Volume XXXVII, No.3

PDA Letter

March 2001

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

SAP Joins the Audit Repository Center, see page 6

PDA Good Electronic Records Management (GERM) Conference, Courses and Exhibition

Registration Form is on Page 29

by Leslie Zeck, PDA

April 2–5, 2001
Hyatt Tampa Hotel
Tampa, Florida

PDA has developed the GERM conference to promote good electronic records management practices. The goal of the conference is to provide a forum for information exchange based on practical experiences and to build on lessons learned from real life Part 11-compliance work.

A multi-track format is being offered to address the following topics:

- Concepts and Practices in GERM
- Diagnosing and Assessing
- Strategies and Approaches
- Hybrid Arrangements
- Record Archival and Retention
- Project Execution
- e-Signatures and e-Records: Global Issues and Legal Considerations
- Authentication
- Outsourcing

Case situations and experiences associated with determining e-record and e-signature exposures and sensitivities relative to existing and planned computing environments will be presented. One track will focus on examples of strategies to evolve legacy environments with the goal of minimizing exposures and threats to operating environments and informational assets. Another track will highlight creative solutions for linking handwritten signatures on paper to the corresponding e-records.

Conference highlights include:

- Discussion of design and implementation of e-record retention environments using current technologies and hybrid arrangements;
- Case studies of project management experiences, cost estimating, prioritization techniques, and business process change management in fulfilling remediation plans; and
- Studies and analysis of emerging global laws and court judgments impacting the use of e-records and e-signature practices in FDA regulated businesses.

The closing plenary session will feature a presentation on the status of the FDA Part 11 Guidance Document.

Jennifer Thomas, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, and member of the Part 11 Task Force, will provide updated information from the FDA. Interactive exhibits and vendor demonstrations will be offered, giving attendees the hands-on opportunity to experience the latest tools and technologies. Make your plans to be in Tampa this April for this important technology-focused conference. Visit PDA's Web site at www.pda.org for additional information. ■

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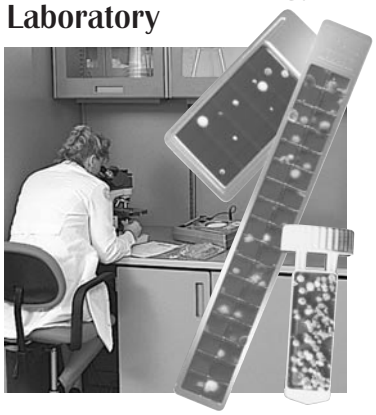

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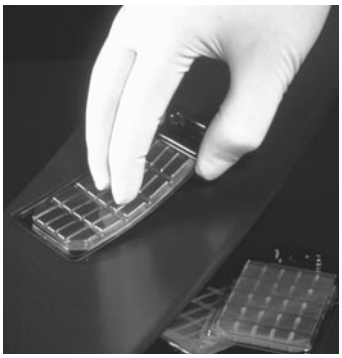

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Important Dates...

- **April 27—next meeting of PDA's biennel training conference subcommittee, PDA-TRI, Baltimore, MD—see page 33**
- **September 17–18—PDA Canadian Chapter Annual Conference—see page 31**

IN THIS ISSUE...

PDA Europe Planning Session

by Edmund M. Fry

On January 29, PDA leaders met at GlaxoSmith-Kline in London to continue discussions on how PDA Europe should be structured to better serve the 1,900-plus PDA members living and working in Europe. The working session was chaired by Joyce Aydlett, Aydlett & Associates, PDA Immediate Past Chair, and was facilitated by Sarah Jones, MRDL. Participants included representatives from PDA's four European Chapters (Italy Chapter, UK & Ireland Chapter, Israel Chapter and Europe Chapter) along with PDA staff.

These discussions will result in a broad outline for a pan-European PDA organization that will interact more effectively with regulatory authorities and the European industry. In the interim, PDA will continue to support existing European Chapters with international educational events in Europe, while the PDA Europe Office, headed by James Lyda, will support member initiatives in the scientific and regulatory areas. ■

Sarah Jones, MRDL; James Lyda, PDA; Joyce Aydlett, Aydlett & Associates; Colin Booth, GlaxoSmith-Kline; Karen Ginsbury, PCI Pharm. Consult. Israel Ltd.; Marco Budini, Eli Lilly Italia SpA; Bernard Kronenberg, Bakrona Basel; Edmund Fry, PDA; Georg Roessling, Schering AG

Flip Charts fill the walls at the GlaxoSmithKline Conference Room

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TR-32 UPDATE

by Harvey Greenawalt, Audit Repository Center

SAP Joins the Audit Repository Center

Manufacturers in regulated industries, such as pharmaceutical manufacturers and medical device manufacturers, must qualify their software suppliers for materials management and good manufacturing processes (GMP). Vendor audits that examine the supplier's software development life cycle are part of this software validation plan. These audits verify that the software vendor uses documented quality management procedures during software development, that it adequately tests the software before release and that it has sound support processes in place.

SAP has reinforced its commitment to pharmaceutical and medical device companies by providing additional lower cost support for the vendor audits and qualifications. For years SAP has fully supported vendor audits at its development headquarters in Walldorf, Germany. Since the first audit by a pharmaceutical customer in 1993, SAP has successfully been audited by more than 35 pharmaceutical and medical device companies. SAP's quality management program for www.mySAP.com development, Horizon (ISO9001 certified), provides the policies, procedures, specifications and testing to meet these requirements.

A PDA task force in 1998–1999 developed a process model and the Audit Repository Center (ARC) as an economical alternative to costly on-site audits (with the necessary expenses of travel and cost of personnel). SAP participated in this development along with pharmaceutical companies, other suppliers and the Food and Drug Administration. SAP was the first ERP software

supplier to participate in the field test of the PDA's process model before official publication of Technical Report No. 32 in October 1999. Under the auspices of ARC, independent certified auditors perform objective audits. The audit reports are then stored in a central library. Pharmaceutical and medical device manufacturers can join ARC and acquire a copy of the audit for their validation records at a greatly reduced overall cost.

SAP is pleased to announce that it has now become a charter member of the PDA licensed ARC. SAP, which was the first e-business solution provider to join, will be audited in the first half of 2001, and the audit report will be stored in the library. SAP is committed to helping its customers implement and run their SAP solutions with the lowest cost of ownership over the system's entire life cycle. SAP is proud to deliver on this commitment by providing ARC audit reports.

For more information, contact Dr. Joseph S. Cardarelli, SAP Pharmaceutical Industry Segment Manager at (610) 661-1739 or joseph.cardarelli@sap.com or Paul Hopkins, Global Quality Management at +49 6227 7-60148 or paul.hopkins@sap.com.

Availability of Audits

Currently ten audits are either available for distribution with another twenty in process or planned to be completed within the next six months.

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

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

Supplier	Product
Accraply, Inc.	Label Applicators, Automatic Labeling Systems, & Custom Designed and Self Adhesive Material Application Systems
Action Point	Input Accel Document Imaging LIMS
Applied Biosystems	SQL*LIMS - Laboratory Information Management System including the QA Stability & Schedule Modules
Decision Management International, Inc (DMI)	Batch Recipe management System
etrials.com, Inc. (Pharmacentric Technologies, Inc.)	Electronic Data Capture - EDC Electronic Patient Diaries - EPD Electronic Trail Management - ETM
Fanuc Robotics North America	Robotic Controllers & Communications
First Consulting Group, Inc.	Custom information based strategy software, operations improvements, management and integration services
Merant Inc.	PVCS Dimensions & PVCS Replicator Configuration Management Systems
Precision Solutions	Custom Development, SLE-Capture of check weight data Custom Software Programming
Qumas, Ltd (Participating Supplier)	Qumas-Doc: Electronic Records Document Management Systems

Upcoming 'Computer Products Supplier Auditing Process Model: Auditor Training' courses:

April 5–6, 2001 ..... Tampa, Florida
May 10–11, 2001 ..... Baltimore, Maryland
May 17–18, 2001 ..... Stockholm, Sweden
June 6–7, 2001 ..... East Brunswick, New Jersey
October 11–12, 2001 ..... Baltimore, Maryland
November 15–16, 2001 ..... Baltimore, Maryland

For further details, visit www.pda.org.

USP UPDATE

by Roger Dabbah, Ph.D.

The March–April 2001 Pharmacopeial Forum's (PF) In-Process section contains a list of monographs proposing to revise the current Packaging and Storage statement as follows: "Preserve in tight, light-resistant containers AND STORE in a cool place." A large number of revisions of existing monographs are also shown in this PF. It is recommended that interested parties review these proposed changes and submit comments since they could become official even without significant comment.

Proposals to reintroduce monographs for Sutilains and Sutilains Ointment have been made. They were previously omitted from USP 24-NF 19 because the products are still being produced and distributed. Also under In-Process Revision are monographs for Urofollitropin and Urofollitropin for Injection.

New NF monographs such as Carbomer Copolymer and Carbomer Interpolymer are proposed, while Ginger Capsules, Goldenseal, Powdered Goldenseal, Powdered Goldenseal Extract, Powdered Milk Thistle Extract, Milk Thistle Capsules and Milk Thistle Tablets have also been proposed as In-Process.

On the basis of comments received, Chapter <823> Radiopharmaceuticals for Positron Emission Tomography, compounding modifications have been made to the proposed revision. This chapter is to be implemented via the Tenth Interim Announcement with an official date of June 1, 2001.

A new section on Harmonization has been created and includes the following general chapters:

- Chapter <61> Microbiological Examination of Non-sterile Products: Microbial Enumeration tests (Stage 4) that require only two enumeration tests, Total Aerobic Microbial Count and Total Combined Molds and Yeasts Count.
- Chapter <62> Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms (Stage 4). Test procedures included but not required for each product are Bile-Tolerant Gram-Negative Bacteria, Staphylococcus aureus, Pseudomonas aeruginosa Burkholderia cepacia, Salmonella Species, Escherichia coli, Candida albicans and Clostridium Species.
- Also under Harmonization are Chapter <281> Residue on Ignition (Stage 5B) and Chapter <788> Particulate Matter in Injections (Stage 5B).

General Information chapters under Harmonization include <1047> Biotechnology Derived Articles-Tests, where the following sections are proposed: Peptide Mapping, Amino Acids Analysis and Total Protein Assay at the inquiry Stage 4; Capillary Electrophoresis and Isoelectric Focus are at the Stage 3 and are appearing for the first time in PF.

Under Pharmacopeial Previews we have a new general Chapter <563>Biological and Chemical Identification of Articles of Botanical Origin.

A Stimuli article by Jeanne Taborsky and L.T.Grady on "Multiple-Unit Dietary Supplement Containers-Water Vapor Permeation in Polyethylene Terephthalate and High Density Polyethylene Containers for Solid Oral Dosage Form." It also appears that PET containers provide greater protection than polystyrene containers but less protection than HDPE containers. ■

Regulatory Briefs

by William Stoedter, PDA

The National Bioethics Advisory Commission has recommended that all federally funded clinical trials performed abroad on human subjects, must first be approved by review boards in both the host country and in the United States. This recommendation would also require the FDA to reject human data gathered in foreign countries if the protocol had not been approved by the ethics boards in both countries. The Commission will also be recommending that there be a requirement that human subjects participating in clinical trials be compensated. Some members of the Commission said that America's system of Institutional Review Boards is inadequate in ensuring the ethical treatment of human subjects and will have to be improved.

The Commission's recommendations will be compiled into a final report and issued in early March.

CDERLEARN, is the location for the Center for Drug Evaluation and Research's educational seminars, which may be found at www.fda.gov/CDERLearn. The first seminar, "New Drug Development in the United States," has been developed by pharmacists in the Office of Training and Communication, CDER. The seminar's objective is to familiarize health care providers with FDA's mission of assuring that safe and effective drugs are available to the American public. The seminar provides an overview of the FDA's role in the new drug development process. It discusses various aspects of the Investigational New Drug Application (NDA) and the NDA process and includes information on drug testing in the laboratory and in patients, the importance of the Prescription Drug User Fee Act (PDUFA), the FDA Modernization Act (FDAMA), generic drugs and post-marketing surveillance. Although the seminar was developed for healthcare providers, it offers an excellent overview of the drug approval process. A self assessment quiz is available at the conclusion of the seminar and physicians can receive one Continuing Education Credit for a score of 80% or above on the quiz. This seminar can be found on the Web at www.fda.gov/cder/learn/CDERLearn/default.htm.

