Volume XXXVII, No.11

PDA Letter

November 2001

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

PDA/FDA Joint Regulatory Conference Summary, page 32

Parametric Release in Europe

by Klaus Haberer, Compliance Advice and Services in Microbiology GmbH, Chair, PDA Parametric Release Task Force

Annex 17 Issued Final

The need for regulations on parametric release, the release of pharmaceuticals based on information collected during the manufacturing process without carrying out a Pharmacopoeial test, has been recognized in Europe for a long time. The reason was a long-standing remark in the European Pharmacopoeia Text 5.1.1., Methods of Preparation of Sterile Products. It is stated that parametric release may be acceptable subject to approval of the Competent Authority. However, attempts of industry to get such approval met widely divergent answers from the various Authorities throughout the European Nations. Hence, the recent initiative by the European Authorities to clarify when such an approval can be granted was truly necessary.

Proposals of the pharmaceutical industry for *Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat* had been elaborated in a PDA working group, and were published as PDA Technical Report No. 30 in the *PDA Journal of Pharmaceutical Science and Technology,* 53 Suppl, 217–222, 1999.

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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 PDA-TRI Courses

Come and exchange important information with industry colleagues to find how multinational companies do business in today's challenging regulatory environment.

The theme of the PDA International Congress, Courses and Exhibition in Basel, Switzerland is *Adding Value to the Pharmaceutical Industry: Leveraging the Future*. The conference will feature a multi-track format of topics important to the indus-

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2001 PDA Annual Meeting, Courses and Exhibition

This December, put your finger on the pulse of the industry! Come to Washington, DC for the PDA Annual Meeting.

10 Reasons Why You Should Attend

1. Hear Industry Colleagues Share Real Life Compliance "How To" Strategies;
2. The Korczynski Lecture: BSE/TSE Risks Associated with APIs and Starting Materials: The Situation in Europe and the Global Implications for Healthcare Manufacturers;
3. More than 20 Interactive Interest Group Meetings;
4. Injunction/Seizure/Consent Decree: Learn how to avoid these actions;
5. **SOLD OUT** Exhibit Hall featuring informative educational displays;
6. PDA-TRI Education Courses;

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

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

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

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

PDA President
Edmund M. Fry

Director, Communications & Marketing
Linda M. Williams

Editor/Web Editor
Joseph G. Bury

Manager, Publications & Production
Janet Raysick

Important Dates...

- PDA Election—voting closes at 5 PM Eastern Time USA, November 21st
- Training Conference Call for Papers Deadline December 14th

IN THIS ISSUE...

Fry

Awards to be Presented at the PDA 2001 Annual Meeting

Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award is 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.

Michael S. Korczynski, Ph.D.

- Past Chairman of the PDA Research Committee, producing a number of Technical Reports. Author of several technical articles in *PDA Journal of Pharmaceutical Science and Technology*.
- Conceived the need for Chapters in 1988; nurtured the development of the first Chapters in PDA.
- Served on the Board of Directors several years, then served as PDA Second Vice President 1982, Vice President 1988–89, and President 1990–91.
- Was Convenor of ISO Technical Committee 198 Working Group 9 (Aseptic Processing) and served as bridge between PDA and ISO.
- Drove the initial international development of PDA; the first International Congress in Basel and the first international chapters in Canada and Japan were developed during his presidency. His international leadership is recognized through the Korczynski Grant used to bring overseas speakers to PDA conferences in the USA.
- Named Researcher of the Year at Abbott Laboratories.
- Chaired or served on many PDA committees, including chairing the National Program Committee in the early 80s, and several program committees over many years.
- Was PDA's first VP, Education and Director of the new Training and Research Institute 1997–2000.

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, other than a Board member, for long-term acts or contributions that are of noteworthy or special importance to PDA.

Regina McCairns

- Chaired or served on numerous program committees; worked effectively and diligently to develop high-quality PDA programs domestically and abroad.
- Served on Training and Education Committee.
- Tireless leader in the Delaware Valley Chapter; helped it grow from its founding to one of the largest and most successful.
- Taught courses for PDA.

Fred Carleton Award

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

Joyce H. Aydlett

- Chair of PDA 1998–99; served several years as Director on PDA Board of Directors.
- Chaired Strategic Planning committee; produced PDA's current Strategic Plan.
- Served on PDA's Research committee and chaired the Microbiology Subcommittee.
- Served as a PDA liaison to ISO Technical Committee 198, Working Group 9 (aseptic processing).
- Chaired the oversight of PDA's European development from 1998 to the present; facilitated the development of the European Steering Committee; served as PDA ambassador at numerous events abroad.
- Served on several program committees over many years, and as presenter on many programs.

Distinguished Service Awards

Given by the PDA Board of Directors for special acts, contributions or service that have contributed to the success and strength of PDA.

The following volunteers, among the original PDA Directors-at-large charged with chapter development, were responsible for founding chapters and worked tirelessly toward their success:

Robert L. Garnick, Ph.D. (West Coast)
John Geigert, Ph.D. (West Coast; also chaired Chapter Council for several years)
Charles J. Cherundolo (Delaware Valley)
Edmund J. Fitzgerald (Canada)

Additional Distinguished Service Awards:

Simon Rusmin, Ph.D.

- Was one of PDA's first chapter Directors-at-large; worked at the chapter level in many activities.
- Represented PDA in its expansion into Asian countries; arranged key meetings with Asian groups that led to founding the Taiwan Chapter and other member recruitment in Asia.
- Recipient of PDA Research Award in 1976.
- Served on other technical committees over many years.

Richard T. Wood, Ph.D.

- Taught Design and Validation of Sterilization Processes and related courses for 10 years; helped train numerous industry professionals in this critical technology.
- Published and spoke frequently for PDA.
- Served on a number of program committees.

Frederick D. Simon Award

Named in honor of Frederick D. Simon, a long-time PDA volunteer who served as PDA's first Director, Scientific Affairs. It is presented each year for the best paper published in the PDA Journal of Pharmaceutical Science and Technology *during the previous calendar year, as determined by a distinguished committee of reviewers.*

"Alternative Microbial Testing: A Novel DNA-Based Detection System for Specified Microorganisms in Pharmaceutical Preparations", Vol. 54, No. 6, p. 470, by **Petra Merker (principal author), Jutta Ladewig, and Klaus-Peter Gerbling of Schering AG; and Lutz Grohmann, Roger Petersen and Frank-Roman Lauter of GeneScan GmbH.**

James P. Agalloco Award

Named in honor of James P. Agalloco in recognition of his work in developing the PDA education program. It is presented to the best faculty member in PDA's Education Program during the previous year, judged on the basis of student evaluations and overall contribution to the PDA education program.

James L. Vesper

- Documentation Systems & Practices (PDA Course 487)
- GMP Quality Auditing for the Pharmaceutical Industry (PDA Course 488)
- Training for Performance (PDA Course 409)
- GMP Fundamentals (PDA Course 493)

Acknowledgements

Thanks to the PDA Award Committee Chaired by Henry Kwan, Ph.D., and to the Fred Simon Award Committee Chaired by Galen W. Radebaugh, Ph.D., Schering-Plough Research Institute with the help of Dr. Karl Herzog, Dr. Steven Gordziel and Dr. Tom Julian. ■

—Edmund Fry

Renew Your Membership Now and Save

All members, regardless of membership expiration date, may renew now at the 2001 rates. If you renew on or before December 31, 2001, you will receive an additional year's membership for only $150.

Effective January 1, 2002, membership dues increase to $195 per year. The increase is made necessary by rising costs, including rent, printing, postage and other costs of providing member benefits. If you have not received a renewal notice, you can use the membership application on page 48 and mark it "renewal". ■

US Regulatory Briefs

Draft Guidance for Industry; Electronic Records; Electronic Signatures, Validation. In the *Federal Register* on September 24, 2001 (Volume 66, Number 185, Page 48886) the FDA announced the availability of the Draft Guidance for Industry; Electronic Records; Electronic Signatures, Validation. In the *Federal Register* of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper ("Part 11"). The preamble to Part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance addresses issues pertaining to the validation of computer systems used to create, modify, maintain, archive, retrieve, or transmit electronic records and electronic signatures subject to Part 11. Part 11 requires such validation, and the guidance is intended to assist people who must meet this requirement. It may also assist FDA staff who apply Part 11 to persons subject to the regulation.

The draft guidance provides specific information on key validation principles, and it addresses some frequently asked questions. Interested persons may submit to the Dockets Management Branch written or electronic comments on the draft guidance.

Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Docket Number 00D-1538. Submit written comments on the draft guidance document by **December 24, 2001**, to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1060, Rockville, MD 20852. For further information contact: Paul J. Motise, Office of Enforcement (HFC-240), FDA, 5600 Fishers Lane, Rockville, MD 20857 (301) 827-0383, e-mail: pmotise@ora.fda.gov. The guidance can be found at www.fda.gov/cber/guidlines.

Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms. In the *Federal Register* on September 24, 2001 (Volume 66, Number 185, Page 48886) the FDA announced the availability of the Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms. The draft guidance defines terms that will be used in other FDA guidance documents about Part 11. FDA believes that rather than repeat definitions in multiple guidances it would be more efficient to consolidate them in one common document. The glossary of terms is intended to assist people who must meet Part 11 requirements. It may also assist FDA staff who apply Part 11 to persons subject to the regulation. Interested persons may submit to the Dockets Management Branch written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Docket Number 00D-1543. Submit written comments on the draft guidance document by **December 24, 2001**, to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1060, Rockville, MD 20852. For further information contact: Paul J. Motise, Office of Enforcement (HFC-240), FDA, 5600 Fishers Lane, Rockville, MD 20857 (301) 827-0383, e-mail: pmotise@ora.fda.gov. The guidance can be found at www.fda.gov/ohrms/dockets/98fr/001543gd.pdf.

ICH Q1D, Bracketing and Matrixing Designs for Stability Testing. In the *Federal Register*, September 25, 2001 (Volume 66, Number 186, Page 49029) t he FDA announced the availability of the International Conference on Harmonization; Draft Guidance on ICH Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products.

The objective of this guideline is to provide harmonized guidance on the application of bracketing and matrixing for stability studies conducted in accordance with principles outlined in the ICH Q1A Harmonized Tripartite guideline covering Stability Testing of New Drug Substances and Products. Q1A notes that the use of matrixing and bracketing can be applied, if justified, to the testing of new drug substances and products, but provides no further guidance on the subject.

This document is an annex to the parent guideline and addresses recommendations for bracketing and matrixing study designs. Specific principles are provided in this guideline for situations in which bracketing or matrixing can be applied without further justification. In other circumstances, bracketing or matrixing is applicable only if further justification is provided. Sample designs are provided in this guideline for illustrative purposes, and should not be considered the only, or the most appropriate, designs in all cases. Design factors are the variables (e.g. strength, container size, fill) to be evaluated in a stability design for their effect on product stability. The full document can be found at www.fda.gov/cder/guidance under "ICH Draft."

New CBER Form 3356 for Establishment Registration. On September 19, 2001, the Center for Biologics Evaluation and Research (CBER) posted the 7/01 edition of FDA Form 3356 on their Web site. The 10/98 edition and the 3/01 edition are now obsolete. This newest edition has been updated to conform to the final regulation for establishment registration and listing. The new form can be found at the CBER Web site, www.fda.gov/cber, under "tissue related documents."

In the Federal Register, October 5, 2001 (Volume 66, Number 194, Page 51053) the FDA announced the availability of the Guidance for Industry on Content and Format for Geriatric Labeling. FDA established the "Geriatric Use" sub-

section in the labeling for human prescription drug and biological products to provide pertinent information about the appropriate use of drugs in the elderly (persons aged 65 and over). This guidance is intended to provide industry with information on submitting geriatric labeling for human prescription drug and biological products, including who should submit revised labeling, the implementation schedule, a description of the regulation and optional standard language in the proposed labeling, the content and format for geriatric labeling supplements, and the applicability of user fees to geriatric labeling supplements.

This guidance discusses which application holders are responsible for submitting revised labeling and summarizes the implementation schedule for submitting geriatric labeling. The geriatric labeling regulation includes six paragraphs that outline various options for statements in the "Geriatric use" subsection, based on the type of information available and the interpretation of that information. The guidance summarizes the requirements and provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling supplements, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail. The full guidance can be found at www.fda.gov/cder/guidance/index.htm. For further information contact: Mary E. Ortuzar, Center for Drug Evaluation and Research (HFD-006), FDA, 5600 Fishers Lane, Rockville, MD 20857 (301) 594-6740, or Toni Stifano, Center for Biologics Evaluation and Research (HFM-600), 1401 Rockville Pike, Rockville, MD 20852 (301) 827-6190.

The FDA is Seeking Qualified Persons to Participate with the Process Analytical Technologies Subcommittee. SUMMARY: FDA is requesting names of qualified persons to participate as discussants with the Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science. The subcommittee will identify and report to the Advisory Committee for Pharmaceutical Science on scientific issues related to application and validation of on-line process technologies such as near infrared and Raman spectroscopy and imaging methods for application in the manufacture of drug substances and drug products. The subcommittee will also report on the potential benefits and risks associated with the application of these new technologies to public health and, as part of this analysis, evaluate the feasibility of the parametric release concept.

Persons from government, industry, academia and other organizations (such as research institutes) applying as discussants with the subcommittee shall have exceptional accomplishments and be leading technical experts in the appropriate fields. In particular, expertise in application of the following scientific disciplines to pharmaceutical development and pharmaceutical manufacturing processes is desired: process analytical chemistry, pharmaceutics, industrial pharmacy, chemical engineering, pharmaceutical analysis, chemometrics, pattern recognition, computer expert systems, information technology and statistics.

