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PDA Letter

July 2001

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

FDA Open Public Meeting Summary, page 16

# 2001 PDA Annual Meeting, Courses and Exhibition

## Compliance: Challenges and Pragmatic Solutions
## December 3–7, 2001
## Marriott Wardman Park, Washington, DC

Make your plans now to attend PDA's largest conference, courses and exhibition. This meeting will attract nearly 1,000 international scientists for high-level education and networking. The conference will feature case studies related to compliance problems and issues and industry solutions on how to resolve them. Topics for discussion include:

- **Regulatory Issues:** meeting new challenges, working with the FDA, experience with Team Biologics, global regulatory trends post-marketing surveillance, systems based inspections;
- **Biotechnology Issues:** cell culture manufacturing advances, alternate production technologies, gene therapy products, biological assays, establishing expiration guidelines, technology transfer, early stage development issues;
- **Manufacturing Issues:** active pharmaceutical ingredients, isolation/barrier systems, blow-fill-seal, new drug delivery technologies, container/closure issues;
- **Non-Parenterals:** solid dosage forms, ophthalmics, topicals;
- **Outsourcing:** supplier partnerships and audits, clinical services, virtual companies, engineering, laboratory, manufacturing, packaging, research and development, and validation;
- **Sterilization:** sterilizing filtration, moist heat sterilization, radiation sterilization, emerging microorganisms (stressed/diminutive bacteria, nvCJD, nanobacteria, etc.);

*continued on page 32*

# Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (APIs)

FDA, in collaboration with PDA, Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA) announce a workshop series on Q7a Training.

- Chicago — October 22–24, 2001
- New Jersey — November 7–9, 2001
- West Coast — Winter 2002
- Puerto Rico — Spring 2002

### Q7a Training Target Audience:

- Manufacturers of Active Pharmaceutical Ingredients;
- Manufacturers of Pharmaceutical Products;
- Auditors of API Manufacturers;
- Consultants to the Pharmaceutical Industry; and

*continued on page 33*

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## Important Dates...

- August 3, 2001—hotel cutoff for PDA Canadian Chapter/A$_3$P International Conference, page 34
- November 9, 2001—hotel cutoff for PDA Annual Meeting, see page 32

## IN THIS ISSUE...


Fry

# Awards

As PDA members know, our Association's honor awards are bestowed at each year's Fall Annual Meeting. These prestigious awards honor PDA members who are recognized by their peers, and the PDA Board of Directors, as having exceptional ability and dedication to PDA. The awards are decided by the PDA Board, from among nominations assembled by an ad hoc Board subcommittee. The subcommittee encourages nominations from the membership. If you know of a worthy PDA member for one of the following, please submit the information directly to me and I will forward the information to the Awards subcommittee for consideration.

## Honorary Membership

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

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

## Gordon Personeus Award

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

1991 Timothy Leahy
1995 Edward J. Smith
1996 Frederick A. Gustafson
1997 James D. Wilson
1998 Kunio Kawamura
1998 Toshinobu Aoyama
1999 Carol M. Lampe
1999 Bernard Kronenberg
2000 Frank Bing
2000 Robert A. Pazzano

## Frederick J. Carleton Award

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

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

## Distinguished Service Award

Given for special acts, contributions or service that have contributed to the success and strength of PDA. Past recipients are:

1993 Jeanne Devers White
1994 Willard Webster
1995 Joseph B. Schwartz
1996 Bengt C. Ljungqvist
1996 Berit M. Reinmuller
1996 Floyd Benjamin
1996 Sol Motola
1997 Stanley Sklar
1997 Daniel L. Gold
1997 Donald E. Baker
1998 Robert L. Dana
1998 Martin W. Henley
1999 Joyce L. DeYoung
2000 Julius Z. Knapp
2000 Duncan E. McVean
2000 Jeanne E. Moldenhauer

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

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

Nominations should be submitted directly to me and include the identity of the specific award (Honorary Membership, Personeus Award, Carleton Award, or Distinguished Service Award) with a concise statement of recommendation. Nominations will be accepted by:

E-mail: fry@pda.org
Fax: (301) 986-0296
Mail: PDA Awards
7500 Old Georgetown Rd, #620
Bethesda, Maryland 20814

**Deadline for submission is September 1, 2001.** ■

***—Edmund M. Fry***

# USP UPDATE

*by Roger Dabbah, Ph.D., USP*

The USP 24, Supplement 4 was published on June 1, 2001 and will become Official on August 1, 2001. New monographs appearing in this Supplement are Ethosuximide Oral Solution, Mesalamine Delayed-Release Tablets, and Metrifonate. The former title of Metrifonate was Trichlorfon and the Title change will be Official February 1, 2003. Note on page 3188 of this Supplement is a section on Commentary, which is not part of the official text of the monograph, but provides the reader with an opportunity to see the basis of the Committee's response to public comments.

In the General Notices (p. 3190) changes, note that we have modified Storage Temperature by the addition of humidity. Specific directions are stated in some monographs with respect to temperature and humidity at which Pharmacopeial Articles are to be stored and distributed, including the shipment of articles to consumers, when stability data indicate that storage and distribution at lower or higher temperature a higher humidity produces undesirable results. In the same Supplement in <643> Total Organic Carbon note that Reagent Water is water having a TOC of not more than 0.10 mg per liter.

The July–August issue of *Pharmacopeial Forum* was published. Note that the revision proposal for General Test Chapter Residue on Ignition <281> IN NOT MOVED FORWARD TO OFFICIAL STATUS via Tenth Interim Revision Announcement.

Starting in 2002, USP plans to publish the USP-NF annually, with one Supplement published approximately halfway through the year.

In the same PF we are publishing a list of proposed omissions from USP 25-NF 20. Notify USP promptly if you think that any article in the omission list should be retained in USP 25-NF 20 (gla@usp.org or fax at (301) 816-8373 TO THE ATTENTION OF Gerry Anderson). Note on page 2678 the list of new USP Reference Standards available, and the Official date for implementation in parenthesis for each new standard.

In the In-Process section of the same PF, there are a number of USP new monographs proposed. These are, Albumin Encapsulated Octafluoropropane Microspheres for Injection, Alendronate Sodium, Brinsolamide, Brinzolamide Ophthalmic Suspension, Bupropion Hydrochloride, Choline Chloride, Ferumoxsil Oral Suspension, Desogestrel, Isoflupredone Acetate, Isoflupredone Acetate Injectable Suspension, Paroxetine Hydrochloride, Propofol, Valarsan and Hydrochlorothiazide Tablets, Vancomycin for Injection, and others. The new NF monographs proposed include Acacia Syrup, Diluted Acetic Acid, Anise Oil, Caraway, Caraway Oil, Cardamon Oil, Cardamon Seed, Compound Cardamon Tincture, Cherry Juice, Cherry Syrup, Chocolate, Chocolate Syrup, Clove Oil, Fennel Oil, Lemon Oil, Licorice Fluid Extract, Orange Oil, Orange Syrup, Sunflower Oil, Sweet Orange Peel Tincture, Vanilla, and Vanilla Tincture.

A proposal for modification of chapter <1035> Biological Indicators for Sterilization, updates the chapter and clarifies several sections in this PF, as well as chapter <1146> Packaging Practice-Repackaging a Single Solid Oral Drug Product into a Unit-Dose Containers.

Under Pharmacopeial Previews are new proposals on Fexofenadine Hydrochloride, Insulin Lispro, and Insulin Lispro Injection. In the NF Previews section, new monographs for Black Cohosh, Powdered Black Cohosh, Powdered Black Cohosh Extract, and Black Cohosh Tablets are proposed. ■

# International Calendar

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

## 2001

### August

August 14, 2001
**PDA UK & Ireland Chapter Roundtable**
***PDA Technical Report Number 1***
***Industrial Moist Heat Sterilisation in Autoclaves***
Sportsman Hotel, Common Road
Chorleywood, Herts

### 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

## 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.**

### New Chair of the Commission

In March, during the 109th session of the European Pharmacopoeia Commission, Professor H. G. Kristensen of the Danish School of Pharmacy, Copenhagen was elected as the Commission's 13th Chair. His term runs from June 2001 until June 2004. Kristensen has been the Chair of the Danish Pharmacopoeia Commission since 1976, was elected first Vice-chair of the European Pharmacopoeia Commission in 1998 and has participated in the Groups of Experts on Dosage Forms and Microbial Contamination. He is professor of Pharmaceutics at the Royal Danish School of Pharmacy and his field of research is the design and processing of solid oral dosage forms. Kristensen was a speaker at PDA's conference in Pisa, Italy in June 1999. He succeeds Professor D. H. Calam.

### International Symposium on Certification System

An international symposium entitled, "Certificate of Suitability of Monographs of the European Pharmacopoeia: New Developments of the Procedure — How to Apply for a CEP," is scheduled for Athens, Greece on November 8–9, 2001. The scientific program will be conducted in English and is slated to include discussion of the following topics:

- Scope of the procedure and links with the licensing authorities and inspection;
- How to apply for a CEP;
- Constitution of a dossier: the administrative viewpoint, critical points and recapitulation of the most common deficiencies;
- Manufacturing method and quality control during manufacture including specific cases (several manufacturing methods and/or sites and/or several grades);
- Impurities originating from the route of synthesis including catalysts and residual solvents;
- Special case: fermentation products;
- TSE risk products evaluation;
- Variations and Quinquennial Renewal, Revision of Monographs; and
- Round table and final conclusions.

Speakers include: Prof. H. G. Kristensen, Chair of the European Pharmacopoeia Commission; Prof. D. H. Calam, Former Chair of the Steering Committee (SC) for the Certification Procedure; Dr. D. De Kaste, Chair of the Chemical Technical Advisory Board; Dr. M. S. Ruiz, Chair of the TSE Technical Advisory Board (TAB); Dr. A. Artiges, Director of the EDQM; Prof. J. H. Trouvin, Chair of the CPMP Biotechnology Working Party (EMEA); Dr. J. L. Robert, Chair of the Joint CPMP/CVMP Quality Working Party (EMEA); and Dr. C. Pouget, Principal Scientific Officer Responsible for the Certification Procedure.

For specific information on the scientific program visit the EDQM Web site at www.pheur.org/conferences/.