In May of 2000, the Office of Generic Drugs (OGD), stopped notifying ANDA sponsors when the approved labeling of the Reference Listed Drug (RLD) changed. Under the Federal Food, Drug, and Cosmetic Act, an ANDA product must have the same labeling information as the RLD. The sponsor of an ANDA is responsible for ensuring that the labeling in its application is the same as the currently approved labeling of the RLD. It is recommended that the sponsors of ANDAs monitor the OGD Labeling Review Branch Homepage often as new RLD labeling is added monthly. The OGD will continue to notify ANDA applicants for any labeling revision approved for the RLD that warrants immediate widespread professional notification, such as changes connected to issuing a Dear Doctor Letter or similar significant changes. The OGD Labeling Review Branch Homepage can be found at http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html.

On January 16, 2001, the FDA issued Standard Operating Procedures and Policies (SOPP) 8413. Postmarketing Commitment Annual Reports. For many years, the FDA and applicants have agreed upon the necessity to conduct additional studies after marketing approval of some applications to help answer unresolved questions about the product's safety. On December 11, 1992, FDA implemented regulations regarding products granted accelerated approval for which approval could be withdrawn if the applicant failed to conduct post marketing studies. FDA had no regulatory authority for other types of post marketing commitment (PMC) if the applicant failed to fulfill its commitment, nor has there been a requirement to submit reports on the status of PMCs.

Congress has attempted to address these issues in the FDA Modernization Act (FDAMA) of 1997. Included in FDAMA was section 130 which added section 506B to the Food, Drug and Cosmetic Act (the Act). Section 506B, Reports of Postmarketing Studies, requires applicants that have agreed to conduct a post marketing study to submit annual reports to the Agency on the status of the study until it is completed or terminated. Further, Section 506B requires FDA to publish annually in the *Federal Register* information on the compliance of the applicants with this reporting requirement.

In implementing Section 506B, CBER and CDER developed the revisions to 21 CFR 314.81(b)(2)(vii) (NDA annual reporting requirements) and 21 CFR 601.37 (annual reports of post marketing pediatric studies for biologics); and a new regulation (21 CFR 601.70) for annual progress reports of post marketing studies for biologics. The proposed rule reflecting these changes and additions was published in the *Federal Register* on December 1, 1999. The final rule implementing Section 506B was published in the *Federal Register* on October 30, 2000 (65 FR 64607) with an effective date of

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

February 27, 2001.

Section 506B does not apply to animal drugs or biologics meeting the definition of a device under the FD&C Act. Further, the requirements for reporting under 21 CFR 601.70 are limited to post marketing commitments that concern a drug's clinical safety, clinical efficacy, clinical pharmacology, and non-clinical pharmacology. For the complete text of SOPP 8413 go to http://www.fda.gov/cber/regsopp/8413.htm.

On January 18, 2001 in the *Federal Register* (Volume 66, Number 12, pages 4688-4706) the FDA submitted the following proposed rule in Docket No. 00N-0989. Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information related to Human Gene Therapy or Xenotransplantation.

The FDA is proposing to amend the biologics licensing regulations regarding confidentiality of information. The amendments would add provisions that would make available for public disclosure, and require submission for public disclosure of, certain data and information related to human gene therapy or xenotransplantation. The proposed regulation would apply specifically to the areas of human gene therapy and xenotransplantation because these areas of clinical research have the potential for unique public health risks and modification of the human genome. The proposed rule would provide for public disclosure of certain data and information related to an investigational new drug application (IND), to provide an opportunity for public education on, and discussion and consideration of, public health and safety issues. In addition, the proposed rule would require sponsors of clinical trials on human gene therapy or xenotransplantation to submit to FDA for public disclosure certain data and information that has been redacted to remove or obscure all information defined as confidential, commercial or a trade secret, or names and other personal identifiers of patients and certain other third parties.

Guidance for Industry, Changes to an Approved NDA or ANDA, Questions and Answers

In January of 2001 FDA issued a new guidance for industry in a question and answer format covering changes to approved NDAs and ANDAs. This guidance has been prepared by the Chemistry, Manufacturing and Control committee (CMCC) in the Center for Drug Evaluation and Research (CDER) at the FDA. The questions are those which have been posed to CDER by applicants. The guidance contains 36 questions and answers covering Reporting Categories, General Requirements, Manufacturing Sites, the Manufacturing Process, Specifications, Packaging and Miscellaneous Changes. The reporting categories in the Changes to an Approved NDA or ANDA guidance supersede those recommended in SUPAC guidances where there are inconsistencies. Therefore, the recommendations in SUPAC-IR that certain scale changes be submitted in supplements are superseded. Copies of the guidance are available from the Office of Training and Communications, Division of Communications Management, Drug Information Branch, HFD-210, 5600 Fishers Lane, Rockville, MD 20857, Telephone 301-827-4573. The guidance can be found on the Web at http://www.fda.gov/cder/guidance/4163fnl.htm.

CDRH has updated its organization structure. Their organizational chart, along with telephone numbers, may be found at: http://www.fda.gov/cdrh/organiz.html. The next update is scheduled for May 2001.

In the *Federal Register*, February 7, 2001 (Volume 66, Number 26) the FDA announced the availability of a Compliance Program (CP) entitled "Inspection of Medical Device Manufacturers." The FDA renumbered CP 7382.830 as CP 7382.845 and revised it to reflect a change in guidance as to how a Quality System, Good Manufacturing Practices (QS/GMP) inspection of a Medical Device Manufacturer should be conducted. This revision also reflects changes that determine when the FDA may consider a firm to be out of compliance with the medical device quality system regulation (21 CFR Part 820). The CP is intended to provide policy and regulatory guidance to FDA's field and headquarters staff. It also contains information that may be useful to the regulated industry. Questions concerning regulatory actions and all comments should be directed to: Wes W. Morgenstern, Division of Program Operations, (HFZ-305), Office of Compliance, Center for Devices and Radiological Health, FDA, 5600 Fishers Lane, Rockville, MD 20857 (301) 594-4699, fax (301) 594-4714. For more information, visit the Office of Regulatory Affairs' home page at http://www.fda.gov/ora.

Guidance for Industry, Statistical Approaches to Establishing Bioequivalence

This guidance provides recommendations to sponsors and applicants who intend, either before or after approval, to use equivalence criteria in analyzing *in vivo* or *in vitro* bioequivalence (BE) studies for investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs) and supplements to these applications. This guidance discusses three approaches for BE comparisons: average, population and individual. The guidance focuses on how to use each approach once a specific approach has been chosen. This guidance replaces a prior FDA guidance entitled Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design, which was issued in July 1992.

Requirements for submitting bioavailability (BA) and BE data in NDAs, ANDAs, and supplements, the definitions of BA and BE, and the types of *in vivo* studies that are appropriate to measure BA and establish BE are set forth in 21 CFR part 320. This guidance provides recommendations on how to meet provisions of part 320 for all drug products. For the complete guidance go to: http://www.fda.gov/cder/guidance/3616fnl.htm.

Guidance for Industry, Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling

This is one in a series of guidance documents intended to assist applicants making regulatory submissions in electronic format to the Center for Drug Evaluation and Research (CDER) and the

continued on page 28

The latest edition of "News Along the Pike" can be found at: http://www.fda.gov/cder/pike/jan2001.htm.

Retention Samples

by William Stoedter, PDA

On January 12, 2001, the Office of Generic Drugs posted the following information on the CDER Web page.

The Division of Scientific Investigations (DSI) and FDA field investigators conduct inspections of clinical and analytical sites that perform bioavailability (BA) and bioequivalence (BE) testing for drug manufacturers seeking approval of a drug product. One of the most common findings from these inspections is the absence of retention samples by the testing facility where the study was conducted. The regulations regarding retention samples of test articles can be found in 21 CFR 320.38 and 320.63. The final rule on these regulations can be found in the *Federal Register* Notice, Vol. 58, No. 80, April 28, 1993.

The purpose of these regulations is to make available to the FDA reserve samples of the tested products administered to study subjects.

The purpose of these regulations is to make available to the FDA reserve samples of the tested products administered to study subjects. The Agency may then analyze these retention samples to ensure that the BA/BE results upon which FDA bases approval of New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDAs) are reliable. For an ANDA, reserve samples of both the test article and the reference standard should be retained at the study site for a period of five years. The test article means the drug product for which the applicant is seeking approval. The reference standard means an approved drug product identified by the FDA as the drug product upon which the applicant relies in seeking approval of its ANDA, usually the innovator product.

Retention samples should be kept at the testing facility where the study was conducted. The study sponsor should provide the testing facility with a supply of the test article and the reference standard sufficient to complete the study and retain the appropriate number of dosage units as reserve samples. The study sponsor should not separate out the samples to be reserved prior to sending the batches to the testing facility. The testing facility will randomly select the reserve samples from the supply sent by the sponsor. This is to ensure that reserve samples are in fact representative of the same batches provided by the study sponsor for the testing. The testing facility should retain enough samples to permit FDA to perform five times all of the release tests required in the application.

It is important to be aware of this regulation because the approval of your application depends on assurance to the FDA that the study was conducted with the appropriate products. The purpose is to eliminate the possibility for sample substitution by the study sponsor, or to preclude the sponsor from altering a reserve sample after a contract research organization completes the study. In the event that a testing facility is unable to retain the reserve samples, a third party should be contracted to retain the samples. It is the responsibility of the sponsor to comply with the regulations cited above. The original text can be found at http://www.fda.gov/cder/ogd/retention_samples.htm. ■

PDA/FDA Workshops on System-Based Inspections

by William Stoedter, PDA

Joint PDA/FDA workshops on System Based Inspections were held in New Brunswick, New Jersey, Los Angeles, California, and San Juan, Puerto Rico. Frederick Blumenschein, Chief, Case Management and Guidance, Office of Compliance, CDER, FDA, presented an overview of how the program was developed and how it is intended to be implemented, at the New Brunswick and Los Angeles workshops. The Drug Manufacturing Inspections Pilot Program was designed to:

- Have a more systematic approach to drug establishment inspections;
- Increase the focus of the inspection;
- Improve the organization of FDA 483s;
- Improve the organization of the Establishment Investigation Report (EIR);
- Improve efficiency in processing regulatory actions; and
- Assure the updating of profile classes (i.e., solid dosage forms, parenterals etc.).

The pilot program will run from January 1, 2001 to June 30, 2001 in the following six districts: Philadelphia, New York, Newark, Los Angeles, Dallas and San Juan. At this time, the FDA is considering implementing this program for foreign inspection in July 2001. Any inspection of a drug company during this period will be performed using the systems approach. When the pilot program is completed, the FDA will evaluate the results to determine if the systems approach improved the efficiency of inspections. Blumenschein said that there is no timetable for evaluating the program and could not say when the evaluation would be complete.

Types of inspections:

- Full inspection option - (the Quality System plus three other systems). This option will be used for the initial inspection of a facility, when a firm has a poor compliance history, when significant changes have occurred at the firm (new technology, equipment, facility, etc.) or as a follow-up to a Warning Letter. This type of inspection can revert to the abbreviated option with concurrence of the District.
- Abbreviated inspection option - (the Quality System plus one other system). This option will be used for surveillance inspections or to satisfy the biennial inspection requirement. The abbreviated inspection is expected to be adequate for routine coverage.
- Compliance inspections - verify correction of previous deficiencies or a “for cause” inspection.

The systems involved are:

- The Quality System;
- The Facilities and Equipment System;
- Materials Systems;
- Production Systems;
- Packaging and Labeling Systems; and
- Laboratory Control Systems.

How a system is covered:

- The inspector will look for written and approved procedures;
- Resulting documentation from the procedures will be reviewed;
- Adherence to the written procedures will be verified;
- The depth of coverage may vary depending upon inspectional findings; and
- The inspection is not limited to finished products, starting and in-process materials may be included.

When evaluating the Quality System, the investigator will determine if the QC unit has fulfilled their regulatory responsibility such as annual product reports and investigations. The data reviewed in the Quality system could be used to identify quality problems and may lead to other major systems to be investigated.

Examples of Quality System Deficiencies would include a pattern of failure to:

- Review and approve procedures;
- Document execution of operations;
- Conduct investigations;
- Assess other systems to assure compliance; and
- Perform annual product reviews or other functions mandated by 21 CFR.