FDA has a special interest in ensuring that women, minority groups and individuals with disabilities are adequately represented and, therefore encourage recommendations of qualified candidates from these groups. Final selections from among qualified candidates will be based on the expertise demonstrated and previous experience with on-line process technologies. Dates: All applications should be received by **November 30, 2001**. Application procedures: Any interested person should include appropriate biographical material and a list of scientific publications relevant to the subcommittee. Addresses: Please submit applications to: David Morley, Office of Testing and Research (HFD-900), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: David Morley (301) 527-5186, FAX: (301) 827-3787, E-mail: morleyd@cder.fda.gov.

On August 17, 2001 CBER Issued Internal SOPP (Standard Operating Procedures and Policies) 8104, Version 2, Documentation of Telephone Contacts with Regulated Industry. SOPP 8104 describes the procedures that CBER staff should routinely follow regarding telephone conversations with sponsors/applicants of investigational and marketing submissions to safeguard the proprietary information in such submissions and to assure that the regulatory review record is complete. The same procedures also apply to contacts with regulated industry and other non-FDA persons regarding issues related to pre-application submissions and meetings, import and export requests, promotional labeling, inspections, investigations, or other regulatory actions.

Contacts are initiated by sponsor/applicants or their representatives to check on the status of submissions, to request information or guidance, or to inquire about other regulatory activities such as inspections or investigations, and enforcement actions. FDA may contact a sponsor/applicant to clarify or advise on issues in submissions, to request information, or notify the sponsor/applicant of a regulatory action. While CBER staff have a responsibility to accommodate reasonable inquiries, these inquiries should not be allowed to disrupt operations. Additionally, CBER staff also has an obligation to prevent disclosure of proprietary information to unauthorized persons and not to interfere with any ongoing regulatory action.

In the past, unauthorized individuals, representing themselves as members of a sponsor firm or as agents for the firm, have attempted to obtain information from various centers within the FDA for their own advantage or personal financial gain. Additionally, some callers have made inquiries with CBER staff during ongoing inspections without full disclosure of their identity or purpose.

All callers should be confirmed as either an authorized employee or agent of the sponsor/applicant firm. When a caller's identity is questioned, the caller should be advised that a designated contact at the

applicant's organization should make the call or the CBER contact should attempt to return the call utilizing recognized phone numbers.

A written authorization from the applicant to the file must be obtained prior to contact with a designated agent (i.e., an individual or firm which has been designated to represent the applicant). The authorization should list the agent's name, telephone numbers (including FAX) at which contact should routinely be made, address, and the nature of the information that may be disclosed to the agent. Copies of the agent authorizations must be supplied to each relevant application.

The Regulatory Project Manager (RPM) in the relevant product office's application division will be the initial contact for industry representatives requesting filing requirements, application status, or appropriate contact for a technical issue. Technical inquiries related to applications or supplements may be handled by the appropriate IND contact person, application chairperson or their designee. All substantive telephone conversations should be documented in writing. The memorandum of the conversation should include the date and time of the teleconference, names of all FDA and sponsor/applicant participants, the subject, a clear and concise summary of advice, decisions, policy or actions, action items, and the signature of the preparer. For all substantive conversations, the memorandum is to be included in the application or file, if applicable, as part of the permanent administrative record. The entire document can be found at www.fda.gov/cber/regsopp/8104.htm.

CBER's Role in Countering Bioterrorism. The President's initiative on Countering Bioterrorism is comprised of a number of essential elements for which CBER plays an integral role. One such element is the expeditious development and licensing of products to diagnose, treat or prevent outbreaks from exposure to the pathogens that have been identified as bioterrorist agents. These products must be reviewed and approved prior to the large-scale productions necessary to create and maintain a stockpile. Staff must guide the products through the regulatory process, including the manufacturing process, pre-clinical testing, clinical trials, and the licensing and approval process. Experts in these areas are needed to expedite the licensing and approval process for these products. This process is extremely complex and early involvement by staff is crucial to the success of the expedited review process.

CBER staff has participated in numerous meetings, briefings, and conferences representing FDA with staff from the Department of Defense, the Department of Health and Human Services (DHHS), and the Office of Management and Budget as well as other DHHS Agencies including the National Institutes of Health and the Centers for Disease Control and Prevention. The Center has also engaged in the development of new regulatory models to accommodate the need for preparedness in the case of an emergency attack. For example, procedures and protocols are being developed to enable the use of in-

vestigational new drugs in a highly controlled, safe manner for particular emergency situations.

Senate Testimony on Reimportation of Drugs. Statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration, before the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism, Senate Committee on Commerce, Science, and Transportation, September 5, 2001.

The amount of prescription drugs for personal use imported through the mail has increased in recent years. According to testimony by the USA Customs Service (Customs) before the Government Reform Committee in May of last year, seizures of parcels containing scheduled or controlled substances at international mail facilities increased by 450 percent in FY 1999, primarily due to drug sales over the Internet. We estimate that approximately two million parcels containing FDA-regulated products for personal use enter the USA each year through international mail facilities that Customs could set aside for FDA review for possible violations of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Under the FD&C Act, unapproved, misbranded, and adulterated drugs are prohibited from importation into the USA, including foreign versions of USA-approved medications, as is reimportation of approved drugs made in the USA. In general, all drugs imported by individuals fall into one of these prohibited categories.

USA made drugs that are reimported may not have been stored under proper conditions, or may not be the real product, because the USA does not regulate foreign distributors or pharmacies. Therefore, unapproved drugs and reimported approved medications may be contaminated, subpotent, superpotent, or counterfeit. In addition, some foreign Web sites offer to prescribe medicines without a physical examination, bypassing the traditional doctor-patient relationship. As a result, patients may receive inappropriate medications because of misdiagnoses, or fail to receive appropriate medications or other medical care, or take a product that could be harmful, or fatal, if taken in combination with other medicines they might be taking.

Under FDA's personal importation policy, as described in guidance to the Agency's field personnel, FDA inspectors may exercise enforcement discretion to permit the importation of certain unapproved prescription medication for personal use. The current policy permits the exercise of enforcement discretion to allow entry of an unapproved prescription drug if:

- The product is for personal use (a 90-day supply or less, and not for resale);
- The intended use is for a serious condition for which effective treatment may not be available domestically (and, therefore, the policy does not permit inspectors to allow foreign versions of USA-approved drugs into the USA);
- There is no known commercialization or promotion to USA residents by those involved in the distribution of the product;

- The product is considered not to represent an unreasonable risk; and
- The individual seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the USA licensed doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

FDA believes that the need for its personal importation policy is far less now than it was when the current version of the policy was developed in 1988. Now, due to faster review times and various regulatory mechanisms through which patients can obtain unapproved treatments for humanitarian purposes, the need to import therapies not available in the USA has diminished. According to a Tufts University study presented in September 2000, 80 percent of new molecular entities approved in the USA in 1996 through 1998 received that approval within a year of its first introduction on the world market, almost double the rate during the years 1991 through 1995.

Earlier this year, FDA and Customs conducted a survey of imported drug products entering the USA through the Carson City, California mail facility (the Carson pilot). The Carson pilot was proposed by Customs as a means to examine incoming mail shipments of pharmaceutical products over a specified time frame in order to identify both the volume and the types of drug products entering the USA.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week. The number of packages set aside was approximately 3,300. Multiplying that number by five weeks provides an estimated total of 16,500 international packages (650 packages per day) that Customs could have set aside for FDA review during the Carson pilot, if the ability to process them was not a factor.

FDA was actually able to examine 1,908 packages during the five-week pilot, an average of approximately 381 packages per week. Of the 1,908 packages examined by FDA, 721 parcels were detained and the addressees notified that the products appeared to be unapproved for use in the USA, misbranded and/or a drug requiring a doctor's prescription. The parcels were shipped from a total of 19 countries, and overall, there was no obvious evidence of the products being imported for further commercial distribution. On average, the Agency was detaining at a rate of 144 packages per week, or about 38 percent of those examined.

Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

The Carson pilot demonstrated that the rate of packages coming into the USA exceeds FDA's capacity to manage, thus, Customs is left with little choice but to forward the majority of packages to addressees. As we stated, we do not believe this is an acceptable public health outcome, and we are working to develop a solution.

International Briefs

Australian Therapeutic Goods Administration (TGA) Issues New Classification of Medicinal Products Nonconformities.

The GMP Audit and Licensing Section now classifies nonconformities observed during GMP audits of medicine manufacturers as "critical" and "significant other." This change has been made to harmonize with the European approach to classifying nonconformities. A "critical nonconformity" is one which has produced, or may result in, a significant risk of producing a product which is harmful to the user. A "significant other nonconformity" is a nonconformity which is not a critical nonconformity and:

- Has produced or may produce a product which does not comply with its marketing authorization; and/or
- Indicates a significant deviation from the Code of GMP; and/or
- Indicates a significant deviation from the terms of the manufacturing license or GMP approval (overseas manufacturers); and/or
- Indicates a failure to carry out satisfactory procedures for release of batches; and/or
- Indicates a failure of the person responsible for QA/QC to fulfill his/her duties; and/or
- Is worth noting for follow-up at the next audit; and/or
- Consists of several related nonconformities, none of which are significant on their own, but together represent a significant nonconformity.

Health Canada Adopts the Common Technical Document (CTD) for Drug Submissions. On September 19, 2001, Health Canada issued a guidance on the use of the CTD in the preparation of drug submissions. As of July 1, 2003, the CTD will officially replace existing formats for all pre-market drug submissions filed with Therapeutic Products Directorate (TPD) and the Biologics and Genetic Therapies Directorate (BGTD). During the transitional period from July 1, 2001 to July 1, 2003, applicants may file submissions prepared in accordance with the CTD, the 1991 guidance *Preparation of Human New Drug Submissions* and the 1992 *Supplement* or the 1997 *Modified FDA Format* policy, subject to conditions in the guidance.

The guidance covers the preparation and filing of CTD formatted drug submissions for human use, filed pursuant to Division 8, Part C of the Food and Drug Regulations (FDRs), such as:

- New Drug Submissions (NDSs);
- Abbreviated New Drug Submissions (ANDSs);
- Supplemental New Drug Submissions (SNDSs);
- Supplemental Abbreviated New Drug Submissions (SANDSs); and

continues on page 20

TR 32 UPDATE

by Harvey Greenawalt, Audit Repository Center

Since the issue of TR 32 in January of 2000, 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 the PDA's licensed audit repository administered by Audit Repository Center (ARC).

The PDA Process has continued to grow steadily. Currently the Process represents a network of over 100 qualified auditors, nine pharmaceutical and biotechnology companies and 19 suppliers worldwide. Process resources range from Japan, Australia, Europe, Scandinavia, Canada, Middle East and 35 states within the United States.

All pharmaceutical companies and suppliers who joined ARC in 2000 have renewed their subscription for 2001–2002.

Subscribers to ARC and the PDA Process continue to report the following benefits:

- 50% reduction in cost of doing audits;
- 400% increase in the number of audits that can be managed by a single individual;
- Enterprise wide sharing of audit information for system validation;
- Standardization of method for analysis and consistent look and feel to reports;
- Seamless integration with acquisition and Software Life Cycle (SLC) practices;
- Fulfillment of Part 11 expectations with regard to computer validation and the use of commercially available computer products; and
- Reduction in the upfront cost of system validation associated with audits.

Currently, 16 audits are available for distribution from ARC. An additional 18 audits are either in process or scheduled to be completed within the next three months. Nine other audits are under consideration for implementation within the coming year.

Available Audits

Table 1.0 provides a summary of the 16 audits that are currently available for immediate distribution to ARC Subscribers on request.

TABLE 1.0 Audits Currently Available in ARC

	Supplier	Product
1	Accraply, Inc.	Label Applicators, Automatic Labeling Systems, & Custom Designed and Self Adhesive Material Application Systems
2	ActionPoint	Input Accel Document Imaging LIMS
3	Applied Biosystems	SQL*LIMS—Laboratory Information Management System including the QA Stability & Schedule Modules
4	Decision Management International, Inc. (DMI)	Regulus™ Document Authoring (DA) a member of the Regulus™ off-the-shelf solution set.
5	Etrials.com, Inc.	Electronic Data Capture—EDC Electronic Patient Diaries—EPD Electronic Trail Management—ETM
6	Entrust Technologies Ltd.	Digital security technology for enterprise resource systems. Public Key Infrastructure Technology (PKI)
7	Fanuc Robotics North America	Robotic Controllers & Communications
8	First Consulting Group, Inc.	Custom information based strategy software, operations improvements management and integration services
9	Infinity QS International (Lyle-Kearsley, Inc.)	Infinity QS Statistical Process Control Software
10	Merant, Inc.	PVCS Dimensions & PVCS Replicator Configuration Management Systems
11	Precision Solutions	Custom Development, SLE-Capture of check weight data Custom Software Programming
12	Qumas, Ltd. (Participating Supplier)	Qumas-Doc: Electronic Records Document Management Systems
13	SSA Global Technologies, Inc.	Mid range ERP software for manufacturing, supply chain and financial application domains
14	Supply Chain Logic, Inc.	General use COTS Asset Tracking/Delivery Systems
15	Schlumberger	Secure ID Card
16	Sparta Systems, Inc.	Track Wise Software

Scheduled Audits

In addition, 18 audits are either in process or scheduled to be completed within the next three months.

Table 2.0 provides a summary of the 18 audits that are currently either in process or scheduled to be completed within the next three months.

Submittal of final audit package is at discretion of the audit sponsor.

