Volume XXXVII, No.6

PDA Letter

June 2001

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

PDA Teams with Davis Horwood International Publishing, Ltd., page 4

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

Emerging Global Regulatory Issues

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

Join PDA for this popular two-and-one-half day annual conference focusing on regulatory issues and cutting-edge topics that impact our industry. Extensive participation from FDA and global regulatory officials is expected. This interactive conference will be of significant value to all professionals involved in pharmaceutical, biopharmaceutical product development, regulatory approval, production and quality assurance including those associated with drug product manufacture, service providers, contract services and US and international regulatory authorities.

Conference highlights include—

I. Interactive Forums:

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

II. Plenary Sessions

III. Emerging Global Regulatory Issues: An FDA Perspective

IV. EU Regulatory Issues Update

V. Progress on the MRA

VI. Impact of EU regulations on US firms

VII. Networking Breakfasts and Luncheons:

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Hyatt Regency Washington on Capitol Hill
400 New Jersey Ave., NW
Washington, DC 20001
Phone:
(202) 737-1234 or (800) 233-1234
Fax:
(202) 942-1576
Rates:
$179.00 single/double

PDA and IABs to Host International Conference on Process Validation

September 6–7, Berlin Hilton, Berlin, Germany.

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

PDA, in collaboration with the International Association for Biologics (IABs), is pleased to present: "Process Validation for Manufacturing of Biologics and Biotechnology Products: A State-of-the-Art Perspective," September 6–7, 2001 at the Berlin Hilton Hotel, Berlin, Germany.

The conference will promote the discussion of a wide-range of topics covering validation throughout the product life cycle. Issues to be discussed include the comparative technical and regulatory perspectives on process validation for biologics and biotechnology pharmaceutical products, proven as well as futuristic strategies that have been/will be developed to validate processes for bulk biopharmaceuticals and appropriate practices and requirements that will serve as a sound basis on which to connect comparability determination and process validation.

This European platform was created in response to the high-level of demand for additional dialogue between US and European regulatory authorities and affected industry representatives. In September 2000, PDA and FDA co-sponsored the conference, "Validation of Manufacturing Process-

continued on page 30

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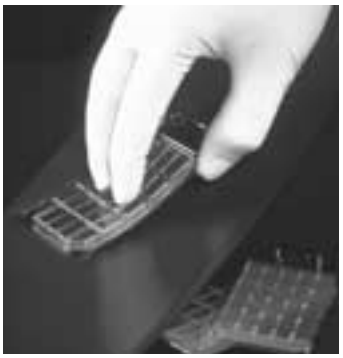

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Janet Raysick

Important Dates...

- **August 3rd – hotel cutoff date for 2001 PDA/FDA Joint Regulatory Conference**
- **Call for Papers—Basel, June 29, 2001**
- **Trainers 2002 Call for Proposals—December 14, 2001**

IN THIS ISSUE...

Fry

PDA and Davis Horwood International Publishing, Ltd. Sign Co-publishing Agreement

by Edmund M. Fry, PDA President

I am pleased to announce that PDA and Davis Horwood International Publishing, Ltd. have formally agreed to co-publish a series of books and other projects. Amy Davis, President of Davis Horwood International Publishing, Ltd. recently said, "We are very pleased to be working with PDA in this exciting publishing venture and look forward to assisting PDA in its effort to present current, practical scientific and technical information to its membership." PDA is equally excited. This partnership not only enables PDA to expand its catalog of titles but also to expedite the delivery of valuable scientific and technical literature. Fifteen titles have been identified for release this year. Six were released in May. They are:

Change Control

By Sören Schwartze

40 Pages | $80.00 | Item No. 17189

This manual is one of the documents in the Serentec Press series: Computer Systems Validation; A Life Cycle Approach, edited by Chris Reid. It provides a well-organized, practical process for the management of changes to the Information and Control Systems used in GXP related operations. Contents include process definitions for system changes to databases, operating systems, standard software, and application software, and recommendations for ways to handle changes in hardware, process and the environment. It provides a complete example change control process, details about planned and unplanned changes, sample report forms for errors/changes, change requests, log of change-related actions, log of maintenance actions, recommended actions in case of changes to the hardware, software, users and much more. A very valuable reference.

