoculated onto stoppers. The surface of (many) stoppers is irregular and can allow spores to become insulated in a crevice. Placing a spore strip in with your bag of stoppers simply does not give the same information as direct inoculation of the stoppers. ■

—compiled by Russell E. Madsen

"There is a published article in the *PDA Journal* that shows that it is dependent upon the stopper formulation. For some stoppers, it is a significantly more stringent test."

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

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

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

Member Info

Please type or print clearly

Last Name _____

Mr.❍ Ms.❍ Dr.❍ First Name _____ MI_____

Job Title _____

Company _____

Address _____

City _____ State/Province _____

Country _____ Zip+4/Postal Code _____

Business Phone# _____ Fax# _____

E-mail _____

Member Profile

Business Environment (check only one)

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

Professional Interest (check all that apply)

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

Payment (US Dollars Only)

Please note: *Contributions or gifts to PDA are not tax-deductible as charitable contributions. However, they may be deductible as ordinary and necessary business expenses.*

Individual Membership $150. Please check the appropriate box:

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

(must be net of all bank charges; include member name) Instructions: SunTrust Bank, ABA #051000020, PDA Account #209364254, Swift#UVBIUS33

Account Number _____ Exp. Date _____

Name _____
(exactly as on card)

Signature _____ Date _____

Federal Tax I.D. #52-1906152

LTR 08/01

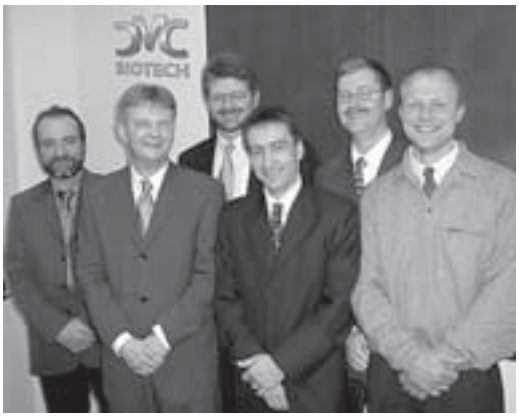
PDA USE:
Date:_____ Check:_____ Amount:_____ Account:_____

Company, Colleague & Product Announcements

James D. Watson, Ph.D., Nobel Prize winner for discovering the structure of DNA, was the keynote speaker at the opening of **Pall Corporation's** new Life Sciences laboratory complex located in Portsmouth, UK. The new suite of laboratories is designed to culture and handle genetically modified organisms and products including both mammalian and microbial cell lines. Eric Krasnoff, Pall's Chairman and CEO, said, "We are highly focused on biotechnology, genomics and proteomics. Pall has invested in key technologies to accelerate our customers' ability to bring new products to market faster. The opening of this laboratory, just one part of our commitment to provide the full spectrum of filtration, purification and separations technologies for our life sciences customers." For more information, contact Patrice Radowitz at (516) 484-3600 x6111 or pat_radowitz@pall.com.

Opening of Pall Laboratory in Portsmouth (L-R): Dr. Charles Lutsch, Aventis Pasteur; Dr. James D. Watson; Dr. David Sherwood, Lonza Biologics; Neil MacDonald, Pall Life Sciences.

Anders Vinther, Ph.D. (photo, top right—second from right) member of the PDA Regulatory Affairs/Quality Committee, committee member of various PDA conferences/task forces and chairman of PDA OOS and Analytical Procedures and Methods Validation Task Force Groups—and five colleagues from Danish based Novo Nordisk & Novozymes have founded CMC Biotech A/S. The six founders have 75+ years of combined experience in the biotech industry in facility design and operation, microbial fermentation, recovery, purification and QA/QC. Funded by venture investment from BankInvest, the primary focus of CMC Biotech A/S is to set up an Active Pharmaceutical Ingredient (API) Contract Manufacturing Organization (CMO) in the greater Copenhagen area of the Medicon Valley region. The company is currently designing its own facility which will be used for process development and production of clinical trial API material based on mammalian



cell culture and microbial fermantation. CMC Biotech A/S also offers lab-scale process development and consulting in the areas of process development & validation as well as GMPs for laboratories, API production and production development, and quality systems. For further information contact Anders Vinther at av@cmcbiotech.com or visit the Web site www.cmcbiotech.com.

Tefen, a consultancy specializing in Operational Improvement within the Pharmaceutical and Biotechnological industries, is launching a global benchmarking survey of QC Laboratories to establish best practice levels within the industry. The study will focus on 15 metrics including Overall Lab Effectiveness, Analyst Utilization, Analyst Efficiency, Cycle Time, On-time Delivery and Costs. The full list of metrics can be viewed in detail at www.tefen.com/benchmarking. So far the survey has attracted major blue chip corporations as well as single site contract laboratories. Tefen is inviting companies of any size to take part. Further details, including an information packs, are available by request at info@tefen.co.uk. The first set of results are to be presented to participants in the first quarter of 2002, while sample results will be published via PDA for non-participants to view. For more information, contact Nick Morgan at 0208 902 9200 x106 or nickm@tefen.co.uk.

PharmaNet, Inc., (www.pharmanet-cro.com), an international drug development company, announced the addition of **Julia Lukas Gorman** and **Steven Koepke, Ph.D.**, to the company's Consulting Group based in Washington, DC. Gorman joins PharmaNet as an Associate Director of Con-

sulting. She previously was with the FDA for 12 years, most recently as Branch Chief, Manufacturing Review Branch 1, Division of Manufacturing and Product Quality within CBER. Koepke joins PharmaNet as Director of Consulting after nine years with the FDA. Most recently, Koepke was Deputy Director, Division of New Drug Chemistry with CBER. For more information call (609) 951-6800 or visit www.pharmanet-cro.com. ■

—Joe Bury

Send us your news . . .

. . . address news releases to Joe Bury via e-mail at bury@pda.org or mail hard copy to PDA headquarters in Bethesda.

2001 PDA Annual Meeting continued from cover

managers. Details on these and all PDA-TRI offerings can be found at www.pda.org.

Make your hotel reservations now! Discover the perfect balance of landmark charm and modern sophistication, in a historic Washington setting at the Marriott Wardman Park Hotel.

- Located in a prestigious Washington neighborhood; just minutes from all the sites and sounds of the nation's capital.
- Eight miles from Reagan Washington National Airport and just steps to on-site Metro stop.

Marriott Wardman Park Hotel

2660 Woodley Road, NW
Washington, DC 20008
(202) 328-2000 Reservations
(800) 228-9290
(202) 234-0015 (Fax)

Be sure to advise the reservationist that you are attending PDA's Annual Conference, to ensure the discounted rate.

$185.00 Single
$205.00 Double
Each Additional Person $20

Cut off Date: November 9, 2001

Check in Time: 3:00 pm Check out 12:00 noon.

To register, or for additional information, please visit our Web site at www.pda.org. ■

—Leslie Zeck

Basel 2002: PDA International Congress, Courses and Exhibition

Adding Value to the Pharmaceutical Industry—Leveraging the Future

Convention Center Basel, Switzerland
February 11–13, 2002 Congress and Exhibition
February 14–15, 2002 Courses

PDA is proud to once again present its prestigious international Congress in Europe, an event that will attract more than 500 international professionals and scientists in the parenteral, sterile products, biotechnology and related fields. Make your plans now to be in Basel, Switzerland in February 2002 for the conference, *Adding Value to the Pharmaceutical Industry—Leveraging the Future.* High-level education and dialogue among industry and regulatory experts, with an emphasis on manufacturing in Europe, will be offered. The conference will be of significant value to individuals interested in the future of pharmaceutical science and technology, including those engaged in manufacturing, production, quality assurance/quality control, engineering and maintenance operations, facility design, product and process development, scale up, validation, compliance and regulatory affairs, and research and development. Don't miss this unique opportunity to hear presentations on the latest science and technology related to:

- **Regulatory Issues**
  Compliance - GMP for clinical supplies, new FDA and EMEA guidance documents, electronic signatures, Active Pharmaceutical Ingredients GMPs, lab topics - Investigating Out of Specification Results;
- **Harmonization Issues**
  International inspections, contract manufacturing, Mutual Recognition Agreement, International Conference on Harmonization, Common Technical Document, pharmacopeial harmonization issues;
- **Technological Issues**
  New technologies - validation and acceptance by regulatory authorities, facility design, utilities, isolators, filtration, environmental monitoring, rapid microbial testing methods, new drug delivery systems;
- **Validation Issues**
  Validation and regulatory acceptance of new technologies, cleaning validation, process validation, facility design, utilities, isolators, steam sterilization, parametric release, filtration, cost reduction; and
- **Biotechnology Issues**
  Improved/new process technologies, validation of virus and prion detection and removal, multi-use facilities, process changes/comparability, high-(bio)tech generics, second-generation molecules, cleaning validation, process validation vs. testing, accepting new analytical technologies, biological vs. chemical purity, bioassays, harmonization topics - ICH Q6B: Specification: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products.

About Basel

Basel, a city canton with nearly 200,000 people and 2000 years of history, is located at the elbow of the Rhine on the borders of France and Germany. It is the centre of the pharmaceutical industry and the site of major trade fairs. The Hotel Le Plaza, Messeplatz 25, Postfach, CH-2041 Basel, Switzerland is conveniently located to the Convention Center Basel. Detailed reservation information will be furnished in future announcements.

The full agenda and a list of papers to be presented for this conference are available on PDA's Web site at www.pda.org.