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

TABLE 2.0

Supplier Name	Supplier Product	Scheduled Audit Date
Agilent Technologies	Chromatography Data Products and Analysis Equipment	Oct. 2001
Automation Tooling Systems, Inc.	Custom programming services for Process Control Software	Nov. 2001
**Bausch & Stroebel	Machine Control for filling line	Jul. 2001
**Control Systems International	Building Automation	Jul. 2001
**Eisai USA, Inc. (Sankyo)	Vision Inspection Equipment and Automation	Jun. 2001
Epicentric, Inc.	Manage and control business webs	Nov. 2001
**Foss-NIR Systems, Inc.	Near Infra Red chemical analysis	Jun. 2001
**Honeywell POMS	POMS MES: Management of Manufacturing Operations from dock to stock for Healthcare and CPG companies.	Aug. 2001
**Infrastructure Management Systems (IMS)	PDF Rendering Tools.	May 2001
**Inktomi	Infoseek and other web based search engines	Nov. 2001
**Interwoven, Inc.	Web Publication Management	Nov. 2000
**Iplanet	Access and Administration Technology	Jun. 2001
JD Edwards	ERP techonology	Oct. 2001
**Loftware	Barcode and label printing technology	Sep. 2001
**MARC Global Systems	Warehouse Management Systems	Apr. 2001
Mercury Interactive	Test Management Tools: Astra FastTrack & TestDirector, Astra LoadTest, LoadRunner & LoadRunner TestCenter, Astra QuickTest & WinRunner	Nov. 2001
**Propack Data	PMX: Enterprise Production Management System	Sep. 2001
**SAP	mySAP.com e-business platform, specifically: aspects of Supply Chain Management, Product Lifecycle Management and Business Intelligence relevant to pharmaceutical manufacturing operations.	Jun. 2001

**Audits that are completed awaiting submittal to Repository by the Subscriber.

USP Update

by Roger Dabbah

USP and IPEC are co-sponsoring the Joint Conference on Excipients this December 11–14, 2001 at the Sanibel Harbor Resort in Fort Myers, Florida. GPhA and PhRMA have endorsed the Conference. Registration information is available at USP's Web site, www.usp.org/conferences or by calling (301) 816-8359. On December 11, 2001, at the same hotel, USP will be presenting a course on the Standards Development Process with emphasis on application to excipients.

The first annual edition of USP-NF (USP 25-NF 20) will become official on January 1, 2002. The USP-NF is also available in three electronic formats: CD, intranet and online.

The September/October 2001 issue of *Pharmacopeial Forum* (PF), under "In Process Revision," includes five new monographs targeted for the Second Supplement of USP 25. These monographs are Bupropion Hydrochloride Extended-Release Tablets; Theophylline Oral Solution; Urifollitropin for Injection; Chondroitin Sulfate Sodium, and Chondroitin Sulfate Tablets (NF). Two new chapters, <1119> *Near Infrared Spectrophotometry* and <1207> *Sterile Product Packaging-Integrity Evaluation* are also published under "In Process" and are slated for the Second Supplement of USP 25-NF 20.

Under "Pharmacopeial Previews," in the same issue of PF, nine new monographs are proposed: Gemcitabine Hydrochloride; Gemcitibine for Injection; Glycerin Injection; 0.1 Normal Hydrochloride Acid Intravenous Injection; Mangafodipir Trisodium; Mangafodipir Trisodium Injection; Naratriptan Hydrochloride; Naratriptan Tablets; and, Sumatriptan Succinate. A new General Chapter, <789> *Particulate Matter in Ophthalmic Preparation* is also published under Pharmacopeial Previews. A companion article under Stimuli by the Scientific & Regulatory Affairs section of PhRMA on *Compendial Standards for Subvisible Particulate matter in Ophthalmic Solutions: Results of an Industry Collaborative Study and Proposed Standards* is the basis for the limits of particulates proposed in proposed Chapter <789>.

On a personal note, I would like to thank PDA and the numerous individuals that have expressed their wishes for a prompt recovery due to my recent encounter with my acute allergic reaction to a new medication. ■

Basel 2002 continued from cover

try. Regulatory and industry experts will discuss the latest science and technology related to regulatory issues, compliance strategies, harmonization issues, validation, biotechnology and more.

Some examples of papers to be presented include:

- Current Status on Parametric Release for Moist Heat Pharmaceutical Products;
- EU GMP Annex 17 on Parametric Release: Impact of the Final Guidance;
- ICH Harmonised Tripartite Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients;
- International Standards on Cleanroom Technology and their Impact on the Pharmaceutical Industry; and
- A Risk-Avoidance Focused Approach to Microbiologically Monitoring Non-Sterile Manufactured Environments.

Exhibits

See the latest in pharmaceutical science and technology at PDA's exhibition in Basel. The exhibit hall is rapidly nearing a sell-out. For information on exhibiting and/or sponsoring an event, contact PDA via e-mail at kiani@pda.org.

And don't forget our Courses:

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- **Managing Risk Using Failure Mode and Effect Analysis (FMEA)**

Make your travel plans now to be in Basel for PDA's International Congress! ■

—Leslie Zeck

2001 PDA Annual Meeting continued from cover

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We look forward to seeing you! ■

—Leslie Zeck

New Publications Catalog Out!

PDA's 2001–2002 Fall/Winter Publications Catalog was recently mailed to members. If you didn't get yours or you'd like another copy, please call us for one or check out our Web site at www.pda.org.

Keep your knowledge current by checking out our newest publications—we've added lots of new books in addition to the technical reports, videos and existing selection of fine, industry-standard scientific and technical publications.

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E-mail: chua@pda.org

Discussions in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) started in 1998 and led to a draft guideline for inspectors in February 2000. This draft PIC/S guideline was slightly modified in March 2000 to become a draft GMP-Annex. In addition, the Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products (EMEA) released a draft Note for Guidance (NfG) in March 2000. Among other associations and individuals, a PDA task force submitted comments of the industry to the European Authorities. Most PDA comments were targeted to the draft GMP-annex which was seen as far too detailed and restrictive, while the NfG draft was considered mostly a reasonable description of the regulatory procedures.

CPMP NfG on Parametric Release

As the first part of the new European regulation, the NfG on Parametric Release was jointly elaborated by the CPMP/CVMP quality working party and an Ad Hoc group of inspectors of the EMEA. It was adopted in February 2001 and is in operation since September 2001. The main focus of the document lies on parametric release of sterile products without carrying out a sterility test. Application of parametric release to other aspects of pharmaceutical quality is kept open in the scope, and examples of such possible applications are given, but the only detailed guidance elaborated concerns the aspect of sterility.

The NfG defines the applicability of parametric release and describes the procedures for application and assessment. It is clearly stated that parametric release can only be applied for products sterilized in their final container by dry moist heat, dry heat and radiation. It is further clearly expressed, that the European Authorities are expecting applications for parametric release only to be submitted in general for products with an existing marketing authorization, where experience has been gained with the manufacturing process.

Assessment of an application will be in collaboration between Inspectorates and the Competent Authorities. The NfG specifies that the documentation needed for an application for parametric release of sterility should show adequate validation and reliable control of the manufacturing process. Clearly defined acceptance criteria for process parameters on the basis of validation records are required, as well as clearly specified procedures for approval or rejection. Strong emphasis is also placed on historical testing results, a point where objections from industry have not been adopted by the authors.

Adherence of the applicant to GMP will be judged during inspections. The basis for such inspections is the EU Guide to GMP, specifically with Annexes 1 and the newly appeared Annex 17.

EU Guide to GMP new Annex 17

Annex 17 to the EU Guide to GMP with the title *Parametric Release* was adopted in its final version in July 2001. It was elaborated by the European Commission working party on Control of Medicines and Inspections. This second part of the European legislature initiative concerning parametric release is intended to cover the specific GMP requirements which have to be met before the Competent Authorities will grant permission to abolish the Test for Sterility.

The final version is drastically different from the draft the PDA working party commented upon. A large number of the comments of industry have been adopted, in that the overly detailed and restrictive document was dramatically shortened. It is now a 3-page document, as compared to a 20-page draft. The document confirms several of the statements of the NfG: Applicability for products terminally sterilized with moist or dry heat or ionizing radiation only, and emphasis on experience with a marketed product including a history of satisfactory sterility test results.

Most of the remaining requirements can be seen as obvious GMP requirements which are not debatable. A specific point where objections were not taken comprises the requirement for a qualified experienced sterility assurance engineer and a qualified microbiologist to be normally present on site. This seems to exclude small companies even if they have performed a highly sophisticated validation effort.

In general this GMP-Annex reads very reasonably. How it will be interpreted by inspectors may, however, depend on a third part of guidance which is not published yet. The PIC/S draft for Parametric Release which is an unofficial guidance to inspectors is yet to be finalized. It is at present unclear how the detailed PIC/S draft, which was commented upon by PDA in its form as draft GMP-Annex 17, will be modified and at what time a final version of the PIC/S guideline may be expected to appear.

Conclusions

In most parts, the new European Regulations on *Parametric Release* are in accordance with what was published in the PDA Technical Report No. 30. Some additional requirements which have been objected to were maintained by the European Regulators, but most of the objections raised by industry have been adopted.

The new regulations give a reasonable and useful basis for applications to abolish the sterility test for products which have been on the market for some time. The outcome of such applications will be interesting to watch. ■

22.09.01
Klaus Haberer, Compliance Advice and
Services in Microbiology GmbH
Robert-Perthel-Str. 49
D-50739 Köln - Longerich
Tel.: +49-221-957 457 0; Fax.: +49-221-957 457 25
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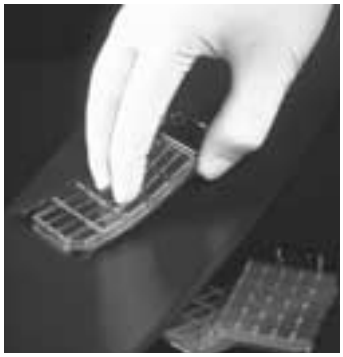

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Regulatory News continued from page 11

- Notifiable Changes (NCs).

This guidance does not address the preparation of Clinical Trial Applications (CTAs) previously known as Investigational New Drug Submissions (INDs).

Note: The use of the CTD formatted submission is permitted for subsequent filings regardless of the format of the original submission, and for the drug component of drug/device combination products.

The full guidance can be found at www.hc-sc.gc.ca/hpb-dgps/therapeut.

—William Stoedter

European Briefs

The Note for Guidance on Comparability of Medicinal Products Containing Biotechnology-derived Proteins as Drug Substance (EMEA/CPMP/BWP/3207/00, September 20, 2001), was adopted by the EMEA in September and will go into effect in March 2002. This Note for Guidance addresses the comparability exercise that is required to compare the quality, safety and efficacy profile of a product of biotechnological origin derived from a modified manufacturing process to the one derived from the currently used process. Such a change is not unusual during the life cycle of a product for a variety of reasons and may be introduced during the development phase or after Marketing Authorization has been granted. Comparability studies are also needed for situations where a manufacturer is seeking approval of a Marketing Authorization for a biotechnology-derived product claimed to be similar to one already authorized. This Note outlines both the points to consider in performing comparability studies as well as various strategies of comparison based on the change in the manufacturing process. It does not cover changes introduced at a very early stage of development.

In September, the CPMP released for consultation, Points to consider on the Development of Live Attenuated Influenza Vaccines (EMEA/CPMP/BWP/2289/01, September 20, 2001). Current requirements and guidelines are relevant only for inactivated influenza vaccines and do not address quality, safety and efficacy issues related to live attenuated influenza viruses produced in eggs. This paper addresses issues specific to live attenuated influenza vaccines including seasonal production, safety controls, proper use in pandemic and inter-pandemic periods, determination of efficacy in different target groups and possible long term protective efficacy**. March 2002 is the deadline for comments.**

In September, the EMEA released ***Accelerated Evaluation of Products Indicated for Serious Diseases (Life Threatening or Heavily Disabling Diseases)*** (EMEA/CPMP/495/96, September 18, 2001). The CPMP timetable for evaluation of medicinal products to be approved centrally has been streamlined to allow for evaluation of a product in less than 210 days in exceptional cases when there are compelling public health reasons. This document briefly outlines the steps to be followed for accelerated evaluation including qualification of the medicinal product for such an evaluation as well as requirements for the completion of the accelerated evaluation.

The EMEA released ***The Committee for Proprietary Medicinal Products September 18–20, 2001 Plenary Meeting Technical Meeting Report*** on September 25, 2001. During this meeting, product related issues such as the centralized procedures, scientific advice procedures, referrals, and inspections were addressed. Non-product related issues included a variety of reports from CPMP Working Parties and Ad Hoc Groups. Annexes with detailed information, are included in this report.

In September, the EMEA Committee for Orphan Medicinal Products (COMP) released the ***Note for Guidance on the Format and Content of the Annual Report on the State of Development of an Orphan Medicinal Product*** (COMP/189/01, September 7, 2001) in for consultation. **The deadline for comments is December 2001.** The intent of this Guideline is to provide advice on the preparation of annual reports required by the EMEA regarding the state of development of designated medicinal products. This Guideline provides information on both the content of the report as well as the documentation format and timeframe for submission.

The *Points to Consider on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin* (EMEA/HMPWP/31/99 Rev. 1, July 10, 2001) was released for consultation by the Herbal Medicinal Products Working Party (HPMWP) in July. This guide replaces previous documents released by the HMPWP. The main aim of this publication is to establish good manufacturing practice and quality standards for herbal drugs in order to ensure consumer safety. This paper addresses the specific concerns of growing, collecting and primary processing of herbal drugs used for medicinal purposes as well as specific issues associated with the agricultural production and collection of herbal drugs in the wild. Producers, traders and processors of herbal drugs should comply with these considerations. **The deadline for comments is October 2001.** ■

—James Lyda

Technical Report No. 35 Approved for Publication

PDA's Subcommittee on Microbiology Training, headed by Richard Prince, Richard Prince Associates, Inc., has completed work on *PDA Technical Report No. 35: A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry*.