### Miscellaneous updates

Certification of Suitability: General chapter on Products with TSE risks: Revised Version available (changes underlined) www.pheur.org/download/pdf_files/50208E.pdf.

Updated lists of certificates of suitability granted (28 May 2001, updated periodically) may be found at www.pheur.org/download/pdf_files/list_certificates_2805.pdf and www.pheur.org/download/pdf_files/list_certificates_TSE_2805.pdf.

Reference Material Catalogue N°31 is now available, http://www.pheur.org/pdf_files/CRS31.pdf.

Available Soon: 38 new or revised European Guidelines for the batch release of blood products and vaccines, and Proceedings of the international symposium on Pestivirus contaminations of bovine sera and other bovine sera contamination (Paris, March 29–30, 2001).

**For more information on any of these topics please contact the EDQM Public relations Unit:**

Mrs. C. Larsen Le Tarnec, +33 (0)3 88 41 28 15, publicrelations@pheur.org or visit the EDQM Web site at www.pheur.org. ■

*—James Lyda*

# 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 the Audit Repository Center (ARC).

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.

## TR-32 Auditor Training in Sweden

Auditor training was provided by a joint effort of PDA and R³-Nordic at Kungl Tekniska Högskolan's (Royal Institute of Technology) Stockholm campus on May 17–18. The course was made possible through the efforts of Bengt Ljungqvist and Berit Reinmüller of KTH and Rick Rogers of the PDA Training and Research Institute (PDA-TRI).

PDA President Edmund M. Fry opened the training with an introduction to the PDA Audit Process defined in TR-32. Rick Rogers, PDA Vice President for Education/Director at PDA-TRI, monitored the quality and implementation of the training.

This was the first training on the PDA Audit Process defined by TR-32 presented outside of the US and represents a commitment to European members for implementation of the TR-32.

Managers from Computer Systems Validation, Information Systems Quality, and Quality Assurance/Quality Control groups of four major pharmaceutical companies and one member from a Swedish consultancy group attended training. Feedback from attendees rated the training course very high, particularly in terms of self-improvement and ease with which they were able to apply what they learned to their respective job functions.

Rick Rogers of PDA-TRI connected with the Royal Institute of Technology to make the training available to the European Pharmaceutical Industry through PDA-TRI. Talks are presently underway to evaluate the training possibilities that would support implementation of TR-32 on a regularly scheduled basis in Stockholm.

## Industry Advisory Board (IAB) Formed

The first meeting of the Industry Advisory Board (IAB) was held at PDA Bethesda on May 24, 2001.

PDA established the IAB to periodically review and approve changes to the process model and data collection tools described in PDA Technical Report No. 32, "Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations." The IAB also monitors auditor qualification and re-qualification requirements. This allows oversight of the Audit Repository Center, L.L.C. (ARC) to ensure that the process remains current with respect to changing technology and regulatory environments and conforms to the requirements of the License Agreement.

The objective of the IAB is to maintain an audit process that meets the requirements for consistency and reliability in execution while facilitating the sharing of results through the audit Process Model and Data Collection Tool. This ensures that the audit information, presented as an audit report by the repository, is usable in supporting procurement activities and in inferring structural integrity of supplier products when engineering and validating computer systems in the pharmaceutical industry.

IAB members from Merck & Co., Inc., Berlex Laboratories, Bristol-Myers Squibb, SAP, Isis Pharmaceuticals, CimQuest, Inc. and ARC attended the meeting, which was chaired by PDA Board member Richard Levy, Ph.D., of Millipore. Russell E. Madsen, Senior Vice President Science and Technology represented PDA.

The results of the metrics for the first year of implementation of TR-32 were presented and reviewed by IAB members. The following was reported and accepted by the IAB:

Suppliers audited using TR-32 Process indicated that audits were performed in an expedient, positive and professional manor by experienced personnel. The suppliers rated this aspect as very important.

Suppliers indicated that the Data Collection Tool contained in TR-32 provided a clear and thorough tool by which to probe the supplier's practices to determine whether their practices met industry expectations.

Results established that there is a good level of agreement between the Auditor and Suppliers—that the Process produces a consistent and reliable result no matter who uses it. The data also indicates that the Process is a time efficient method to reduce cost, satisfy regulatory requirements and provide shareable data, which promotes clarification and understanding of the audit objectives.

Subscribing pharmaceutical companies have realized a cost savings when using audits contributed by a Participating Supplier. This issue is indicated as very important to the Subscribers.

Subscribing Pharmaceutical companies feel that the Process provides them with clear, useable information that meets their needs. These characteristics were indicated to be very important to the Subscribers.

The IAB concluded that performance for the first year of implementation of TR-32 appears to have met expectations and provides a sound reliable product that meets the needs of industry suppliers and Pharmaceutical Industry Subscribers.

## Availability of Audits

Currently, forty-five 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 audits that are currently available for distribution from the repository.

## Auditor Resources

To date, ninety-seven auditors have been trained and qualified by PDA. Forty-eight percent of these auditors are from pharmaceutical industry companies, with nine percent coming from the European Union and Japan.

For more information about the audit repository visit ARC's Web site at www.auditcenter.com. ■

**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.

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<br>Electronic Patient Diaries – EPD<br>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 |

# US Regulatory Briefs

**Congressional Testimony by Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research, FDA, on the *Pediatric Exclusivity Provisions*, May 8, 2001.**

In 1997, as part of the *Food and Drug Administration Modernization Act* (FDAMA) (Pub. L. 105-115), Congress enacted a new provision that provides marketing incentives to manufacturers who conduct studies of drugs in children. This law, which provides six months exclusivity in return for conducting pediatric studies, is commonly known as the *Pediatric Exclusivity Provision*. From the inception of this program the industry has responded enthusiastically to the incentives offered in the *Pediatric Exclusivity Provision*. FDA continues to believe that this program holds the promise of significantly expanding children's access to and safe use of important therapeutics.

The Agency has implemented the *Pediatric Exclusivity Provision* according to the requirements of FDAMA by:

- Publishing a list of drugs for which pediatric information may be beneficial;
- Working with sponsors to develop and issue Written Requests for pediatric studies;
- Reviewing submitted studies;
- Making exclusivity determinations; and
- Submitting a Status Report to Congress in January 2001.

The Agency also has made organizational changes to support the implementation of the *Pediatric Exclusivity Provision*, including assembling a Pediatric Team and creating a Pediatric Advisory Subcommittee. The Subcommittee has been convened four times since its creation to address broad ethical and scientific issues related to pediatric drug development.

Finally, the Agency has published several guidances to facilitate the implementation of the exclusivity provision:

- *Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (original July 1998 and updated September 1999);
- *Pediatric Oncology Studies in Response to a Written Request* (Draft June 2000); and
- *General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products* (Draft November 1998).

In addition, the Agency also has produced a guidance ICH-E11, *Clinical Investigation of Medicinal Products in the Pediatric Population* (December 2000), developed at the international level, to address pediatric studies. Conclusion: Superior drug treatment information is expected to permit quicker recoveries from childhood illnesses, with fewer attendant hospital stays, physician visits and parental work days lost, but could increase certain prescription drug prices.

The increase in the number of pediatric clinical trials for FDA-regulated products clearly has resulted in information valuable for the use of drugs in the pediatric population. FDA wants to build on these improvements with more studies and new labeling information. There are still a large number of drug and biological products that are inadequately labeled for children. FDA wants to persist until these are all studied.

FDA wants to work with Congress to ensure that the benefits of an incentive program continue as they consider the reauthorization of the *Pediatric Exclusivity* program.

For the full testimony visit "FDA News" at www.fda.gov.

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 is Announcing the Availability of a Draft Guidance for Industry Entitled, *"Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution."*** From the *Federal Register*, May 15, 2001 (Volume 66, Number 94, Page 26867, Docket No 01D-0192). The draft guidance is intended to assist registrants in obtaining and submitting the necessary forms for listing information of drug and biological products. This draft guidance will also assist those private label distributors that are not required to register, but elect to submit designated information directly to FDA. The FDA proposes to make available through the Internet, rather than through conventional mail, the following registration and listing forms: Form FDA 2656 (Registration of Drug Establishment), Form FDA 2656e (Annual Update of Drug Establishment), Form FDA 2657 (Drug Product Listing) and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors). **Dates**: Submit written comments on this draft guidance document by July 16, 2001. General comments on agency guidance documents are welcome at any time. **Address**: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. **For Further Information Contact**: For human drugs—Kathy Smith, CDER (HFD-90), FDA, 5600 Fishers Lane, Rockville, MD 20857, (301) 594-1086. For biological drugs—Robert A. Yetter, CBER (HFM-10), FDA, 1401 Rockville Pike, Rockville, MD 20852, (301) 827-0373, yetter@cber.fda.gov. For veterinary drugs—Lowell Fried, CVM (HFV-212), FDA, 7500 Standish Pl., Rockville, MD 20855, (301) 827-0165, lfried@cvm.fda.gov.

**Two counterfeit therapeutic products have been discovered this year.** In January, Serono, Inc., in cooperation with the FDA, started informing patients, physicians and distributing pharmacies about a counterfeit version of Serono's Serostim® 6mg for injection that has appeared in the marketplace. The counterfeit product, which is definitely not Serostim®, was neither manufac-

tured nor distributed by Serono and may pose a health risk to patients.

On May 10 of this year, Amgen Inc. began notifying health care professionals that it recently became aware of the existence in the US of a counterfeit drug product labeled as Neupogen® 300 mcg vials in ten-pack boxes. In cooperation with the FDA, Amgen is informing patients, physicians, pharmacies, and wholesalers about this serious health risk. The counterfeit vials examined to date contain a clear liquid but no active ingredient. The counterfeit product, which is definitely not Neupogen® (Filgrastim), was neither manufactured nor distributed by Amgen and may pose a serious health risk to patients.

The FDA is very concerned about counterfeit drug products in the marketplace and the serious public health implications related to the use of these counterfeit products. Both Serono and Amgen acted promptly and professionally when they became aware of this problem. More information can be found at www.fda.gov/medwatch.

**A Guidance for Industry on IND Meetings for Human Drugs and Biologics was issued on May 25, 2001, by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).** This document provides guidance on formal meetings between sponsors of Investigational New Drug applications (INDs) and CDER or CBER on Chemistry, Manufacturing and Controls (CMC) information.