Educational Courses

The PDA Training and Research Institute (PDA-TRI) provides unprecedented education, training and applied research in pharmaceutical sciences and associated technologies. PDA-TRI offers courses at their US facility in Baltimore, MD and throughout the world. The course structure is associated with core competencies that are designed to maintain and advance knowledge within the biopharmaceutical sciences and technology, including analytical chemistry, biotechnology, computer science, formulation pharmacy, informatics and communication, laboratory methods and assays, new technologies, process engineering and manufacturing product design and development, regulatory affairs, sterilization technology and training. Courses providing in-depth education on technology topics relating to the Congress will be held on February 14–15 following the Congress.

Exhibits

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

Nahid Kiani
PDA
7500 Old Georgetown Road
Bethesda, MD USA 20814
Tel: (301) 986-0293 x128
Fax: (301) 986-0296
E-mail: kiani@pda.org ■

—Leslie Zeck

PDA Isolation Technology Conference

October 15–17, 2001 • Hilton East Brunswick • East Brunswick, New Jersey

PDA will host a follow-up to the October 2000 conference on isolation technology issues held in Irvine, California. The East Brunswick, New Jersey conference will be of significant value to individuals involved in the design and construction of isolators; production sterile products, clinical supplies, active pharmaceutical ingredients, radiopharmaceuticals toxic compounds; and/or those responsible for corporate environmental safety.

Participants will discuss the following critical isolator issues:

- Sterility testing in isolators, including various types of isolators, a range of test volumes, and various types of products;
- Containment of potent compounds and the application of isolators for the protection of workers handling potent, and/or toxic materials;
- Isolators for manufacturing/filling in biotechnology, clinical supply manufacture, process development, and small-scale production;
- Isolators for high speed filling, with a focus on the use of open isolators for the filling of glass containers—case studies, design and operating issues will be discussed;
- Environmental monitoring, with a discussion of viable and non-viable monitoring of isolators used for aseptic operations;
- Cleaning of isolators especially those utilized for containment applications;
- Operational issues such as leak testing, glove integrity, safety interlocks, etc.; and
- Discussion of current regulatory issues.

Visit PDA's Web site at www.pda.org for additional information on this important conference. ■

—Leslie Zeck

PDA/FDA Viral Clearance Forum

October 1–3, 2001 • Hyatt Bethesda, Bethesda, MD

PDA, in collaboration with FDA, will host a Viral Clearance Forum on October 1–3, 2001 in Bethesda, Maryland. This three-day workshop will offer opportunities for discussion of current guidance, critical issues and approaches to viral clearance issues for biologics. The meeting will bring together representatives from the US FDA and international regulatory agencies, academicians, pharmaceutical/biotechnology manufacturers, manufacturers of enabling technologies and contract testing organizations (CTOs).

One representative from the FDA and one representative from industry will moderate each session. Session topics include:

- Overall process Validation: Regulatory Issues;
- Virus Challenges: Preparation and Standardization;
- Virus challenges: Choices;
- Standardization of Assays: Critical Issues and Potential Problems;
- Virus Assays: Regulatory and Technical Issues;
- Evaluation of Discrete Steps: Regulatory Issues;
- Filtration: Technology and Performance;
- Filtration: Applications and Validation;
- Generic Approaches to Virus Removal & Inactivation; and
- Chromatography Reuse.

A regulatory overview of considerations for designing and implementing programs to ensure viral safety of biologics (including biotechnology products) will be provided. Hannelore Willkommen of the Paul-Ehrlich-Institut will present a European perspective, including elements that are sometimes missed in applications. Glenda Silvester of the EMEA, and Dr. Takao Hayakawa, Director, Division of Biological Chemistry and Biologicals at the National Institute of Health Sciences, Japan, have also been invited to share global perspectives. Key industry researchers will discuss the implementation of new technologies and divergence in strategy between product classes.

The goals of the conference are to:

a. Discuss the current state of the art and new viral removal technologies, including filtration, chromatography and inactivation technologies;
b. Discuss current issues related to the reuse of chromatographic columns and the impact on viral clearance requirements;
c. Discuss the need to define specifications for viral preparations to be used as controls in spiking and infectivity assays and to standardize or validate traditional infectivity assays; and
d. Discuss the need to standardize traditional PCR, PERT and real-time PCR-based assays as well as microbial PCR assays and host cell DNA assays.

Networking receptions with poster presentations will be held on Monday, October 1 and Tuesday, October 2, 2001. ■

—Leslie Zeck

Participation in this conference is limited and is expected to SELL OUT. Ensure your ability to partake in the discussions with leading regulatory representatives by registering today. For additional information, or to register for this conference, visit PDA's Web site at www.pda.org.

Registration Form

2001 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibit

September 10-14, 2001 Hyatt Regency Washington on Capitol Hill, Washington, DC

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

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

Job Title Membership Number (if known)

Company (indicate full company name)

Business Address

City State/Province Zip + 4/Postal Code Country

Business Phone Fax E-mail

☐ Substituting for

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

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

	PDA Member	Nonmember	Government/Academic
Full conference (9/10-9/12) *(includes Monday reception; does not include optional breakfast or lunch)*	☐ $895	☐ $1,045	☐ $350
Monday only (9/10) *(includes Monday reception; does not include optional breakfast or lunch)*	☐ $395	☐ $545	☐ $250
Tuesday only (9/11) *(does not include optional breakfast or lunch)*	☐ $395	☐ $545	☐ $250
Wednesday only (9/12) *(does not include optional breakfast or lunch)*	☐ $295	☐ $445	☐ $150

Course Registration	PDA Member	Nonmember
PDA-TRI COURSE #499: PDA Audit Process Model Management Overview Training (9/13)	☐ $380	☐ $530
PDA-TRI COURSE #486: Improving Sterile Drug Submission to the FDA (9/13)	☐ $680	☐ $830
PDA-TRI COURSE #414: How to Design an Effective Regulatory Training Program (9/13)	☐ $380	☐ $530
PDA-TRI COURSE #361: Cleanroom Management (9/13-14)	☐ $1,010	☐ $1,160
PDA-TRI COURSE #469: Assay Validation (9/14)	☐ $680	☐ $830
PDA-TRI COURSE #350: Strategic and Practical Approaches to Part 11 Compliance (9/14)	☐ $680	☐ $830

TOTAL CONFERENCE AND COURSE FEES $_____

Optional Event Registration	
Monday Breakfast B1: Orientation to FDA (9/10)	☐ $25
Monday Breakfast B2: FDA Biologics Deviation Reporting (9/10)	☐ $25
Monday Roundtable Lunch L1: Isolator User Issues (9/10)	☐ $30
Monday Reception (9/10) – *Extra Ticket needed*	☐ $70
Tuesday Breakfast B3: Intro. To Global Health Authorities (9/11)	☐ $25
Tuesday Breakfast B4: Intro to Audit Repository Center (9/11)	☐ $25
Tuesday Roundtable Lunch L2: Writing a Quality Agreement (9/11)	☐ $30
Wednesday Breakfast B5: How to Communicate Effectively with FDA (9/12)	☐ $25
TOTAL OPTIONAL EVENT FEES	$_____

3. Please check the appropriate box

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

Account Number_____ Exp. Date_____

Name Exactly as on Card _____

Signature_____ Date_____

4. Return completed form with payment (payment must be included to be considered registered) made to:

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

Federal Tax I.D. #52-1906152

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

Please tell us how you learned about this event

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

Business Environment (check one)

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

Professional Interest (check all that apply)

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

Confirmation: Written confirmation will be sent to you once payment is received. You must have written confirmation to be considered enrolled in a PDA event. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time. If you are pre-registering as a substitute attendee, indicate this on the registration form. A nonmember substituting for a member must pay the additional fee. **Refunds:** Refund requests must be made in writing. Registrants whose written requests for refunds are received at PDA on or before **August 10, 2001** will receive a full refund less a $35 (US) processing fee. Registrants whose written requests for refunds are received after **August 10** and on or before **August 24** will receive 50% of the registration fee. After that, no refunds can be made.

PDA Use: Date:_____ Check #:_____ Amount:_____ Account:_____ **LTR 08/01**

REGISTRATION FORM PDA/FDA Viral Clearance Forum

October 1-3, 2001 ❖ Hyatt Regency ❖ Bethesda, Maryland

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

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

Job Title Membership Number (if known)

Company (indicate full company name)

Business Address

City State/Province Zip + 4/Postal Code Country

Business Phone Fax E-mail

☐ Substituting for

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

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

	PDA Member	Nonmember	Government/Academic
Full registration (10/1-3)	☐ $995	☐ $1,145	☐ $275
Monday only (10/1): *includes lunch and reception*	☐ $450	☐ $600	☐ $175
Tuesday only (10/2): *includes lunch and reception*	☐ $450	☐ $600	☐ $175
Wednesday only (10/3): *includes lunch*	☐ $350	☐ $500	☐ $150
TOTAL FEES			$_____

Full Forum Registration Includes: Forum reference materials on site, Lunch each day, Reception and Poster Session on October 1 and October 2.

Government/Academic: You must be an employee of an official government agency or accredited university to quality for this discounted rate.