The Facilities and Equipment System should cover the construction and maintenance of buildings and equipment. Equipment qualifications, calibrations, maintenance, cleaning, and validation of the cleaning process would be reviewed.

Examples of Facilities and Equipment Deficiencies would include a pattern of failure to:

- Validate cleaning procedures;
- Document investigations of discrepancies;
- Establish and follow a control system for implementing changes; and
- Qualify equipment, including computers.

In the Materials System, the measures and activities to control finished products, components, containers and closures would be reviewed. This would include validation of computerized inventory control processes, drug storage, distribution controls and records.

When reviewing the Production System, the investigator will examine procedures used to control the manufacturing functions such as batch compounding, dosage form production, in-process sampling and testing and process validation.

Measures and activities to control the Packaging and Labeling System will be reviewed. Written procedures, label exam and usage, label storage and issuance, packaging and labeling operations and validation of these operations will be reviewed.

In the Laboratory Control System, laboratory procedures, testing, analytical methodology development, assay validation and the stability program will be examined.

Attendees said that the most striking feature of this inspection system is the fact that if any one system is out of control (i.e., does not meet the above test) the FDA

Examples of laboratory system deficiencies would include a pattern of failure to:

- Establish and follow a control system for implementing changes;
- Document investigations of discrepancies;
- Follow analytical and Out Of Specification (OOS) procedures;
- Validate analytical methods;
- Establish stability indicating methods; and
- Perform at least one Identity test on raw materials.

If any one system is out of control, the firm is out of control. The FDA feels that operating under a state of control produces finished drug products for which there is an adequate level of assurance of quality, strength, identity and purity. Attendees said that the most striking feature of this inspection system is the fact that if any one system is out of control (i.e., does not meet the above test) the FDA considers that the firm is out of control. That status could halt the approval of new products, prevent the shipment of government orders and cast doubt over all of the firm's current products, and is essentially the equivalent of an injunction.

If evidence is found supporting significant and/or a trend of deficiencies within a covered system, a Warning Letter may be issued. The seriousness and/or frequency of problems will be the basis for a decision to take regulatory action. The issuance of a Warning Letter renders all product profiles unacceptable.

The pilot program can be found at www.fda.gov/cder/dmpq/index.htm MACROBUTTONHtmlResAnch or www.fda.gov/cder/dmpq/index.htm. Compliance Program Guidance Manual for FDA Staff, 7356-002-draft: DRUG MANUFACTURING INSPECTIONS (Pilot Program) (1/9/01). ■

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PDA/FDA Conference on Team Biologics, A Three Year Review

by William Stoedter, PDA

On December 7, 2000, PDA and the FDA held a joint conference on Team Biologics in Bethesda, Maryland. The meeting was brought to order by PDA President Edmund M. Fry, with opening statements by Frank S. Kohn, Ph.D., Director of Manufacturing at Wyeth-Lederle Vaccines and Pediatrics, (Conference Co-Chair) and Kathryn Zoon, Ph.D., Director of CBER, FDA.

Team Biologics, Past, Present and Future

Deborah Ralston, Director, Office of Regional Operations, Office of Regulatory Affairs (ORA) presented Team Biologics, Past, Present and Future. Team Biologics started as a partnership between CBER and ORA combining the diverse skills and knowledge of both groups. The focus of Team Biologics is inspection and compliance. There are two components of Team Biologics, the blood cadre concentrating on blood and plasma facilities and the core team concentrating on biopharmaceutical manufacturers. The blood cadre has 130 ORA Investigators and 20 ORA Compliance Officers and is responsible for approximately 2500 domestic and foreign blood banks and plasma centers.

The Core Team currently has 14 investigators, one national expert and two Compliance Officers responsible for plasma fractionation products, licenced *in vitro* products, allergenic and biotech products and vaccines.

The goals of Team Biologics are:

- To assure a comprehensive regulatory posture among all products;
- Promote uniformity between CBER and the field on inspections and GMP interpretations;
- Develop and maintain a highly trained workforce;
- Develop an organized approach to inspections with clearly defined CBER and ORA roles;
- Design a process for dispute resolution between CBER and ORA;
- Provide for oversight and assurance of consistent quality;
- Bring about maximum efficiency of operations; and
- To evaluate new methods of implementing inspection and enforcement programs.

Team Biologics, A Three Year Review

Steven Masiello, Director, Office of Compliance and Biologics Quality, CBER and Co-chair of the meeting gave a three year review of Team Biologics. The increased focus on GMPs has resulted in longer inspections, more 483s, more post inspection meetings and more Warning Letters. Team Biologics has resulted in the enhancement of biologics manufacturing through major changes in management thinking, better training of employees, increased investment in facilities, an emphasis on controlling the process and the significant improvement of communication between industry and the agency.

Prior to Team Biologics, inspections of therapeutic companies ranged from 4–5 days with an average of five and a mean of five days. After Team Biologics, the inspections ranged from one day to 27 days with an average of 11 days and a mean of 10 days. For vaccine companies the pre-Team Biologics inspections ranged from five to 41 days with an average of 16 days and a mean of 11 days. With Team Biologics inspections ranged from one to 45 days with an average of 17 days and a mean of 12 days.

Addressing inspectional outcomes, Mr. Masiello said that the industry has not yet "turned the corner" on inspections resulting in official action from the agency. Warning Letters for non-blood establishments in fiscal years 1999 and 2000 were constant at 12 for each year, up from six in 1998. He also stated that the agency took action when the firm's failure to move toward a correction was documented, when the firm relies on the FDA to identify problems and where the timeline for corrections is unacceptable.

Industry Experience with Team Biologics

Kathleen Schady, Ph.D., Vice President, Quality Assurance, Biologics & Parenterals, Pharmaceutical Sourcing Group Americas (PSGA), presented the results of an industry survey on Team Biologics inspections. Sixteen (16) companies responded and eleven (11) have had one or more Team Biologics inspections. Two companies were monoclonal antibody manufacturers, two were vaccine manufacturers, and nine were biotech manufacturers. The respondents reported seven foreign inspections and 19 domestic inspections. The areas focused on during the inspection were (in descending order):

- Deviations and Investigations;
- Process Validation;
- Sterility Assurance, Bioburden Control, Media Fills;
- Documentation;
- Change Control; and
- Production and Process Control.

The survey indicated that the investigators had a very high knowledge, understanding and experience in the following areas:

- GMPs;
- Facilities, Equipment and Utilities; and
- Conducting Inspections.

Respondents stated that they used a variety of methods to prepare for an inspection and the following are the most common:

- Self Audits, Mock Inspections, Frequent Walk-Throughs;
- Develop an Inspection Plan and Form an Inspection Team;
- Review Previous 483s assuring all Issues are Closed Out;
- Review and Evaluate Similar Firms 483s and EIRs;
- In-Depth Reviews of Key Documents and Systems; and
- Prepare an Inspection Manual and Train All Staff.

There were four instances where the investigators asked for information that the respondents felt were "Out of Bounds."

- Audit Reports;
- Financial Information;
- Information on Products Not Licensed in The United States; and
- Personal Notebooks.

Conclusion

The following was learned from this survey:

- The Biologics Industry has a way to go to improve overall GMP compliance;
- CBER has made considerable effort to inform industry of expectations; and
- More communication would be helpful to support the improvement efforts. ■

International Briefs

EMEA

The European Agency for the Evaluation of Medical Products (EMEA) has a new Web site which may be found at http://www.emea.eu.int. For a time, the old Web site will run parallel with the new site, however, any content posted after January 3rd will only be accessible on the new site.

CPMP

The Committee for Propriety Medicinal Products (CPMP) held its 67th plenary meeting on January 23–25, 2001. At the meeting, Dr. Daniel Brasseur was elected Chairman and Dr. Eric Abadie was elected Vice-Chairman. Both will serve three-year terms.

CPMP Working Parties and Ad-Hoc Groups

The Committee agreed that the current Working Parties/Ad Hoc Groups Chairpersons will remain in charge until the February 2001 plenary meeting, at which time new nominations will take place.

A partial list of documents prepared by the CPMP Working Parties and Ad-Hoc Groups adopted during the January 2001 CPMP meeting include:

Biotechnology Working Party

CPMP/BWP/4310/00, concept paper on the development of a CPMP Points To Consider on stability and traceability requirements for vaccine intermediates. Status: Adopted in January 2001.

CPMP/BWP/269/95 rev. 3, Note for guidance on plasma-derived medicinal products. Status: Adopted in January 2001.

Efficacy Working Party

CPMP/EWP/1776/99 draft, Points to consider on missing data. Status: Released for three months consultation in January 2001.

The committee adopted a joint CPMP/CVMP Note for Guidance on Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products. Following adoption by the CVMP (Committee for Veterinary Medicinal Products) in February 2001, this Note for Guidance will be published on the EMEA Web site.

SIAMED 2000

Speeding up drug regulation in Europe

SIAMED is a Spanish acronym which stands for Sistema de Informacion Automatizda sobre Medicamentos or automated information systems about medicines.

The EMEA and the World Health Organization (WHO) are close to completing their model system for computer-assisted drug registration (SIAMED 2000). Development of this system is proceeding rapidly and a fully operational version will be available by June 2001.

The aim of the joint project is to develop an upgraded system that enables the EMEA to track its core processes and retrieve key registration data, which can be modified for use by National Regulatory Authorities. Both organizations are dedicated to making SIAMED 2000 freely available to such authorities worldwide. The EMEA plans to make the upgraded product available to its partners within the European Economic Area (EEA), Central and Eastern European countries (CEEC) and other European countries. This will facilitate harmonization of

continued on page 28

Interest Groups Update

by Russell E. Madsen, PDA

Various PDA Interest Groups (IGs) met at the Annual Meeting in Philadelphia last December and summaries of many of these meetings were published in last month's edition of the *PDA Letter*. Visit www.pda.org for more information. Following are highlights from the Stability IG meeting.

Stability Interest Group

by Rafik H. Bishara, Ph.D.
Eli Lilly & Co.

Fifty participants attended the third Stability IG meeting. The group identified 14 technical issues for future discussion and possible training of the pharmaceutical industry and the FDA:

1. Matrixing design (Contact Agency for clear feedback. Document agreement and share minutes with FDA.);
2. Bracketing (Include extremes. Differentiate between scientific and business decisions.);
3. Unified storage statement;
4. Stability of biologics and biopharmaceuticals;
5. Establishment of dating and dating extensions;
6. Compatibility (extractable: one time testing, identification test);
7. Stability of needless presentations (sterility issues);
8. Industry/FDA training (frequency, location, design of curriculum, answer to industry questions, include real life situations, criteria for bracketing and matrixing implementation, studies for post approval changes, breakup sessions for biologics, biopharmaceuticals, generics, others);
9. Joint FDA Guidance/ICH Q1A training;
10. WHO conditions (long term studies at 30° C / 60% RH vs. 30° C / 60 % RH);
11. Global shipping stability studies (Hot to hot, hot to cold, cold to cold , cold to hot);
12. What does it mean when MKT goes above 25° C for a week?;
13. Include FDA field inspectors in training; and
14. Include some Compliance and GMPs in training. ■

2001 Spring Interest Group Meetings

The following Interest Groups met at the PDA 2001 Spring Conference in Las Vegas, March 11–14, 2001, and will be reported in future editions of the *PDA Letter*:

Monday, March 12
4:15 p.m.–5:30 p.m.

Contract Manufacturing
Leader: Michael R. Porter, Eli Lilly & Company

Ophthalmics
Leader: Richard M. Johnson, Alcon Laboratories, Inc.

Stability
Leader: Rafik H. Bishara, Ph.D., Eli Lilly & Company

Vaccines
Leader: Frank S. Kohn, Ph.D., Wyeth-Lederle Vaccines & Pediatrics

Tuesday, March 13
4:15 p.m.–5:30 p.m.

Computer Systems
Leader: Michael L. Wyrick, KMI/Parexel

Inspection Trends/Regulatory Affairs
Leader: Robert L. Dana, Bristol-Myers Squibb Co.

Lyophilization
Leader: Edward H. Trappler, Lyophilization Technology

Quality Assurance/Quality Control
Leader: Don E. Elinski, Geneva Pharmaceuticals, Inc.

Wednesday, March 14
10:30 a.m.–12:00 p.m.

Biotechnology
Leader: Frank Matarrese, Chiron Corporation

Filtration
Leader: James D. Wilson

Microbiology/Environmental Monitoring
Leader: Jeanne E. Moldenhauer, Ph.D., Vectech Pharmaceutical Consulting, Inc.