Electronic Records and Electronic Signatures

By Chris Reid and Barbara Mullendor

50 Pages | $99.00 | Item No. 17177

Electronic Records and Electronic Signatures (ERES) provides practical guidance on the interpretation of 21CFR Part 11 and the steps you need to take to address current and future compliance issues. This quick guide is designed to help you identify ERES business benefits, establish policies, procedures and processes that ensure compliance and define and evaluate system requirements. Topics covered include:

- Procedural and administrative controls including details about policies, training, system validation, security, backup, inspection of hardware and software;
- Technical requirements of 21CFR Part 11, including descriptions of open versus closed systems, user access, audit trails, creating electronic records, sequencing operations, applying and re-assigning electronic signatures; and
- Evaluation processes explains the steps necessary for a two-part evaluation including details about the high-level ERES assessment needed for Phase 1 and the technical input and operational resources necessary for Phase 2 evaluation.

This excellent resource and reference also contains invaluable appendices containing examples of warning letters, a valuable list of records specifically identified in predicate rules, numerous examples of electronic records relating to specific system types and very extensive sets of ERES assessment questionnaires. This guide is a must-have for everyone concerned with any aspect of ERES regulation.

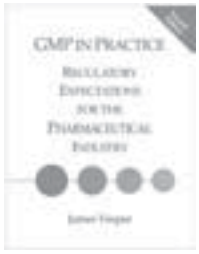
GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry

By James Vesper

224 Pages | $119.00 | Item No. 17191

Here is a comprehensive, easy-to-use reference, designed to simplify and enhance understanding of most of the current GMP expectations and how they apply to ongoing manufacturing tasks. Inside you'll find:

- Twenty-five "GMP Tasks" that encompass most of what happens in a drug manufacturing facility;
- Three to eight expectations that regulators and quality



assurance auditors would want to see met and additional details on how to meet these expectations; and
- Excerpts from US, Canadian and European Community GMP regulatory requirement documents illustrating the regulatory basis for each expectation.

This guidebook will help you make high-quality, well-informed decisions that contribute to a product's safety, identity, strength, purity and quality; decisions in keeping with the intent and spirit of GMP.

Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections

By Lucia Clontz

175 Pages | $119.00 | Item No. 17176

This text addresses the main quality control systems that should be implemented in a microbiology laboratory with a focus on current issues and inspection trends. It will help you produce timely, compliant results through each phase of laboratory work from development through the stability and batch release data needed after getting your product to market.

Written by an experienced microbiologist, this manual contains chapters covering:
- Current inspection trends;
- Chemical and biological reference standards;
- Laboratory equipment and facilities;
- Preparation of media, buffers and reagents;
- Environmental monitoring;
- Water systems for laboratory use;
- Data trending and statistical process control;
- Use of disinfectants and sanitizers;
- Training of laboratory personnel; and
- The quality assurance program for the laboratory.

The Internal Quality Audit

By Monica Grimaldi and Janet Gough

100 Pages | $119.00 | Item No. 17179

Here is the common-sense guidance you need to perform an effective, systematic internal quality audit. As a quality professional, you are well aware of the repercussions caused by a nonconforming product entering the marketplace; customers may experience adverse effects or worse, and your company will certainly lose credibility and profit. This book helps you identify and prevent systemic weaknesses by providing the evaluation tools you need to prevent such occurrences.

Contents include:
- Staffing;
- Partnering not policing;
- Setting a company wide schedule;
- Reporting and assessing;
- Establishing scope and depth;
- Determining regulations;
- Reviewing documents, previous reports and records;
- Understanding measurements;
- Creating the audit plan;
- Keeping notebooks;
- Tips on how to audit a system or process, observe activities, and identify nonconformance; Auditing batch records, history files, or other documentation;
- Compiling the observations;
- Remaining unbiased;
- Preparing the report;
- Writing report guidelines; and
- Formatting and presenting the audit report.