3. Please check the appropriate box

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

Account Number_____ Exp. Date_____

Name Exactly as on Card _____

Signature_____ Date _____

4. Return completed form with payment (payment must be included to be considered registered) made to:

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

Fax: (301) 986-1093 (Credit Cards Only)

Federal Tax I.D. #52-1906152

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

Confirmation: Written confirmation will be sent to you once payment is received. You must have written confirmation to be considered enrolled in a PDA event. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time. If you are pre-registering as a substitute attendee, indicate this on the registration form. A nonmember substituting for a member must pay the additional fee. **Refunds:** Refund requests must be made in writing. Registrants whose written requests for refunds are received at PDA on or before **September 1, 2001** will receive a full refund less a $35 (US) processing fee. Registrants whose written requests for refunds are received after **September 1** and on or before **September 15** will receive 50% of the registration fee. After that, no refunds can be made.

Please tell us how you learned about this event

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

Business Environment (check one)

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

Professional Interest (check all that apply)

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

LTR 08/01

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

2001 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibit

Emerging Global Regulatory Issues

Nearly Sold Out! Don't Hesitate to Register for this Important PDA Event!

September 10–14, 2001
Hyatt Regency Washington on Capitol Hill • Washington, DC

Join PDA for this popular two-and-a-half day annual conference focusing on regulatory issues and cutting-edge topics that impact our industry. The PDA/FDA Joint Regulatory Conference provides a unique opportunity to interact with all levels of FDA staff including division directors, local inspectors and scientists. Prepare in advance by submitting your technical and regulatory questions for the FDA and industry panelists and your colleagues. PDA is pleased to announce the confirmed participation of these FDA officials at the conference:

David Asher, FDA, CBER
Jean Blackston Hill, Chemist, ORA
Frederick Blumenschein, Chief, Case Management and Guidance, CDER, Office of Compliance
Robert Coleman, Local District Inspector
Peter H. Cooney, Ph.D., Associate Director, Microbiology, FDA, CDER
Marie T. Falcone, Small Business Representative, Central Region, Office of Regulatory Affairs
Joseph C. Famulare, Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER
David Hussong, FDA, CDER
Brenda Kiliany, Consumer Safety Officer, CDER
Randy Levin, FDA, CDER
Murray Lumpkin , FDA, CDER
Steven A. Masiello, Director, Office of Compliance and Biologics Quality
Lorrie Harrison McNeill, Public Affairs Specialist, CBER
Sharon O'Callaghan, CBER, Office of Compliance and Biologics Quality
Michael Ortwerth, FDA, CDER
Paul Stinavage, FDA, CDER
Helen N. Winkle, Acting Director, Office of Pharmaceutical Sciences, CDER
Robert A. Yetter, FDA, CBER

Conference highlights include interactive forums focusing on issues related to:

- Analytical Lab Inspections;
- BSE/TSE;
- Computer Systems Validation;
- GMPs in Development;
- Hot Topics in Aseptic Processing;
- Part 11;
- Preparing for Inspections;
- Process Validation for Biologics/Drugs;
- Revalidation of Existing Facilities and Processes;
- Risk Management; and
- Systems-Based Inspections.

Plenary sessions will address:

- Emerging Global Regulatory Issues: An FDA Perspective;
- EU Regulatory Issues Update;
- Progress on the MRA; and
- Impact of EU Regulations on US Firms.

Optional networking breakfasts and luncheons will focus on:

- FDA 101: An Introduction to Working with the Agency;
- Introduction to Global Health Authorities;
- Introduction to ARC;
- How to Communicate Effectively with the FDA;
- Isolator User Issues; and
- Writing Quality Agreements.

Tabletop exhibits will feature the latest technologies, products and services. Participate in PDA's networking "Dine-Around" dinners at some of Washington's most exclusive restaurants.

Training courses will again be offered this year. Six separate offerings will be presented. In keeping with the thrust of the conference, the courses all deal with compliance issues in some way:

- New Drug Submissions;
- Assay Validation;
- Part 11 Compliance;
- CGMP Training Programs; and
- Cleanroom Management.

The courses are targeted for all levels of personnel in the organization. As is the case with all PDA-TRI training courses, participants will leave these sessions with concrete goals designed to improve the compliance posture of their organizations. More details on these and all PDA-TRI course offerings can be found on PDA's Web site at www.pda.org.

This highly interactive conference will be of professional value to all 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.

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

—Leslie Zeck

Hyatt Regency Washington on Capitol Hill

400 New Jersey Ave., NW
Washington, DC 20001

Tel:
(202) 737-1234
(800) 233-1234

Fax:
(202) 942-1576

Rates:
$179.00 single/double

PDA
An International Association For Pharmaceutical Science And Technology

We Don't Want to Lose Touch with You!

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

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

Member Info

Please type or print clearly

Last Name _____

First Name _____ Middle Initial _____

Member Number (if known) _____

Degree/Credential _____

Job Title _____

Company _____

Address _____

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

Country _____

Business Phone# _____ Fax# _____

Do we have your current E-mail?

E-mail _____

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

Process Validation for Manufacturing of Biologics and Biotechnology Products: A State-of–the-Art Perspective

PDA anticipates more than 300 participants at its international conference on process validation for biologics, September 6–7, 2001 in Berlin, Germany. This conference, presented in collaboration with the International Association for Biologics (IABs), will provide a European platform for dialogue between European and US regulatory authorities, and the affected industry representatives, on the comparative technical and regulatory perspectives on process validation for biologics and biotechnology pharmaceutical products.

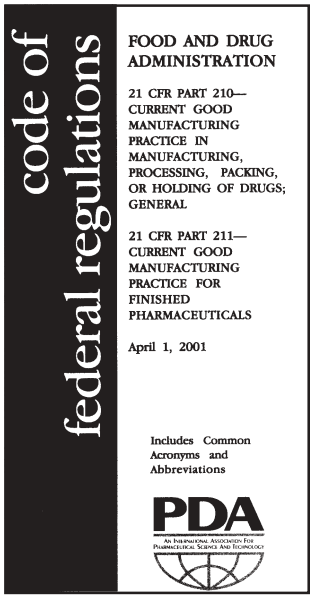
Regulatory officials from around the globe will participate in discussions on a range of topics covering validation throughout the product life cycle, as well as appropriate practices and requirements that will serve as a sound basis on which to connect comparability determination and process validation.

It's not too late to make your plans to participate! This conference will be of significant value to process scientists, manufacturing and quality professionals, regulatory affairs professionals, analytical chemists, process engineers, virologists and others. For the full registration brochure and hotel and registration information, please visit our Web site at www.pda.org.

If you are unable to participate, IABs will be publishing the conference proceedings which will be made available for ordering on PDA's Web site. ■

—Leslie Zeck

2001 CGMP Pocket Guide Now Available



To Order, use the form on page 44 or Contact PDA—www.pda.org (301) 986-0293

The popular "**CGMP Pocket Guide**" that is produced annually by PDA is **NOW AVAILABLE**. This new update contains **21 CFR Part 210**—Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General and **21 CFR Part 211**—Current Good Manufacturing Practice for Finished Pharmaceuticals (updated April 1, 2001). For your reference, a listing of common acronyms and abbreviations is included.

These handy Pocket Guides are a convenient way to keep 21 CFR Parts 210, 211 at your fingertips. Order now for yourself, your staff and your clients. Quantity discounts are available, plus you may order the Pocket Guides with your logo printed on the covers.

Quantity Discounts

Discounts are available for bulk quantities* (member prices; shipping and handling additional):

1–100 copies ..... $4 each
101–1,000 ..... $3 each
1,001+ ..... $2 each

* For an additional charge your booklets can be personalized to include your company logo on the cover. *Minimum quantities do apply, contact PDA for details.*

Item No. 13004

CGMP Pocket Guide to 21 CFR Parts 210, 211 (April 2001)
Single copy price is $4 member/$7 nonmember

To Order your copies use the form on page 44. Contact Janny Chua PDA at (301) 986-0293 ext. 127, chua@pda.org if you have questions.

For Personalized Orders Only, Contact Janet Raysick at PDA, (301-986-0293 ext. 120, raysick@pda.org).