This guidance covers three kinds of meetings that may be held between sponsors and the Agency:

1. Pre-investigational new drug applications (pre-IND);
2. The end of phase 2 (EOP2); and
3. Pre-new drug application (pre-NDA) or pre-biologics licence application (pre-BLA).

These meetings may be requested by the sponsor to address outstanding questions and scientific issues that arise during the course of a clinical investigation, aid in the resolution of problems and facilitate the evaluation of drugs. The meetings, which often coincide with critical points in the drug development and/or regulatory process, are recommended, but not mandatory and additional meetings may be requested if warranted.

General information about meetings can be found in the following documents:

Section 119 of the *Food and Drug Administration Modernization Act* (Pub. L. 105-115); Regulations applicable to meetings on investigational products in 21 CFR 312.47; FDA guidance for industry on *Formal Meetings with Sponsors and Applicants for PDUFA Products* (February 2000); FDA guidance for industry on *Fast Track Drug Development Programs, Designation, Development and Application Review* (November 1998); and FDA policies and procedures for formal meetings with external constituents described in CDER's Manual of Policy and Procedures (MAPP 4512.1) and CBER Standard Operating Procedures and Policies (SOPP) 8101.1.

The full guidance can be found at www.fda.gov/cber/guidelines.htm.

**In the *Federal Register*, May 3, 2001, (Volume 66, Number 100, page 28526), the FDA Announced the Availability of a Guidance for Industry Entitled, "*Bioanalytical Method Validation*."** This guidance provides recommendations to sponsors of INDs, NDAs, ANDAs, and their supplements in developing validation information for bioanalytical methods for PK evaluations of human clinical pharmacology, BA studies and BE studies. The information in this guidance generally applies to bioanalytical procedures such as gas chromatography (GC), high-pressure liquid chromatography (LC), combined GC and LC mass spectrometric (MS) procedures such as LC-MS, LC-MS-MS, GC-MS, GC-MS-MS and immunological and microbiological procedures performed for quantitative determination of drugs and or metabolites in biological matrices such as serum, plasma or urine. The guidance also applies to other bioanalytical matrices such as tissue and skin samples.

## Paragraph IV Patent Certifications

The FDA is making available, on a trial basis, a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification.

If an ANDA sponsor wants to market a product before the patent expires on the innovator product, the ANDA sponsor must submit Paragraph IV certification to the FDA and notify the NDA and patent holders. Paragraph IV certification states that the ANDA sponsor believes that the patent is invalid, not enforceable and/or fringed by the ANDA. If the ANDA sponsor is sued for patent infringement by the patent holder within 45 days, the FDA cannot approve the ANDA for 30 months (unless the patent litigation is resolved sooner).

This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification) and the reference-listed drug. The Agency will not disclose when the ANDA was received by the Office of Generic Drugs or the identity of the applicant. This information will be updated on a monthly basis and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Regulatory Support Branch at (301) 827-5862, before making any decisions based on this information. The list can be found at www.fda.gov/cder/ogd/ppiv.htm.

***—William Stoedter***

# International Regulatory Briefs

**Note:** All EMEA and CPMP guidance documents can be accessed at the EMEA Web site, www.emea.eu.int/index/indexh1.htm.

### Q&A on BSE and vaccines

In April the EMEA released, *"Questions and Answers on Bovine Spongiform Encephalopathies (BSE) and Vaccines"* (EMEA/CPMP/BWP/819/01, April 24, 2001). A great deal of information has been previously published regarding BSE, TSE and the developments in Europe. This document uses a question and answer format to discuss BSE, vaccines, the use of bovine material in vaccines, related safety issues in the manufacturing process and the risk of BSE transmission through vaccines. At the present time, the EMEA has been advised that the risk of BSE contamination of vaccines used in the EU is extremely small and that the risk posed by the use of bovine materials in vaccines is very remote and theoretical.

### Reduction, elimination or substitution of Thiomersal in vaccines

In April the EMEA issued *"Points to Consider on the Reduction, Elimination or Substitution of Thiomersal in Vaccines"*(CPMP/BWP/2517/00, April 26, 2001). This document, prepared by the CPMP's Biotechnology Working Party (BWP), went into effect in May 2001. The CPMP has concluded that, for vaccination in infants and toddlers, it would be prudent to promote the general use of vaccines without Thiomersal, and other organo-mercurial preservatives, especially for single dose vaccines. Thiomersal, an organo-mercurial preservative, is included in some inactivated vaccines for human use for its antimicrobial capacity and to perform other functions affecting antigenicity and stability. Thiomersal may be added as a preservative during formulation of the final bulk stage or may be present as a residue from its use as an antimicrobial during an early stage of the manufacturing process. Manufacturers have the option of reducing the amount of thiomersal in finished products, eliminating thiomersal altogether or eliminating thiomersal but substituting it with an alternative preservative. There are various methods of obtaining vaccines without organo-mercury containing preservatives. Development and validation may be necessary before such modifications can be implemented because of the possible impact on microbiological quality, solubility, antigenicity, immunogenicity, reactogenicity and stability. This document gives general guidelines for the three proposed changes and addresses the quality, safety and efficacy issues arising from such modifications and the nature of the data to be submitted.

### Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products

In May the EMEA released the final "*Note for Guidance on Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products*." (CPMP/BWP/3088/99, April 24, 2001) Prepared by the Biotechnology Working Party (BWP) of the CPMP, this note for guidance covers all gene transfer medicinal products covered by the Centralized Procedure and becomes effective October 2001. The objective of the note is to provide recommendations and assistance in generating data supporting marketing authorization applications within the EU.

The note specifically covers:

- Addition and expression of a gene(s) for therapeutic purposes (e.g. gene transfer products and cancer vaccines);
- Inoculation of nucleic acids for the purpose of vaccination against foreign antigens (e.g. DNA vaccination); and
- Transfer of nucleic acids with the aim of modifying the function or expression of an endogenous gene.

The 30-page document includes sections on: Development genetics, production, purification, product characterization, and consistency and routine batch control of final processed product. In addition, it provides considerations for individual gene transfer strategies, consideration on the use of genetically modified organisms, and the

pharmacological/toxicological evaluation of gene transfer products. There is also a glossary of terms.

### Manufacture and Quality Control of Human Somatic Cell Therapy Medicinal Products

In May the EMEA issued "*Points to Consider on the Manufacture and Quality Control of Human Somatic Cell Therapy Medicinal Products*" (CPMP/BWP/41450/98, May 31, 2001). Prepared by the CPMP Biotechnology Working Party (BWP) the guidance was originated in 1998 and adopted in May 2001. The guidance defines cell therapy medicinal products that would fall under the definition of medicinal product, as those human somatic autologous or allogenic cells which (a) are subject to a manufacturing process carried out in a dedicated facility complying with GMP. The process encompasses expansion or more than minimal manipulation which may be designed to alter the biological, physiological or functional characteristics of the resulting cells; and (b) further to such manipulation, the resulting cell product is definable in terms of qualitative and quantitative composition which may include biological activity. The 11-page document includes guidance on the following: Source and characterization of somatic cell populations, source and characterization of other materials and reagents used in the manufacturing process, cell culture procedures, development pharmaceutics, validation of handling procedures and equipment, quality assurance system, and batch identification, finished product, lot release testing.

### Start of Shelf-Life of the Finished Dosage Form

In May the EMEA issued *"Note for Guidance on Start of Shelf-Live of the Finished Dosage Form"* (Annex to Note for Guidance on the Manufacture of the Finished Dosage Form, CPMP/QWP/072/96, May 31, 2001). This very brief guidance describes how dates shall be determined for expiration dating and notes that the 'date of production of a batch is defined as the date that the first step is performed involving combining the active ingredient with other ingredients. For medicinal products consisting of a single active ingredient filled into a container, the initial date of the filling operation is taken as the date of production.' The annex does not pertain to biological medicinal products, including biotechnology-derived products. The effective date is December 2001.

### Application for Marketing Authorization for Veterinary Products

In May the EMEA's Committee for Veterinary Medicinal Products (CVMP) released the standard

operating procedure, *"Submission of an Application for the Granting of a Community Marketing Authorization"* (EMEA/CVMP/008/95-Rev. 30, May 17, 2001). Originally developed in 1995, this revised EMEA SOP provides practical advice regarding the steps to be followed for the submission of an application for the granting of a Community Marketing Authorization. The 11-page guidance has no legal standing but is intended as practical advice to the industry. It is not available from the EMEA home page but can be obtained through the subscription service.

***—James C. Lyda***

**The Japanese National Institute of Health Sciences (NIHS), Guideline for Bioequivalence Studies of Generic Products.**

This guideline describes the principles of procedures of bioequivalence studies of generic products. The objective of the study is to assure therapeutic equivalence of generic products to innovator products. In the bioequivalence study, bioavailability should be compared for innovator and generic products. If this is not feasible, pharmacological effects supporting efficacy or therapeutic effectiveness in major indications should be compared (these comparative tests are hereafter called pharmacodynamic studies and clinical studies, respectively). For oral drug products, dissolution tests should be performed, since they provide important information concerning bioequivalence.

Terms used in the guideline are defined as follows:

- Bioavailability: The rate and extent of absorption of parent drugs or active metabolites from a dosage form into systemic circulation.
- Bioequivalent Products: Drug products having the same bioavailabilities.
- Therapeutically Equivalent Products: Drug products having the same therapeutic efficacies.
- Innovator Products: Products being approved as new drugs by clinical trials or related drug products.
- Generic Products: Products whose active ingredients, strengths, dosage forms and regimen are the same as those of innovator's products.

The full guidance can be found at www.nihs.go.jp/drug/DrugDiv-E.html.

**The Common Technical Document (CTD) will be the expected format for medical product applications in the US by July 2003.** In the EU and Japan the CTD will become the mandatory format in July of 2003.

The International Conference for Harmonization (ICH) clarified these implementation dates at their recent meeting in Chiba, Japan during the week of May 21, 2001.

The CTD Implementation Working Groups (IWGs) have started work on explanations and clarifications for the CTD that will be published on the ICH Web site in the form of questions and answers.