Understanding GMP: An Expert's View on Merging Global Regulatory and Manufacturing Perspectives

By Martyn Becker

224 Pages | $119.00 | Item No. 17174

Now at Merck, Sharp, and Dohme Ltd., Martyn Becker is an ex-UK MCA Manager and Senior Medicines Inspector. In this book, he shares his expertise and perspectives on GMP regulations, legislation, applications and practical challenges and solutions to applying GMP to the manufacturing environment. Anyone concerned with quality and GMP should have this book on a shelf nearby; it is a must-read offering an insider's view that is at once helpful and insightful.

In addition to the above titles, the following publication will be available in mid July:

Microbiology for Pharmaceutical Manufacturing

Edited by Richard Prince

900 Pages | $279.00 | Item No. 17185

This book systematizes and updates the technical discipline of pharmaceutical microbiology. Providing valuable knowledge for the novice and expert alike, it contains the wisdom and guidance of 40 leading pharmaceutical microbiologists, engineers, and other thought leaders. ■

Titles may be ordered through www.pda.org or by calling PDA at (301) 986-0293.

For information on other PDA publications, visit our Web site www.pda.org and click Technical Resources and Documents.

USP UPDATE

by Roger Dabbah, Ph.D., USP

In last month's *PDA Letter* it was announced that Eric Sheinin, Ph.D., joined USP as Vice President, Information and Standards Development. Reporting to Sheinin in the scientific areas are: Todd Cecil, Ph.D., Director, Non-Complex Actives; Sue Harris, Director, Non Complex Actives & Excipients; Srini Srinivasan, Ph.D., Director, Dietary Supplements; Larry Paul, Ph.D., Director, General Policies and Requirements; and Roger Dabbah, Ph.D., Director, Complex Actives.

Features of USP that are often overlooked are the sections on Reagents, Indicators and Solutions and the Reference Tables. Proposal for changes or additions are also published in Pharmacopeial Forum (PF). For example, in the May–June 2001 PF, there is a proposal for Container Specifications for Capsules and Tablets. The Table indicates the relevant "tight", "well-closed", or "light-resistant" specifications applicable to containers in which a specified drug that is repackaged should be dispensed. Also in the same section of USP one can find Description and Relative Solubility of USP and NF Articles. Proposals for changes or addition to this section are also published in PF.

Starting on page 2602 in the May–June 2001 PF is a listing of "Items from Earlier Numbers of PF that Have Not Yet Appeared in a Supplement, and are therefore Candidates for Subsequent Supplements."

Manuscripts for publication in PF that contain original research reports, evaluation of new or existing pharmacopeial methods, commentaries and other articles relevant to compendial issues or proposals can be submitted to USP. These items are published to stimulate discussions and for continual review of pharmacopeial standards. Instructions to Authors are also published in PF. ■

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Compliance Associate III, Quality & Regulatory Affairs

Make the most of your compliance experience during cGMP inspections (PAI inspection experience an asset), where you interacted directly with the FDA and other international regulatory bodies such as TPP, EMEA. Reporting to the Senior Manager, Compliance, you will conduct Quality audits to independently assess internal and external suppliers of critical goods and services in a timely, cost-effective, quality-oriented manner. Central to your function are the development and maintenance of the program for independent assessments according to cGXP and industry standards, to ensure that audits meet regulatory, industry and company requirements. You will be expected to prepare audit reports to ensure timely reporting to senior management, as well as recommend, monitor and evaluate corrective actions. Keeping abreast of FDA, TPP, EU and ROW compliance policies and trends, you'll be in a position to help establish Compliance systems and policies, and provide leadership and training to audit team members.

A team-oriented leader with strong communication and interpersonal skills, and knowledge of regulatory requirements - including cGMP or cGCP (cGLP an asset) for US, EU, Canada and ROW, will excel here. Your degree in Chemistry, Biological Sciences or Biotechnology has been followed by at least five years of Quality experience within the pharmaceutical industry, preferably in the manufacturing of parenterals (all stages from raw materials to the finished product), or clinical data management. Of this experience, at least two years will have preferably been as a Lead Auditor. Proficiency with MS Office and formal training in auditing are required, ideally with Lead Auditor certification such as CQA. You must be able to travel up to 20% of the time.