2001 PDA Annual Meeting Exhibitors

AAI International
AAC Consulting
Abbott One 2 One
ABC Laboratories
Acculab/Accuqenix
Advanced Particle Systems
Akron, Inc./Taylor Pharmaceuticals
American Pharmaceutical Partners, Inc.
American Stelmi
Amersham Pharmacia Biotech Inc.
Anatel Corporation
Aqua-Chem Inc.
ART Instruments, Inc.
Associates of Cape Cod, Inc.
Automatic Liquid Packaging, Inc.
Baxter Healthcare Corporation
BD Diagnostic Systems
BD Pharma
Ben Venue Laboratories
bioMerieux, Inc.
Biolog, Inc.
Bioscience International, Inc.
Biotest Diagnostics
BioReliance
BioWhittaker
BOC Edwards Pharmaceutical Systems
Bosch Packaging Technology
Capmatic, LTD.
Carlisle Barrier Systems
Carltex, Inc.
Catalytica Pharmaceuticals, Inc.
Celsis Laboratory Group
Charles River Laboratories
Chase-Logeman Corporation
Chemunex, Inc
Chesapeake Biological Labs, Inc.
CimQuest, Inc.
Compliance Software Solutions Corp.
CompuPharma
Contract Pharma
Cook Pharmaceutical Solutions
Covance
CRB Consulting Engineers, Inc.
Cyrovac
Dabrico Inc.
Decon Labs, Inc.
Dickson
Disetronic Medical Systems
Duoject Medical Systems, Inc.
Dupont Qualicon
Ecolab, Inc.
Eisai USA, Inc.
Electro -Steam Generator Corp.
Ellab Inc.
EM Science
Environmental Tectonics Corp.
Evans Vaccines Limited
Evercan -Wilco
FDC Packaging
Froma Vitrum Inc.
Formatech, Inc.
Foss Nirsystems, Inc.
Gavin Pharmaceutical Services
General Econopak, Inc.
Genesis Machinery Products, Inc.
George Uhe Company
Getinge/Castle, Inc.
Groninger USA
Hollister-Steir Labs, LLC
Hull Company
HyClone Laboratories
Interpharm Press
Irvine Analytical Laboratories, Inc.
Kaye Instruments
KMI
La Calhene
Lancaster Laboratories
Learnwright, LLC
Lighthouse Instruments, LLC
Lives International
Magellan Laboratories Incorporated
Matrix Contract Services
MECO
Meissner Filtration Products, Inc.
Meridian Medical Technologies
Microcheck
Micron Training
MIDI Inc.
MIDI Labs
Minntech Corporation
Nicomac Inc.
Nikka Densok USA, Inc
Northview Biosciences
Novaseptic America
Novatek International Inc.
Orbisphere
Osmonics
Pacific Scientific Instruments
Pall Biopharmaceuticals
Patheon Inc.
Performance Analytical Services
PDA
Pharma - Technik Smeja
Pharmaceutical Development Center
Pharmaceutical Processing
Pharmaceutical Systems, Inc.
Pharmaceutical Technology
Phoenix Imperative Inc.
PML Microbiologicals
PowderJect Pharmaceuticals PLC
PTI - Packaging, Technologies, & Inspection
Q-One Biotech
Quintiles Consulting
Raven Biological Laboratories
RCM Solutions
Remel, Inc.
RommeLag
Russell Publishing LLC
Safety Syringes Inc.
Saint-Gobin Desjonqueres
Sartorius Corporation
Schering-Plough, Third-Party Business
Schott Pharmaceutical Packaging, Inc.
Schott Scientific Glass, Inc.
Scientific Software
Seidenader Equipment Inc.
Sensitech Inc.
Sera Care Life Sciences
Serail Div. of S.G.D. North America, Inc.
SGM Biotech, Inc.
SL Pharma Labs, Inc.
Sparta Systems, Inc.
Spectral Data Services, Inc.
Stedim
Stelex, Inc.
STERIS Corporation
STS duo TEK
The Baker Company, Inc.
The Texwipe Company LLC
The Validation Group, Inc.
TMI – ORION.O2E
Total Systems Design
VelQuest Corporation
Veltek Associates, Inc.
Victor International
Virtis Company
West Pharmaceutical Services
Wheaton Pharmatech
Wimmer Systems, LLC
Westinghouse Safety Management Solutions

For Exhibiting Opportunities for this and other PDA Events, contact

Nahid Kiani

at kiani@pda.org or (301)986-0293 ext. 128

The Extractables Puzzle: Putting the Pieces Together

Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Solutions

November 12–13, 2001 • Doubletree Hotel • Rockville, MD

Please consider participating in this important and timely conference!

Registration information will be mailed and posted to PDA's Web site at www.pda.org in July.

The purpose of this Conference is to develop answers to the questions "What regulations apply to the assessment of extractables?" and "How can I implement a program to assess extractables based on sound scientific principles in accordance with current regulations?" The Conference will also determine the state-of-the-art in extractables science and explore analytical, material, regulatory and toxicology issues.

In September 1996, PDA hosted a scientific forum on *Container/Closure Extractables*. This November, the Conference will build on those discussions and provide a forum for continued discussion of the chemical and biological characterization of extractables from packaging and processing materials.

Discussions will focus on:

- Materials, regulatory, analytical and toxicology issues;
- Interpretation and implementation of new regulations;
- Comparison of regulations that apply to drugs, devices and biologics;
- National and international differences in compendial standards – FDA, ICH, European documents;
- Biological qualification of extractables; and
- Solutions of problems using case studies as examples.

This Conference will cover the four disciplines that are necessary for the assessment of extractables: analytical chemistry, material science, toxicology and regulatory affairs. Speakers representing both US and European industrial and regulatory segments will present. A survey of current practices will be conducted from among Forum registrants and other PDA members, with a presentation of survey results at the Forum. Each registrant will receive a "regulatory sourcebook" which includes a comprehensive reference list of key documents and a compendium of definitions of important terms.

This Conference will be of significant value to the following pharmaceutical and biotechnology industry professionals:

Analytical Chemists;
Formulators;
Material Scientists;
Material and Component Suppliers;
Packaging Scientists;
Regulatory Affairs Professionals;
Toxicologists; and
CMC and DMF Writers.

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

—Leslie Zeck

Poster abstracts are being sought for presentation during the Monday, November 12 reception.

Guidelines for submission of poster abstracts:

1. Abstract is limited to approximately 100 words in length, using a 1 to 1.5-inch margin.
2. Include the following information on the abstract:
   PDA 2001 Extractables Conference
   November 12–13, 2001
   Rockville, Maryland
3. Include a concise title that engages and stimulates interest.
4. Include primary contact name, address, telephone and e-mail information. Also include names and credentials of all abstract authors.
5. Submit ***electronically*** with file saved in Microsoft Word or Rich Text format by October 12, 2001 to: royal@pda.org.

The Survey

Conference participants and visitors to the PDA Web site (www.pda.org) are invited to complete an anonymous survey of their current practices regarding extractables. Questions cover the four dimensions of this Conference: regulatory, toxicology, materials and analysis. Results will be tabulated and presented at lunch on the second day of the Conference.

Training Workshop

ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)

Three days. Four different options.

Chicago, IL: October 22–24, 2001
Princeton, NJ: November 7–9, 2001
California: February 25–27, 2002
San Juan, Puerto Rico: April 8–10, 2002

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

This three-day workshop, the only training to be officially co-sponsored by the US Food and Drug Administration (FDA) will provide training of FDA personnel alongside industry participants. The faculty is comprised of both regulators and industry representatives who served as members of the ICH Expert Working Group that developed the document. Substantial time has been allotted for question and answer sessions.

Highlights:

- This is the only joint Q7A Training being sponsored by the FDA;
- This is the only Q7A Training currently being conducted by members of the Expert Working Group that developed the guidance; and
- The joint industry/regulatory/faculty participation will facilitate a mutual exchange of discussion on issues related to the Q7A document.

Training will be presented by the following members of the International Conference on Harmonization (ICH) Q7A Expert Working Group:

John DeFoe, *Pfizer Inc.*
John A. Eltermann, Jr., *FDA, CBER* (*invited*)
Steven Fairchild, *Quantic* (former EMEA)
Betsy P. Fritschel, *Johnson & Johnson*
Stephanie Gray, *GlaxoSmithKline* (former FDA)
Lothar Hartmann, *F. Hoffmann-LaRoche Ltd.*
Max Lazar, *Hoffmann-La Roche Inc. (retired)*
Edwin Rivera Martinez, *FDA, CDER*
Joseph Phillips, *Quintiles* (former FDA)
Paolo Romagnoli,
European Generic Medicines Association

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

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

Participants in the training will gain an understanding of the intent of the Expert Working Group that developed the Q7A guidance document and will learn to:

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

The Q7A Guidance Document can be found on the following Web site: www.ifpma.org/ich5q.html#gmp. ■

—Leslie Zeck

Plan now to attend this important three-day training workshop. The exact same content will be offered at each location. Select the dates and destination most convenient to you. To register, visit PDA's Web site at www.pda.org for a copy of the brochure.

PDA Italy Chapter

A Brief Report on Our History and Our Future

by Vincenzo Baselli, Chapter President

The PDA Italy Chapter was founded in October 2000 and now has about 200 members. When we organised the June '99 conference in Pisa entitled, *Validation and Risk Analysis in the Manufacture of Sterile Pharmaceuticals, Bulk Drugs and Related Healthcare Products,* our numbers were about 60, so our growth looks very promising.

The group of people involved in this "adventure" has now also grown, others having been attracted by the three further events organised by the initiators:

- *A Day with FDA*, a workshop held in Glaxo, Verona in May 2000;
- *The Future of Validation-Evolving Requirements for Pharmaceutical Development and Manufacturing*, a conference we organised in Milan in October 2000; and
- *Global Pharmaceutical Manufacturing And Quality Strategies*, an important conference held in Taormina in April 2001.

The PDA Italy Chapter was founded in October 2000 and now has about 200 members.

The chapter has an executive committee consisting of four members and a steering committee of nine members. The executive committee is responsible for the Chapter policy while the steering committee provides the necessary support and organisation in the different branches of activity.

The Executive Committee

Vincenzo Baselli (Pall), President
Antonino Giannetto (SIFI), Vice-President
Stefano Macciò (CTP), Treasurer
Gabriele Gori (B&L), Secretary

The Steering Committee

Gilberto DalMaso (GSK), Quality Area—Pharmaceutical
Stefano Salmieri (Farmabios), Quality Area—APIs
Rodolfo Franceschini (Kedrion), Manufacturing
Paolo Curtò (DOC), Engineering
Giuseppe Gazzara (Fresenius), Education & Training
Claudia Nardini (Bayer B.), R&D Area
Volker Eck (Pharmacia), Communication & Internet
Paolo Sanesi (Pegaso), Vendor
Antonio Imperatore (Ascotec), Chapter promotion & Membership

The branches of activity are:

- Event organisation;
- Technical groups;
- Regulatory and Associations working contacts; and
- Communication and promotion of the Association.