The provision for testing the electronic Common Technical Document (eCTD) advanced to Step 2 of the approval process at the Chiba meeting. This will allow "real case" testing of the eCTD by all ICH parties. The provision also contains a specifications document and the Document Type Definition (DTD) standard to be used with the eCTD.

The ICH Medical Dictionary for Regulatory Activities (MedDRA) has undergone a large number of changes in terminology, including new terms, modification of existing terms and changes in linkages between terms. MedDRA 4.0 is expected to be available on June 15, 2001.

More information on ICH and MedDRA can be found at the ICH Web site, www.ifpma.org/ich1.html. ■

***—William Stoedter***

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# FDA Open Public Meeting Summary

*by Rebecca A. Devine, Ph.D., Regulatory Consultant*

On May 8, 2001 the FDA held an open public meeting. The purpose of the meeting was to: (1) prepare for the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Meetings held May 21–24, 2001 in Tokyo, Japan; (2) update the public on the implementation and progress of the ICH Common Technical Document (CTD); and (3) solicit input for possible new ICH topics.

Representatives of the Office of International Affairs of FDA presented an overview of the history of ICH including the administrative functioning of ICH committees. The ICH began in 1990 as a joint effort of three global regions: the European Union, the US and Japan. Canadian and Swiss authorities participate as observer countries. The goal of the ICH is to identify and eliminate reliance on a number of duplicate studies, each of which is designed to satisfy a different regulatory authority. There is a steering committee and technical groups that both function within the ICH. There are four expert working groups: Safety, Quality, Efficacy and Regulatory Communications. The Expert Working Groups within the topics develop consensus on technical issues.

One recent product of the ICH process is the ICH Common Technical Document (CTD). Representatives from the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER) presented updates on the status of implementation of the CTD for drugs and biologics. The CTD is composed of 5 modules. Module 1 contains regional administrative information. Module 2 contains a Table of Contents, Introduction, Quality Overall Summary, Nonclinical Overview, Clinical Overview, Nonclinical Written and Tabulated Summaries and a Clinical Summary. Module 3 contains the Quality section, Module 4 the Nonclinical Study Reports and Module 5 the Clinical Study Reports. Modules 2–5 are common to each region, while Module 1 contains regional-specific information.

A harmonized electronic CTD (eCTD) is also currently being worked on as part of the ICH process, but will not be available for approximately six months after the CTD. (For information on the eCTD, visit www.fda.gov/cder/m2/eCTD.htm). The eCTD is targeted to reach Step 2 (harmonized draft available for comment in each region) in May of 2001. Each region is in the process of developing an implementation program for the CTD. A general guidance document is being prepared by FDA to provide information on the implementation of the CTD in the US. The target date for acceptance of the CTD format in the US is the end of July 2001. The general considerations guidance is to be issued in time for this voluntary submission of the CTD format.

The FDA guidance is expected to contain information on what is to be submitted, a physical description of the submission and how the CTD requirements are to be addressed. It will also list previous guidance that will be made obsolete by the CTD, the logistics of submission and the timeframe for submission. The guidance will also provide specific information regarding the order and placement of information in the form FDA 356h, how to assemble and format the submission and information on the binding volumes, colors, size, etc. FDA reviewers and document room staff will be trained in the near future, and it is anticipated that a feedback mechanism for industry will be developed during implementation. For products regulated as drugs by CDER, the representative indicated that the need for changes to the drug regulations is currently being assessed. For biological products regulated by CBER, it is anticipated that it will not be necessary to rewrite any regulations in order to fully implement the CTD. For biological products the CTD format will first be implemented for the biotechnology "specified products" such as proteins and polypeptides, their derivatives, and products of which they are

**Only one presenter provided comments. The commenter requested that the regions consider synchronization of the mandatory implementation. He also expressed concern that the mixing of old and new formats during a transition period be allowed, since many companies have already begun preparing applications in the old format. It was also requested that the CTD not be considered an "alternate format" but the only format to be used. The need for flexibility was stressed. He also asked that global electronic standards be put in place if possible for the eCTD.**

components. CBER is currently assessing the format for application to other products it regulates such as vaccines and blood products.

The next step in implementing the CTD for biological products is to rewrite the guidance on the content and format of the chemistry, manufacturing and controls sections of the application. The CBER representative indicated that the use of the CTD format in advance of the July date is not precluded, however, communication with CBER before submission of the format is strongly encouraged.

The status of the CTD in the EU, Japan and Canada was also updated. For all three of these regions a July 2001 voluntary implementation is also projected. In Europe the CTD will be applicable to all categories of medicinal products, in Japan the CTD will be used for new chemical entities, new biologics, new indications and new dosage forms and routes of administration. Canada is also implementing the CTD for new drugs and biologics, then will follow with abbreviated new drugs and supplemental applications. Mandatory implementation in Europe (with some flexibility) and Japan is already being slated for July 2002 and July 2003 respectively.

The public was presented with an opportunity to speak at the meeting. Only one presenter provided comments. The commenter requested that the regions consider synchronization of the mandatory implementation. He also expressed concern that the mixing of old and new formats during a transition period be allowed, since many companies have already begun preparing applications in the old format. It was also requested that the CTD not be considered an "alternate format" but the only format to be used. The need for flexibility was stressed. He also asked that global electronic standards be put in place if possible for the eCTD.

The last part of the meeting was to request input from the public on future topics for ICH consideration. A draft concept paper on the "Activities of ICH from Development throughout Post Marketing of New Drug Products" was provided that would consider post marketing activities such as risk communication, early rollout of drugs, and the periodic safety update report as possible future ICH topics. Another paper that was a statement on the "Future of ICH" from the ICH Steering Committee was also made available for comment. There were no specific public comments on the future topics issue and the meeting was adjourned. The Step 5 CTD is expected to publish at any time as this article went to print, and the general FDA guidance will be available on the FDA Web site as soon as possible after the May ICH meeting in Japan. Transcripts of the open public meeting are available from the Freedom of Information Office (HFI-35), FDA, 5600 Fishers Lane, Rm. 12A-16, Rockville, MD 20857. ■

# PDA to Publish Technical Reports on Environmental Monitoring and Isolation Technology

PDA plans to publish two technical reports during the third quarter of 2001. One of them, Technical Report No. 13, Revised, *Fundamentals of an Environmental Monitoring Program*,updates an earlier edition. Technical Report No. 34, *Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products*, is new. PDA feels both of the reports will be useful and valuable additions to the technical literature.

## Technical Report No. 13, Revised

This technical report expands substantially upon the first edition of Technical Report No. 13, published by PDA in 1990. Its purpose is to identify microbiological and particulate control concepts and principles as they relate to the manufacture of sterile pharmaceutical products, and although it cannot possibly supplant the wealth of information published on this subject, the report provides summary information and appropriate references for the reader to consult, if necessary. The objective of the Task Force, chaired by Jeanne E. Moldenhauer, Vectech Pharmaceutical Consultants, Inc., was to contemporize the first edition through the utilization of current definitions, recognition of improved environmental monitoring procedures and equipment. The task force consisted of members representing global companies to ensure that the methods, terminology, and practices reflect the procedures utilized globally.

This document is intended to serve as a source for clean room environmental test methods, and although some non-viable particulate and endotoxin testing data are included, its primary focus is microbiological control. The concepts for sterile product manufacturing are the most stringent application, but these concepts can also be applied to non-sterile product manufacture. The focus is environmental monitoring as it relates to facility control and compliance. This document was compiled to aid in setting up a program that is meaningful, manageable and defendable.

In order to ensure a consistently acceptable production environment, a comprehensive environmental control program should be supported by: (a) sound facility design and maintenance; (b) documentation systems; (c) validated/qualified sanitization/disinfection procedures; (d) reliable process controls; (e) good housekeeping practices; (f) effective area access controls; (g) effective training, certification/qualification and evaluation programs; and (h) quality assurance of materials and equipment.

Environmental surveillance is a tool utilized to evaluate the effect of controls on the manufacturing environment. A process to assess the clean room and other controlled environments of a pharmaceutical facility can serve as an adjunct to the sterility assurance program for the microbial quality of drugs. The items addressed in this document include definitions, standards, surveillance support systems, system surveillance, validation systems, appendices of definitions and typical frequencies and levels and a bibliography.

## Technical Report No. 34

Technical Report No. 34, "*Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products*," was developed by PDA's Isolation Technology task force, co-chaired by James P. Agalloco, Agalloco & Associates, and James E. Akers, Ph.D., Akers Kennedy & Associates. TR 34 addresses essential user requirements for the application of isolator technology to a broad range of manufacturing, development and testing applications in the health care product manufacturing industry. This technical report covers not only product sterility assurance, but also the use of isolators for the containment of hazardous materials.

The absence of authoritative implementation and validation guidance for this technology and the considerable confusion that has emerged between "isolators" and "barriers" were prime motivators for PDA to develop this document. It is the product of an international committee made up of representatives of PDA's Japan Chapter, $A_3P$, The Parenteral Society and $R^3$-Nordic.

An important component of this technical report is the glossary (Appendix A). The health care industry has lacked a uniform set of definitions with respect to isolator technology. The committee recognizes that in order to suggest truly usable technical information we must ensure that there can be no confusion among readers as to the application of recommendations made within this technical report.

The committee also recognized that in some regions of the world processing environments called "isolators" are widely used in the clinical pharmacy setting. These devices have some general features in common with isolators as defined in this

document, however they are distinctly different from the isolator systems currently in use for sterile product manufacturing and testing in the health care product industry. This technical report does not pertain to devices that do not meet the minimum performance criteria defined and explained in this document.

The establishment of a clear distinction between what is and what is not an isolator is essential to understanding this document. In it, PDA suggests the following definition of isolator:

> An isolator is sealed or is supplied with air through a microbially retentive filtration system (HEPA minimum) and may be reproducibly decontaminated. When closed it uses only decontaminated (where necessary) interfaces or Rapid Transfer Ports (RTPs) for materials transfer. When open it allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination. It can be used for aseptic processing activities, or containment of potent compounds or simultaneously for both asepsis and containment.