Clinical Data Manager, Clinical Research & Medical Affairs

You will plan, implement and/or maintain all Clinical Data Management (CDM) activities and provide advice, guidance and assistance to the clinical study teams to achieve high quality databases for various clinical trials and post marketing surveillance.

You have a Bachelor's degree and at least five years' experience in the pharmaceutical industry with at least three years in clinical trial data management to a Clinical Data Manager level, along with experience providing technical leadership to Clinical Data Associates and Data Entry Specialists. A proven understanding of the relationship between Clinical Data Management (CDM) processes and clinical trial concepts (e.g., phases, types, sponsor's responsibilities), as well as a strong commitment to quality standards, flexibility, thoroughness & adaptability is essential. Knowledge of GCP requirements and database applications (i.e. ClinTrial, Access, Oracle), and SAS programming skills are a definite asset.

For complete details on these and other opportunities with QLT, **please visit our Web site.**

QLT offers relocation assistance and a competitive benefit/compensation program, including a stock option purchase plan. Please submit your resume and cover letter to:
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We thank all applicants for their interest and advise that only short-listed candidates will be contacted.

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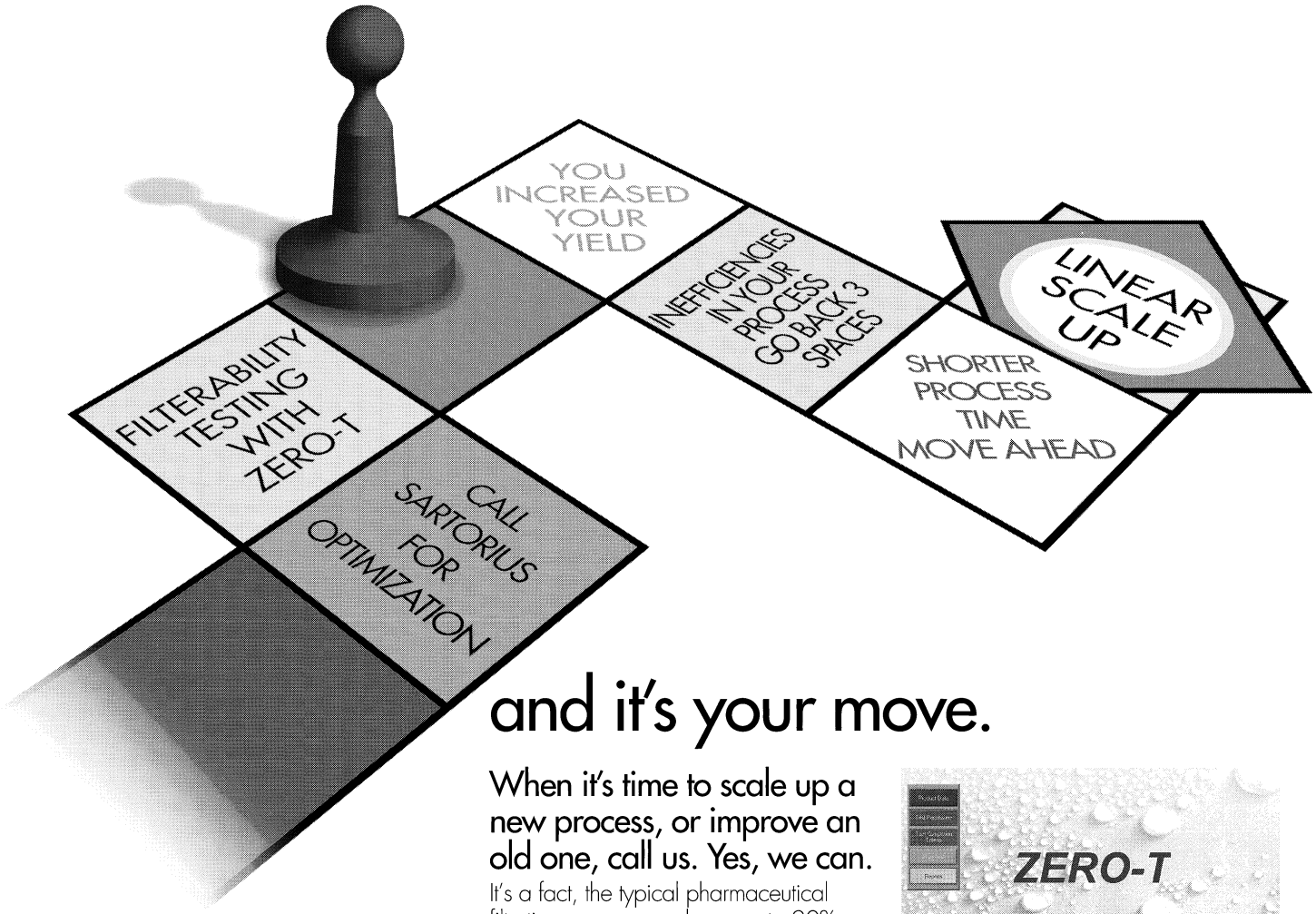