Event organisation

For the near future three events have been scheduled:

1. Two half-day meetings to present the "hot" topics discussed at the *PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibit* are being organised in the second half of October in Milan and Rome.
2. A two-day Conference on "*Technology Transfer*" in early 2002 in Milan.
3. Tentative program on APIs and ICH Q7A later in 2002.

Technical groups

Technical groups have been set up based on the important issues in the pharmaceutical field at this time. Our aim is to work on these subjects in connection with PDA task forces, interest groups or committees, where they exist, to exchange knowledge and experiences.

Subject	Co-ordinator	PDA TF	PDA IG
Technology transfer (including process validation/Scale up)	CN	NO	NO
Aseptic Processing (including Media Fill, Environmental Monitoring)	RF	YES	YES
API CGMP Q7a	SS	YES	NO
Water / Clean steam/ Gas	PC	YES	NO
Education/Training	G.Gaz.	YES	YES
Sterility Test/New Microbiological Test / PDA TR 33	GD	YES	NO
Biological Process Validation	CN + RF	YES	YES

Regulatory and Associations working contacts

We have a strong interest in starting up regular contacts and a working co-operation with the Italy

Ministry of Health. A positive first meeting took place in early May and another meeting will be organised after they receive information on the range of PDA activities. In addition we are working to establish a relationship with the other major associations operating in the Pharmaceutical field in Italy such as AFI, ISPE and ASSCA.

Communication and promotion of the Association

To promote the growth of the Association we are working to accomplish the following:

- A quarterly electronic newsletter that will be sent to all the PDA members, the Associations, people we know have shown interest in PDA and "opinion leaders";
- Information on new technical documents such as Technical Reports will be spread in the market electronically; and
- A Web site (www.pda-it.org) has already been registered with the support of Pharmacia.

The start-up is set in summer 2001.

We are off to a promising start thanks to the support and participation of our members in Italy. ■

Korea and Taiwan Chapter Activities ...

Byong Ho Youn, Ph.D., HanDok Pharmaceuticals Co., Ltd.; Edmund Fry, PDA President; Woo-Hyun Paik, Chair, PDA Korea Chapter; and June Yeon Park, Pall Korea (PDA Korea Chapter Secretary) tour the HanDok Aventis plant in Chungbuk Province, Korea, June 2001.

Woo-Hyun Paik, Ph.D., Chair, PDA Korea Chapter; Edmund M. Fry, PDA President and She-Shong Tsai, President, PDA Taiwan Chapter at the PDA Booth, Taiwan Chapter Annual Meeting, Taipei, June 7, 2001.

Upcoming PDA-TRI Education Courses

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

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

To register, call PDA headquarters in Bethesda, Maryland at (301) 986-0293. PDA-TRI Location/Hotel Information follows.

Contamination Control Basics (PDA #213), *Two dates remaining*: September 7, 2001; November 30, 2001—*taught by Sandra A. Lowery, President of Quality Systems Consulting*; $750 PDA members/$900 nonmembers.

Fundamentals of D, F & z Value Analysis (PDA #301), September 17–18, 2001; *taught by John Shirtz, Manager QA Microbiology, Catalytica Pharmaceuticals, Inc.*; $1,500 PDA members/$1,650 nonmembers.

Validating a Steam Sterilizer (PDA #322), *one date remaining:* October 25–26, 2001—*taught by Ronald Kraus, Associate Director of KMI Systems and Christopher Mansur, Sr. Computer Validation Compliance Specialist, Genetics Institute*; $1,500 members/$1,650 nonmembers.

Computer Products Supplier Auditing Process Model: Auditor Training (PDA #474), October 11–12 and November 15–16, 2001 in Baltimore, Maryland; $950 PDA members/$1,100 nonmembers. *For more information, vist our Web site,* www.pda.org. ■

PDA-TRI Location/Lodging Information

For additional hotel information, please visit www.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.

Unless otherwise noted, PDA Institute courses are held at: PDA Training and Research Institute, 1450 South Rolling Road, Baltimore, MD 21227, Tel: (410) 455-5800; Fax: (410) 455-5802. PDA has not secured any specific room blocks for participants attending courses at the Training and Research Institute. There are several hotels in the Inner Harbor (downtown Baltimore) and BWI airport areas. These include, but are not limited to:

- **Baltimore Hilton & Towers Inner Harbor**—Tel: (410) 539-8400; Fax: (410) 625-1060
- **Baltimore Marriott Inner Harbor**—Tel: (410) 962-0202; Fax: (410) 625-7892
- **Embassy Suites-BWI**—Tel: (410) 850-0747; Fax: (410) 859-0816
- **Holiday Inn-BWI**—Tel: (410) 859-8400; Fax: (410) 684-6778
- **Holiday Inn Inner Harbor** —Tel: (410) 685-3500; Fax: (410) 727-6169
- **Homewood Suites BWI****—Tel: (410) 684-6100; Fax: (410) 684-6810
- **Hyatt Regency Baltimore Inner Harbor**—Tel: (410) 528-1234; Fax: (410) 685-3362
- **Sheraton Inner Harbor Hotel**—Tel: (410) 962-8300; Fax: (410) 962-8211.
- **Marriott Residence Inn-BWI****—Tel: (410) 691-0255; Fax: (410) 691-0254. ■

***no on-site restaurant*

Last Call—Aseptic Processing 2001

A Comprehensive Program in Manufacturing Sterile Products

October 1–5 & November 5–9

Baltimore, Maryland

For Course Content Information, contact PDA-TRI directly at (410) 455-5800.

For Registration Information, contact PDA at (301) 986-0293 or visit www.pda.org.

Very few slots remain in this popular lab course—

Call now to register.

Palm Springs Courses

October 16–18, 2001

Miramonte Resort, Indian Wells, CA

Training for Performance (PDA #409) — October 16, 2001

Drug Labeling Regulation (PDA #464) — October 16, 2001

Introduction to Validation (PDA #397) — October 16–17, 2001

Auditing Foreign Active Pharmaceutical Ingredient (API) Manufacturers (PDA #473) — October 16–17, 2001

Knowledge & Skills of the Successful QA/QC Manager in the Pharmaceutical Industry (PDA #410) — October 16–17, 2001

GMP Fundamentals (PDA #493) — October 17, 2001

Computer-Related Systems Validation (PDA #651) — October 17–18, 2001

Root Cause Analysis (PDA #754) — October 18, 2001

Introduction to Writing and Auditing CGMP Documentation (PDA #755) — October 18, 2001

Designing Regulatory Training That Works (PDA #407) — October 18, 2001

This event is being held at:

Miramonte Resort
45-000 Indian Wells Lane
Indian Wells, CA 92210

Toll Free:
1 (800) 237-2926

Tel:
(760) 341-2200

Fax:
(760) 568-0541

A block of rooms has been reserved at this hotel. Participants must contact the hotel directly, **mention PDA** and reserve a room **no later than September 16** when making reservations in order to obtain the group rate of **$159.00.** ■

Visit www.pda.org for updates!

PDA-TRI Thanks the Following...

Sponsors

Abbott Laboratories
Allegiance Healthcare Corporation
Alma, Inc.
Becton Dickinson Microbiology Systems
Berkshire Corporation
Biolog, Inc.
bioMerieux Vitek, Inc.
Biotest Diagnostics Corporation
Chemunex, Inc.
Cole-Parmer
Comar, Inc.
Contec, Inc.
Corning, Inc.
Dow Corning, Inc.
DuPont Pharmaceutical Co.
Dycem Ltd.
Eagle Picher
Eisai U.S.A., Inc.
Electrol Specialties Company
Endosafe
Environmental Monitoring Technologies
General Econopak, Inc.
Genesis Machinery Products, Inc.
GlaxoSmithKline
Helvoet Pharma
IDEXX Laboratories, Inc.
Interpharm
Kimberly Clark, Corp.
KMI/Systems
La Calhene, Inc.
Larson Mardon Wheaton
Micro Diagnostics
Micronova Manufacturing, Inc.
MIDI Laboratories, Inc.
Millipore Corporation
Nalge Co.
Pacific Scientific Instruments
Pall Corporation
Particle Measuring Systems, Inc.
PML Microbiologicals
Raven Biologicals, Inc.
Research Equipment Services
Rhone-Poulenc Rorer
Sartorius AG
Siemens Building Technologies, Inc.
SGM Biotech, Inc.
STERIS Corporation
Veltek Associates, Inc.
VWR Scientific Products
West Pharmaceutical Services
Wilco AG
Wyeth-Ayerst Laboratories

Contributors

Amgen, Inc.
Automated Liquid Packaging, Inc.
Berkshire Corporation
Chesapeake Biological Laboratories, Inc.
Cotter Corp.
Eli Lilly and Co.
Fedegari
Kaye Instruments, Inc.
Kimberly Clark, Corp.
National Instrument Co., Inc.
Neslo, Inc.
Perfex Corporation
Pharmacia
Sievers Instruments, Inc.
Technovation

PDA-TRI Education Courses Registration Form

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

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

Membership Number

Job Title Company

Business Address

City State/Province ZIP/Postal Code

Tel Fax E-mail

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

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

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

3. Please check the appropriate box:

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

Account Number_____ Exp. Date _____

Name _____
(exactly as on card)

Signature_____ Date _____

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

4. Return completed form with payment made to:

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

Payment must be included to be considered registered.