### Publication Schedule

Both Technical Reports will be scheduled for publication as supplements to the *PDA Journal of Pharmaceutical Science and Technology*. They are expected to appear by the September–October 2001 issue. ■

***—Russell E. Madsen***

# Cole to Succeed Wilson as PDA Filtration Interest Group Leader

James D. Wilson, Vice President RA/QA, The Validation Group, has announced his intention to step down as leader of the PDA Filtration Interest Group following the PDA 2001 Annual Meeting in December. Wilson has successfully led the interest group since its inception and has been responsible for its success. In addition to his leadership role on the interest group, Wilson was also a key member of PDA's Sterile Filtration Task Force, the group that developed Technical Report No. 26, *Sterilizing Filtration of Liquids*. He has had a distinguished career in the pharmaceutical industry, including tenures at Abbott Laboratories and Isomedix and has been an active member of PDA for many years.

Jack Cole will succeed Wilson as leader of the Filtration Interest Group following the December meeting. Cole is President of Jack Cole Associates, consultants in technical marketing to the life sciences industries. Prior to that he was Corporate Vice President, Healthcare Marketing at Pall Corporation.

Cole is a long-term member of PDA and has served in many capacities, including President and Board Member and chaired many committees. He has written and lectured on pharmaceutical filtration extensively at PDA and other venues. Cole is a PDA Honorary Member and past recipient of the Carleton award. He also currently serves on the faculty of Rutgers University's Department of Chemical and Biochemical Engineering, working in their Pharmaceutical Engineering Training Program.

Please plan to attend the Filtration Interest Group meeting in December to wish James Wilson well and to welcome Jack Cole as he assumes leadership of the group. ■

***—Russell E. Madsen***

# Interest Groups Will Meet at Annual Meeting

PDA Interest Groups will convene at the 2001 PDA Annual Meeting, December 3–7, in Washington, DC at the Marriott Wardman Park Hotel. Be sure to attend the Interest Group sessions of your choice. See page 40 for a list of Interest Groups and leaders. Interest Group sessions are open to IG members and nonmembers alike. See you there!

# FDA Jurisdiction Over Exported Products

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,

I have heard the FDA can take issue with a product exported to another country that fails US specifications while meeting specifications of the other country. Could you please clarify how the FDA has jurisdiction in this situation? Any references to regulations or guidelines would also be appreciated.

## Response 1

21 CFR 211, the US GMPs, apply to all pharmaceuticals manufactured in the US whether destined for US markets or overseas markets. If the product you are making was originally intended to meet US specifications, and it fails, then according to GMPs, your only options are to either reject the batch, or to rework the batch. Sending it to another market where the specifications are different is not an option. Earlier in my life I worked as a pharmacist in an overseas refugee camp. I can tell you that the amount of crud we got from multi-national companies who sent us product that did not meet US specifications was unbelievable. And typically it did not meet refugee specifications either.

## Response 2

A product manufactured in the US and shipped is in interstate commerce. FDC Act section 301(a) prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device or any cosmetic that is adulterated or misbranded.

## Response 3

I believe this was called drug "dumping" in the old days and the subject of several scandals (subpotent or ineffective antibiotics?). As others point out, it is unlawful in the US. Unfortunately, US law does not apply if the manufacturing chain of custody (including testing and release) occurs outside of the US. Then local country law would apply. Regardless, it is an unsavory practice in my opinion.

## Response 4

I come from a country where a drug with 50% efficacy of the original US drug would have been of more benefit than having no drug at all. This is a difficult philosophical/humanistic question. We forget sometimes that for 80% of the population of this Earth the option is not to have US standard of drugs. The option is: no drug at all.

## Response 5

The preceding point is an important one. If the FDA or other regulatory agency makes a manufacturer destroy a life-saving product for some deviation from specification or GMP instead of selling/giving it away in another country, they may be letting real people suffer and die. Letting real people suffer and die because a drug doesn't meet an advanced country's stringent specifications for GMP is quite a crass thing to do. When you consider the fact that all of the polio vaccine manufactured in the 50s and 60s which saved countless children from death and permanant disability would have certainly been rejected if required to meet today's standards for GMP, it makes one apt to challenge the knee-jerk thinking that "all product which doesn't meet specs should be destroyed."

## Response 6

I am in absolute agreement with what you are saying and I feel this stringent regulation about absolute GMP is an impediment to establishing more pharmaceutical companies in third world countries and hence making the prices of drugs higher than they should be. I feel the third world countries are passing through the stage which the developed countries have already

gone through and furthermore one should remember that then the idea of GMP was either non-existent or in its infancy.

## Response 7

I wouldn't want to have you as a reviewer for any drug application with this type of logic. All specifications are set because they are proven safe before approval. You apparently don't believe in the science or you would not advocate such an unwise course.

You are right in saying that some of the drugs might help some of the people, but what about the harm they would also do? You cite polio vaccine but apparently fail to remember or didn't do enough research to know that some out of specification material was produced, even for this most important advance, and harmed a number of people.

I'm afraid that your heart is in the right place, but your science is flawed.

## Response 8

How quickly we have forgotten the episodes with thalidamide in the 1960s. FDA would not let it into the US based upon safety concerns. The tragic deformities in newborns bore out the legitimacy of FDA's concerns. Granted that is a case of blocking a product from being imported instead of exported, but I believe the principle is the same.

If we really want to help people, we don't need to distribute something to them that is flawed, dangerous, or which will promote false hope. Producing the same substances to the same specs by generic manufacturers outside of the US at a lower price I think is closer to a realistic solution.

## Response 9

We all should know that there are standards without any doubt to be met, and there are standards. The war in Yugoslavia finally made it impossible to ship material not meeting local standards, because lots of worthless junk had been dumped there. I had to destroy two tons of sulfametrol/trimethoprim tablets, because some of them had bad film coatings—bad for the taste and bad for stability, but the material was needed immediately in one poor country, and I had no chance to send it. I tried WHO and other organizations to understand the problem and give a clearing, but I would not even get an answer. This probably cost a lot of people their lives or at least good health—at a zero risk situation. And it was bad for the environment because I had to send it to incineration. Don't tell us that science dictates to meet all standards!

## Response 10

I don't know all of the facts in this situation but must question your motivation. Most standards between countries are equivalent and based on safety and efficacy guidelines along with a reasonable risk to benefits assessment. You would argue that what I would not take is good enough for a poor country.

Are you distressed that you cannot cut your losses by selling this material, to regain some or all of your costs? It is a common ploy for companies to ship outdated or near outdated products to poor countries to gain tax credits for the material. Could this possibly be your motivation? Doesn't it trouble you that the UN turned down the material, especially since it is run by many of the same countries you would want to ship this material to?

I personally would be wary of anyone or any company who would follow such policies.

There was a *Washington Post* newspaper series highlighting the testing of good medicines in poor countries. It was not very complimentary. They could really have a grand time with a situation such as you propose.

## Response 11

Regarding the preceding response,

a) Naturally, I am talking of sending it without billing.
b) My coworkers and I would have paid for the freight.
c) The defect was less than perfect film coating (in less than 1% of the tablets) with two effects: bad taste, and an possible negative effect in the long term stability, which would not matter because the material was dearly needed and that immediately.
d) No, we did not want to sell it to the UN but try to find someone with a brain and the nerve to say that this would be a present, not harming anyone but saving lives, and that it could be done.

So — no money, we would even have paid the freight. You should know that a cosmetic defect does not mean death to the user. Of course all other parameters were met.

## Response 12

Your actions, as detailed, appear noble but you should not forget that a large majority of pharmaceuticals are recalled for cosmetic purposes, not necessarily by the government but the manufacturers. Often this can be due not to the product changing but rather the container or carton label fading.

Please remember that the specifications were established to assure that the product will meet these minimum requirements for efficacy and

safety, over the labeled expiration date of the product, including stability. What date would you have put on this product? Your reply indicates that you don't know. Also, if the coating had a effect on the release of the product it would definitely not be equivalent to normal batch. There are just too many unknowns and I can't imagine a company that would want to assume such a risk, particularly in the litigious US.

It is human nature to suspect less than adequate quality when an easily observable quality specification, particularly cosmetic ones, are not met. There are many other instances of this behavior, including removing the color from gasoline.

## Response 13

I believe that the statistics will show that the US, since it has agreed to more liberal standards, has also achieved the same product withdrawal rate of the rest of the world. Products have reached the market that should never have been approved and people have been injured or worse yet died because of this policy. It has hurt both the industry's and the Agency's image.

Do you forget the recent approval of a product in the US that was being withdrawn from the European market? If there is such good communication between the regulatory bodies and reporting of all data to the authorities, how could this happen?

I would suggest that anyone interested in just how far the Agency has drifted, at time, from true science read the book "Deadly Medicine."

## Response 14

In my post, I was in no way suggesting that drug companies should be permitted to distribute "flawed, dangerous" materials. What I suggested was that companies shouldn't be forced to reject and destroy life saving products simply because of a failure to meet a specification in cases where such a failure would not substantially impact the fitness-for-use of the product: better to donate such materials somewhere that they could be used. To be sure, I would not advocate human use of an injectable that failed endotoxin specifications, nor the unfettered use of a teratogen (as suggested in your alarmist "use-the-worst-case-as-the-standard" response). My point was that an "if it fails spec, always reject" mind set is silly, and in the case of life-saving products that are expensive/hard to obtain, contrary to public health.

## Response 15

There is no "situation." I raised the point to spur discussion. My motivations are 2-fold:

1. To illustrate that the current state of drug regulation sometimes lets people suffer and die for stupid reasons.
2. To combat the ubiquitous human tendency to "turn off your brain and follow the rules."

## Response 16

I'm with you on this one. It seems to me that the humanitarian view-point has been hijacked by an alarmist on this subject. In making rejected product available, I don't think safety and efficacy issues should be compromised either. That is not to say there won't be product rejected that would otherwise be perfectly suitable for donation because of aesthetic or minor defects. I think it would be possible to draft an industry charter to set out the principles of maintaining product safety/efficacy and thus provide guidelines to manufacturers, regulatory bodies and aid agencies in reviewing whether a batch of rejected product would be allowed to be donated.