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TR-32 UPDATE

by Harvey Greenawalt, ARC and John Cassons, SSA Global Technologies

The Audit Repository Center (ARC) and PDA are happy to announce that SSA Global Technologies has joined ARC as a Participating Supplier.

Since the issue of TR-32 in January 2000, the inventory of available audits in PDA's licensed audit repository, administered by ARC, has grown at an average rate of one audit per month.

SSA Global Technologies Joins PDA Process

SSA Global Technologies (SSA GT) becomes the first ERP Vendor to have an audit report available to its clients from ARC.

Since the late 80s, SSA GT has supplied ERP systems to Pharmaceutical Industry manufacturers using its BPCS product.

It is a requirement that a supplier of software to the pharmaceutical industry submits its development methodology to audit by its clients as an element of their own Computer System Validation Protocol.

Initially, the need by SSA GT's clients for an Audit Report (that verified the soundness of its documented quality management system for software development) was satisfied by its major clients forming user groups and carrying out joint audits of SSA GT. In addition, some clients conducted their own audits.

SSA GT was a participant in the PDA task force set up in 1998 to develop a process model and the ARC for vendor audits, with the objectives of:

- Independence;
- A high degree of integrity;
- A reduction in costs to the vendor through fewer audits being conducted (an Audit carried out according to PDA Technical Bulletin No. 32 is capable of being valid for 2 years); and
- Reduction in costs to pharmaceutical manufacturers through not having the cost of personal and travel expenses involved in conducting audits at a vendor's site.

Under the auspices of ARC, an independent certified auditor conducted the audit of SSA GT R&D organization in Chicago on February 20–22, 2001. The resultant report was agreed to by SSA GT and accepted into the Repository on April 27, 2001. SSA GT's clients may now obtain copies of the audit report by subscribing to ARC.

SSA GT holds regular meetings of its major pharmaceutical clients in the forum of Pharmaceutical Global Guide Groups. These forums assist SSA GT in determining its strategy for the Pharmaceutical Industry. SSA GT's clients proposed that a reliable process for obtaining audits was a first priority for SSA GT to address as an element of its Validation Support Package. SSA GT has reinforced its commitment to its clients and the industry by being the first ERP Vendor to have its audit report available through ARC.

For more information, contact John Casson, SSA GT Pharmaceutical Industry Segment Manager at +44 1276 69211 or e-mail john.casson@ssa.co.uk or Maggy Burnes, Global Quality Development Manager at +1 312 4747350 or e-mail mburnes@ssax.com.

About SSA Global Technologies, Inc.