TR 35 describes a step-wise, competency-based microbiology training program for the following individuals:

- Production workers engaged in contamination control or other non-laboratory activities of a "microbiological" nature;
- Laboratory microbiologists and analysts;
- Management with oversight of, or interaction with, the Microbiological Function (namely, management of QC, QA, Manufacturing, Validation, Engineering); and
- Regulatory authority investigators.

The rationale for developing this training path was largely based on the recognition that there is a need for a systematized and consistent approach for microbiological training of individuals engaged in work activities connected to contamination control and microbiological testing of pharmaceutical articles. The concepts of pharmaceutical microbiology must be effectively understood and acted upon by management and staff to increase the probability of consistently manufacturing batches of suitable product quality. Many firms today have separate departments, with different training requirements, responsible for ensuring that employees are suitably trained. However, due to this decentralization, employees working in, or working with, the Microbiological Function, do not receive consistent training. This can lead to varying microbiological control practices within a manufacturing facility.

A basic outline of the proposed training model is as follows:

- Description of the Microbiological Function;
- Microbiological Concepts;
- Theoretical Considerations Associated with Industrial Microbiology;
- Manufacturing Training Considerations
  - Aseptic Processing Plants
  - "Non-sterile" Plants;
- Laboratory Training Considerations;
- Additional Training Considerations
  - Regulatory
  - Competency-based (Proficiency) Approach;
- Summary;
- Appendix 1: Step-Wise, Competency-Based Training Program for Manufacturing Personnel;
- Appendix 2: Step-Wise, Competency-Based Training Program for Laboratory Personnel; and
- Appendix 3: Reference Materials

TR 35 is scheduled for publication as a supplement to the November/December 2001 issue of the *PDA Journal of Pharmaceutical Science and Technology*. As usual, all PDA members will receive a copy of the technical report as a member benefit (expect delivery in mid–late December).

PDA Subcommittee on Microbiology Training

Ted Collins, *Celltech Pharmaceuticals*
Strother Dixon, *PDA Training and Research Institute*
Jayne Dovin, *GlaxoSmithKline*
Kimberly Fitzsimmons, *Aventis Behring*
Robert Friedel, *Perritt Laboratories*
Jill Giulianelli, *Wyeth-Ayerst ESI*
John Lindsay, *Aseptic Solutions, Inc.*
David McAlister, *Amgen*
William Miele, *Bayer Corporation*
Ann O'Leary, *Ricerca*
Richard Prince, *Richard Prince Associates Inc.*
Maureen Reagan, *Quality Systems Consulting, Inc.*
Rick Rogers, *PDA Training and Research Institute*
Simon Rusmin, *Consultant*
Jamie Stanek, *Merck & Co.*
Albert Wellstein, *Consultant*

—Russell E. Madsen

Interest Group Sessions Planned for PDA Annual Meeting

PDA Interest Groups (IG) have planned a full schedule of meetings in conjunction with the PDA Annual Meeting which will be held December 3–5, 2001 at the Marriott Wardman Park Hotel, Washington, DC. Following is brief summary of the IG sessions planned for the meeting. Please see the meeting brochure, available on PDA's Web site (www.pda.org), for a complete schedule of IG meetings.

Biotechnology

Frank Matarrese, Chiron Corporation

The IG is planning a work session to refine a list of topic items and plan for the 2002 activities of the group.

Computer Systems

Michael Wyrick, KMI/PAREXEL, Inc.

PDA Part 11 Task Group member Christie Deitz will present the latest draft of their document, *Good Electronic Records Management Practices and Compliance Models*. The remainder of the meeting will be centered on discussions of topics of mutual interest and plan for future IG activities.

Contract Manufacturing

Michael Porter, Eli Lilly & Co.

The IG will meet to discuss topics of mutual interest and plan for future activities.

Drug/Device Delivery Systems

Michael Gross, Aventis Behring

The IG will meet to discuss topics of mutual interest and plan for future activities.

Filtration

James Wilson, The Validation Group (Jack Cole will assume leadership following the 2001 Annual Meeting)

George T. Quigley, Executive Vice President, ErtelAlsop, will present a paper entitled, *Cellulose Based Depth Filters for Pharmaceutical and Biotech Fluids*. Jim Akers will discuss filtration in isolator-based environments.

GMP Purchasing

Nancy Kochevar, Amgen, Inc.

This new IG will hold an organizational meeting to discuss topics of mutual interest and plan for future activities.

Inspection Trends/Regulatory Affairs

Robert Dana, Elkhorn Associates, Inc.

Based on previous member input, the meeting will focus on the recently concluded FDA pilot on the systems approach to the conduct of inspections. A panel discussion, led by a few industry speakers, will discuss the pilot in the context of their own experience and future expectations. Fred Blumenschein, FDA, is tentatively scheduled to round out the panel with a perspective from the Agency.

Isolation Technology

Dimitri Wirchansky, Jacobs Engineering Group, Inc.

The IG meeting will focus on containment technology for solid dosage processing. Topics will include: Split Butterfly Valves — Description, Features, Containment Levels and Manufacturers (e.g., Glatt, Buck (Niro), others); Cone Valves — Description, Features, Containment Levels and Manufacturers (e.g., Matcon, others); Isolators — Uses and Features, Examples of Applications, Double Containment and Containment Levels; Dover Pack Technology — Description, Features and Containment Levels; and CIP, Integration with Equipment.

Lyophilization

Edward Trappler, Lyophilization Technology

The IG will discuss the draft of the PDA technical report on isolation technology, as well as other subjects of interest to the group.

Microbiology/Environmental Monitoring

Jeanne Moldenhauer, Vectech Pharm. Consult., Inc.

The topic for the IG will be media fills and responding to the changing regulatory views. The following speakers have been invited:

Richard Friedman, *FDA*
Charles Moore, *Hollister-Stier*
Barry Friedman, *Cambrex Bioscience*, Issues with the Media Itself and the Filter Configuration
Kunio Kawamura, The Operating Characteristic Curve of the Media Fill Test
Rutger Vandiest, *JanBe Extern*

Ophthalmics

Richard Johnson, Abbott Laboratories Inc.

The IG will meet to discuss topics of mutual interest and plan for future activities.

Packaging Science

Edward Smith, Packaging Science Resources

The agenda will include updates and discussion of the following subjects:

- Review of the PDA Forum on Extractables held November 12–13, 2001 — *Mike Gross, Aventis;*
- Update on the proposal by the European Agency for Evaluation of Medicinal Products to require "Highly Purified Water" for the initial rinse of containers/closures — *Frank Keim, American Stelmi;*
- Update on PACPAC;
- Update on USP <381> revision and harmoni-

continues on page 24

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Interest Groups continued from page 22

zation with EP/ISO;
- Update of ISO/TC 76 (medical packaging components) meeting held October 31–November 2, 2001 in New Orleans;
- Update on the activities of the PDA Task Force on USP Packaged Water and Harmonization with EP/ISO — *Bob Swift, Schott;*
- Latex Sensitivity update;
- Temperature Controlled Shipping (Cold Chain Management) — *Patty Kiang, Schering-Plough;*
- Glass Standards–Update on PSIG Task Force — *Roger Asselta, Helvoet Pharma;* and
- Discussion of the formation of a new Task Force on Standardized Audits for Packaging.

New Interest Group on Pharmaceutical Water will organize at 2001 PDA Annual Meeting

Pharmaceutical Water

Theodore H. Meltzer, Capitola Consulting Company

This new IG will hold an organizational meeting to discuss topics of mutual interest and plan for future activities. The major discussion topic will be the preparation of WFI by reverse osmosis.

Production and Engineering

David Maynard, Maynard & Associates, LLC

Subjects for discussion include:

- Controlled area designations — USA vs. EU;
- Manufacture, control of water — USP purified; and
- Cleaning levels — campaigns vs. individual production concerns with technology transfer.

QA/QC

Don Elinski

The IG meeting discussion will center on "Quality Systems, The How and How Not To."

Solid Dosage Forms

Pedro Jimenez, Eli Lilly and Co.

The solid oral dosage interest group will be hosting Dr. Fernando Muzzio during the PDA Annual Meeting. Dr. Muzzio will be leading a discussion about current issues with the USP dissolution test. The information gathered during this meeting will be used to develop a research proposal for the development of a new dissolution test that is less technique dependent and robust.

Stability

Rafik Bishara, Eli Lilly and Co.

The Stability Interest Group Session will offer an open forum to discuss stability programs for APIs and finished dosage forms in light of the recent proposals by the FDA and ICH. Sharing experiences about development and manufacturing stability under a global protocol will be investigated.

Sterilization/Aseptic Processing

Jim Agalloco, Agalloco & Associates

Among the presentations will be an update on the revision of PDA TM 1 on steam sterilization.

Training

Thomas Wilkin, Schering-Plough Corp.

The meeting will be an interactive discussion focusing on current training topics of importance. Attendees will initially contribute to the development of key topics of interest (e.g., evaluation of training, guidelines for training, SOP and Web based training, etc.) followed by in-depth discussion of approaches. An update on the planning and content of the upcoming 2002 PDA Training Conference will also be given along with other training-related information of interest. Please direct any questions to the Training Interest Group Chairperson: Thomas Wilkin, Ed.D., Director, Technical Operations Training, Schering-Plough Corp, Kenilworth, NJ 07033 (908) 298-5213.

Vaccines

Frank Kohn, Wyeth-Lederle Vaccines

The Vaccines IG is planning on having a speaker and roundtable talk on *Clinical Vaccine GMP Certification Program, New Europe Requirements*. Scott Woollens, Director of Vaccine CMC World Wide Compliance, Wyeth Vaccines is scheduled to be the main speaker. A roundtable will follow to discuss open vaccine industry issues.

Validation

Bohdan Ferenc

The group will discuss Points to Consider for Change Control.

Visual Inspection of Parenterals

John Shabushnig, Pharmacia Corporation

The PDA Visual Inspection of Parenterals (VIP) Interest Group has been meeting twice a year for the last five years. Meetings take place at the PDA Annual and Spring Meetings. Our next meeting will be at the Annual Meeting in Washington, DC this December. This is an open forum for the discussion of visual inspection processes. Participants come from both pharmaceutical manufacturers and inspection equipment builders. We routinely provide a review of any inspection related regulatory activity since the last meeting. Discussion topics are solicited from the members of each session and then prioritized by group vote. Past topics have included the evolving Japan foreign material regulations, validation strategies for inspection methods, inspection of lyophilized cakes and powders for foreign material, performance of automated inspection equipment, inspector qualification, reinspection of culled product and statistical audit sampling plans. This interest group is currently sponsoring a task force to develop a scientifically based specification for visible particulate matter in parenteral products. Progress on this task will be included in the discussion at this session. Anyone with an interest in visual inspection is encouraged to attend and participate. ■

—Russell Madsen

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21 CFR Part 11

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...

Question 1

Dear Forum,

Perhaps the Forum can shed some light on current industry thinking regarding this regulation [21 CFR 211]. I have only read the regulation (not the preamble or any guidelines, etc.) and have two areas of concern.

1. Many people have expressed the idea that all electronic records, regardless of their nature, regardless of their use, fall under the scope of Part 11. Why, then, does the regulation define electronic records in 11.3 and describe which electronic records fall under the regulation? It does not seem to me that the storage of data to "durable media" is the only factor that should be considered when determining whether or not this regulation applies to a particular system.

"This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records [or] requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations." [11.1b]

2. "A printout is an image, an extraction of the electronic record and it's the electronic record, not the paper, that is in fact the master." I find this hard to understand. In some cases, the critical entity is not the one which was created first, but the one which was reviewed and approved. If you use MS Word to write and print a validation protocol—and that paper version is the entity that is reviewed, approved, archived, used for execution, included in the summary report, etc.—then why would that be considered anything but the master? MS Word and the electronic files it creates simply make revising and searching (for informational purposes) easier. In this example, the same paper document that was reviewed and approved will be the document that is used by those executing the validation and reviewed by FDA.

In other areas of compliance and validation, "intended use" is (and has been) a critical factor for guiding industry in determining appropriate levels of testing and compliance. Why should this regulation change that? I try to keep in mind the purpose and the spirit of the regulation as well as the letter of the law. If you generate data that is not required by, or shown to, the FDA, why must that data comply with Part 11? There are many systems that should be validated but do not necessarily fall under the records requirements specified in that regulation.

I would appreciate any input or discussion.

Response 1

One important factor you have not cited that is [that] the real problem is the ability [or inability] to track all data and changes and identify who made changes, when and on whose authority. This means you have to keep copies of everything and it must always be reviewed and authorized. Look at all of the 483's through the years and you will find this to be the primary cause of citations and recalls. FDA doesn't reject electronic data but it doesn't allow you to get rid of it either.

Response 2

Glad to hear a voice of reason in this discussion. In response to your first comment, one of the guiding principles should be that Part 11, should you choose to use electronic records, applies to those records required by FDA requirements, e.g., by GMPs, IND and NDA filings, etc. While this isn't the only criterion, it is one of the main ones.

As regards your second comment, you should read the preamble as your common sense statement is right on the mark, in my opinion. One quote from the preamble is (and this reflects FDA's thinking, but not actual legislation) "Part 11 is not intended to apply to computer systems that are merely incidental to the creation of paper records that are subsequently maintained in traditional paper-based systems. In such cases, the

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

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

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

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

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

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E-mail—
wilsojdel@chartertn.net

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Amgen, Inc.
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Robert L. Dana
Elkhorn Associates Inc.
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Liverpool, NY 13088
Tel: (315) 457-3242
Fax: (315) 451-7363
E-mail—
rld1242@aol.com

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

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

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

Ophthalmics
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Abbott Park, IL 60064-6091
Tel: (847) 938-1750
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E-mail—
richard.m.johnson@abbott.com

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Packaging Science Resources
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Fax: (301) 986-9085
E-mail—
tedmeltzer@att.net

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Tel: (908) 431-1919
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davmaynard@aol.com

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

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computer systems would function essentially like manual typewriters or pens and any signatures would be traditional handwritten signatures."