## Response 17

For those interested in the regulatory side, please check the revision in 1997 of "FDA Export Reform and Enforcement Act of 1996" available at www.fda.gov/ora/import/impexp/ora_impexp_page.html. The requirements for the issuance of Certificates of Exportability for approved drug products and unapproved drug products are provided along with the required forms. You can also call the compliance division of CDER at (301) 594-3150 for more information. ■

***—compiled by Russell E. Madsen***

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# Company, Colleague & Product Announcements

Torbeck and Associates recently announced that Mr. **Lynn D. Torbeck**, President, was elected to the USP Biostatistics Expert Committee. Torbeck is a statistical consultant to the pharmaceutical industry. He was recently invited by the FDA's Office of Compliance to present at one of their regularly scheduled Quality Systems Seminars and to discuss the statistical implications of the CGMP's. The seminar was held on April 23, 2001 at the FDA's facilities in Rockville Maryland. Torbeck can be reached at (847) 424-1314 or Lynn@Torbeck.org. See also www.Torbeck.org.

On June 7, 2001, **Christine Lee, MD**, Director of the Haemophilia Centre and Haemostasis Unit of the Royal Free Hamstead NHS Trust in London, accepted the **Alpha Therapeutic Corporation**/ Clyde McAuley, MD Award at the Plasma Forum — a meeting of the blood plasma collection and fractionation industry held in London. Lee, a Professor of Haemophilia at the Royal Free and University College Medical School, was honored for her research efforts benefiting women with bleeding disorders. For more information, contact Karen L. White at (323) 227-7018 or www.alphather.com.

**Patheon** announced the opening of a Pharmaceutical Development Services (PDS) facility at its site in Swindon, United Kingdom. The facility is Patheon's second PDS unit, complementing its recently expanded drug development operations in Toronto, Canada. Offering formulation, analytical development and clinical trial manufacturing services, the new Swindon facility handles both high and low-potency molecules and a wide range of dosage forms, including sterile products. The Swindon development facilities comprise 9,500 square feet and include four clinical trial and pilot scale manufacturing suites, a formulation laboratory and an analytical laboratory. The area is equipped with a full range of equipment to handle solid, semi-solid, liquid and sterile dosage forms. Sterile product development capabilities include the handling of liquid injectables (vials and ampoules), powders for injection, opthalmic drops, ointments and prefilled syringes. Patheon is an independent provider of drug manufacturing and development services in the rapidly growing pharmaceutical outsourcing sector. Patheon operates nine CGMP facilities in Canada and Europe, and currently serves a growing client base of pharmaceutical and biotechnology companies from its North American and European operations. For more information, contact Laura Macdougall at (905) 812-6763 or visit www.patheon.com.

Illinois Tool Works Inc. (ITW) and **The Texwipe Company LLC** announced on May 22, 2001 the signing of a definitive Asset Purchase agreement under which ITW will acquire Texwipe by the end of June 2001. Founded in 1963 by the Paley family, Texwipe designs, manufactures and markets specialized products, including contamination control supplies and process materials for use in critical manufacturing environments. Texwipe has successfully built its brand name and ongoing relationships with leading companies in each of its served end-markets, including the semiconductor, data storage, medical device, pharmaceutical, biotechnology, food processing, fiber optic, aerospace and automotive markets. Texwipe's broad product line includes wipers, swabs, sterile and non-sterile cleaning solutions, mops, face masks, stationery, PVA brushes and tape substrates. ITW is a $10 billion diversified manufacturer of highly engineered components and industrial systems. The company consists of approximately 600 decentralized operations in 43 countries and employs 55,000 people. For more information, contact Debora Rothwell at (201) 327-9100, ext. 252.

The **US Pharmacopeia** (USP) announced on June 19, 2001 the launch of its Public Policy Center (PPC), one of seven public health programs. The USP PPC is being established to improve the public health through the development of objective health and science policy research. The topics that the PPC will consider include science and health policy issues associated with high quality, safe and effective drug and therapeutic products, optimal health care information and patient safety. USP Senior Vice President for Program Development Jacqueline L. Eng is directing the Center. "While the USP PPC is new, USP's involvement in policy issues is not," said USP Executive Vice President and CEO Roger L. Williams, M.D. "USP has been a consistent contributor over its 180-year history to public policy deliberations through our open and collaborative drug standards development process. We anticipate that the USP Public Policy Center will contribute significantly to public policy debate and serve as a resource to federal and state legislative regulatory bodies, to the health and scientific communities, and to patient advocates and consumers." The Center will utilize the expertise of well-qualified researchers and experienced poli-

cy analysts. The Center also will seek to build collaborative relationships with other health and science policy centers, private foundations, and governmental entities whose expertise will contribute to the development of evidence-based alternatives for policy decision makers. For further information, visit www.usp.org/ppc. The Center's e-mail address is PublicPolicyCenter@usp.org.

**Anatel Corporation** recently introduced AnaTOC, a new technology for TOC analysis. This exclusive photocatalytic, end-point detection system ensures complete oxidation of all organics present in the water sample in the fastest time possible and without any conventional reagents or gases. Cost per sample is less than five cents including all consumables and standard maintenance. The closed-loop design eliminates the need for any carrier gas and the inconvenience associated with conventional wet chemistry and combustion methods. For more information, contact Jill Gregory at 1-800-373-0531 or (303) 442-5533.

**VWR International**, a global laboratory products and safety equipment distributor, now offers the new National Safety Council DLH Emergency Response Kits. This patented line of first aid kits is designed to make first response quicker and more effective than ever before. Each product comes complete with individual color and icon-coded injury packs containing everything required to treat most common injuries. Easy-to-follow, step-by-step visual instructions are included for every procedure to assist the user in providing relief until professional help arrives. VWR is a global distributor of laboratory chemicals, equipment, supplies and cleanroom products to meet the performance and productivity needs of university, government, industrial, life science, pharmaceutical and other laboratories. For more information, contact VWR International at 1-800-932-5000 or visit www.vwr.com. ■

***—Joe Bury***

## Send us your news . . .

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

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

# Emerging Global Regulatory Issues

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

**Ensure your seat at the table with FDA by registering early for the PDA/FDA Conference!**

PDA's popular annual event, 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. PDA is pleased to announce the confirmed participation of these FDA officials at the conference:

Jean Blackston Hill, Chemist, ORA
Frederick Blumenschein, Chief, Case Management and Guidance, CDER, Office of Compliance
Robert Coleman, Local District Inspector
John Dietrick, Compliance Officer, 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
Richard L. Friedman, Compliance Officer, Division of Manufacturing and Product Quality, Office of Compliance, CDER
Brenda Kiliany, Consumer Safety Officer, 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
Helen N. Winkle, Acting Director, Office of Pharmaceutical Sciences, CDER

## 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.
- Educational Tabletop Exhibits
  (See vendor list on next page)

## 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.

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. ■

*—Leslie Zeck*

### Submit Your Questions for FDA

**Join PDA for this popular two-and-a-half day annual conference** focusing on regulatory issues and cutting edge topics that impact our industry. Prepare in advance by submitting your technical and regulatory questions for the FDA and industry panelists and your colleagues by e-mail to royal@pda.org. For additional information, visit PDA's Web site at www.pda.org.

## 2001 PDA/FDA Joint Conference Tabletop Exhibit Location

| Company | Booth # |
|---|---|
| Amersham Pharmacia Biotech, Inc. | 17 |
| Audit Repository Center | 1 |
| Carlisle Barrier Systems | 4 |
| CompuPharma, Inc. | 13 |
| Genesis Machinery Products | 10 |
| Learnwright, LLC | 16 |
| Millipore Corporation | 9 |
| Novatek International | 14 |
| NuGenesis Technologies | 20 |
| Optical Image Technology, Inc. | 7 |
| Pacific Scientific Instruments | 6 |
| Pall Corporation | 2 |
| Phoenix Imperative, Inc. | 15 |
| RCM Solutions | 8 |
| Sensitech, Inc. | 3 |
| SL Pharma Labs, Inc. | 11 |
| The Biologics Consulting Group | 12 |
| The Validation Group, Inc. | 18 |
| VelQuest Corporation | 5 |
| West Pharmaceutical Services | 19 |

### Hyatt Regency Washington on Capitol Hill

400 New Jersey Ave., NW
Washington, DC 20001

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Fax: (202) 942-1576

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The Hyatt is conveniently located in Capitol Hill, just blocks to the US Capitol, Congressional Office buildings, US Supreme Court, Library of Congress, Air & Space Museum, Smithsonian, Union Station and the Metro subway; 6 miles to Ronald Reagan Washington National Airport, 25 miles to Dulles International Airport or Baltimore/Washington International Airport; 2 blocks to Union Station's Amtrak and Metro rapid transit.

**Reserve your room before the August 3 deadline—be sure to mention PDA to get the special rate.**

# The Extractables Puzzle: Putting the Pieces Together

## Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Answers

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

PDA is hosting a national conference entitled, "The Extractables Puzzle: Putting the Pieces Together." The purpose of the conference will be to assess the state-of-the-art in extractables science and to explore analytical, material, regulatory and toxicology issues. Conference highlights include:

**Materials Presentations:**

- Pharmaceutical Industry Expectations from Vendors of Primary Packaging Components;
- European Perspectives;
- Extractables/Leachables from Rubber, Glass & Plastic Materials;
- Extractables from Aerosol Pump & other Specialized Components; and
- Analysis of Filter Materials.

**Analytical Presentations:**

- Extraction Protocols & Migration Studies;
- Analysis of Organic Extractables;
- Analysis of Inorganic Extractables;
- Development of Specifications & Acceptance Criteria; and
- Strategies for Evaluating Risks Associated with Container Extractables.

**Toxicology Presentations:**

- Overview of Toxicity Tests for Assessing Extractables;
- Applying US & European Regulations & Policies to the Toxicity Testing of Specific Drug Product Types; and
- Appropriateness of Current Regulations on Toxicity Assessment.

**Regulatory Presentations:**

- Summary of Published Requirements/ Guidances Relative to Extractives;
- Comparative Analysis of International Regulations & Guidances;
- Comparative Analysis of International Compendia; and
- Regulatory Recommendations: What's Needed.

A networking reception will provide additional opportunities for discussion. Regulators, regulatory affairs professionals, analytical chemists, toxicologists, material and component suppliers, formulators, and materials and packaging scientists should plan to attend this important conference. ■

*—Leslie Zeck*

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.

### 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

The program for this conference is still in development.

Visit our Web site at www.pda.org for up-to-date information.