Federal Tax I.D. #52-1906152

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

LTR 08/01

PDA USE:
Date:_____ Check:_____ Amount:_____ Account:_____

REGISTRATION FORM– PDA/IABS INTERNATIONAL CONFERENCE

Process Validation for Manufacturing of Biologics and Biotechnology Products: A State-of–the-Art Perspective
6-7 September 2001 • Hilton Hotel • Berlin, Germany

201					

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

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

PDA or IABs Membership Number (if known)

Company (indicate full company name)

Business Address

City State/Province Zip + 4/Postal Code Country

Business Phone Fax E-mail

☐ Substituting for

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

2. Fees: Individuals registering at the nonmember rate receive one full year of PDA membership. (If you DO NOT want to become a PDA member, please check this box ☐).

☐ PDA or IABs Member:	[20]	EUR 1895
☐ PDA or IABs Nonmember:	[21]	EUR 2095
☐ Government Rate: *(you must be an employee of an official government agency to qualify for this discounted rate.)*	[22]	EUR 500

Hotel Deposit: ☐ Hilton: EURO 220 ☐ 4 & 3 Star Hotels: EURO 200
In order to guarantee your reservation, a deposit should be paid along with your hotel reservation. The deposit includes a single administration fee of EURO 13 per room. You do not have to pay a deposit if you guarantee your hotel reservation with a credit card but the administration fee will be charged in any case.

TOTAL EUR _____

3. Hotel Reservations. Please make the following reservations:

Arrival_____ Departure_____ No. of nights_____ Late arrival after 18 h ☐ yes ☐ no

Hotel Category	Single Room	Double Room	Junior suite
5-star Hilton Berlin	☐ EUR 224.97	☐ EUR 245.42	
4-star hotels	☐ EUR 170-175	☐ EUR 190-200	☐ EUR 260
3-star hotels	☐ EUR 105	☐ EUR 130	

The prices shown are per room for one night and include service charge and VAT. Breakfast is included in the price of the 3-star hotels. There is an additional charge for breakfast at the Hilton Hotel and the 4-star hotels.

4. Payment

☐ I USE THE FOLLOWING CREDIT CARD ☐ VISA ☐ American Express ☐ MasterCard/EuroCard

Name as indicated on the card: _____

Card holder's signature: _____ Date: _____

Card holder's street address: _____

Postal code, city: _____ Country: _____

Card number: ⌜ ⌝ ⌜ ⌝ ⌜ ⌝ ⌜ ⌝ Expiration Date: _____

☐ WIRE TRANSFER. I have transferred the amount to your bank CPO HANSER SERVICE w/PDA, Deutsche Bank 24 (bank code 100 700 24) account no. 5 8922 1110. I have instructed my bank that I also have to pay for the fees of the German bank.

☐ I ENCLOSE A BANK CHEQUE FOR DM/EUR _____. If you use a cheque of a non-German bank, please add EUR 15 to the total amount in order to cover German bank charges. Personal cheques cannot be accepted. *Do not forget to indicate participant's name on your payment.*

☐ I GUARANTEE MY HOTEL RESERVATION with my credit card mentioned above and I authorize the hotel and/or CPO HANSER SERVICE, in case of non-utilization of the reserved room to collect possible costs and the administration fee of DM 25/EUR 12,78 from the credit card institute.

5. Return completed form with payment to:

CPO HANSER SERVICE GmbH
Schaumburgallee 12
D-14052 Berlin, GERMANY
Telephone: +49-30-300669-0 • FAX: +49-30-3057391

Confirmation: Written confirmation will be sent to you once payment is received. You must have written confirmation to be considered enrolled in a PDA event. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time. If you are pre-registering as a substitute attendee, indicate this on the registration form. A nonmember substituting for a member must pay the additional fee. **Refunds:** Refund requests must be made in writing. Registrants whose written requests for refunds are received at CPO HANSER SERVICE on or before **20 August 2001** will receive a full refund less a $35 (US) processing fee. Registrants whose written requests for refunds are received after 20 August and on or **before 27 August** will receive 50% of the registration fee. After 27 August, no refunds can be made.

Signature _____ Date _____ **LTR 08/01**

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

Computer Systems
Michael L. Wyrick
KMI/Parexel
2080 St. Andrew's Court
Franklin, IN 46131
Tel: (317) 736-0853
Fax: (317) 736-9249
E-mail—
mwyrick@belmont.kminc.com

Contract Manufacturing
Michael R. Porter
Eli Lilly & Company
DC 3814
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 277-2595
Fax: (317) 277-9693
E-mail—
porter_michael_r@lilly.com

Drug/Device Delivery Systems
Michael A. Gross, Ph.D.
Aventis Behring
1020 First Avenue
P.O. Box 61501
King of Prussia, PA 19406-0901
Tel: (610) 878-4490
Fax: (610) 878-4461
E-mail—
michael.gross@aventis.com

Filtration
James D. Wilson
115 Newell Village Circle
Seymour, TN 37865
Tel: (865) 609-1694
Fax: (865) 609-1690
E-mail—
wilsojdel@chartertn.net

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

Inspection Trends/ Regulatory Affairs
Robert L. Dana
Elkhorn Associates Inc.
4828 Patrick Place
Liverpool, NY 13088
Tel: (315) 457-3242
Fax: (315) 451-7363
E-mail—
rld1242@aol.com

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

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

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

Ophthalmics
Richard M. Johnson
Abbott Laboratories Inc.
Dept. 03-QA Bldg. AP6C
100 Abbott Park Road
Abbott Park, IL 60064-6091
Tel: (847) 938-1750
Fax: (847) 938-3016
E-mail—
richard.m.johnson@abbott.com

Packaging Science
Edward J. Smith, Ph.D.
Packaging Science Resources
237 Chapel Lane
King of Prussia, PA 19406
Tel: (610) 265-9029
Fax: (610) 265-2307
E-mail—
esmithpkg@aol.com

Production and Engineering
David W. Maynard
Maynard & Associates, LLC
2162 US Highway 206
Belle Mead, NJ 08502
Tel: (908) 431-1919
Fax: (908) 874-8161
E-mail—
davmaynard@aol.com

Quality Assurance/ Quality Control
Don E. Elinski
Lachman Consulting Services
120 Peregrine Circle
Broomfield, CO 80020
Tel: (516) 222-6222
Fax: (516) 683-1887
E-mail—
elinski@aol.com

Solid Dosage Forms
Pedro J. Jimenez, Ph.D.
Eli Lilly & Company
Eli Lilly Corporate Center
Indianapolis, IN 46285
Tel: (317) 277-3618
Fax: (317) 276-4669
E-mail—
jimenez_pedro_j@lilly.com

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

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

Training
Thomas W. Wilkin, Ed.D.
Schering-Plough
Building K-1-2 F41
2000 Galloping Hill Road
Kenilworth, NJ 07033
Tel: (908) 298-5213
Fax: (908) 298-2720
E-mail—
thomas.wilkin@spcorp.com

Vaccines
Frank S. Kohn, Ph.D.
Wyeth-Lederle Vaccines & Pediatrics
4300 Oak Park
Sanford, NC 27330
Tel: (919) 775-7100 ext. 4304
Fax: (919) 774-1142
E-mail—
kohnf@labs.wyeth.com

Validation
Bohdan M. Ferenc
1 Brandywine Ct.
Succasunna, NJ 07876
Tel: (973) 927-9152
E-mail—
biferenc@aol.com

Visual Inspection of Parenterals
John G. Shabushnig, Ph.D.
Pharmacia Corporation
7171 Portage Road
M/S 2130-41-108
Kalamazoo, MI 49001-0199
Tel: (616) 833-8906
Fax: (616) 833-5195
E-mail—
john.g.shabushnig@pharmacia.com

Calendar from back cover

November 15-16, 2001
PDA-TRI Laboratory Course: An Introduction to Developing Effective Audit Strategies for CGMP Cleanrooms
PDA-TRI Baltimore, MD

November 28-29, 2001
PDA-TRI Laboratory Course: Identification of Microorganisms Using Comparative DNA Sequencing
PDA-TRI Baltimore, MD

November 30, 2001
PDA-TRI Laboratory Course: Contamination Control Basics
PDA-TRI Baltimore, MD

DECEMBER

December 3-7, 2001
2001 PDA Annual Meeting, Courses and Exhibition
Compliance: Challenges and Pragmatic Solutions
Marriott Wardman Park, Washington, DC
PDA-TRI Courses:
December 6
Auditing Techniques for CGMP Compliance
December 6-7
Advanced Regulatory Compliance Training for the Supervisor/Manager
Computer-Related Systems Validation
December 7
Change Control and Documentation

December 10-11, 2001
PDA-TRI Laboratory Course: Environmental Mycology—Identification Workshop
PDA-TRI Baltimore, MD

2002

JANUARY

January 14-18, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 1)
PDA-TRI Baltimore, MD

FEBRUARY

February 11-15, 2002
Basel 2002: PDA International Congress, Courses and Exhibition: *Adding Value to the Pharmaceutical Industry—Leveraging the Future*
Basel Convention Center, Basel, Switzerland

February 11-15, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 2)
PDA-TRI Baltimore, MD

February 25-27, 2002
Training Workshop
ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)
Hotel TBA, California, US City TBA

MARCH

March 11-15, 2002
2002 PDA Spring Conference, Courses and Tabletop Exhibition: Environmental Monitoring and Aseptic Processing: Reaching a Common Understanding of the Regulatory and Technical Requirements
Rosen Hotels and Resorts, Orlando, FL