PDA Responds to FDA's Comments on TR 28

by Russell E. Madsen, PDA

PDA Technical Report No. 28 was published in October 1998 as a supplement to the *PDA Journal of Pharmaceutical Science and Technology*. It was written by the Joint PDA/PhRMA Task Force on Sterile Bulk Pharmaceutical Chemicals. FDA commented on PDA TR 28 in February of 1999. Since then the Task Force has been reviewing the Agency's comments. Based on recent industry experience with sterile API contamination events and contributing factors, the Task Force responded to FDA's Comments in a letter dated February 12, 2001 to Joseph C. Famulare, Director, Division of Manufacturing and Product Quality at FDA. The Task Force believes that FDA may not have completely considered the effects that this technology will have in the industry as a whole.

In their letter to FDA, the Task Force targeted issues which impact the use of process simulation testing for sterile bulk pharmaceutical chemical manufacture.

As a general rule, closed systems, which have been demonstrated by scientifically sound testing protocols to maintain sterility integrity during the period routinely required for manufacture of a production campaign, need not be further subjected to simulation testing as long as previously identified process and monitoring systems and product sterility history remain in control and within all validation parameters. Further simulation testing, if necessary, is not considered an appropriate activity unless it closely duplicates the actual manufacturing process (i.e., dissolution, filtration, crystallization, drying, etc.). When simulation testing is deemed necessary and determined to be feasible, the following rules should apply:

- Process simulation testing must not increase the potential for microbial, particulate or other contamination of the process system or the product. Nutrient growth media should never be used in bulk systems because of the potential for contamination.
- Process simulations shall be performed only immediately after sterilization and should be followed by a thorough cleaning of the system.
- Process simulation testing for closed systems should be replaced by parametric monitoring once the parameters have been correlated to system integrity established during process simulation testing.
- Campaign length and system integrity for closed systems can be established by conducting process simulation testing for the full length of the campaign. Once established, system integrity over the campaign length can be verified by parametric monitoring once the parameters have been correlated to system integrity established during the process simulation test.

The letter also listed several items which should be resolved before the Task Force considers revisions to TR 28. The full text of that letter is available on the PDA Web site at www.pda.org. ■

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Use of Microsoft Access in FDA-regulated Databases (Part 2 of 2)

compiled by Russell E. Madsen, PDA

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 is a continuation of a two-part series that began last month in the *PDA Letter*. The discussion explores the viability of using Microsoft Access in FDA-regulated databases in the pharmaceutical industry. As always, the opinions expressed are those of the writers.

Question

We heard from two different consultants that the FDA is not approving computerized systems based on Microsoft Access. The main two reasons were:

1. Lack of security means
2. No audit trail.

Now for the questions:

1. Is this true? If yes where was it published?
2. If a system is based on Access but programmed in a way that solves the security and audit trail problems, is this enough?

Response 17

"Why then does he state that '…an Access proponent will be immediately crossed off my bid list.'?"

Answer—Because Jet is not an appropriate solution and MSDE is usually not a good solution either. And since those are the only two engines that ship with Access 2000, and just Jet for Access 97 and earlier—poof—no Access.

The commentator also wrote "for many department level systems, Jet will suffice." I'll point to the same white paper he did: "Enterprise applications require scalability, security and robustness, which can be implemented with MSDE or SQL Server but not with Jet." Part 11 compliant systems require security and robustness, so it sounds to me like MS is saying that Jet is not suitable for Part 11 systems. Since MSDE only became an option with Access 2000 (and not the default option at that), then we can extend that Microsoft also means that Access 97 and earlier are not appropriate because they utilize Jet.

MSDE is an option, although with some limitations. While based on the SQL engine, it has many of the administrative tools stripped from it. While it is a nice tool to allow you to develop a SQLish database on a workstation (as opposed to a server environment) that can be easily migrated to SQL Server, why not just go all the way, right from the beginning. This is taken right from Microsoft's own KB Web site "For desktop or shared database solutions that have growth potential, using MSDE as the data engine technology provides a low-cost solution for the near term" The words "near term" makes it pretty clear to me that MSDE is best suited as a stop gap measure on your way to another platform or just as a development tool. When investing the time, effort, and man hours to develop, validate, and populate a database, why do it twice? Go straight for the end result—SQL.

Other MSDE and Jet limitations garnered from various Microsoft white papers:

"Five concurrent users or less is recommended with MSDE" — That's a pretty small user group, definitely only appropriate for small applications, as is confirmed by MS in the following:

"Jet and MSDE are optimized for individual or small workgroup solutions."

—Note that is not the "thousands of users" that the commentator stated in an earlier post. Furthermore, in the same white paper, MS says this about Jet:

"Recommended for up to about 20 total users"

—Note that is total, not concurrent users.

"Jet can handle up to 2 GB of data per MDB file. MSDE also supports 2 GB of data per database."

—Again, another limitation that means MSDE is best suited for small applications and small groups. Once proper audit trails and logs are implemented, coupled the fact that you can't "delete" any data, 2 GB isn't very much room. On the other hand, SQL, Oracle, and DB2 all support data sets in the Terabyte range.

—Finally, MS reiterates their target audience for Access 2000 (including Jet and MSDE engines):

"Access targets the desktop category and works best for individuals and workgroups managing megabytes of data."

—Even though it can handle 2 GB of data, the fact that it was designed to manage Megabytes of data means you will take performance and usability hits long before you hit that 2 GB limit.

As the commentator is likely to point out, if you have clearly defined requirements and development methodology for your database, AND you can live within these limitations, then Access 2000 and MSDE could work for you. Personally, I don't think most Part 11 compliant systems can live within most of those limitations—Access (with either Jet or MSDE) is geared for small scale, desktop, and development work, and is very likely to be quickly outgrown.

Here is some good news for Access users concerned about Part 11. Microsoft does provide a tool to port Jet databases to SQL. It is my understanding (not having used it) that you must first migrate to Access 97 or 2000, then migrate from that to SQL 7. Your data tables and simple queries will migrate; however, complex queries, reports, relationships, etc. WON'T migrate. It is a round about way to get there, but at least you have a migration path for the data.

Response 18

Thanks for taking the time to put together a good discussion of the issues raised in this thread. Let me first reiterate my main point—it is inappropriate to dismiss Access with respect to 21 CFR Part 11 compliance. The real discussion should focus primarily on needs analysis and the choice of database engine that fit the requirements. I see you attempt to do this in your most recent post where you discuss the pluses and minuses of Jet, MSDE and SQL Server.

Can we agree that MS Access is a viable front end for any of these engines? Let me say that yes, we can use Visual Basic as a front end, but the advantage of using the Access reporting engine far outweighs any performance disadvantage we may incur. And yes, inexperienced folks may think Access out of the box is 21 CFR Part 11 compliant but that is a training, education issue, not a technical issue. So again, do you see any problem with using Access as a front-end to the appropriate engine? I don't and that is why I think it is inappropriate to state "…an Access proponent would be crossed off my bid list." I'd love a direct response to this simple question—and for the sake of argument let's assume we are talking about Access as a front-end to SQL Server.

Now, with respect to choice of database engines. Let's look at a typical scenario. Let's assume BioCo is a biotech start-up with 100 employees. They have a QA group of 6 people. They have an IT staff of 2 - they do not have a database administrator or any experience with client server systems. They want to implement a training database that cross references effective documents with job titles. When a document is made effective they want to capture what type of training is required and to generate a report indicating which individuals are in need of training. Once training is provided they want to update training records. They want a department level database that is 21 CFR Part 11 compliant.

In this case I maintain Jet is the appropriate back-end. You will not generate terabytes of data, and you will not incur the enterprise level demands (2,500 concurrent users performing multi-table transactions). It would be ridiculous to implement SQL server for this type system—analogous to using a chartered plane to get across town. Let me ask you another specific question grounded in a real-world situation. I'm sure you are acquainted with Blue Mountain Software's Calibration Manager application. It is my understanding that it is used in many companies that have been inspected by the FDA. It uses the Jet database engine—do you think they should be using SQL server and would you tell the FDA they are wrong in accepting the use of Jet?

So three simple questions:

1) Can we agree that Access or Visual Basic are acceptable front-ends to a 21 CFR Part 11 compliant system?

2) Can we agree that a simple department level database—carefully designed and implemented can best use Jet and not require a client-server system?

3) Do you think the FDA is wrong in accepting the use of Calibration Manager—a Jet based application?

Response 19

This is a great discussion…but FDA does not endorse or reject specific software products. FDA "endorses" or "rejects" the implementation environment of software products based on the regulations. The implementation must be in accordance with the regulations. This is the reason why the FDA may reject the implementation of "Calibration Manager" in one facility and accepts the implementation of the same product in another facility.

Then, instead of referencing "Access" or "Calibration Manager," it may be better to the people who want to learn the implementation of the regulations to software, to talk about specific issues and configurations related to the implementation.

Response 20

The commentator writes "…instead of referencing "Access" or "Calibration Manager," it may be better to the people who want to learn the implementation of the regulations to software, to talk about specific issues and configurations related to the implementation."

I couldn't agree more! It is incorrect to make the broad claim that a given product can or cannot be validated to 21 CFR Part 11 requirements. It's whether it is (or can be) documented that a product meets the requirements for a given implementation. And yes, a well designed product can be poorly implemented such that FDA will reject its use in that implementation. My main argument

in this thread is that while some software may be inappropriate for use in a regulated environment, it is absurd to include the Access front-end and the Jet database engine among them. It is hard enough to develop therapeutic products in our regulated industry—we shouldn't *apriori* throw out some very powerful tools at our disposal which can be used in a very effective manner to facilitate this our work. Instead we should educate ourselves as to how and when we use those technologies and not cross them off our list.

Response 21

While you accurately quote from "Microsoft Access 2000: Choosing between MSDE and Jet White Paper" that Jet is "Recommended for up to about 20 total users" this has not at all been my experience. Many experts in the field also disagree.

Prince & Murach write in Client/Server Programming with Access on page 26:

"When you use the Jet engine with a Jet database as shown by the first example in figure 1–12, the front-end software sends queries to the Jet engine, which opens the database file on the server. True client/server or not, though, a system like this can perform very well with as many as 100 clients using the application at the same time. That's why you may as well think of this as one of the development options for a client/server system."

Stan Lesynski writes in Access 97 Expert Solutions on page 28:

"Although a powerful product, there are places in a corporate environment where Jet, the data back-end of Access, hits the wall, runs out of performance horsepower, and must yield to more serious data management products. A common rule of thumb is that Access as a frontend, with Jet as a backend, is limited to around 50 simultaneous users on one database. The key word here is simultaneous; Access can support many more casual users."

From the Microsoft Office 2000/Visual Basic Programmer's Guide—File-Server vs. Client/Server:

The performance and simplicity of a file-server architecture make it ideal for small- to moderate-sized solutions. The primary deciding factor when choosing whether to use a file-server or client/server architecture is the number of users who will be working with your solution. As an absolute limit, an Access database can handle up to 255 simultaneous users, but if users of your solution will be frequently adding and updating data, an Access file-server is generally best for a maximum of about 25 to 50 users.

Roger Jennings, Contributing Editor of Fawcett Technical Publications, Inc.'s Visual Basic Programmer's Journal and author of more than 20 Access, Visual Basic, and Windows 9x and NT books, perhaps says it best when he writes in Using Access 2000:

Controversy over the future of conventional shared-file multiuser Jet applications borders on rampant among Access developers and Microsoft marketers. The shared-file, "Jet is alive and well" axis insists that Jet is a viable back-end for workgroup-size online-transaction processing (OLTP) applications. The "Jet is dead" cabal, whose membership is dominated by SQL Server marketing honchos, consider the Microsoft Data Engine (MSDE) to be Microsoft's "strategic database" for Office applications and SQL Server 7.0 to be the natural back-end choice for everyone else. Hooking prospective purchasers of SQL Server 7.0 licenses by offering free samples of MSDE has a counterpart in other, less politically correct marketing campaigns.

The reality is that multiuser Jet does run out of steam in heavy-duty OLTP applications having many simultaneous users. The point at which concurrency and file corruption problems begin to appear in Jet back-end databases depends on a variety of factors. Each upgrade to Jet has improved multiuser reliability, but many developers still consider 20 to 50 simultaneous updating users to be the practical limit for Jet 4.0. The absolute maximum number of concurrent connections to any Jet database is 255. Thus Jet isn't a serious contender for an e-commerce orders database on a highly-trafficked Web site. The 1 GB maximum table size and 32-index limit makes Jet impractical for use in data marts and warehouses of medium or larger scope.