Another contributor states in a post to this forum, "The purpose of the regulation is not to make life difficult for the industry, but rather to ensure the health and safety of the consumer." I would respectfully disagree with the second portion of the statement. Part 11 was generated in response to a few companies in the industry that wanted to be able to create electronic batch records and electronic signatures, i.e., this was initiated by industry, not FDA. I happened to work for one of those companies at the time, but I will state clearly and forcefully that I had nothing to do with this request. Moreover, I request that anyone who has any data showing specifically how this ensures the health and safety of patients please publish it on this forum. In other words, how many patients have been harmed due to the lack of electronic records?

The sad thing is that it seems to have made life difficult for the industry, at least judging from the amount of discussion and work that has occurred because of it. The even sadder thing is that it has little to do with the performance of drugs in patients.

Response 3

1. Not all electronic records fall under Part 11. Only those records required by predicate rule (part 58, 211, etc). If the record is not required by predicate rules, then Part 11 need not apply. The "durable media" thing somehow took on a life of its own and is a source of confusion. Hopefully, the forthcoming guidance documents will clarify this and the next issue.

2. Not going to comment on #2; no winner has emerged yet!

Response 4

In response to another respondent's post, there are no arguments from me about its origin. The FDA came in to lasso the situation, but has definitely taken ownership responsibility.

I will state however, that I've had the opportunity to speak with many FDA officers in the past year, including Paul Motise and Tom Chin. Anyone up on Part 11 knows who these gentlemen are. The quote chosen from my earlier post paraphrases a statement several of those officers have made to me. It doesn't reference origin, but rather present day philosophy. In that sense it's perfectly accurate, and necessarily references the main interest the FDA should have — a politically correct statement if nothing else. To the main point, I hope you all can conjure up a scenario in which individuals could falsify data in order to keep from repeating an analysis or getting in trouble from a superior. It's that sort of malicious activity that is more avoidable in an electronic environment where records can be altered/deleted after creation. In that sense, it certainly could have an impact on drug quality.

Do I care what the racemic mixture of enantiomers is for a certain drug? I don't if one is noneffectual, but I certainly do if one is toxic (as many are). So I'm glad that it is becoming more difficult for individuals to partake in deviant activity. And as the regulation evolves from a voluntary "if you choose electronic records, do it like this" to the inevitable "electronic records are more secure and reliable, so you WILL do it this way," some will applaud and some will balk. In any case I argue it's for the better.

Response 5

In addition to be applicable to those records in electronic form, as explicitly defined in a regulation or law (predicate rule), Part 11 is applicable to records in a secondary basis, for example a standard operating procedure, explicitly required by regulation in which a firm says it will record and preserve certain information. The recorded information may not be explicitly identified in a regulation, but the firm imposes the requirement upon itself by virtue of its standard operating procedure.

Response 6

I agree with the comments on your Question 1 that have been previously posted.

On your Question 2, I am including a paragraph from a question brought up by Dr. Selby from Hope International and Paul Mostise's response. MS Word is used to create SOP's. What frequently happens is that they go through the approval procedure and then the signed paper copy has been the designated master. When they are updated, we go back to the electronic record and make the changes. Is it acceptable to call the paper record the master, if whenever you make changes to the electronic record, the paper print out is checked, reviewed and signed as the master?

Answer: It's my way of thinking that the printout is an image, an extraction of the electronic record and it's the electronic record, not the paper, that is in fact the master. So I would disagree with you if you said the paper is the master. It speaks to a dual standard. Otherwise companies would say, we have two sets of books, we have the paper printouts which we consider the official record and we have and electronic record which is something else.

It almost looks like we have two schools of thought on this issue. I'm not sure who is right but I definitely would use caution with this "official" document thinking when you keep the same record electronically.

Response 7

I appreciate all of your responses and would like to address part of the previous message, which follows:

"MS Word is used to create SOP's. What frequently happens …it's the electronic record, not the paper, that is in fact the master. So I would disagree with you[r statement where you] said the paper is the master. It speaks to a dual standard."

I think this is an interesting debate. One might argue, however, that, if the paper SOP is the document that is both approved and used, then it is the only item that can affect your operations and your product. In addition to this, if it is also the document shown to regulators, it should be the only item that concerns them. The fact that an existing electronic version is usually updated when it is time to revise an SOP may not be relevant, because the SOP is printed again and can (should?) be reviewed in its entirety—just as if it were a new SOP. In that case, had someone made unauthorized (and clandestine) changes to the electronic version, you would have the same chance of catching the problem during review of the next paper version as you do during review of a brand new SOP that has the same problems. There is no difference between an SOP produced by typewriter and one produced by word processing software to those who review, approve, and use the SOP—only to the individual who must make all the revisions. It does raise an interesting question, however, about the use of revision histories for such documents. Revision histories are designed to save time and direct reviewers to specific areas of a document (and, perhaps, away from other areas).

Ultimately, however, I believe that the rule should apply differently in this situation than it would to electronic records from HPLCs on a SCADA system (collecting product test results), for example.

Perhaps all my hot air is wasted on this subject. I understand the first draft guidance has arrived. All may be interested in the following draft guidance documents from the FDA:

Draft Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms http://www.fda.gov/OHRMS/DOCKETS/98fr/001543gd.pdf

Draft Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation http://www.fda.gov/OHRMS/DOCKETS/98fr/001538gd.pdf. ■

—compiled by Russell Madsen

Chapter News

Southern California Chapter Web Site Unveiled

This chapter has a new Web site www.pdasc.org which was prepared by student volunteers associated with a colleague of the Southerm California Chapter President, Kikoo Tejwani.

The new Web site will contain a complete roster of upcoming events, including registration forms, along with a listing of chapter officers, volunteers and other information. Please check out the site! ■

Company, Colleague & Product Announcements

PDA Board Member **Robert L. Dana** has founded Elkhorn Associates, Inc., an independent firm providing consulting services in the areas of Quality and Regulatory Compliance. He recently retired from Bristol-Myers Squibb, where he was Senior Director, Compliance Assurance Services, responsible for providing support for and oversight of the company's quality systems and GMP, GCP and GLP compliance programs. Dana is a member of PDA's Regulatory Affairs/Quality Control Committee and the leader of the Inspection Trends/Regulatory Affairs Interest Group. For further information, e-mail Dana at elkhornassoc1@aol.com.

Millipore recently introduced K-Prime 40-IV, a new addition to the K-Prime 40 family of chromatography systems for BioPharmaceutical Process Scale Applications. Like other K-Prime products, the K-Prime 40-IV is based on the design concept of an automated, fully instrumented and validated, pre-engineered system with short delivery. The K-Prime 40-IV extends the capability with flow rates of 5 to 30 liters/minute up to 5 bar. Both system hold-up and unit size are minimized through the use of industrially proven instrumentation and modular valves together with a compact, innovative stainless steel pipework design that results in superior chromatographic performance. The result is a robust, compact but easily serviced unit with both isocratic and linear gradient capabilities. Common Control Platform (CCP™), Millipore's comprehensive application shell, is particularly suited for the pharmaceutical industry where reliability, flexibility, and connectivity between diverse unit operations are required. CCP™, Version 5.0 provides increased control functionality and batch reporting to meet the latest industry standards and is CFR 21, Part11 compliant. Millipore is a multinational, high technology corporation that applies its purification technology to critical research and manufacturing applications in the Bioscience industry. Headquarters are located in Bedford, Massachusetts. For more information telephone Technical Service (1-800-MILLIPORE) or visit www.millipore.com.

Open Text™ Corporation recently announced the availability of Livelink Certification™, a highly collaborative commerce and knowledge management application designed specifically to meet the pharmaceutical industries' need to satisfy the requirements of FDA's Part 11 regulations governing electronic records and electronic signatures. "Livelink Certification is fully integrated as part of the secure, reliable Livelink platform." Livelink's richly-featured enterprise services include virtual team collaboration, business process automation, enterprise group scheduling and information retrieval services, all tightly integrated into a solution that is easily customized and extended. For everything from the creation of complex e-community relationships to the automation of simple e-business processes, Livelink delivers true dynamic collaboration between individuals, organizations, and large trading communities. Livelink servers are fully Web-based and open-architected to ensure rapid deployment and easy access to its full functionality through a standard Web browser. For more information, visit www.opentext.com/livelink/. ■

—Joseph G. Bury

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Forum Report: USP and Compendial Issues

Eric Sheinin, PhD, USP
Susan Schneipp, Abbott Laboratories
Rafik Bishara, PhD, Eli Lilly (Moderator)

A recent shift in USP activities is the development of training programs for industry and other USP constituents. Examples are the USP open conferences, which have been held in recent years. More recently, USP has been developing and delivering its own training courses for industry. Examples include *Fundamentals of Dissolution*, a two-day lecture/lab course delivered at USP Headquarters or a one-day lecture course on site; *USP-NF Standards Development Overview 2001*, a one day course conducted onsite; and the soon to be announced lab course *Fundamentals of Titration*.

A concern with the expansion of USP training is that it could be considered "state-of-the-art" and have a regulatory bearing beyond the training aspect. This is due to the quasi-regulatory nature of USP and the reality that FDA frequently chooses to enforce what are considered USP Guidance Chapters. It has been suggested that USP training should not address certification, accreditation or competency.

The USP Revision Process and the Pharmacopeial Forum offer manufacturers a way to influence the USP process and manufacturers are encouraged to submit resolutions and "stimuli" to the revision process. A goal for industry is to avoid unnecessary compliance mandates.

Upcoming USP events include the open conference on excipients, December 11–14, 2001 in Fort Myers, Florida and a Joint Conference on Sterile Product Manufacturing, co-sponsored by PDA and USP, in Fort Myers, Florida on May 19–22, 2002. It is possible that either of these open conferences may be repeated in the EU or Japan.

The PDG (Pharmaceutical Discussion Group) is the means of harmonizing the pharmacopoeias. The PDG meets at the same time as the ICH Steering Committee and Working Groups although it is technically not a part of ICH. The PDG process for monograph revision currently includes about 51 monographs under revision. There are a total of 250 to 300 excipient monographs in the USP and it is estimated over 1,000 additional excipients are used without the benefit of a USP monograph.

There was some discussion of the development of a new grade of water (Highly Purified Water) through a pending monograph by the European Pharmacopoeia. There does not seem to be similar activity by USP or Japan. Sheinin indicated USP would seriously regard recommendations for harmonization of water standards in the ICH regions. The PDA comments on the EMEA *Note for Guidance on Quality of Water for Pharmaceutical Use* have been forwarded to USP and also to FDA.

When asked what are the hottest topics from USP's perspective, Sheinin mentioned, "…Uniformity of mass and uniformity of content in general, and how both are applied to aerosols in particular."

In a major change, USP is going to go to annual printing of the Pharmacopoeia beginning in January of 2002 with two supplements per year. Previously, the US Pharmacopoeia was printed every five years with ten intermediate supplements. ■

—James Lyda

International Calendar

2001

NOVEMBER

November 30, 2001
Visual Inspection of Injectables
Hilton Hotel, Berlin, Germany

2002

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

PDA/FDA Conference

September 10–12, 2001 • Washington, DC

FDA Presentations at the Opening Plenary Session

PDA President Edmund M. Fry opened the Conference and noted that there were over 400 registrants representing 18 countries in attendance. The figures included 47 delegates from Europe and 35 from Japan. The event was the 12th Annual Joint Conference with FDA and Robert Myers, Schering Plough, PDA Chair, seized the moment and commented that the Conference had become the "Pride of PDA". Myers thanked FDA for their commitment and support. Program Chairman, Kathleen Greene, Novartis, followed with a breakdown of events and programs.

Office of the Commissioner

Walter Batts, Office of the FDA Commissioner, gave the opening FDA presentation. His first announcement was that he had nothing to report regarding the selection of a new FDA Commissioner. He continued by saying that FDA staff, like everyone else, continues to speculate.

Batts stipulated that global participation is not a new phenomenon for FDA. In the past, however, participation was guided by the solution to specific technical problems or FDA's desire to assist lesser-experienced governments in solving problems. This has changed in recent years with harmonization and global problems driving FDA's international role. In the last year, some issues that have spurred FDA activity include counterfeiting of pharmaceuticals, E-commerce, Mutual Recognition Agreement with Europe and the new round of WTO trade talks. Batts characterized the international regulatory situation now as having moved from "regulatory teamwork" to "regulatory interdependence".

There is a mushrooming of clinical trials overseas with approximately 300 studies in 1990 and over 2000 studies in 1999. These studies took place in 28 countries in 1990, and there were 79 countries involved in 1999. It's estimated that 25% of all the data for safety and effectiveness used in the FDA approval process now comes from overseas drug studies.

CDER, Office of Pharmaceutical Sciences

Helen Winkel, Acting Director of the Office of Pharmaceutical Sciences (OPS), CDER, stressed the current developments in CDER. First among these is reinforcement of the science base, a continuing FDA theme for some years. She noted that there were 98 new drug approvals in the year 2000, up from 83 in 1999. On the generic side, there were 305 approvals in 2000 compared to 242 in 1999. This number for generics is expected to increase considerably in coming years. Collaborative activities by OPS include the PQRI (Pharmaceutical Quality Research Institute), standards and ICH (International Conference on Harmonization) work. OPS has started an advisory committee to assist with chemical and technical issues (as opposed to disease or product issues which are the focus for other advisory committees). There is a new OPS Web site, which will help demonstrate the activities of OPS.