APRIL

April 8-10, 2002
Training Workshop
ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)
Caribe Hilton, San Juan, Puerto Rico

April 8-12, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 1)
PDA-TRI Baltimore, MD

MAY

May 6-10, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 2)
PDA-TRI Baltimore, MD

SEPTEMBER

September 9-13, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 1)
PDA-TRI Baltimore, MD

September 23-26, 2002
2002 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibition
Hyatt Regency on Capitol Hill, Washington, DC

OCTOBER

October 7-11, 2002
PDA 2002 Biennial Training Conference
Charting a Course for Success
Hyatt Regency Tampa, Tampa, FL

October 7-11, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 2)
PDA-TRI Baltimore, MD

October 28-November 1, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 1)
PDA-TRI Baltimore, MD

NOVEMBER

November 18-22, 2002
PDA-TRI Laboratory Course: Aseptic Processing Training Program (week 2)
PDA-TRI Baltimore, MD

DECEMBER

December 10-13, 2002
2002 PDA Annual Meeting, Courses and Exhibition
New Orleans Marriott, New Orleans, LA

PDA
An International Association For Pharmaceutical Science And Technology

PDA Books Available

Change Control; *S. Schwartze*; 2001; 40 pp; $80.00. This book provides a complete example change control process, details about planned and unplanned changes, sample report forms for errors/changes, change requests, log of change-related actions, log of maintenance actions, recommended actions in case of changes to the hardware, software, users and much more. A very valuable reference.
Item No. 17189

Cleaning & Cleaning Validation: A Biotechnology Perspective; *R. Brunkow* et al.; 1995; 190 pp; $125 members/$145 nonmembers.
Item No. 13002

Electronic Records and Electronic Signatures; *C. Reid and B. Mullendor*; 2001; 50 pp; $99.00. Electronic Records and Electronic Signatures (ERES) provides practical guidance on the interpretation of 21CFR Part 11 and the steps you need to take to address current and future compliance issues. This quick guide is designed to help you identify ERES business benefits, establish policies, procedures and processes that ensure compliance and define and evaluate system requirements.
Item No. 17177

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry; *J. Vesper*; 2001; 224 pp; $119.00. This is a comprehensive, easy-to-use reference, designed to simplify and enhance understanding of most of the current GMP expectations and how they apply to ongoing manufacturing tasks.
Item No. 17191

Microbiology for Pharmaceutical Manufacturing; *R. Prince, ed.*; 2001; 900 pp; $279.00. This book systematizes and updates the technical discipline of pharmaceutical microbiology. Providing valuable knowledge for the novice and expert alike, it contains the wisdom and guidance of 40 leading pharmaceutical microbiologists, engineers, and other thought leaders.
Item No. 17185
— **Available mid July 2001**

Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections; *L. Clontz*; 2001; 175 pp; $119.00. Written by an experienced microbiologist, this manual contains chapters covering: Current inspection trends; Chemical and biological reference standards; Laboratory equipment and facilities; Preparation of media, buffers and reagents; Environmental monitoring; Water systems for laboratory use; Data trending and statistical process control; Use of disinfectants and sanitizers; Training of laboratory personnel; and The quality assurance program for the laboratory.
Item No. 17176

The Internal Quality Audit; *M. Grimaldi and J. Gough*; 2001; 100 pp; $119.00. Here is the common-sense guidance you need to perform an effective, systematic internal quality audit. As a quality professional, you are well aware of the repercussions caused by a nonconforming product entering the marketplace; customers may experience adverse effects or worse, and your company will certainly lose credibility and profit. This book helps you identify and prevent systemic weaknesses by providing the evaluation tools you need to prevent such occurrences.
Item No. 17179

Pocket Code of Federal Regulations GMP Guide - 2001 Edition; 21 CFR Part 210-CGMP in Manufacturing, Processing, Packing, or holding of drugs; general. 21 CFR Part 211; 56 pp; $4 member/$7 nonmember. CGMP for Finished Pharmaceuticals. Reproduced in pocket size by PDA. April 1, 2001,
Item No: 13004

Understanding GMP: An Expert's View on Merging Global Regulatory and Manufacturing Perspectives; *M. Becker*; 2001; 224 pp; $119.00. Now at Merck, Sharp, and Dohme Ltd., Martyn Becker is an ex-UK MCA Manager and Senior Medicines Inspector. In this book, he shares his expertise and perspectives on GMP regulations, legislation, applications and practical challenges and solutions to applying GMP to the manufacturing environment. Anyone concerned with quality and GMP should have this book on a shelf nearby.
Item No. 17174

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

To Order, Use Form on Page 44

Select PDA Technical Reports Available

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.

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; $90 members/$140 nonmembers (paper copy); **TR 32**. $50 members/$75 nonmembers (CD-ROM format) TR32 CD.

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

TR 29 Points to Consider for Cleaning Validation; This document provides guidance relative to the validation of cleaning for a broad range of processing systems and product types within the pharmaceutical industry. The report includes perspectives on the application of cleaning validation guidance in the areas of finished pharmaceuticals, bulk pharmaceutical chemicals, biopharmaceuticals and clinical products. It is the pharmaceutical companion to "Cleaning and Cleaning Validation: A Biotechnology Perspective" published by PDA in 1996. 1998; 23 pp; $75 members/$125 nonmembers.

Select PDA Proceedings Available

2001 PDA Good Electronic Records Management (GERM) Conference Proceeding, April 2–6, 2001, Tampa, Florida; 2001, 492 pages.
Price: $150.00 members, $175.00 nonmembers
Item No. 04029

2001 PDA Spring Conference Proceeding Modern Pharmaceutical Microbiology-Advancing the Science, March 11–16, 2001 Las Vegas, Nevada; 2001, 368 pages.
Price: $150.00 member, $175.00 nonmember
Item No. 04030

PDA Archive on CD-ROM

PDA Archive on CD-Rom - PDA Archive Retrieval Index; The PDA Archive will give you easy access to more than 50 years of research papers written by highly qualified research scientists in the pharmaceutical industry. All PDA Journal articles, Technical Reports and Monographs, and selected Meeting Proceedings are available on this fully searchable CD-ROM. The archive is updated each year adding six issues of the PDA Journal, all PDA Technical Reports and Monographs, and selected PDA Meeting Proceedings. The archive is a 4-CD set. Archive; Price: $395 members/$495 nonmembers;
Item No: 01101

2000 Update
Price: $95 members/$195 nonmembers;
Item No: 01002

Ordering Documents and Publications from PDA

Use this form to order any of the documents mentioned in the *PDA Letter*. If ordering by mail, include a check payable to PDA to the address below. Be sure to include shipping and handling charges in the total. If ordering by fax, please include all credit card information. All orders must include payment.

Name _____ Member No. _____

Company _____

Address _____

City _____ State _____ Country _____ Zip/Postal Code _____

Tel: _____ Fax: _____ E-mail: _____

Payment type: ☐ Check drawn on a US bank ☐ MC ☐ VISA ☐ AMEX

☐ Wire Transfer

Credit Card # _____ Exp. _____

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

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

Questions? (301) 986-0293 x133 or *info@pda.org* Signature _____

Document No.	Title	Qty.	Price	Total

Shipping
Domestic US orders are shipped via UPS Ground. Second-day and Next-day Air service is available. Call or e-mail for prices.

Domestic US Shipping & Handling Rates

If your order totals:	*Add:*
$ 15.00 and under	$ 5.95
$ 15.01–$ 75.00	$ 7.95
$ 75.01–$150.00	$ 9.95
$150.01–$250.00	$11.95
$250.01 or more	$13.95

International orders (including Puerto Rico & Canada): Please add 20%, minimum $18.00, maximum $150.00. Items are sent priority air, but 2-day service is available for some countries; please call for details.

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

Federal Tax I.D. #52-1906152

Please allow 4-6 weeks for delivery on some items.

Subtotal	
Shipping & Handling	
5% Tax *(MD Residents Only)*	
TOTAL	

LTR 08/01

PDA USE:
Date: _____ **Check:** _____ **Amount:** _____ **Acct:** _____

Biotest

Surface Sampling
Particle Counting
Laboratory Services
Air Sampling
Rapid Hygiene

Contract Microbiology Laboratory

Biotest Diagnostics Corporation has a certified microbiology laboratory available providing quantitative and qualitative analysis of your environmental samples.

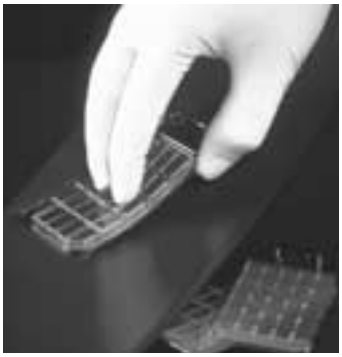
- Microbial identifications of bacteria, yeast and mold to genus/species
- 10 day turnaround time
- "Perfect Score" participant in the EMPAT Program
- Confidential reports for total plate/strip counts and cfu/volume of air
- Consultation with expert Microbiologists on staff
- Free shipping when using Biotest test slides and strips

APC Plus

Airborne Particle Counter

Convenient, economical and entirely portable particle counter detects the presence of airborne contaminants. Accurately and simultaneously measures four particle size ranges: 0.3, 0.5, 1.0 and 5.0 µm. Can be used to monitor controlled environments where particulate contamination is of concern.