And later…Jet plays a major role in more than 25 Microsoft products, and variants of the Jet database engine serve as the message store for Microsoft Exchange and the in-memory database of SQL Server 7.0.

Access…fulfills all the requirements of a professional relational database management system, as well as a front-end development tool for use with client/server databases

In summary:

Jet is a well regarded database engine and can be used with an upper limit of 20–50 concurrent users. The upper limit is a function of the imple-

mentation (Network OS, Server RAM, client configuration, etc). It is impossible to make a generalization on this limit as the limit needs to be determined via testing for a specific configuration—but it is obvious Jet is an option for a department level system. It is a mistake to invoke SQL Server as the only viable database engine without considering the alternatives. I do agree with the commentator that Jet has some real limitations and that there are instances where SQL Server may be the best choice—but I disagree that the only choice a small QA department has in modernizing its record keeping is to go with SQL Server or to abandon the effort. A well-designed and tested system incorporating Jet is a very attractive option.

As an aside, I don't think I said that Jet could be used by thousands of users as you imply in a previous post. Instead I quoted the fact that an Access front-end coupled with a SQL Server back-end could handle thousands of users—not Access with Jet, not Access with MSDE, but Access with SQL Server.

Response 22

Thanks for chiming in. You reiterated what was probably my fist post on this thread: The FDA doesn't categorically rule out any brand of software.

We the users hold the purse strings, and it is up to us to hold software vendors accountable, not the FDA.

In your example of BioCo you fell for a very common trap. The FDA will not accept lack of resources as an excuse for not being compliant. If BioCo wants to compete in an FDA regulated industry, they need to staff accordingly and utilize compliant computer systems (i.e., not Jet), otherwise, they should use paper, pens, and file cabinets. Part 11 compliance is not optional.

As for your questions:

Q1) Can we agree that Access or Visual Basic are acceptable front-ends to a 21 CFR Part 11 compliant system?

A1) Sometimes. Generally the reason developers use VB and VBA is because they don't fully understand or lack experience using more advanced and robust tools like SQL Server, C++, or better yet, Oracle. For our industry, lack of experience and training are unacceptable excuses for not using robust tools for a given project. A design methodology that is critically reviewed by knowledgeable people will filter out these projects early on. I'd just assume not even waste that much time and take them right off the bid list. Let me ask you this, what tool set does Microsoft use for designing the core of Microsoft Office Applications? It isn't VB or VBA. They know that as easy as VB/VBA can be, they are not the most appropriate or robust tools available. In my opinion, a Part 11 compliant database is more critical that MS PowerPoint. What some software vendors are having difficulty grasping is that for our industry, Part 11 is Mission Critical. Not utilizing Mission Critical tools should no longer be acceptable.

Q2) Can we agree that a simple department level database—carefully designed and implemented can best use Jet and not require a client-server system?

A2) For a Part 11 compliant system, NO, ABSOLUTELY NOT! When we use "Commercial Off-The-Shelf" software, we don't have access to the source code or low level testing. Therefore, we have to heavily rely on the original software manufacturer to develop and test the limitations of the CORE tools/software. Any further development we do utilizing their tools MUST remain within the constraints the original vendor supplies. Microsoft says in clear English "…scalability, security and robustness, which can be implemented with MSDE or SQL Server but not with Jet." Unless you have special access to MS's source code and development testing that gives you some sort of insight that their QA and Engineering department doesn't have, you have to play by their rules! When MS says over and over, that Jet is neither robust nor secure, ignoring those warnings is irresponsible.

Q3) Do you think the FDA is wrong in accepting the use of Calibration Manager—A Jet based application?

A3) Like I said in my fist post, FDA doesn't categorically approve or disapprove of software products. I on the other hand as an end user can by using my wallet. I have not used or seen Cal Manager in over 5 years, so I don't know much about their current product or its limitations. Like I stated in one of my earlier posts, the FDA has used Part 11 to raise the bar on the industry. What was acceptable 4 years ago, probably isn't any longer. It is now our turn as industry to raise the bar on software vendors, integrators, and developers. We can no longer accept inadequate security or robustness, regardless of the quality of development methodology or how much code a developer wraps around a problem. If Microsoft says their own product, Jet, is not secure or robust, who knows better?

Response 23

It seems to me the FDA doesn't care whether a developer uses VB or C++. Great developers/products can use Jet and VB, bad developers/products can use SQL Server and C++.

You state that Jet is not Part 11 compliant.

I'd be interested to know that in your experience, what specific 21 CFR Part 11 requirement will Jet with a properly developed Access/VB front end not meet?

I understand that in your opinion Jet is not a good choice. So be it, but it doesn't move the discussion forward to rely on marketing terms like robust & mission critical when discussing 21 CFR

Part 11 compliance. While I understand that one commentator is against Access, this thread is attempting to determine if the FDA is against Access, i.e., is there a specific 21 CFR Part 11 requirement that Access and/or Jet cannot meet?

It would be helpful stick to specific requirements, appropriate specifications, and failed test cases to show that specific approach has no merit or that a requirement cannot be met. In my experience it is possible to meet these requirements with a well crafted Visual Basic front end.

Response 24

I'd like to push back and say, no I don't hate Access. It is a very useful tool that I frequently use myself. Where you and I diverge is on its suitability for use in Part 11 systems. While I agree with you that good tools will not guarantee a suitable product, on the flip side, I do not agree with you that poor tools can be use to build a suitable product, regardless of the development methodology. Wrapping code around an inferior core to address FUNDAMENTAL shortcomings of a tool (Jet in this case) is not an appropriate solution.

Yes, everyone agrees that the FDA doesn't care if you use VB, C++, Jet, Oracle. What they do care about is whether or not it is validated. This means that we, the users, must show it is reliable, secure, and Part 11 compliant. Where you and I seem to disagree is on those evaluations—are VB/VBA and Jet reliable, secure, and compliant. I maintain No, they are neither stable nor secure enough.

I stated earlier that I'm not going to go bullet by bullet how Jet doesn't measure up, besides you know the security, locking, and auditing deficiencies as well as I do. You said as much when you stated in an earlier post that neither Access nor Jet were compliant out of the box. Again, where we diverge is the resolution to this. You maintain that using a good development methodology to generate code you will build on top of Jet will correct these deficiencies. I maintain that this is poor implementation, and that key functionality needs to exist as part of the core DB engine. Otherwise, once someone is past your front end (as either an admin or because of a crash or lapse in user integrity) you've lost all your Part 11 enforcements. If that functionality is part of the core DB engine, then loss/bypass of the front end doesn't jeopardize the integrity of the data.

As an example, Part 11 (mainly from the preamble p.13460 and 11.300d) requires that for a system using user ID/passwords to be able to detect and log attempted unauthorized access to the records and system. Because of the nature of a Jet database, anyone trying to get at the database bypassing the front end (be it either direct file access, ODBC calls, or Access security hacks) will not be tracked by the database. Can network security log these attempts? Somewhat, but not really to the appropriate extent. Also you've just added an immense amount of unnecessary complexity to the system to do something that is not part of its core functionality. It is significantly more robust, simple, and coherent to have complete security managed from a single server based system—like SQL/Oracle/DB2 offer.

I can hear the cries from the group now, "We aren't expected to make our systems hacker proof, just secure enough for trained users!" I'm not stating that we need to be 100% hacker proof, but 11.300d and the preamble make it pretty clear that we are supposed to be able to log, alarm, and respond to ANY unauthorized attempts, and it doesn't differentiate between simple attempts from untrained users and more persistent attempts from users that have had a lapse in judgement.

Finally, I still maintain that when validating COTS we HAVE to remain inside of the constraints that the vendor supplies, otherwise we are not being consistent. We can't play the "COTS card" when we feel it saves us work, then say it doesn't matter when it doesn't suit our needs. When Microsoft says it is not appropriate to use Jet for a secure robust environment, we have to defer to them—they hold the source code and code level tests. Access and Jet were designed from day one for desktop databases—their very file structure speaks to this. It is inappropriate to try and extend it past that base when there are already more suitable tools in place that offer a much more complete solution right off the shelf. ■

TSE Risks in Medicinal Products Expanded — EMEA Guidance Effective Immediately

by James Lyda, PDA

On February 20, the EMEA released a revised "*Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products*," (EMEA/410/01 - Final). The new *Note for Guidance* is stated to reflect the current scientific knowledge regarding TSE and is offered without prejudice to future measures which Community Institutions might take in this area. The combined CPMP-CVMP guidance replaces CPMP NfG on TSE (CPMP/BWP/1230/98/Rev.1) of September 2000 and CVMP NfG on TSE (EMEA/CVMP/145/97 Rev) of June 1999.

The 11-page release provides guidance as animals as source of material, parts of animals bodies used as starting materials, process validation, age of animals and specific products (tallow and gelatin). There is also an Annex for sourcing of materials from well monitored herds. The revised NfG is available on the EMEA Web site, www.emea.eu.int/pdfs/vet/regaffair/041001en.pdf. ■

International Calendar

2001

April 5–6, 2001*
PDA & PDA Italy Chapter Conference on
Global Pharmaceutical Manufacturing and Quality Strategies
Grand Hotel Timeo
Taormina, Italy

May 13–16, 2001
R3 Nordic Annual Symposium
Stockholm,
Sweden

May 17–18
PDA/TRI Course: **Computer Products Supplier Auditing Process Model: Auditor Training**
Contact:
Leif Mansson
Kamrersvagen 63
SE-23734 Bjared, Sweden
E-mail: contam@minpost.nu
Tel: +46 (0) 46-29 2581

September 2–5, 2001
PDA/IABs Conference on Process Validation for Biologicals and Biological Products
Hilton Berlin
Berlin, Germany

2002

February 11–13, 2002
PDA International Congress, Courses and Exhibition
Basel Congress Center
Basel, Switzerland

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

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fax (analog) +41 61 703 1689.

millennium

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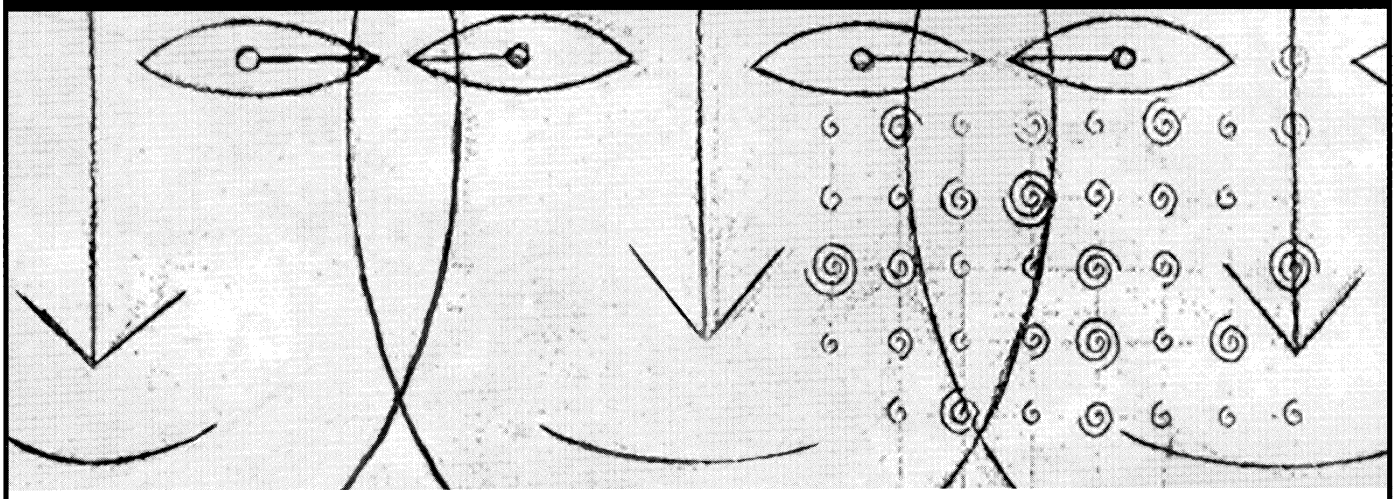

Millennium is a different kind of biopharmaceutical company with a powerful vision of personalized medicine. We're working to understand how specific changes in genes relate to disease—so we can deliver precisely the right medicine to precisely the right patient at precisely the right time. Your skills, creativity and passion—combined with our unparalleled technology platform, innovative business models, and unique partnerships—can help us make this vision a reality.