New initiatives this year include reduction of CMC guidance for new drug and generic supplements. This would include minimizing the type of post approval CMC categories and reduction of CMC content of the annual report for "low risk drugs". The amount of studies and data collection required by companies would not change, merely the amount that would be submitted to FDA. The data would remain onsite for inspection review as needed. This initiative would not affect the FDA pre-approval inspection program and will be enhanced by the development of further PAC/SUPAC guidance's. The key issue is defining the acceptance criteria for "low risk drugs".

Another initiative is the optimal regulation of new manufacturing technologies. Winkel noted that CDER needs to move into the recent developments and "catch up" with the industry. Examples include near-IR, which allows real time control and reduction of sampling in the manufacturing process. This initiative is now under internal discussion and CDER expects this activity to become a third subcommittee on the OPS Advisory Committee. In addition, there will be a workshop on this theme in the year 2002.

To enhance the review process, CDER will continue to strengthen the capacity of the Office of Generic Drugs. They also plan a "process mapping" of OPS to determine the existing review process and opportunities for improvement. In addition, OPS will continue its initiative to support research. Challenges for 2002 include new technology, informatics, genomics, drug safety, harmonization, counterfeiting, the PDUFA fee, and the common technical document.

CBER, Office of Compliance and Surveillance

Steven Massiello, Director, covered recent developments including applications, pre-approval inspections, "counterfeit" biologics, bioresearch, deviation reports, and advertising and promotion.

CMC aspects of applications continue to evolve. The common technical document (CTD) for biologics could be considered a change in format but not necessarily content. FDA is accepting applications submitted in the CTD format immediately.

On another front, there have been some problems and confusion regarding contract manufacturers and quality assurance oversight. There are some issues of "taking responsibility" for the manufacturing operation when a contractor has been used. This needs to

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2002 PDA Spring Conference, Courses and Exhibition

Aseptic Processing Issues:
Reaching a Common Understanding of the Regulatory and Technical Requirements

March 11–15, 2002 • Rosen Hotel, Orlando, Florida

For Information on the Tabletop Exhibits, contact Nahid Kiani, (301) 986-0293 ext. 128
E-mail: kiani@pda.org

Budget your company's time and money wisely. Devote two-and-a-half days to discussions related to aseptic processing issues at the landmark PDA Spring Conference. The agenda for the conference, developed by industry experts and members of the Aseptic Processing Task Force, will address such topics as:

- Airflow velocity measurements;
- Surface monitoring of sterile product contact surfaces during aseptic filling operations;
- Alert and action level excursions during microbial monitoring of aseptic filling operations;
- Identification requirements for environmental and sterility test isolates;
- Media fill acceptance criteria and duration;
- Gowning qualification and frequency of requalification;
- Resolving dis;
- Agreements about 483 items and filing requirements; and
- HEPA filters.

Network with your industry colleagues. Tabletop exhibits, featuring the latest products and services in our industry, will be a conference highlight. Interactive breakfast roundtables, discussion groups and a reception will provide attendees with additional opportunities to interact.

Watch your mail for the official brochure or visit PDA's Web site at www.pda.org. ■

—Leslie Zeck

PDA 2002 Biennial Training Conference

October 7–11, 2002 • Hyatt Regency, Tampa, FL

Call for Proposals
Deadline: December 14, 2001!

Please send presentation proposals and biography to:

Leslie Zeck
PDA
7500 Old Georgetown Road, Suite 620
Bethesda, MD 20814-6133
(301) 986-0293 x129; FAX: 301-986-0296
zeck@pda.org

Please submit a 100-word (maximum) proposal describing the session and the presenter's ability to deliver a high-quality, credible presentation. A conference sub-committee will review the proposals for 90-minute presentations at the conference. Please use the template provided on PDA's Web site at www.pda.org.

To best meet the needs of PDA Training Conference attendees, we request that prospective presenters draft presentation proposals from the following list of selected topics:

- ✏ Web-distributed Learning;
- ✏ Measurement and Evaluation;
- ✏ Instructional Design;
- ✏ Transfer of Training;
- ✏ Learning Maps;
- ✏ Building Management Buy-In;
- ✏ Adult Learning Theories;
- ✏ Competency Modeling;
- ✏ Career Development Process;
- ✏ Managing Course Delivery;
- ✏ Human Performance Technology;
- ✏ Challenges of Training Internationally;
- ✏ Practical Skills for New Trainers; and
- ✏ …other related topics.

We look forward to your submission. ■

—Leslie Zeck

Training Workshop

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

If you missed out on the first-two sold-out offerings, you still have several opportunities to participate!

FDA, in collaboration with PDA, Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA), has recently completed two workshop training sessions on Q7A Guidance in the USA (Chicago, IL and Princeton, NJ). The ICH Q7A document, the first GMP guidance jointly developed between regulators and industry, is intended for use worldwide. It impacts any manufacturer who manufactures in, or intends to supply into, the ICH regions (USA, Europe, Japan). The workshop series will continue in the following locations in the USA and will contain identical subject matter:

Newport Beach, CA: February 25–27, 2002
San Juan, Puerto Rico: April 8–10, 2002

In collaboration with International Generic Pharmaceutical Alliance (IGPA) and Irish Pharmaceutical and Chemical Manufacturers' Federation (IPCMF), PDA will also offer the training in the following European locations:

Dublin, Ireland: May 2002
Milan, Italy: June 2002
Frankfurt, Germany: September 2002

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

Highlights:

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

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

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

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

Who Should Attend:

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

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

Learning Objectives

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

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

—Leslie Zeck

PDA GMP Guidance for APIs Training to be Offered in Europe.

See highlighted paragraph above.

PDA/FDA Conference from page 32

be clarified in all contracting situations.

Issues relating to TSE include documentation and verification of source materials, risk associated with shared manufacturing or storage of equipment, and FDA's recent imposition of donor referrals/criteria for blood donors having lived in Europe. On the pre-approval inspection front, there continue to be issues associated with media filling and the traditional validation of aseptic manufacturing.

The counterfeiting issue is something new for biologics and Massiello suggested his primary goal is to "raise consciousness" regarding the risk. The situations may more accurately be described as diversion, employee theft, and in some cases, possible counterfeiting. When FDA discovers incidents like this they are referred to the Office of Criminal Investigations (OCI) for follow-up.

Bioresearch inspections (inspections of clinical investigators) increased in 2001 with more planned in the year 2002. For the past 4 years, the violation rate (category "OAI" Official Action Indicated) has fluctuated between 12 and 17 percent for all inspections. Massiello regards this as too high, but indicated this may continue. There were two suspensions of investigators in 1999 and 2000, the first in a number of years for CBER.

The biological deviation reporting continues to increase. As CBER anticipated, there has been an increase which will continue in the reporting of "non-blood" deviation reports (these were previously known as Accident and Error Reports).

Massiello noted that team biologics will continue in the future with the format that CBER will conduct the pre-approval inspections for new licensed biologics and the follow up statutory inspections every two years will be conducted by team biologics for most products. There will be an increased focus on tissue inspections in the coming years.

System Based Inspections Forum

Frederick Blumenshein (CDER, FDA) reported on the pilot program which ran from January 1, 2001 to July 30, 2001, to evaluate the efficiency of conducting GMP inspections based on operational systems. The six systems are: the Quality System, Facilities and Equipment, Materials, Production, Packaging and Labeling, and the Laboratory Control System. The pilot program was tested in six districts: Philadelphia, San Juan, Newark, New York, Los Angeles and Texas. The System Based Inspections model offers the investigator the option of a full inspection or an abbreviated inspection. The abbreviated inspection consists of the Quality System and one other system. The full inspection option is used for new firms or facilities, as a follow up to a warning letter or for "recidivist firms" (a new phrase being used by the FDA), these are firms that go in and out of compliance.

More than 150 inspections were performed in this pilot program and overall, the program was well received by the Investigators, Field Supervisors and Compliance Officers. The Investigators completed a questionnaire after each system based inspection. The Investigators were asked to rate various aspects of the program using a rating of one to five where "one" would be a low rating and "five" would be an excellent rating.

- When asked if the system approach made the inspection easier, 90% rated the program at 3 or better;
- When asked if the system approach produced a more focused inspection, 80% rated the program at 3 or better; and
- When asked if the system approach made the inspection more efficient, 80% rated the program at 3 or better.

The next step is for the final report on the pilot program to go to committee in November. If approved, the system based inspection program will be expanded to all districts. Blumenshein stated that for now, the program will continue to be used in the six districts identified above, as well as for some foreign inspections.

Hot Topics in Aseptic Processing

Peter Cooney, Ph.D., Paul Stinavage, Ph.D., and Richard Friedman, all of CDER, presented the FDA current thinking on aseptic processing.
Cooney reminded the audience that there is no US requirement for the use of terminal sterilization in the manufacture of sterile products. The 1991 proposed rule requiring terminal sterilization has never been finalized and it has never been withdrawn, so it still stands as a proposed rule. On the subject of the long anticipated update to the "Aseptic Processing Guide" Cooney said that it is under review by the CDER staff and will be put out for comments when that review is complete. Finally, Cooney reminded the audience that the Microbiology review staff is composed of 13 reviewers (12 with Ph.D.s) who are available for consultation and are committed to help industry make scientifically sound decisions.

Richard Friedman discussed his view of the incubation requirements for media fills. If a company has a well defined procedure with descriptions of interventions, and a system for the disposition of units removed after interventions, then that same procedure can apply to removing vials during media fills. Friedman also said there is no need to incubate vials that are broken or damaged in a way that compromises the integrity of the container/closure system. The firm should document and reconcile units that are not incubated. Vials with cosmetic defects should be incubated so as not to detract from the integrity of the media fill qualification. On the subject of statistics, Friedman cautioned the audience that the 95% confidence level should not be extrapolated outward in a linear manner. Having three positive units out of a media fill of 3000 units has always been accepted as meeting the requirements of the Aseptic Processing Guide, but having twelve positive units out of 18,000 would give the agency cause for concern about the state of control in a company's aseptic processing program. ■

—James Lyda and William Stoedter

PDA BSE/TSE Issues Forum

December 5–6, 2001 • Marriott Wardman Park Hotel • Washington, DC

Plan now to attend this cutting-edge conference on BSE/TSE issues. The conference will bring together the world's leading experts on BSE/TSE, including heads of industry task forces assigned with monitoring this important issue for their companies. Examine the regulatory and scientific issues with your industry and regulatory colleagues.

The conference will address the following:

- The State-of-the-Science;
- Clearance Studies and Inactivation of the Agents;
- USDA Bovine Spongiform Response Plan Summary;
- HHS Action Plan;
- FDA Action Plan: An Overview;
- Disinfecting and Sterilizing Devices;
- Laying the Regulatory Groundwork;
- EU Regulatory and Industry Perspectives;
- US Regulatory and Industry Perspectives; and
- Industry and Regulatory Views of the Future.

Special sessions will focus on the following topics:

* Gelatin;
* Milk and Milk Derivatives and Bi-Products; and
* Tallow Derivatives.

The following speakers have been invited to participate in this cutting-edge forum:

David Asher, *FDA, CBER*;
Paul Brown, Ph.D., Senior Research Scientist, *National Institute of Neurological Disorders and Stroke, National Institutes of Health*;
Thierry Chignon, Senior Consultant, *Quintiles, Europe*;
Dr. Linda Detweiler, *APHIS, USDA*;
Kiki Hellman, *FDA, CDRH*;
Murray Lumpkin, Ph.D., *Office of the Commissioner, FDA*;
Brian Matthews, Ph.D., *Alcon Laboratories, UK*;
Rheinhard Schreiber, Former Head, *Gelatin Manufacturers of Europe*; and
David Taylor, Ph.D., Consultant Scientist, Edinboro, Scotland.

Examine Regulatory and Scientific Issues related to prions and BSE/TSE

An industry panel discussion will facilitate the exchange of important information on how multinational companies are dealing with global regulations in this environment of change.

Be at the forefront on this issue. Make your plans now to attend this state-of-the-science conference in Washington, DC. To register, visit www.pda.org and click "BSE/TSE Issues Forum." ■

–Leslie Zeck

PDA/USP Joint Conference on Sterile Product Manufacturing

May 19–22, 2002 • Sanibel Harbour Resort, Fort Myers, Florida

New regulations have been developed and changes in existing regulations have occurred since the last open conference on the topic of sterility assurance. PDA, in collaboration with the USP, will host an "open" conference on sterile product manufacturing to address this shifting regulatory climate. Participants in the conference will:

- Explore the continuum of the microbial control and test in the manufacture of sterile pharmaceutical products;
- Determine the inconsistencies in compendial, regulatory and industrial practices in microbial control and identify how they an be made more consistent; and
- Establish consensus positions whenever possible.

The conference will address the following topics:

1. Advanced aseptic processing;
2. Moist heat sterilization;
3. Environmental monitoring;
4. Criteria for processing simulation testing;
5. Sterilization by membrane filtration; and
6. Microbiological analysis.

Participation in this conference is limited to 300 participants to ensure scientifically useful feedback from participants. Please watch for the brochure on this important conference by visiting either www.pda.org or www.usp.org/conferences. ■

—Leslie Zeck

Process Validation for Biologics and Biotechnology Products

September 6–7, 2001 • Berlin

by Vince Anicetti, Genentech and James Lyda, PDA

Note: *The Berlin meeting confirms it*—There is much movement and general agreement in the area of process validation for biologics and biotechnology derived drug products. Over 200 attendees joined regulatory authorities from around the world for two intense days of discussions and technical debate on the critical aspects of validation. The following summary of the opening session of the conference provides the current 'baseline' for process validation studies and regulatory expectations at this time.