Plan now to be in Basel, Switzerland in February 2002 for this prestigious benchmark congress, *Adding Value to the Pharmaceutical Industry: Leveraging the Future.* The event will attract at least 500 international professionals and scientists in the parenteral, sterile products, biotechnology and related fields for high-level education and dialogue among industry and regulatory experts. It is the seventh international congress PDA has hosted in Europe since 1992.

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

Interactive presentations and sessions will focus on the following topics:

#### 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.

## 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 or to get on the exhibit reservation list, 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

## About Basel

Basel, a city canton with nearly 200,000 people and 2,000 years of history, is located at the elbow of the Rhine on the borders of France and Germany. It is the center of the pharmaceutical industry and the site of major trade fairs. 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. ■

***—Leslie Zeck***

# The Parenteral Drug Association Foundation for Pharmaceutical Sciences, Inc.

## Is Pleased to Announce the Availability of the Following Grants for Graduate Students

### The Millipore / Charles P. Schaufus Grant

Up to $60,000, payable as $10,000 in cash and $10,000 in Millipore equipment per year for three years.

### The P.D.A. Foundation Kapoor Research Grant

Up to $15,000 per year for two years. Funded by the P.D.A. Foundation, the Kapoor Charitable Foundation and others.

### The P.D.A. Foundation Schering-Plough Research Institute Grant in Biotechnology

Up to $15,000 per year for two years. Funded by the P.D.A. Foundation and Schering-Plough Research Institute

Schering-Plough Research Institute is the pharmaceutical research and development arm of Schering-Plough Corporation of Kenilworth, N.J., a research-based company engaged in the discovery, development, manufacturing and marketing of pharmaceutical products worldwide.

Qualified and interested parties can submit an application on-line at our website www.pdafoundation.org. The deadline for submission of grants is September 15, 2001. If candidates need additional information, please contact the P.D.A. Foundation office at 516.248.6713 or by e-mail to Nina Demuth at hndemuth@aol.com

The Parenteral Drug Association Foundation for Pharmaceutical Sciences, Inc. (P.D.A. Foundation) is a non-profit organization whose mission is to promote the good of the public by identifying needs in the fields of parenteral and related sciences and technologies. The P.D.A. Foundation raises and dispenses funds in support of research and educational activities that meet those needs.

*Foundation*

FOR PHARMACEUTICAL SCIENCES, INC.

The P.D.A. Foundation is a 501 ( C ) 3 corporation. A copy of our annual report is available upon request and is on file with the New York State Attorney General.

The space for this announcement was provided courtesy of the P.D.A. (http://www.pda.org)

The design was provided courtesy of L2R Creative (http://www.l2rcreative.com)

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

**Register early to ensure your participation. Last year's conference on this topic in Washington, DC was sold to capacity.**

**Space is limited at the Berlin venue so be sure to register now.**

PDA, in collaboration with the International Association for Biologics (IABs), is pleased to present an international conference on process validation for biologics, September 6–7, 2001 at the Berlin Hilton Hotel, Berlin, Germany.

This conference 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. Representatives of the FDA, scheduled to present at the conference, include Christopher Joneckis, Ph.D., Mary Malarkey and Emily Shacter from CBER. The EMEA will be represented by John Purves, Ph.D., Head of Sector, Quality of Medicines, and Jean-Hugues Trouvin, Current Chair, EMEA Biotechnology Working Party. Anthony Ridgway, Ph.D., Acting Director, Bureau of Biologics and Radiopharmaceuticals, Biologics and Genetic Therapies Directorate, and Harold Rode, Ph.D., Health Products and Food Branch, will represent Health Canada.

A range of topics covering validation throughout the product life cycle will be discussed, as well as appropriate practices and requirements that will serve as a sound basis on which to connect comparability determination and process validation.

This conference will be of significant value to process scientists, manufacturing and quality professionals, regulatory affairs professionals, analytical chemists, process engineers, virologists and others.

Conference highlights include discussions on:

- Regulatory requirements and expectations for process validation;
- How the EMEA and FDA approach bulk biological drug substance process validation in marketing applications;
- Current process validation practices that have been found;
- The use of prospective, concurrent and retrospective validation;
- Validation of post-approval changes;
- Defining critical process parameters;
- Use of scaled-down manufacturing models;
- Validation concerns for cell substrates and animal sources;
- Validation aspects of reprocessing and reworking;
- Validation of viral removal and inactivation;
- Physical methods of separation;
- Current issues in validation of chromatography;
- Establishing process robustness;
- Validation of clinical trial materials; and
- New approaches to process validation.

This conference is expected to sell out. For the full registration brochure and hotel and registration information, please visit our Web site at www.pda.org. ■

*—Leslie Zeck*

# PDA Isolation Technology Conference

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

Case studies are being sought from industry representatives on these and related issues.

**To submit an abstract** to be considered for presentation, visit PDA's Web site at www.pda.org for instructions under "Call for Papers" for this important conference.

PDA will host a follow-up to last year's important conference on isolation technology issues. This 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.

Attendees 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. ■

*—Leslie Zeck*

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# 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).

Each session will be moderated by one representative from the FDA and one representative from industry. 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. Implementation of new technologies and divergence in strategy between product classes will be discussed. Hannelore Willkommen of the Paul-Ehrlich-Institut has been invited to present a global perspective, including elements that are sometimes missed in applications.

The goals of the conference are to:

- Discuss the current state of the art and new viral removal technologies, including filtration, chromatography and inactivation technologies;
- Discuss current issues related to the reuse of chromatographic columns and the impact on viral clearance requirements;
- 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
- 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, 2001 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.

*continued from cover, 2001 PDA Annual Meeting*

- Laboratory Testing: out of specification results, environmental/bioburden test methods, biological assays, stability testing, impurity profiles;
- Computers: Y2K contingencies, validation, electronic records and signatures; and
- Environmental Monitoring and validation of environmental monitoring processes.

## Conference Highlights:

- PDA's Interest Group meetings and presentations;
- Visit the Exhibit Hall (90% sold; call Nahid Kiani at (301) 986-0293 x128 to reserve your booth today), 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 hands-on training courses offered by PDA's Training and Research Institute.

**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.

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

For additional information on this conference, please visit our Web site at www.pda.org. ■

*—Leslie Zeck*

**HOTEL INFO**

Marriott Wardman Park Hotel
2660 Woodley Road,NW
Washington, DC 20008

Tel: (202) 328-2000

Reservations: (800) 228-9290

Fax: (202) 234-0015

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: 3:00 pm
Check out 12:00 noon

*continued from cover, Good Manufacturing Practice Guide*

- Food and Drug Administration Inspectors.

Training will be presented by the following members of the International Conference on Harmonization (ICH) Q7a Expert Working Group:

Betsy Fritschel, Johnson & Johnson
Joe Phillips, FDA (retired)
Lothar Hartmann, Hoffmann-La Roche, Inc.
Edwin Rivera Martinez, FDA
Max Lazar, Hoffmann-La Roche, Inc. (Retired)
Paolo Romagnoli, European Generic Medicines Association

Attendees will learn:

- How the FDA will inspect manufacturers to the Q7a requirements;
- How the document is intended to function and the thought process behind the guideline; and
- How to interpret all 19 chapters of Q7a.

Please visit the Web sites listed to the right for additional information, or contact info@pda.org. ■

***—Leslie Zeck***

For More Information on Q7a Training visit:
www.pda.org
www.genericaccess.org
www.phrma.org

*continued from back cover*

November 12–13, 2001
**The Extractables Puzzle: Putting the Pieces Together**
Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Answers
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

November 15–16, 2001
**PDA-TRI Laboratory Course: How to Develop 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

**March**

March 11–15, 2002
**2002 PDA Spring Conference, Courses and Tabletop Exhibition**
Rosen Hotels and Resorts, Orlando, FL

**April**

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

# The PDA Canadian Chapter and the A3P are Co-Sponsoring an International Conference & Exhibition

### ...in Montréal September 17–18, 2001. There will be French to English simultaneous translation on both days.

On Monday, September 17, the suppliers of equipment, goods and services will be displaying the latest technology and trends. There will be technical representatives from each exhibiting company to articulate their products and services. The exhibition schedule will provide ample networking opportunity. Cocktail breaks will be served in the exhibit area. There is no charge to attend the Exhibition. Interested vendors please contact the chapter for more information.

On both days, technical presentations will be made by experts in pharmaceutical technology from Canada, the United States, Switzerland and France. For a complete program and registration form, please visit the PDA Canada Web site at www.pdacanada.org.

**Conference Information:**

| | |
|---|---|
| Dates: | September 17 & 18, 2001 |
| Location: | Holiday Inn Montreal Mid-town<br>420 Sherbrooke West<br>Montréal,H3A 1B4, Canada |
| Tel: | (514) 842-6111 or 1(800) 387-3042 |
| Fax: | (514) 842-9381 |

**Hotel Reservation:**

**Contact the hotel directly by August 3, 2001,** to make room reservations at the PDA Conference rates of C$149 for standard room single or double; C$169 for corporate room single or double. ■

*—Virginia Ventura*

# Woo-Hyun Paik, Ph.D., Chairman of PDA Korea Chapter Wins "Dong-Am Medicine Award"

Woo-Hyun Paik, Ph.D., Chairman of the PDA Korea Chapter, was awarded the "Dong-Am Medicine Award" by the Minister of Health and Welfare (MOHW) of Korea on March 29, 2001. The award was established by Yakup Shinmoon, a Korean pharmaceutical industry publication. The Yakup Shinmoon prize is the most prestigious in Korea, and was given to Paik in recognition of his contribution to the advancement of the Korean pharmaceutical industry.

Woo-Hyun Paik, Ph.D. receives the "Dong-Am Medicine Award" from Won-Gil Kim, Minister of Korean Ministry of Health and Welfare, observed by Dr. Il-Hyuk Kim, Chairman of Judging Committee of the Medicine Award.

Paik has worked in the pharmaceutical industry for more than 40 years. He has served as plant manager, QC manager and R&D director in several pharmaceutical companies. He is recognized as the pioneer in implementation of GMP in the Korean pharmaceutical industry. He edited "KGMP Commentary" and has trained many industry technicians. The Korean GMP issued in 1977 was drafted by Paik.

Paik has served for many years as a member of Central Pharmaceutical Council of MOHW, the GMP Steering Committee of Korea Pharmaceutical Manufacturers Association(KPMA), and the Appraisal Committee for government New Drug Development Projects.