Joining our team, you'll enjoy the rich cultural and recreational opportunities available in Boston, Cambridge and the surrounding areas of beautiful New England. And as part of our emerging Clinical group, you'll have extraordinary opportunities to grow professionally as you help us build our expertise.

QC Associate

Perform routine and non-routine testing of various samples using defined standard test procedures. Requires a BS in Chemistry or a related science and up to 2 years laboratory experience. Experience with spectrophotometry, electrophoresis, chromatography and wet chemistry analysis performed in a QC GMP environment preferred.

Senior QC Associate

Be responsible for methods validation and validation reports and conduct chemical/biochemical analyses of in-process bulk and final dosage forms to support IND, NDA, BLA and MAA filings. Requires a BS/MS in Chemistry or Biochemistry and 7–9 years experience in an analytical method development and QC laboratory. Experience with spectrophotometric, chromatographic, and electrophoretic methods and knowledge of GLPs and GMPs essential.

QC Supervisor

Support analysts, write reports, plan and execute analytical technology transfer, design QC and reference material documentation systems, and help manage the laboratory. Requires a BS/MS in Chemistry or a related science with 6-9 years related industry experience, QC GMP experience, and good communication and management skills.

QC Manager

Manage the QC function to support the pharmaceutical analysis of commercial products and candidate drugs in late-phase clinical development. Requires 8–10 years experience in QC laboratories, including 2–3 years as a supervisor; knowledge of domestic and international regulatory requirements, GLPs, GMPs and compendial test methods/guidelines; and management skills and the ability to interface with other departments and project teams.

Senior Regulatory Affairs Associates

Coordinate and prepare submissions to the FDA, including INDs, IND amendments, periodic reports, and BLA supplements, working with regulatory authorities and participating in the development of regulatory strategies. Requires a BS in a health-related discipline, 3-5 years Regulatory Affairs experience, including preparation of INDs and regulatory filings, and expertise with Microsoft-based applications.

Associate Director/Quality Assurance

Reporting to the VP of QA/QC, guide the development, implementation and maintenance of a GMP Quality Assurance function, including establishing procedures and work practices and Global Compliance Guidelines to promote the establishment of a Quality culture. Require a BS, MS or PhD in Chemistry, Analytical Chemistry or Biological Sciences and 10-12 years of experience in the biopharmaceutical industry with 4+ years in QA.

Associate Director/Quality Control

Lead Millennium's QC operations for commercial products and products at different phases of development, including developing and implementing QC strategies and participating in product development. Requires an MS/ PhD in Analytical Chemistry and 10-12 years in the biopharmaceutical industry, with 5+ years of management experience, demonstrated ability to lead teams and interface with other departments and organizations, and knowledge of domestic and international regulatory requirements, GLPs, and GMPs.

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continued from page 12

Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). This specific guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products, including launch materials. In some cases, guidance differs from CDER to CBER because of differences in the procedures and computer infrastructure in the centers. The agency will work to minimize these differences wherever possible. Agency guidance documents on electronic submissions will be updated regularly to reflect the evolving nature of the technology and the experience of those using this technology. For the complete guidance go to: http://www.fda.gov/cder/guidance/3729dft.htm. ■

continued from page 17

regulatory authority tracking systems within Europe with relevant benefits in terms of transparency and effectiveness of the drug registration process.

The WHO originally developed SIAMED to help national authorities strengthen implementation of drug regulations as part of their overall public health activities. The system was developed in the early 1990s and required revision to take advantage of the current state of the art information technology. Collaboration with EMEA offered the opportunity to revise the existing system.

The EMEA has an obvious need to introduce an operational computerized system to track applications submitted for evaluation by its Scientific Committees, the Committee for Veterinary Medicinal Product (CVMP) and the Committee for Propriety Medicinal Products (CPMP). Such applications are considered to be critical activities to meet the Agency's public health goals.

For further information:

EMEA Point-of-Contact, Tony Humphreys, e-mail anthony.humphreys@emea.eudra.org.

WHO Point-of-Contact, Valerio Reggi, e-mail reggiv@who.int. ■

REGISTRATION FORM

Hyatt Regency Tampa, Tampa, Florida

Good Electronic Records Management Conference (April 2-6, 2001) and PDA-TRI Course: PDA Computer Products Supplier Auditor Process Model: Auditor Training (April 5-6, 2001)

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

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

Membership Number

Job Title Company

Business Address

City State/Province Zip + 4/Postal Code Country

Business Phone Fax E-mail

☐ Substituting for

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

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

GOOD ELECTRONIC RECORDS MANAGEMENT CONFERENCE	PDA Member	Nonmember
Full Conference Registration (Includes all sessions, meal tickets and bonus session. DOES NOT include fee for PDA-TRI Course. See below for Course Registration.)	☐ $ 995	☐ $ 1,145
Monday, April 2 Only	☐ $ 225	☐ $ 375
Tuesday, April 3 Only	☐ $ 499	☐ $ 649
Wednesday, April 4 Only	☐ $ 499	☐ $ 649
ADDITIONAL/GUEST TICKETS		
☐ **Lunch Ticket, Tuesday, April 3. _____ @ $35 each**	$	
☐ **Lunch Ticket, Wednesday, April 4. _____ @ $35 each**	$	
☐ **Reception Ticket, Tuesday, April 3. _____ @ $75 each**	$	
PDA COMPUTER PRODUCTS SUPPLIER AUDITOR PROCESS MODEL: AUDITOR TRAINING PLEASE NOTE: You must submit a separate application and registration form to enroll in this course. A nonrefundable application fee of $100 is charged. Applicants not accepted to the course will be refunded all course fees, less the $100 nonrefundable application fee. Download application and registration forms from www.pda.org/PDF/Auditor/Training020501.PDF or contact PDA. **PDA #474, April 5-6**	☐ $ 950	☐ $ 1,100
Total	$	$

3. Please check the appropriate box

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Confirmation: Written confirmation will be sent to you once payment is received. You must have written confirmation to be considered enrolled in a PDA event. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time. If you are preregistering as a substitute attendee, indicate this on the registration form. A nonmember substituting for a member must pay the additional fee. **Event Cancellation:** PDA reserves the right to modify the material or instructors without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA cannot be responsible for discount airfare penalties or other costs incurred due to a cancellation. Course enrollment is limited for the benefit of all attendees; this necessitates early registration. **Refunds:** Registrants whose written requests for refunds are received at PDA on or before **March 16, 2001** will receive a full refund less a $35 processing fee. Registrants whose written requests for refunds are received after **March 16, 2001** and on or before **March 23, 2001** will receive 50% of the registration fee. No refunds will be issued for cancellations received after **March 23, 2001**. Substitutions may be made at any time.

Business Environment (check one)

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

Professional Interest
(check all that apply)

- ☐ Aerosols
- ☐ Analytical Chemistry
- ☐ Blow-Fill-Seal
- ☐ Biologicals
- ☐ Biotechnology
- ☐ Calibration
- ☐ Contract Manufacturing
- ☐ Computer Validation
- ☐ Drug/Device Delivery Systems
- ☐ Formulation Development
- ☐ Filtration
- ☐ GMP Compliance/ Inspection Trends
- ☐ Inspection Trends/ Regulatory Affairs
- ☐ Isolation Technology
- ☐ Liquids
- ☐ Lyophilization
- ☐ Manufacturing/Production
- ☐ Microbiology/ Environmental Monitoring
- ☐ Maintenance
- ☐ Ointments
- ☐ Ophthalmics
- ☐ Packaging Science
- ☐ Parenterals
- ☐ Production & Engineering
- ☐ Quality Assurance/ Quality Control
- ☐ Research
- ☐ Solid Dosage Forms
- ☐ Stability
- ☐ Sterilization/Aseptic Processing
- ☐ Training
- ☐ Vaccines
- ☐ Validation
- ☐ Visual Inspection of Parenterals

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Company, Colleague & Product Announcements

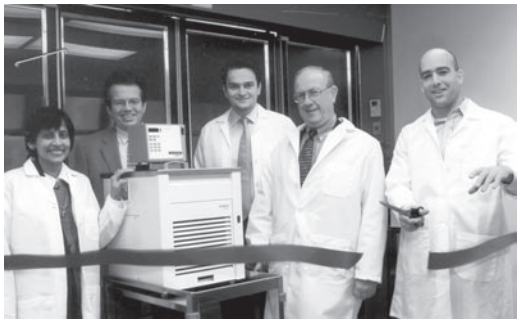
Shionogi Qualicaps, a worldwide manufacturer of two-piece capsules, has created a new division to support the sales and service of its fully automatic, high-speed capsule filling and capsule sealing equipment. Until now this equipment has been marketed in the US and Europe by one of Shiongi's partners. All of Shionogi Qualicaps' capsule filling and sealing equipment features a patented Rotary Rectification System, which provides for smooth capsule transportation at high speed and allows for monitoring of the filling and sealing processes. Shionogi Qualicaps' (www.qualicaps.com) sealing equipment meets the latest FDA directive on tamper-evident sealing. Sealed capsules are virtually impossible to open and re-close without visible damage. For further information contact Tamara Smith at (336) 449-3953.

Process Facilities Inc. of Boston, MA has named **Kumar Gupta** as Vice President of Pharmaceutical and Biotechnologies.

Gupta is an internationally recognized expert in the pharmaceutical industry specializing in the design of secondary manufacturing and biotechnology facilities. Process Facilities Inc. (www.processfraccilities.com) is a full service engineering, architecture, validation and construction management firm specializing in clean manufacturing industries, including pharmaceuticals, biotechnology, microelectronics, fine and specialty chemicals, food and consumer products. For further information contact Debbie Shain at (617) 946-9400 ext. 1372 or dshain@processfacilities.com.

GenVec, Inc. recently announced that **Wayne T. Hockmeyer, Ph.D.** has been elected to its Board of Directors. Hockmeyer is currently chairman of **MedImmune, Inc.**, a company he founded and led since its inception in 1998. In another development, GenVec announced on February 12 that it has obtained an exclusive license to Pigment Epithelium-Derived Factor (PEDF) from Northwestern University for all ocular gene therapy applications. This license covers methods invented by investigators at Northwestern University for inhibiting abnormal blood vessel formation. GenVec (www.genvec.com) is developing PEDF as a gene therapy product candidate to prevent blindness by inhibiting the abnormal blood vessel formation that occurs in the eyes of individuals with macular degeneration and diabetic retinopathy. For further information contact Jeffrey W. Church at (240) 623-5511.

Ricerca, LLC, a drug development company, announced the completion of three additional



CGMP kilo-scale API (Active Pharmaceutical Ingredient) preparation laboratories. The new laboratories are designed to provide the quantities of drug compound needed to begin preclinical metabolism and toxicity testing, CMC stability and characterization studies necessary for filing an IND, as well as the CGMP preparation of early stage clinical supplies. This latest expansion follows by six months a previous increase in the company's kilo lab capacity, providing the capacity for Ricerca (www.ricerca.com) to handle approximately 20 API scale-ups per year. For further information contact Carol A. Duane at (440) 357-3471.

3M extended its inhalation capabilities to provide aerosol manufacturing at its pharmaceutical production plant in Pithiviers, France. This addition expands 3M (www.3M.com) Drug Delivery Systems' capacity to provide innovative HFA drug delivery technology worldwide. The facility in Pithiviers received its first approval to manufacture a commercial product in December 2000. Airomir™ (salbutamol sulfate inhalation acrosol) will be produced at the site for the European market. For further information contact Sue Thoreson in the US at (651) 736-3549, smthoreson@mmm.com or Paul Williams outside the US at 44 (0) 1509 613299, pwilliams@mmm.com.

Carmen Corrado has been named Vice President, Pharmaceutical Manufacturing at **Hoffmann-La Roche Inc.** (www.rocheusa.com). In this new position, Corrado will be responsible for the day-to-day management of all pharmaceutical manufacturing. This includes Roche's tablet, liquid and capsule production and sterile operations. In addition, Corrado will manage scheduling, training, maintenance and operating costs for the production units. For further information contact Paul Minehart at (973) 562-6595.