Expectations for Validation

Speakers: Vince Anicetti, *Genentech*; John Purves, *EMEA*; Anthony Ridgeway, *Health Canada*; Chris Joneckis, *CBER, USA FDA*; Richard Francis, *GSK*

While there is much discussion worldwide today on the principles of process validation, the purpose of this conference, and the earlier one in Washington, was to bridge regulatory principles with the complex issues involved in the technical implementation of process validation.

The session began with an historical perspective on process validation for biologics as presented by John Purves, Head, Quality of Medicines, EMEA. The importance of process validation for biologics begins with the production of animal derived products in the 1920s, for example insulin, and continues with the increasingly complex biopharmaceuticals in development today. Due to this complexity, there may be more "unknowns" about the process and the products. The philosophy of control historically has been that it is the manufacturer's responsibility to produce biologic product of appropriate quality. This included heavy supervision of the manufacturing processes, regulatory inspection of manufacturers and the use of biological assays versus physico-chemical assays.

The purpose of increasing controls in today's environment is to reduce uncertainty and unknowns by improved analytical ability to determine identity, composition and purity of the drug product. There was consensus that during drug development, the manufacturer needs to identify the critical steps and parameters associated with the product and process. This will lead to the development of manufacturing controls with process validation serving as the bridge.

ICH guidance provides an important perspective. The Q6A guidance on setting specifications, for example, provides the possibility of deletion of tests based on process validation data. The Q7A guidance on GMP's for APIs provides guidance on active pharmaceutical ingredients of a biological or biotechnology nature (from FDA's perspective, Q7A will apply primarily to "specified" products). It is clear that a master validation plan is expected and desired by regulatory authorities in all the regions and that plan will be requested during the application review or during the inspection.

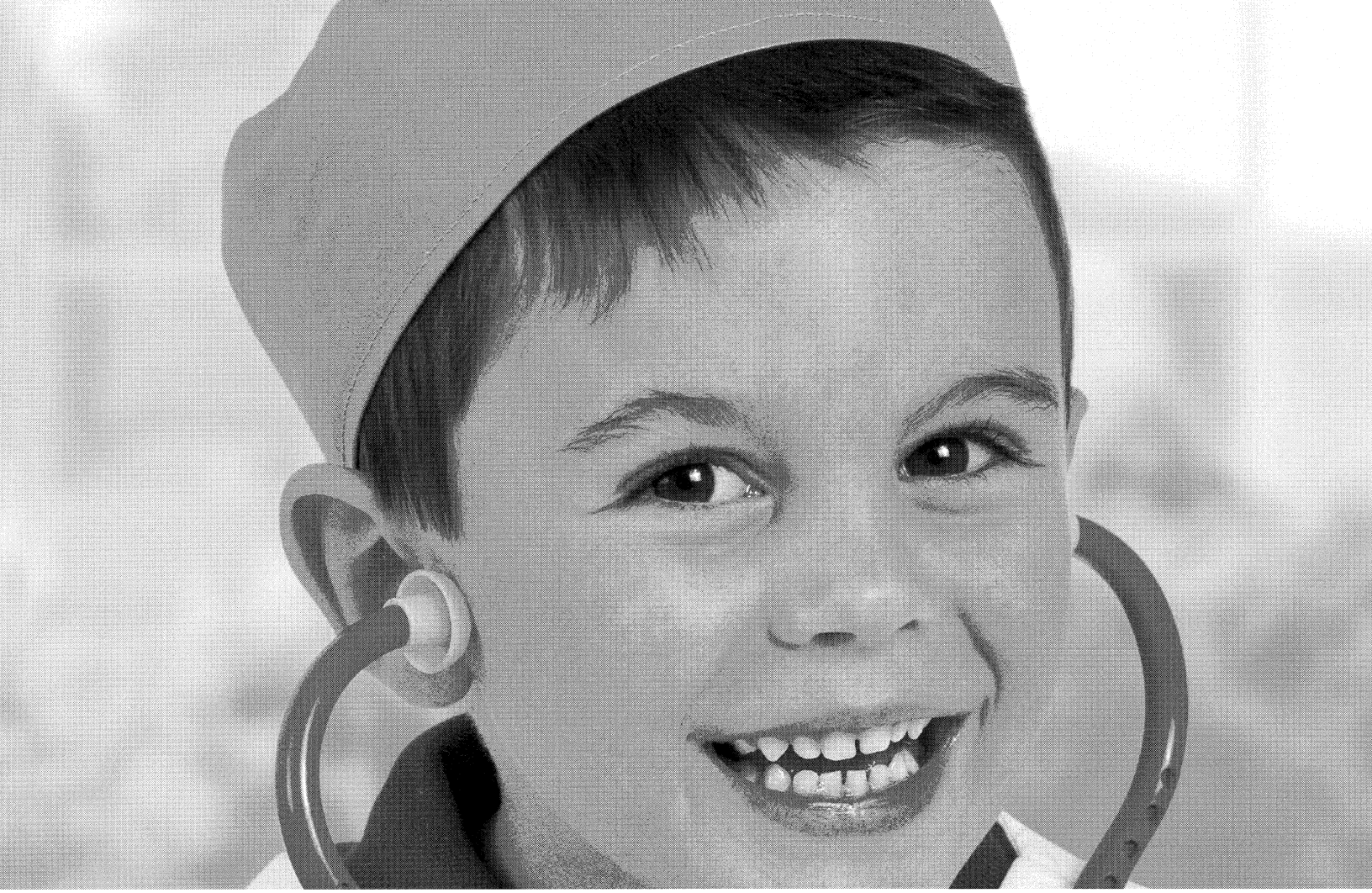
There is widespread use of concurrent validation particularly in the area of resin reuse. The existing concurrent validation guidance by the authorities is worded "negatively" but continues to be widely used for certain aspects. FDA expects prospective validation to be used for the development and marketing of new drugs or new processes.

Canadian authorities describe a willingness to examine or consider well thought out "novel approaches" to validation including matrix, family and bracketing. These are not new terms, but they are new when applied to process validation. They may be useful for resin and membrane sanitization and storage, and possibly for viral clearance studies. A negative aspect of these "novel approaches"

continues on page 43

Session: Expectations for Process Validation (L-R): Dr. John O'Conner, Genentech; Christopher Joneckis, Ph.D., FDA; Anthony Ridgway, Ph.D., Health Canada; John Purves, Ph.D., EMEA; Vincent Anicetti, Genentech (Conference co-Chair).

Session: Viral Clearance (seated L-R): Gerhard Poelsler, Baxter Biomedical Research Centre, UK; Hannelore Willkommen, Ph.D., Paul-Ehrlich-Institut, Germany; James Robertson, Ph.D., National Institute for Biological Standards and Control, UK (standing L-R) Enzo Bucci, Ph.D., Kedrion, SpA, Italy: Guiseppe Vicari, M.D., Italy.



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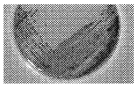	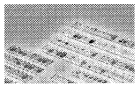	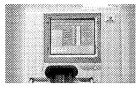	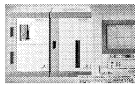	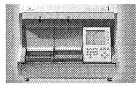	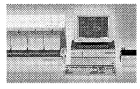	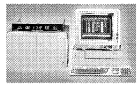

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2001 PDA-TRI Laboratory Programs—Year in Review

For course ***registration information***, direct your inquiries to PDA by phone (301) 986-0293 or E-mail info@pda.org.

For course ***content information*** direct your inquiries to PDA-TRI by phone (410) 455-5800 or email info-tri@pda.org.

As 2001 draws to a close, we look back on quite a successful year for PDA's laboratory training programs. Held at the PDA-Training and Research Institute (PDA-TRI) located just outside of Baltimore, MD, these courses stand unparalleled in their unique combination of lecture and hands-on laboratory exercises. This year alone, this unprecedented professional training drew nearly 200 course attendees from several different areas of pharmaceutical science.

Our Aseptic Processing Training Program, now in its third year of existence, brought almost 100 participants to the Institute from the following countries: Australia, Belgium, Canada, Denmark, Finland, Israel, Sweden, Switzerland, the United Kingdom, and the United States and Puerto Rico. Under the guidance of John Lindsay and David Matsuhiro, both of Aseptic Solutions, Inc., the two week Aseptic Processing Training Program has been refined to offer practical hands-on training on industry regulatory standards and the latest trends in aseptic processing. The course draws on the vast expertise of the PDA-TRI faculty in topic areas like contamination control, depyrogenation, documentation, environmental monitoring, facility design, filtration, finished product testing, lyophilization, moist heat sterilization, rapid microbial identification, regulatory affairs, and validation.

In addition to practical Aseptic Processing training, a wealth of other hands-on laboratory topics were offered at the Institute. These courses spanned the gamut from cleaning validation to auditing CGMP cleanrooms.

Most notably, PDA-TRI was pleased to introduce several new courses including: Basic Microbiology: Theory & Practice; Contamination Control Basics; and the widely anticipated Environmental Mycology Identification Workshop. In an effort to expand our course offerings in the areas of microbiology, the Institute recently acquired a number of compound microscopes and a video microscope system which will enable even more practical training for individuals working in pharmaceutical quality assurance/control, clinical manufacturing, and research & development capacities.

If you're interested in learning more about the PDA-TRI laboratory training courses, please contact the Institute at (410) 455-5800, or e-mail weininger@pda.org. Suggestions for new courses or faculty members are always welcome.

Don't forget, register today for the 2002 Aseptic Processing Training Program. This popular program fills quickly and there are four offerings to choose from:

Option 1:
January 14–18 (Week 1) &
February 11–15 (Week 2)

Option 2:
April 8–12 (Week 1) &
May 6–10 (Week 2)

Option 3:
September 9–13 (Week 1) &
October 7–11 (Week 2)

Option 4:
Oct. 28–Nov. 1 (Week 1) &
November 18–22 (Week 2)

More detailed information is available from the PDA Web site. Visit www.pda.org to download a brochure and registration information for any of our scheduled courses. ■

— Casey P. Weininger

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.

Identification of Microorganisms Using Comparative DNA Sequencing (**PDA #232**), November 28–29, 2001—*taught by Michael G. Waddington, Accugenix*; $1,500 PDA members/$1,650 nonmembers.

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

Aseptic Processing 2002 Training Program (**PDA #100**), Dates: Four Options, contact PDA for details —*taught by John Lindsay and David Matsuhiro, Aseptic Solutions, Inc.*; $6,500 PDA members/$6,695 nonmembers.

Environmental Mycology Identification Workshop (**PDA #230**), January 30–31, 2002; May 16–17, 2002; September 19–20, 2002; December 4–5, 2002—*taught by John Brecker*; $1,500 PDA members/$1,695 nonmembers. ■

PDA-TRI On the Road—An Overview of Lecture Courses

In an effort to better serve our members, PDA-TRI offers course series in many locations. Over the past several months, lecture courses have taken us from the shores of Jersey to the bayou of New Orleans. We also offered several new courses that contributed to the success of our educational initiatives in 2001.

Our summer course series began in New Jersey at the beautiful Hilton—East Brunswick. Over 80 participants from around the world attended this series on June 5–7, 2001. Various topics were covered from Cleaning Validation to Pharmaceutical Water Designs.

The next course series was held in conjunction with the Southeast Chapter Summer Meeting, in Chapel Hill, NC on July 18–19, 2001. PDA-TRI offered three courses: Parenteral Packaging: Rubber, Glass, Plastic, and Metal Seals; Writing and Auditing CGMP Documentation; and Using INFOSEC Technology and Procedures for 21 CFR 11 Solutions.

"Compliance in the Crescent City", our New Orleans course series, was held at the Hyatt Regency on August 6–8, 2001. Conducting Compliant Deviation Investigations for Pharmaceutical Industry, offered by Jeffrey Masten from Aventis Behring, was the sold-out hot topic at this event! One of PDA-TRI's most recent additions, A Practical Approach to Aseptic Processing and Contamination Control taught by Sandra A. Lowery, President of Quality Systems Consulting, was another success. Using cleanroom attire donated by GENERAL ECONOPAK, INC. (GEPCO), Lowery demonstrated the proper gowning method to reduce personnel contamination in the cleanroom. Six other courses pertaining to compliance aspects were also offered.

Our Summer Course Series ended on a sad note September 11, 2001. The PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibit was in progress at the Hyatt Regency on Capitol Hill in Washington DC when the terrorist attack on the Pentagon, World Trade Center and in Pennsylvania caused PDA to cancel the remainder of the conference/course series. Two of the courses scheduled for the PDA/FDA Conference (Improving Sterile Drug Submission to the FDA and How to Design an Effective Regulatory Training Program) have been re-scheduled to be held in conjunction with the PDA Annual Meeting December 6–7, 2001.

PDA-TRI will continue to take courses on the road in 2002. In the USA, course series are scheduled for Lake Tahoe in January, Florida in June, Vermont in August and Las Vegas in November.

For course ***registration information***, direct your inquiries to PDA by phone (301) 986-0293, e-mail info@pda.org or go to PDA's Web site at www.pda.org. For course ***content information*** direct your inquiries to PDA-TRI by phone (410) 455-5800 or email info-tri@pda.org. ■

— Janet Kearney

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Process Validation continued from page 38

is that once in place the manufacturer may be reluctant to introduce process changes since it affects the entire matrix or family scheme.

Retrospective validation seems to be recognized in all regions, especially for processes and products that have been in existence for a long time and are regarded as well controlled. However, it is clearly viewed as the least favorable alternative.

FDA will probably have an advisory committee on process validation including both drugs and biologics later in calendar year 2001. At the time of this meeting the details were not known. FDA's 1987 process validation guideline references that there would be an assurance that the process operates effectively but this is not necessarily the same thing as a guarantee. FDA noted that worst case testing is in order but they do not consider this to be the same as " testing to failure."