Paik established the PDA Korea Chapter in 1997 and has been working actively as the chairman of KPDA since that time. ■

*—Virginia Ventura*

# PDA UK & Ireland Chapter Roundtable

## PDA Technical Report Number 1: Industrial Moist Heat Sterilisation in Autoclaves

PDA's UK & Ireland Chapter will hold a one-day Roundtable Meeting to discuss the progress of revised PDA Technical Report Nr.1. Chairman of the Roundtable is Dr. Nigel Halls, GlaxoSmithKline (GSK), with additional speakers Wilf Allinson and Ian Symonds, also of GSK, and Keith Shuttleworth, of Keith Shuttleworth and Associates.

This roundtable will survey the current status of PDA's landmark technical report on the validation of steam sterilization cycles used in the industrial pharmaceutical environment originally published in 1979. The current revision is much more inclusive and comprehensive in scope. The roundtable will address some of the major technical issues remaining in the draft including porous load sterilization and steam quality, both of which are associated with differing regional interpretations in recent years.

### Date & Location

The meeting will be held on August 14th from 09:30 to 16:00 at the Sportsman Hotel, Common Road, Chorleywood, Herts.

### Cost

£30 for PDA members, Nonmembers £50. Lunch is included.

### Registration

To register, e-mail or call Rachel Harrison, GSK, and request a registration form to be e-mailed to you: e-mail rlh49476@GlaxoWellcome.co.uk; tel 44 (0)1833 692370).

Please act quickly as the meeting is being restricted to 30 participants.

*—James Lyda*



# Upcoming 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 and look for the brochure coming soon!**

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# 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*

# Do You Know What This Is or How to Identify It?

*Aspergillus flavus* (soil-inhabiting fungus; can cause Pulmonary Aspergillosis)

Fungi, which comprise one of the five kingdoms of life, are eukaryotic, spore-bearing, non-photosynthetic organisms. They can be found in soil and water and are a major component of dust. Two common morphologies of fungi are yeast and molds. Many strains of yeast are useful in fermentation processes used to make bread, wine, beer and cheese. The most noted use of molds is in the production of drugs, including antibiotics like penicillin and cephalosporin. Fungi also play a role in many crop, animal, and human diseases, and are a frequent contaminant in pharmaceutical production facilities.

### PDA-TRI To Offer Hands-On Environmental Mycology Course

A new, hands-on **Environmental Mycology Identification Workshop** will be offered December 10–11, 2001 at the PDA Training and Research Institute in Baltimore, MD. This course is designed for QC laboratory personnel in the food, drug and cosmetics industries that must evaluate Quality Assurance samples for the presence of fungi, as well as individuals involved in environmental assessment laboratories. The individual who attends this lab course will be able to confidently and rapidly identify mold and yeast species that could be problematic in the processing of pharmaceutical, biopharmaceutical, and food products. Participants who complete this course can provide their firm with an in-house resource of skill and knowledge to apply to the more common mycological issues in their QA laboratories. ■

For more information about this and other PDA-TRI courses, please visit the PDA Web site (www.pda.org) or contact the Training and Research Institute at 410-455-5800.

**SPACE IS LIMITED, SO REGISTER TODAY FOR THIS HANDS-ON WORKSHOP!**

# Upcoming New Orleans Courses

**August 6–8, 2001**

**Hyatt Regency New Orleans, New Orleans, LA**

August 6, 2001
- **Understanding the Regulatory Compliance Requirements of the US Pharmacopoeia (PDA #480)**

August 6–7, 2001
- **A Practical Approach to Aseptic Processing and Contamination Control (PDA #110)**
- **A System-Based Approach to an FDA Inspection (PDA #104)**

August 6–8, 2001
- **Tablet Formulation (PDA #162)**

August 7, 2001
- **Good Documentation Practices in the Pharmaceutical Industry (PDA #451)**

August 8, 2001
- **Everyday Compliance: Introduction to the CGMPs & Drug Regulation (PDA #472)**
- **Conducting Compliant Deviation Investigations for the Pharmaceutical Industry (PDA #114)**
- **Identification of Microorganisms Using Comparative DNA Sequencing (PDA #234)**

■

**Make your reservations directly with the hotel by July 16, 2001**, and mention PDA to secure the group rate of $109.00 - single occupancy. After July 16, reservations—if available—will be at the hotel's prevailing rate.

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

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

# Last Call—Aseptic Processing 2001

**July 23–27 & August 20–24**

**October 1–5 & November 5–9**

**Baltimore, Maryland**

**Very few slots remain in this popular lab course—call now to register.**

**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.

**A Comprehensive Program in Manufacturing Sterile Products**

# 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 07/01**

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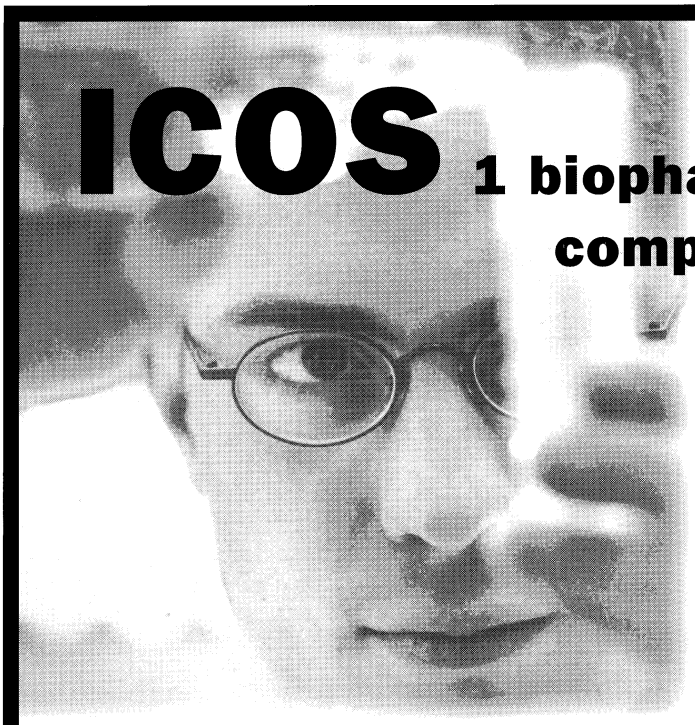
Date:_____ Check:_____ Amount:_____ Account:_____



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### Isolation Technology
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*kohnf@labs.wyeth.com*

### Validation
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**E-mail—**
*biferenc@aol.com*

### Visual Inspection of Parenterals
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*john.g.shabushnig@pharmacia.com*

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**LAL**

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**Anti-factor Xa Activity**

**Method Validation and Development**

For more information or to arrange a visit, contact:

Elizabeth A. Raike, President
Phone: 732-918-0207 Fax: 732-918-6680
104 Green Grove Road Ocean, NJ 07712

## 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

**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

## PDA Archive on CD-ROM

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Item No: 01101

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

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## 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.

To Order, Use Form on Page 44

**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**
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**2001 PDA Spring Conference Proceeding Modern Pharmaceutical Microbiology-Advancing the Science**, March 11–16, 2001 Las Vegas, Nevada; 2001, 368 pages.
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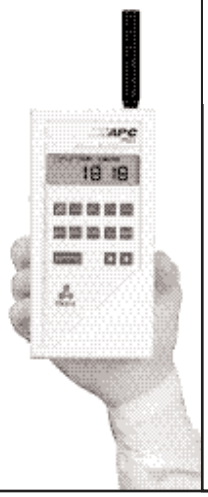

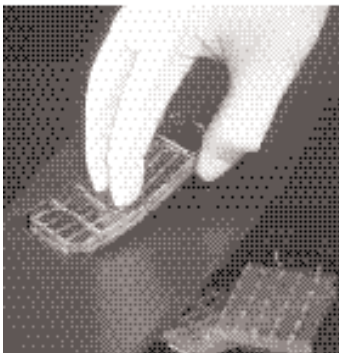

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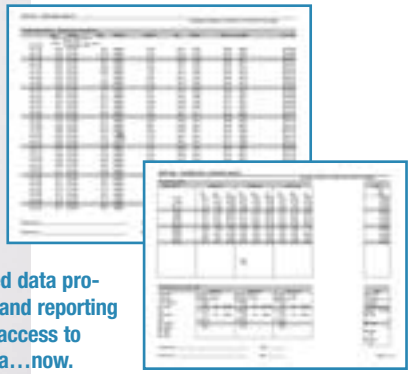

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# Calendar of Events

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**July**

July 18–19, 2001
**PDA Southeast Chapter Meeting & PDA-TRI Courses**
Sheraton Chapel Hill, Chapel Hill, NC
July 18
**Using INFOSEC Technology and Procedures for 21 CFR 11 Solutions**
July 18–19
**Parenteral Packaging: Rubber, Glass, Plastic, and Metal Seals**
July 19
**Writing and Auditing CGMP Documentation**

July 23–27, 2001
**PDA-TRI Aseptic Processing Course (week 1)**
Baltimore, MD

July 26, 2001
**New England Chapter-PDA Quarterly Meeting**
Marriott Hotel, Cambridge, MA

**August**

August 6–8, 2001
**PDA-TRI New Orleans Course Series**
New Orleans, LA
August 6
**Understanding the Regulatory Compliance Requirements of the US Pharmacopoeia**
August 6–7
**A System-Based Approach to an FDA Inspection**
**A Practical Approach to Aseptic Processing and Contamination Control**
August 6–8
**Tablet Formulation**
August 7
**Good Documentation Practices in the Pharmaceutical Industry**
August 8
**Conducting Compliant Deviation Investigations for the Pharmaceutical Industry**
**Everyday Compliance: Introduction to the CGMPs & Drug Regulation**
**Identification of Microorganisms Using Comparative DNA Sequencing**

August 14, 2001
**PDA's UK & Ireland Chapter Roundtable - *PDA Technical Report Number 1: Industrial Moist Heat Sterilisation in Autoclaves***
Sportsman Hotel, Common Road, Chorleywood, Herts

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
**Q7a Guidance Training Workshop**
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
**Q7a Guidance Training Workshop**
Hyatt Regency Princeton, Princeton, NJ

*continued on page 33*

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