Pall Corporation and **Viragen** announced they have entered into a development and licensing agreement to recover white blood cells (leukocytes) from blood filters. Pall (www.pall.com) will grant exclusive, worldwide license (except Japan) to proprietary technology that will enable Viragen to efficiently remove and recover leukocytes from used leukoreduction filters. The goal is to provide additional sources of leukocytes for Viragen's production of interferons for therapeutic use. **Sam Wortham**, Medical Division President of Pall Corporation stated, "The recovery of leukocytes, now essentially a medical waste, and transforming them into a valuable pharmaceutical holds great promise. We are excited to work with Viragen as we expand our activities in biotechnology." For further information contact Diane Foster at (516) 484-3600 ext. 6109, Diane_Foster@pall.com.

The new MAXIM™ Sanitary Benchtop Tangential Flow Filtration System for Process Development and Pilot Scale Applications is now available from **Pall Biopharmaceuticals** (www.pall.com/biopharmaceuticals), a division of Pall Corporation. The MAXIM™ system is a versatile benchtop unit designed for the development of TFF processes for scale-up, production small batches of biopharmaceuticals, as well as scale-down investigations. System applications include product concentration, diafiltration, clarification and fractionation. For further information contact Patrice Radowitz at (516) 484-3600 ext. 6111 or pat_radowitz@pall.com or Shara Goldstein at (516) 484-3600 ext. 6112 or shara_goldstein@pall.com.

Verion, Inc., a drug delivery company that has developed a patented high-pressure technology that promises to significantly improve the way drugs are delivered, announced that it has entered into a joint venture with **Elan Pharma International Ltd.**, an affiliate of Elan Corporation, plc. The joint venture, **Verion Newco Ltd.**, will use both companies' patented drug delivery technologies—Verion's Pressure Pulse Technology (PPT) and Elan's NanoCrystal™ technology—to develop new controlled-release drug compounds. Details of the agreement were not disclosed. For further information contact Brian Butcher at (610) 594-9220, bbutcher@verioninc.com.

Fristam Pumps, Inc. (www.fristam.com) is pleased to announce the completion of a 33,000 square foot addition. The addition doubles Fristam's plant size, allowing them to substantially improve the flow of products through the plant and accommodate continued growth. Some of the highlights of the new addition include a state of the art 5,500 sq. ft. polishing facility complete with a central dust collection system, satellite dust collectors and an air purification system; an expanded test stand facility with new tanks and a fully automated control panel; and larger assembly and stockroom areas. For further information contact Wendy Andrew at (608) 831-5001. ■

The Capital Area Chapter will hold a Vendor Exposition in Rockville, Maryland on May 9, 2001. For more information and registration forms, visit the calendar section of PDA's Web site (www.pda.org). ■

PDA Canadian Chapter Finalizes Annual Conference Date

The PDA Canadian Chapter has finalized the date for its Annual Conference. The conference will be held September 17–18, 2001, in Montreal, Quebec, Canada.

The theme will be based on current regulatory updates. Confirmed speakers from the Canadian TPP and the French Regulatory Agency will be featured. A speaker from the FDA is being recruited. For additional information on the Canadian Chapter's Annual Conference, contact the chapter (see page 46 for PDA Chapter Contacts). ■

Trainers' Conference a Huge Success

by Rick Rogers, PDA

This past October 23–26, more than 225 trainers and vendors came together in New Orleans for the largest meeting of CGMP Trainers ever. PDA's third biennial CGMP Trainers Conference and Exhibition was the culmination of two years' of effort on the part of the Training Interest Group's Conference Sub-committee.

The committee's two prior conferences were held at Tyson's Corner in McLean, Virginia in September 1996 and on the Inner Harbor in Baltimore, Maryland in October 1998.

PDA's third biennial CGMP Trainers Conference and Exhibition was the culmination of two years' of effort on the part of the Training Interest Group's Conference Sub-committee.

Delegates at this year's conference were presented with the largest range of learning options of any conference to date. The first day of the conference was filled with plenary sessions addressing industry-wide training issues. The lead speaker was Thomas Arista, Consumer Safety Officer with the FDA who gave the group a powerful overview of the FDA's current position relative to CGMP training issues. The Agency's position on these matters is vital to the industry and Arista's insights were a valuable lesson to the assembled trainers.

The first day of the conference was also marked by presentations from Frank Jedliskowski with Wyeth-Ayerst Pharmaceuticals and Anne Marie Dixon with Cleanroom Management Associates, Inc. Jedliskowski presented the conference with a perspective on the Human Resources issues facing the industry today and offered an outline of how Wyeth-Ayerst has responded to some of the challenges. Dixon quite poignantly addressed some of the technological hurdles facing CGMP trainers today and challenged the group to find new ways to engage the ever-changing workforce under their charge.

Anyone who has ever attended another PDA conference can attest to the fact that the Trainers' Conference can be distinguished in a number of ways. Not least among them is the fact that at the Trainers' Conference the delegates get involved. New Orleans was no exception as all 200+ in attendance pooled their collective minds and worked together in a large group exercise called the "100 Best Training Ideas." Registrants rotated through numerous groups where each outlined and shared a successful training idea with fellow group members. Ideas were collected in categories ranging from simple "Ice-breaker" exercises to more elaborate CGMP compliance applications. The leader of this exercise was Don Balogh of Novartis Pharmaceuticals who is still organizing the huge response. It is hoped that the results of the exercise will be made available to conference attendees, however, the results were so overwhelming to compile that the committee has not yet decided how to release them.

The second day of the conference offered delegates their choice of sessions from among a number of concurrent sessions that addressed a wide-range of training issues. Throughout the day, 26 workshops were available with presentations given by some of the leading voices in CGMP training. Each of the sessions was 90 minutes in length and offered in four time slots arranged throughout the day. The workshops, as usual, were exceptionally well received.

On the third day of the conference, delegates were given the opportunity to attend two half-day workshops given by Sivasailam Thiagarajan, Ph.D. Doctor Thiagarajan is known in training circles simply as Thiagi. He engaged the attendees in powerful, interactive training strategy sessions designed to improve workplace performance. Everyone who participated in the two workshops went home with fresh training ideas.

In addition to these events, delegates were also offered a day-and-a-half trade show of tabletop exhibits given by vendors supporting the CGMP Training community. The exhibit area was sold out, as vendors offered many different kinds of products and services including consulting services, training videos, computer based training, record-keeping systems, distance learning, and many others.

The City of New Orleans was a perfect backdrop for the conference, which was held at The Hotel Intercontinental. The facilities were particularly sound in terms of executing the various technical activities and the relaxing ambiance was a significant perk considering the heavy workload. Work that began during the conference day continued late into evening. The City of New Orleans and the conference organizers offered many opportunities to participate in evening receptions, a riverboat cruise, and discussion among peers.

The success of the conference was due almost entirely to the efforts of the dedicated group of Conference Subcommittee volunteers. The Subcommittee is composed of a diverse group that includes training professionals who represent

the pharmaceutical industry, vendors who support it and the FDA. It is a standing Subcommittee with some of the committee members having served for eight years. Members of the 2000 committee include:

Joyce Winters (Co-Chair), Manager, Training & CL for **Wyeth-Ayerst Labs**
Rob Wachter (Co-Chair), Team Leader with **Eli Lilly & Co.**
Donald J. Balogh, Senior Training Specialist with **Novartis Pharmaceutical Corp.**
Paul B. Conlon, Director, Training and Technical Support with **KMI/Parexel, LLC**
David L. Fant, Manager, GMP Operations with **Sanofi-Synthelabo Pharmaceuticals**
Gary German, Director, Division of HR Development, **Office of Regulatory Affairs, FDA**
Wanda Neal, Meetings Manager, **PDA**
Thomas G. Nimmer, Assistant Manager, Compliance Education, **Amgen, Inc.**
William F. O'Connor, Manager, GMP Training, **DuPont Pharmaceuticals Co.**
Rick H. Rogers, VP of Education, **PDA-TRI**
Richard T. Sands, President, **RTS Training Services**
Thomas W. Wilkin, Ph.D., Director, Technical Operations Training, **Schering-Plough Corp.**
Leslie Zeck, Director of Programs, **PDA**

Are You Interested In Helping Out?

PDA's next biennial training conference will be held in October of 2002. The site of the conference will not be announced for another two months, but work is already well under way. Would you like to help out with the next conference? Can you make the commitment necessary to join the Subcommittee? The Conference Subcommittee meets about four times a year, usually at PDA's headquarters in Bethesda, Maryland. The next meeting is scheduled for April 27th at the PDA's Training and Research Institute in Baltimore, Maryland. Committee members are expected to be able to make at least a two year commitment to the group, attend most of the meetings, and of course to be able to attend the conference in October of 2002.

If you are interested in helping out, contact any member of the current committee or the Chair for the 2002 conference, Rob Wachter, at 317-276-9641 or wachter_robin_o@lilly.com. ■

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COMPUTER VALIDATION SPECIALIST—Manufacturing

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New Subcommittee Organized Around Microbiological Training

Rick H. Rogers, PDA

Tom Wilkin, Chair of PDA's Training Interest Group, has just announced that a new subcommittee has been formed for the purpose of providing guidance in the area of technical training for pharmaceutical microbiologists.

The new subcommittee, chaired by Richard Prince of Richard Prince Associates, Inc., is an outgrowth of the Microbiology Interest Group. Jeanne E. Moldenhauer, Chair of the Microbiology Interest Group, has long acknowledged the need for benchmarking training qualifications for pharmaceutical microbiologists. There are no pharmaceutical industrial standards or regulatory guidelines currently established to indicate the type and level of skills and training a pharmaceutical microbiologist should have. This determination is so vital to any pharmaceutical manufacturing operation because the new standards would serve to substantially enhance a company's potential compliance position. The lack of such guidance may be interpreted to mean that the industry is unnecessarily vulnerable to regulatory interpretation and other initiatives.

The subcommittee has met once. With a broad scope focusing on the "microbiological function" within the plant, early discussions indicate that there are at least two distinct groups for whom training guidelines would be especially valuable. One group would obviously be the "entry-level microbiologist" who is new to the pharmaceutical industry and the other would be the professional from a microbiology-related field.

As to the "entry-level microbiologist", pharmaceutical microbiology requires skills not taught in most schools such as an understanding of the industry and the regulations that surround it. The neophyte microbiologist, and for that matter the manager of the microbiological lab, are currently working without a definition of either a baseline or "graduated" industry skill set.

The second target audience for the subcommittee is the professional from a field related to microbiology. An example, frequently cited by microbiologists, is the chemist from the analytical lab who is thrust into the microbiology setting. Some of their skills apply in the microbiology setting, other do not. Moreover, the chemist is not wholly prepared to assume the role of the microbiologist.

While the subcommittee is still in its early stages of development, particularly in terms of providing technical training guidance, several areas of concern have already been clearly identified. It is anticipated that the guidelines will almost certainly address such topics as basic microbiological principles and theory, contamination control, testing and of course the regulations related to microbiological activities.

The subcommittee members include:

Richard Prince, Richard Prince Associates, Inc.
James Stanek, Merck & Co., Inc.
Ann O'Leary, Ricerca, Inc., Painesville, OH
David McAlister, Amgen, Inc.
Simon Rusmin, Consultant
Ted Collins, Medeva Pharma
Jill Giulianelli, Wyeth-Ayerst ESI Lederle
Maureen Reagan, Quality Systems Consulting, Inc.
Albert Wellstein, Consultant
Strother Dixon, PDA
Rick H. Rogers, PDA

Individuals interested in making a contribution to the subcommittee should contact the Chair, Richard Prince at (973) 564-8565 or rpaincorp@aol.com. ■

Individuals interested in making a contribution to the subcommittee should contact the Chair, Richard Prince at (973) 564-8565 or rpaincorp@aol.com.