There was a consensus that we are at a point of evolution in process validation for biotechnology and biologic drugs particularly in determining the limitations of novel approaches such as family and matrix. There was some discussion of accelerated product development, which is a reality in today's marketing and regulatory world. Drugs may be coming to the marketplace with less manufacturing experience than there might have been in the past. This may have an impact in process validation studies and CBER is beginning to see some evidence of this in products going to market.

Richard Francis presented some key points from an industry perspective. He noted that there is a similar definition for process validation in FDA, Europe and most global regions. Process validation is no longer an option but it is a "must have" requirement for obtaining and maintaining the product license. The diminishing but sometimes expressed motivation for process validation studies was "we do this because the FDA wants us to do it..." He presented the following conclusions:

What are the drivers for process validation?

1. Regulatory agencies will not approve your product without it.
2. Even if the above was negotiable this activity is a critical industrial requirement as it proves the process.
3. Proving the process is essential as failures are expensive and can result in loss of commercial position.
4. Proving the process is essential as failures can threaten patient safety, which can never be tolerated. This alone justifies the cost.

In summary, process validation:

A. Defines all critical process control parameters;
B. Defines process response variables which facilitate the qualification and characterization of process performance;
C. Is an expensive and critical stage of development (Don't rush it, do understand it!);
D. Always maintain the link between small scale studies and actual large scale runs; and
E. Always be prepared for surprises. Use data, not speculation, rumor and assumptions, to define your processes and guarantee patient safety. ■

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Under terms of the secondary membership agreement between PDA, the Parenteral Society (PS) and the Nordic Association for Contamination Control (R^3-Nordic), PDA members may "add on" membership to either association for a nominal fee. This secondary membership feature entitles PDA members to receive full Parenteral Society and R^3-Nordic membership benefits.* The membership will begin January 2001 for a 12-month period.

Here is how it works: **1)** use this page or a photocopy, **2)** fill in the requested information, **3)** attach a check in US dollars, drawn on a US bank, net of all bank charges, for $75.00 (Parenteral Society), $25.00 ($R^3$-Nordic), or complete the credit card information and **4)** mail or fax to PDA. All secondary membership forms must be received by January 31, 2001. We are unable to process memberships received after this date.

PDA will forward all secondary membership applications directly to the Parenteral Society administrative offices in England, or directly to the R^3-Nordic administrative offices in Sweden. Under the terms of the agreement, this application must be renewed each year. If you have any questions, please contact Virginia Ventura at PDA, (301) 986-0293, ext. 122.

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Aseptic Processing: The Importance of Microbiology and Environmental Monitoring in Media Fill Validation Author: Michael Jahnke; The second in this series of four books. Provides current, practical techniques that focus on considerations in the preparation and monitoring of aseptic manufacturing, taking into account the national and international requirements, and guidelines concerning the validation of aseptic processing. Topics include: Risk analysis, HAACP, Documentation and qualification; Qualification and training of personnel; Scope of validation; Overall requirements; Release requirements; Documentation; Authorization. The guide also includes an excellent Manufacturing and Testing Master Batch Record, and 25 extremely valuable charts, graphs, and figures. 80 pages; $90 members/$109 nonmembers **Item 17181**

Change Control Author: Soren Schwartz; Edited by Chris Reid, this manual provides a well-organized, practical process for the management of changes to the Information and Control Systems used in GxP-related operations. 28 pages; $90members/$109 nonmembers **Item 17189**

Electronic Records and Electronic Signatures Compliance Assessment Authors: Chris Reid and Barbara Mullendore; *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. 58 pages; $90 members/$109 nonmembers **Item 17177**

External Quality Audit, The Authors: Janet Gough and Monica Grimaldi; Will help you to effectively evaluate suppliers to determine reliability, quality and value. 100 pages; $120 members/$149 nonmembers **Item 17180**

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry Author: James Vesper; A quick guide to GMP, designed to simplify and enhance understanding of most of the current GMP expectations and how they apply to ongoing tasks in any given pharmaceutical manufacturing situation. 224 pages; $100 members/$124.50 nonmembers **Item 17191**

Hosting a Compliance Audit Author: Janet Gough; This is the guidance you need to host a compliance inspection. 106 pages; $120 members/$149 nonmembers **Item 17192**

Internal Quality Audit, The Author: Janet Gough and Monica Grimaldi; This book provides guidance for performing a systematic internal quality audit with guidelines and a common sense approach to an often difficult task. 175 pages; $120 members/$149 nonmembers **Item 17179**

Introduction to Environmental Monitoring of Pharmaceutical Areas Author: Michael Jahnke; Topics discussed include all aspects of cleanrooms, air handling systems, HAACP and risk analysis along with numerous useful charts, tables and figures. 80 pages; $90 members/$109 nonmembers **Item 17182**

Microbiological Risk Assessment in Pharmaceutical Clean Rooms Author: Bengt Ljungqvist and Berit Reinmuller; This monograph clearly explains the Limitation of Risk Method (LR-Method). 32 pages; $75 members/$90 nonmembers **Item 17175**

Microbiology in Pharmaceutical Manufacturing Author: Richard Prince, Editor; Providing valuable knowledge for the novice and the expert alike, many of the world's greatest pharmaceutical microbiologists and engineers, as well as other thought leaders, have invested their considerable talents and prestige in developing this comprehensive collection of timely information on this critically important subject. This book encapsulates current knowledge in a truly wide array of microbiological applications for the reader. It is hoped that this book will demystify the field of microbiology by describing it plainly and systematically from various scientific, technical, and functional perspectives. 750 pages; $240 members/$299 nonmembers **Item 17185**

Practical Change Control for Health Care Manufacturers Author: Angie Jamison; Quick Guide. 124 pages; $120 members/$149 nonmembers **Item 17173**

Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections Author: Lucia Clontz; Addresses the main quality control systems that should be implemented in a microbiology laboratory with a focus on current issues and inspection trends. 175 pages; $120 members/$149 nonmembers **Item 17176**

Understanding Active Pharmaceutical Ingredients Author: Seigfried Schmitt; Written by a Chartered Chemist and Member of the Royal Society of Chemistry, and edited by Trevor Deeks, this succinct document provides an overview of API use, including regulatory and validation details. 60 pages; $80 members/$109 nonmembers **Item 17188**

Understanding GMP: An Expert's View on Merging Global Regulatory and Manufacturing Perspectives Author: Martyn Becker; This ex-MCA inspector, now at Merck, shares his expertise and perspectives on GMP regulations, legislation, applications, and practical challenges and solutions to applying GMP to the manufacturing environment. 224 pages; $120 member/$149 nonmember **Item 17174**

Select PDA Technical Reports Available

TR 34 Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products; This technical report addresses essential user requirements for the application of isolator technology to a broad range of manufacturing, development and testing applications in the health care product manufacturing industry. It covers not only product sterility assurance, but also the use of isolators for the containment of hazardous materials. 2001; 32 pages; $75 member $125 nonmember. **Item No. 01034**

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

TR 32 Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations; Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; 277 pp; $90 members/$140 nonmembers (paper copy; **Item No. 01032**); **CD**—$50 members/$75 nonmembers (CD-ROM format; **Item No. 01132**).

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. **Item No. 01031**

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. **Item No. 01029**

TR 13 Fundamentals of an Environmental Monitoring Program; The purpose of this document is to identify microbiological and particulate control concepts and principles as they relate to the manufacture of sterile pharmaceutical products. It expands substantially upon the first edition of Technical Report No. 13 (Revised), *Fundamentals of a Microbiological Environmental Monitoring Program*, published by PDA in 1990. While this publication cannot possibly supplant the wealth of information published on this subject, it provides summary information and appropriate references for the reader to consult, if necessary. The objective was to contemporize the first edition through the utilization of current definitions, recognition of improved environmental monitoring procedures, and equipment. This document serves as a source on clean room environmental test methods, and although some non-viable particulate and endotoxin testing data are included, its primary focus is microbiological control. The concepts for sterile product manufacturing are the most stringent application, but these concepts can also be applied to non-sterile product manufacture. The focus is environmental monitoring as it relates to facility control and compliance. This document was compiled to aid in setting up a program that is meaningful, manageable, and defendable. 2001; 44 pages; $75 member $125 nonmember. **Item No. 01013**

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APRIL

April 8-9, 2002
PDA Canadian Chapter/A3P International Conference & Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec Canada

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

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

April 18-19, 2002
PDA-TRI Laboratory Course:
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA-TRI Baltimore, MD

April 29-May 1, 2002
PDA Isolation Technology Conference
Hilton East Brunswick, East Brunswick, NJ

April 29-May 3, 2002
PDA-TRI Course:
GMP Trainer Certification
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MAY

May 6-10, 2002
PDA-TRI Laboratory Course:
Aseptic Processing Training Program (week 2)
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May 16-17, 2002
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

May 19-22, 2002
PDA/USP Joint Conference on Sterile Product Manufacturing
Sanibel Harbour Resort, Fort Myers, FL

May 21-22, 2002
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PDA-TRI Baltimore, MD

JUNE

June 3-5, 2002
PDA-TRI Florida Course Series
The Diplomat Resort Country Club & Spa, Hollywood, FL

AUGUST

August 27-29, 2002
PDA-TRI Vermont Course Series
Sheraton Burlington Hotel & Conference Center
Burlington, VT

SEPTEMBER

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

September 19-20, 2002
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
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

September 26, 2002
PDA-TRI Course:
Audit Process Model Management Overview Training
Hyatt Regency on Capitol Hill, Washington, DC

OCTOBER

October 1-2, 2002
PDA-TRI Course: Computer Products Supplier Auditing Process Model—Auditor Training
PDA-TRI Baltimore, MD

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

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October 28-November 1, 2002
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NOVEMBER

November 4-8, 2002
PDA-TRI Course: GMP Trainer Certification
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November 18-20, 2002
PDA-TRI Las Vegas Course Series
Alexis Park Resort & Spa, Las Vegas, NV

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LTR 11/01

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Validator® 2000 Version 2.20

21 CFR Part 11 Compliance – Simplified

Satisfying heightened regulations for electronic records is a major undertaking. Fortunately, in the world of thermal validation, compliance is easy. Rely on the updated Validator 2000 from Kaye.

The Validator 2000 is specifically designed for validating thermal processes in accordance with FDA 21 CFR Part 11 requirements. Process data is captured in secure, unmodifiable electronic records that are encrypted and saved in a format accessible only through the system software. A unique ID/password combination is required for all system users and all actions are time-stamped and recorded.

In the newly released Version 2.20, we've added a number of system enhancements including a tamperproof audit trail of events, PDF report output capability, and the ability to specify minimum password lengths.

This stand-alone system simplifies the entire validation process by reducing setup time, minimizing sensor handling, and presenting critical study data in easily customized report formats. Of course, the Validator 2000 delivers the accuracy and reliability you've come to expect from Kaye. Ultimately, you enjoy peace of mind knowing you're backed by over forty years of thermal measurement experience, and a heritage of innovation and service.

To learn more, visit our website at

kayeinstruments.com

Or, call us to request information or arrange for a demonstration.

World Headquarters
Kaye Instruments, Inc.
North Billerica, MA, USA,
tel. +1 978 262-0005
fax +1 978 439-8181

European Headquarters
Kaye Instruments GmbH,
Pforzheim, Germany
tel. +49-(0)7231-14335 0
fax +49-(0)7231-14335 29

When there's no room for error . . . Trust Kaye.

Be sure to visit our booth #302 at the PDA Annual Meeting

KAYE®

Calendar of Events

2001

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
Improving Sterile Drug Submissions
December 6-7
Computer-Related Systems Validation
December 7
Change Control and Documentation
How to Design an Effective Regulatory Training Program

December 5-6, 2001
PDA BSE/TSE Issues Forum
Marriott Wardman Park, Washington, DC

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

2002

JANUARY

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

January 16-18, 2002
PDA-TRI Lake Tahoe Course Series
Hyatt Regency Lake Tahoe Resort & Casino
Incline Village, NV

January 16
A Comprehensive Guide to OOS Regulations
A Practical Guide to Change Control
Cost Effective Validation
Metrology and Calibration in the GMP Setting
Training for Performance
January 16-18
GMP Training Manager Workshop
January 17
GMP Fundamentals
Strategic and Practical Approaches to Part 11 Compliance
January 17-18
Basic Concepts in Cleaning and Cleaning Validation
Validation by Design
January 18
Basic Statistical Tools for Quality Assurance and Manufacturing Personnel
Designing Regulatory Training that Works

January 24-25, 2002
PDA-TRI Laboratory Course:
Fundamentals of D, F & z Value Analysis
PDA-TRI Baltimore, MD

January 30-31, 2002
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

FEBRUARY

February 5-6, 2002
PDA-TRI Course: Computer Products Supplier Auditing Process Model—Auditor Training
PDA-TRI Baltimore, MD

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

PDA-TRI Courses:

February 14
Failures, Investigations and Change Control
February 14-15
Active Pharmaceutical Ingredients (APIs): Manufacture & Validation
Basic Concepts in Cleaning and Cleaning Validation
February 15
Managing Risk Using Failure Mode and Effect Analysis (FMEA)

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

February 25-27, 2002
Training Workshop
ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)
The Sutton Place Hotel, Newport Beach, CA

February 25-March 1, 2002
PDA-TRI Course: GMP Trainer Certification
PDA-TRI Baltimore, MD

MARCH

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

March 14
Identification of Microorganisms Using Comparative DNA Sequencing
March 14-15
A Practical Approach To Aseptic Processing and Contamination Control
Assessing Packaging and Processing Extractables/Leachables
Cleanroom Management
CMC Regulatory Compliance of Biopharmaceuticals
March 15
How to Design an Effective Regulatory Training Program
Process Validation: An Introduction

March 21-22, 2002
PDA Denver Chapter Meeting and Course Series
Omni Interlocken Resort, Broomfield, CO

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

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