- User friendly control panel
- Programmable count and hold times
- Meets JIS for counting efficiency
- Two concentration modes– particles/ft^3 and particles/liter
- Temperature and RH sensors built-in
- Easy to use software included
- Remote and facility monitoring software available



HYCON® Contact Slides

Monitoring liquids and ambient air is not sufficient for most products and processes. Surface monitoring is a must and is recommended in HACCP, ISO and USP guidelines. HYCON® Contact Slides detect surface viable contamination that may adversely affect your product or process.

- Flexible self-contained culture-medium-coated slides ensure surface contact
- Excellent for irregular surfaces
- Provides a 25 cm^2 contact surface
- Various agar media available

Biotest HYCON® RCS High Flow Microbial Air Sampler

The RCS High Flow Microbial Air Sampler allows you to monitor contaminants in any area where reproducible results are necessary. The RCS High Flow monitors air quality—

Faster—the RCS High Flow has an air flow rate of 100 liters per minute, reducing sampling time to 10 minutes for 1 m^3.

Easier—the upgraded infrared remote control with a newly designed keyboard panel and integrated display transmits and receives data from the instrument up to a distance of 10 m.

Better—the rotor, protection cap, and air direction ring are all detachable, easy to clean and autoclavable, allowing less margin for contamination when sampling in any environment.

The instrument is portable and precise and with the use of Biotest HYCON® agar media strips, results are always reproducible. Whether you are monitoring the microbiological quality of ambient air, testing your air handling equipment, or verifying the results of decontamination efforts, you'll find the RCS High Flow to be an effective, reliable sampling device.

Call us at 800.522.0090 for more information.

CE

Biotest DIN EN ISO 9001 HYCON

Biotest

BIOTEST DIAGNOSTICS CORPORATION
66 Ford Road, Suite 131, Denville, New Jersey 07834
Phone: 973.625.1300 • 800.522.0090 • Fax: 973.625.9454
www.BiotestUSA.com

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

Australia Chapter
Contact: **Mary Sontrop**
ZLB Bioplasma AG
Tel: +41-31-344-4305
Fax: +41-31-344-5555
E-mail: *mary.sontrop@zib.com*

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

Capital Area Chapter
Areas Served: Maryland, District of Columbia, Virginia, West Virginia
Contact: **Allen Burgenson**
DynPort Vaccine Company, LLC
Tel: (301) 607-5046
Fax: (301) 607-5099
E-mail: *BurgensA@dynport.com*
Web site: ***www.pdacapitalchapter.org***

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

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

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

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

Japan Chapter
Contact: **Hiroshi Harada**
Tel: +81-3-3815-1681
Fax: +81-3-3815-1691
E-mail: *van@bcasj.or.jp*

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

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

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

Mountain States Chapter
Areas Served: Colorado, Wyoming, Utah, Idaho, Nebraska, Kansas, Oklahoma, Montana
Contact: **John M. Elvig**
Colorado Quality Assoc., Inc.
Tel: (303) 666-0319
Fax: (303) 926-9006
E-mail: *carl10@prodigy.net*

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

Southeast Chapter
Areas Served: North Carolina, South Carolina, Tennessee, Virginia, Florida, Georgia
Contact: **Mary Carver**
Eisai, Inc.
Tel: (919) 474-2149
Fax: (919) 941-6934
E-mail: *carver@eisai.com*
Web site: ***www.pdase.org***

Southern California Chapter
Areas Served: Southern California
Contact: **Maria Wagner**
International Medication Systems Limited
Tel: (626) 459-5279
Fax: (626) 459-5592
E-mail: *mariaw@ims-limited.com*

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

United Kingdom and Ireland Chapter
Contact: **Colin Booth**
GlaxoSmithKline
Tel: +44-1-920-883-637
Fax: +44-1-920-882-295
E-mail: *cb3883@glaxowellcome.co.uk*

West Coast Chapter
Areas Served: Northern California
Contact: **Randall Tedder**
Filtrex, Inc.
Tel: (510) 783-3700
Fax: (510) 783-8715
E-mail: *randallt@filtrex.com*

PDA
An International Association For Pharmaceutical Science And Technology

WHEN THERE'S NO ROOM FOR ERROR...**TRUST KAYE.**

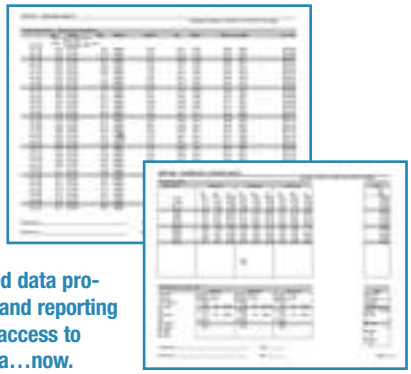
Introducing

ValProbe™

Another innovation from the leader in process validation.

Process monitoring has never been easier.

Wireless design. Advanced data processing. Wide operational ranges. FDA compliant. Customized reporting. It all adds up to a revolutionary wireless process monitoring and validation system with unprecedented ease-of-use benefits.



Advanced data processing and reporting provide access to your data…now.

Accuracy and flexibility you can count on…because it's from Kaye.

The ValProbe system employs a wireless probe design which eliminates the need for hard-wired sensors, simplifying access to hostile, remote, and hard-to-reach environments. Operating from –60° C to 360° C and 0–75 psi, it's suitable for a wide range of applications including steam and Et0 sterilization, tunnels, ovens, incubators, rotating machinery, and conveyors.

Innovation from the leader.

ValProbe's ability to rapidly process data from up to 50 sensors saves time and provides quick access to critical temperature, humidity, and pressure data. Of course, the ValProbe system complies with FDA Regulation 21 CFR Part 11, ensuring that the most stringent requirements for electronic signatures and records are met.

To request more information or a demonstration of this breakthrough process validation system, call us at

1-800-964-5293

or visit us at www.kayeinstruments.com

- **ACCURACY**
- **COMPLIANCE**
- **EASE OF USE**
- **SERVICE**

KAYE®

Calendar of Events

2001

AUGUST

August 20-24, 2001
PDA-TRI Laboratory Course:
Aseptic Processing Training Program (week 2)
PDA-TRI Baltimore, MD

August 27-29, 2001
PDA-TRI Laboratory Course:
Basic Microbiology—Theory & Practice
PDA-TRI Baltimore, MD

SEPTEMBER

September 6-7, 2001
PDA/IABs Conference on Process Validation of Biologics and Biotechnology Products: A State-of-the-Art Perspective
Berlin Hilton Hotel, Berlin, Germany

September 7, 2001
PDA-TRI Laboratory Course:
Contamination Control Basics
PDA-TRI Baltimore, MD

September 10-14, 2001
2001 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibit
Emerging Global Regulatory Issues
Hyatt Regency Washington, DC on Capitol Hill
Washington, DC
PDA-TRI Courses:
September 13
How to Design an Effective Regulatory Training Program
Improving Sterile Drug Submissions to the FDA
PDA Audit Process Model Management Overview Training
September 13-14
Cleanroom Management
September 14
Assay Validation
Strategic and Practical Approaches to Part 11 Compliance

September 17-18, 2001
PDA-TRI Laboratory Course:
Fundamentals of D, F & z Value Analysis
PDA-TRI Baltimore, MD

September 17-18, 2001
PDA Canada Chapter/A3P International Conference and Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec, Canada

OCTOBER

October 1-3, 2001
PDA/FDA Viral Clearance Forum
Hyatt Bethesda, Bethesda, Maryland

October 1-5, 2001
PDA-TRI Laboratory Course:
Aseptic Processing Training Program (week 1)
PDA-TRI Baltimore, MD

October 11-12, 2001
PDA-TRI Course: Computer Products Supplier Auditing Process Model—Auditor Training
PDA-TRI Baltimore, MD

October 15-17, 2001
PDA Isolation Technology Conference
Hilton East Brunswick, East Brunswick, NJ

October 16-18, 2001
PDA-TRI Palm Springs Course Series
Miramonte Resort, Indian Wells, CA
October 16
Drug Labeling Regulation
Training for Performance
October 16-17
Auditing Foreign Active Pharmaceutical Ingredient (API) Manufacturers
Introduction to Validation
Knowledge & Skills of the Successful QA/QC Manager in the Pharmaceutical Industry
October 17
GMP Fundamentals
October 17-18
Computer-Related Systems Validation
October 18
Designing Regulatory Training That Works
Root Cause Analysis
Writing and Auditing CGMP Documentation

October 22-24, 2001
Training Workshop
ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)
The Allerton Crowne Plaza, Chicago, IL

October 22-24, 2001
PDA-TRI Laboratory Course:
Cleaning Validation
PDA-TRI Baltimore, MD

October 25-26, 2001
PDA-TRI Laboratory Course:
Validating a Steam Sterilizer
PDA-TRI Baltimore, MD

NOVEMBER

November 5-9, 2001
PDA-TRI Laboratory Course:
Aseptic Processing Training Program (week 2)
PDA-TRI Baltimore, MD

November 7-9, 2001
Training Workshop
ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)
Hyatt Regency Princeton, Princeton, NJ

November 12-13, 2001
The Extractables Puzzle: Putting the Pieces Together
Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Solutions
Doubletree Hotel, Rockville, MD

November 12-14, 2001
PDA-TRI Laboratory Course:
Basic Microbiology—Theory & Practice
PDA-TRI Baltimore, MD

November 15-16, 2001
PDA-TRI Course: Computer Products Supplier Auditing Process Model—Auditor Training
PDA-TRI Baltimore, MD

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

continues on page 41