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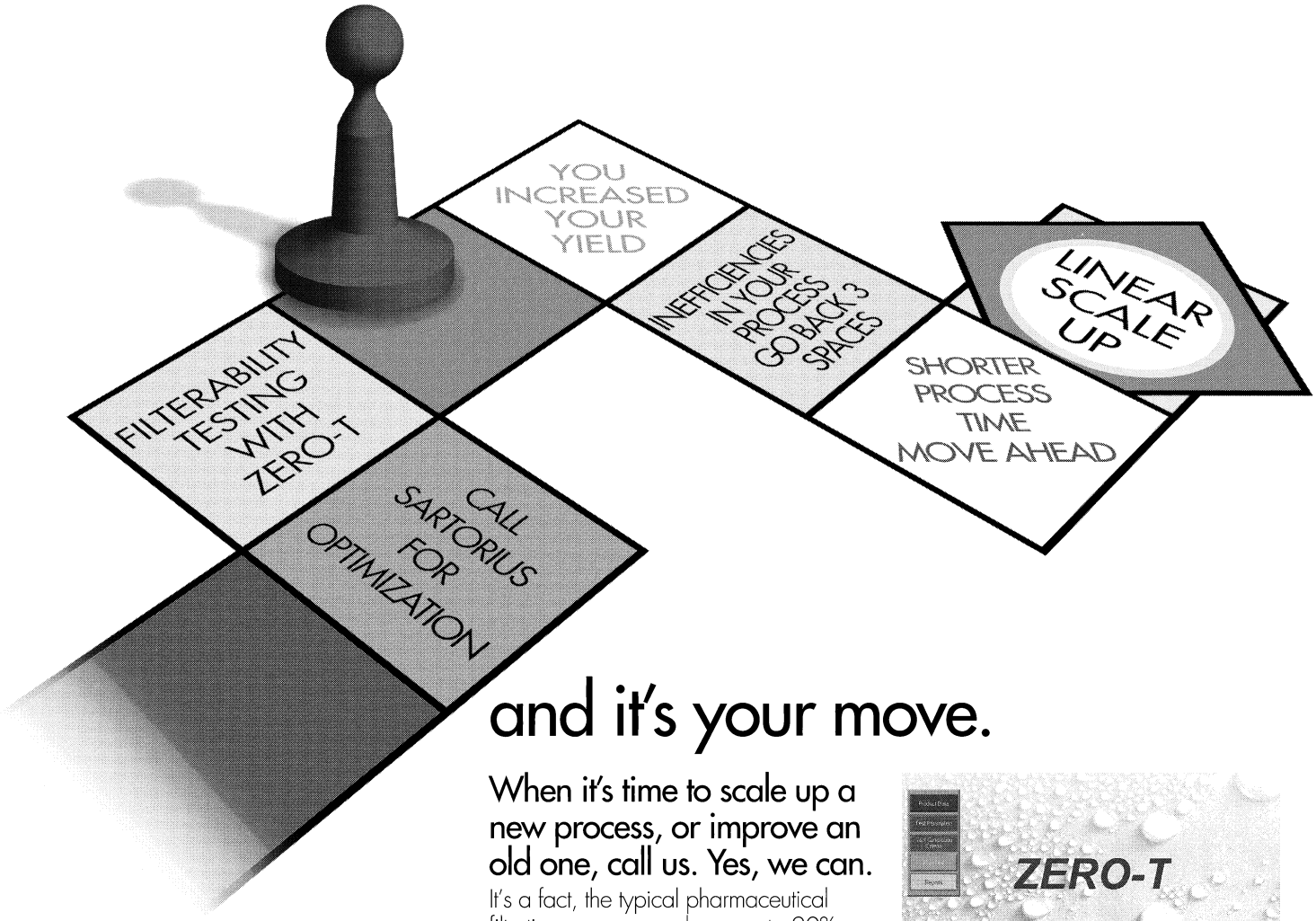

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Continued from Back Cover

AUGUST

August 14–16, 2001
PDA-TRI New Orleans Course Series
New Orleans, LA

August 20–24, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

SEPTEMBER

September 2–5, 2001
PDA/IABs Conference on Process Validation for Biologicals and Biological Products
Hilton Berlin
Berlin, Germany

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

September 10–13, 2001
PDA/FDA Joint Conference, Courses and Tabletop Exhibit
Hyatt Regency Washington, DC on Capitol Hill
Washington, DC

September 17–18, 2001
PDA-TRI Course: Fundamentals of D, F & z Values
Baltimore, MD

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

OCTOBER

October 1–3, 2001
PDA/FDA Viral Clearance Forum and Tabletop Exhibit
Hyatt Bethesda
Bethesda, Maryland

October 1–5, 2001
PDA-TRI Aseptic Processing Course (week 1)
Baltimore, MD

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

October 15–17, 2001
PDA-TRI Palm Springs Course Series
Palm Springs, CA

October 15–17, 2001
PDA Isolation Technology Conference
Hilton New Brunswick
New Brunswick, NJ

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

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

NOVEMBER

November 5–9, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

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

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

DECEMBER

December 3–7, 2001
PDA ANNUAL MEETING, COURSES AND EXHIBITION
Marriott Wardman Park
Washington, DC

2002

FEBRUARY

February 11–13, 2002
PDA International Congress, Courses and Exhibition
Basel Congress Center
Basel, Switzerland

See page 39 to sign up for PDA-TRI courses.

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

Upcoming PDA-TRI Education Courses

These courses will be held at PDA-TRI in Baltimore, Maryland. For course content information, call PDA-TRI directly at (410) 455-5800. To register, call PDA headquarters in Bethesda, Maryland at (301) 986-0293. Below is PDA-TRI Location/Hotel Information.

Contamination Control Basics (PDA #213), *Four dates remaining*: April 30, 2001; June 29, 2001; September 7, 2001; November 30, 2001—*taught by Sandra A. Lowery, President of Quality Systems Consulting*; $750 PDA members/$900 nonmembers.

Ensuring Measurement Integrity in the Validation of Thermal Processes (PDA #319), May 1–2, 2001—*taught by Göran Bringert, Director of Pharma and Biotech Markets, Kaye Instruments, Inc.*; $1,500 members/$1,650 nonmembers.

Validating a Steam Sterilizer (PDA #322), *Two dates scheduled:* May 3–4, 2001; October 25–26, 2001—*taught by Ronald Kraus, Associate Director of KMI Systems and Christopher Mansur, Sr. Computer Validation Compliance Specialist, Genetics Institute*; $1,500 members/$1,650 nonmembers.

Computer Products Supplier Auditing Process Model: Auditor Training, April 5–6, 2001 in Tampa, Florida; May 10–11 and October 11–12, 2001 in Baltimore, Maryland; **May 17–18, 2001 in Stockholm, Sweden**; $950 PDA members/$1100 nonmembers. *For more information, vist our Web site,* www.pda.org. ■

PDA-TRI Location/Lodging Information

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

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

***no on-site restaurant*

For additional hotel information, please visit *www.baltconvstr.com*, the Baltimore Convention and Visitors Bureau's website. **Transportation to PDA-TRI:** All listed hotels are no more than a 15–20 minute taxi ride to the Training and Research Institute. All hotels can assist you with taxi arrangements. Registrants may prefer to rent a car for easier access to and from the Institute. ■

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- Conference Fee (Nonmembers) ..... US$995 ❍
- Conference Fee (Government) ..... US$495 ❍

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Refunds: Refund requests must be in writing. If received at PDA Headquarters by March 5, 2001, a full refund, less a processing fee, will be made. If received by March 19, 2001, 50% of the registration fee will be refunded. After that time, no refunds will be made.

Event Cancellation: PDA reserves the right to modify the material or instructors without notice or to cancel an event. If the event must be canceled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. Course enrollment is limited for the benefit of all attendees; this necessitates early registration.

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FDA Documents Available

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

Guide to Inspections of Pharmaceutical Quality Control Laboratories; July 1993; Office of Regulatory Affairs; 15 pp; $15 members/$30 nonmembers. FDA 28

Guide to Inspections of Validation of Cleaning Processes; July 1993; Office of Regulatory Affairs; 9 pp; $15 members/$30 nonmembers. FDA 29

Guide to Inspections of High Purity Water Systems; July 1993; Office of Regulatory Affairs; 13 pp; $15 members/$30 nonmembers. FDA 31

Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories; July 1993; Office of Regulatory Affairs; 8 pp; $15 members/$30 nonmembers. FDA 32

Guideline on Sterile Drug Products Produced by Aseptic Processing; June 1987; CDER, CBER, Office of Regulatory Affairs; 43 pp; $15 members/$30 nonmembers. FDA 33

Guideline on Validation of Analytical Methods: Definitions & Terminology (Q2A); March 1, 1994; CDER; 4 pp; ICH Step 5 Final Guideline. $15 members/$30 nonmembers. FDA 53

Review Guidance, Validation of Chromatographic Methods; November 1994; CDER; 33 pp; $25 members/$40 nonmembers FDA 108

Validation Documentation Inspection Guide; 1993; ORA; 27 pp; ***Not available on the Internet.*** $25 members/$40 nonmembers. FDA 110

Guideline on the Validation of Analytical Procedures: Methodology; May 19, 1997; ICH; 5 pp; ICH Step 5 Final Guideline. $15 members/$30 nonmembers. FDA 125 (revised)

Draft Guidance for Industry: Manufacturing, Processing or Holding of Active Pharmaceutical Ingredients; April 17, 1998; CDER/CBER/CVM; 57 pp; Revised draft of FDA GMP guidance for APIs originally released in September 1996. $35 members/$50 nonmembers. FDA 158

General Principles of Software Validation Guidance for Industry; June 1, 1997; CDRH; 20 pp; $25 members/$40 nonmembers. FDA 187

Stability Testing of Drug Substances and Drug Products; June 1998; CDER/CBER; 114 pp; FDA's revised draft guidance for industry on stability testing. $35 members/$50 nonmembers. FDA 220

Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production; Draft Guidance; September 1998; CDER; 11 pp; $15 members/$30 nonmembers. FDA 229

PDA Books Available

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

PDA Technical Reports Available

Evaluation, Validation and Implementation of New Microbiological Testing Methods; This report is intended to provide a general approach to the introduction of new microbiology methods in a government-regulated environment. It is also intended to provide guidance for the successful evaluation, validation and implementation of new microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. These new methodologies offer significant improvements in terms of the speed, accuracy, precision and specificity with which testing can be performed. 2000; 37 pp; $75 members/$125 nonmembers. TR 33

Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations; Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification Task Group (SA&Q), which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA&Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; $90 members/$140 nonmembers (paper copy)**; TR 32**. $50 members/$75 nonmenbers (CD-ROM format) TR 32 CD.

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

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. TR 29

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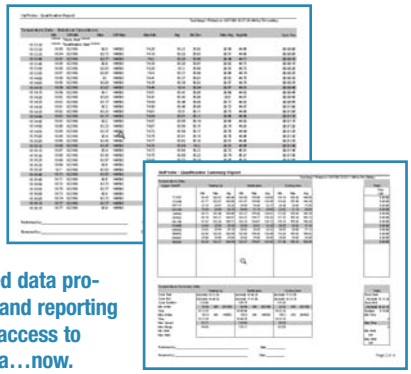

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Calendar of Events

See page 37 for the continuing list.

APRIL

April 2–6, 2001
PDA Good Electronic Records Management (GERM) Conference, Course and Exhibition
Hyatt Tampa
Tampa, FL
April 5–6
PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training

April 5–6, 2001
Global Pharmaceutical Manufacturing and Quality Strategies
Grand Hotel Timeo
Taormina, Italy

April 23–27, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

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

MAY

May 1–2, 2001
PDA-TRI Course: Ensuring Measurement Integrity in the Validation of Thermal Processes
Baltimore, MD

May 3–4, 2001
PDA-TRI Course: Validating a Steam Sterilizer
Baltimore, MD

May 10–11, 2001
PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training
Baltimore, MD

May 14–18, 2001
PDA-TRI Aseptic Processing Course (week 1)
Baltimore, MD

May 17–18, 2001
PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training
(*in conjunction with the R3 Nordic Annual Symposium*)
Stockholm, Sweden

JUNE

June 5–7, 2001
PDA-TRI New Jersey Course Series
Hilton - East Brunswick
East Brunswick, NJ
June 5, 2001
- Using INFOSEC Technology and Procedures for 21 CFR Solutions
- PDA Audit Process Model Management Overview Training
June 5–6, 2001
- Basic Concepts in Cleaning and Cleaning Validation
June 5–7, 2001
- GMP Training Manager Workshop
- Active Pharmaceutical Ingredients: Manufacture Validation
- Pharmaceutical Water Systems Design and Validation
June 6, 2001
- Designing Regulatory Training that Works
June 6–7, 2001
- PDA Computer Products Supplier Auditor Training
June 7, 2001
- Writing and Auditing CGMP Documentation
- A Practical Guide to Change Control

June 18–22, 2001
PDA-TRI Aseptic Processing Course (week 2)
Baltimore, MD

June 29, 2001
PDA-TRI Course: Contamination Control Basics
Baltimore, MD

JULY

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

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

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