SSA GT provides enterprise software and services to the world's industrial sector companies, specifically the automotive supply, consumer goods (incorporating fast moving consumer goods, food beverage and tobacco and consumer electronics), pharmaceutical/chemical and general manufacturing industries. SSA GT is dedicated to the assessment, design, development, implementation and support of business solutions that improve business processes and increase profitability. SSA GT's core product, BPCS, is a flexible ERP platform that easily integrates with strategic partner applications to deliver e-commerce, business intelligence, and customer relationship management and supply chain solutions. Headquartered in Chicago, Illinois, SSA GT operates offices throughout North America, Europe, the Middle East, Africa, Asia/Pacific/Japan and Latin America. To find out more, visit the SSA GT Web site at www.ssagt.com.

Auditor Resources

To date, 91 auditors have been trained and qualified by PDA. Forty-eight percent of these auditors are from pharmaceutical industry companies, with seven percent coming from the European Union and Japan. Nine independent consulting firms have placed agreements in effect to provide qualified auditors to the industry.

Availability of Audits

Currently, 40 audits are either available for distribution, in process or planned to be implemented within the next six months.

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

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

Table 1.0 Audits Currently Available in ARC

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

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Computer Products Supplier Auditing Process Model: Auditor Training,

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

$950 PDA members/ $1,100 nonmembers.

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

Regulatory Briefs

FDA Issues New Requirements for Bolstering Child Protection in Clinical Trials. In a "Talk Paper" issued April 20, 2001, the FDA issued an interim rule to provide additional safeguards for children enrolled in clinical trials of medical products. This action was mandated by the *Children's Health Act of 2000* that calls for specific measures to better promote the unique needs of children participating in clinical trials. The new rule is designed to help the Agency and clinical researchers address many of the ethical issues that will accompany the expected increase in the enrollment of children in clinical trials. Recent initiatives such as the Agency's *1998 Pediatric Rule* and the pediatric provisions of the *FDA Modernization Act of 1997* have encouraged sponsorship of more pediatric clinical trials that can provide vital information about how therapeutic drugs and devices work, specifically in children. This data can provide important insight into how these products can be formulated, administered and labeled in ways that maximize their benefit and minimize their risk to children. Under the new regulation, Institutional Review Boards, responsible for maintaining safeguards for clinical trial subjects, will now have specific standards for determining whether proposed pediatric clinical trials can be ethically conducted. A key aspect of the new rule sets standards and procedures for assuring that children have assented to participating in clinical trials (when possible) and that their parents or guardians are able to give fully informed consent to the child's participation in a study. The interim rule was published in the *Federal Register*, April 24, 2001 (Volume 66, Number 79, page 20589) and became effective April 30. Written comments on the rule (Docket No. 00N-0074) can be submitted to FDA by **July 23, 2001** at the following address: Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, RM 1061, Rockville, MD 20857.

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

Be sure to include the Docket Number

Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements. This Draft Guidance for Industry was published in the *Federal Register* jointly by CDER and CBER, April 23, 2001 (Volume 66, Number 78, Page 20468). This guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure. FDA-approved patient labeling is also called Information for the Patient, Patient Information, Medication Guide, and Patient Package Inserts. Because the regulations do not specify how to address each risk, sponsors can use discretion in fulfilling the brief summary requirement under 202.1(e)(3)(iii). Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the Package Insert, Professional Labeling, Prescribing Information, and Direction Circular). This labeling is written for health professionals, using medical terminology. FDA believes that this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, but may be difficult for consumers to understand. FDA does not intend to object to the use of FDA-approved patient labeling to fulfill the brief summary requirement for DTC print advertisements if the labeling is reprinted in full and discusses in consumer-friendly language the following information from the advertised product's approved physician labeling:

- All the contraindications;
- All the warnings;
- All the major precautions; and
- All other frequently occurring side effects that are likely to be drug-related.

Written comments on this draft guidance should be submitted by **July 23, 2001**. Submit comments to Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, RM 1061, Rockville, MD 20857. All comments should be identified with Docket No. 01D-0162. For further information contact: (CDER) Nancy Ostrove (301) 827-2828, (CBER) Toni Stifano (301) 827-6190.

The FDA announced the availability of a draft guidance for industry entitled, "Providing Regulatory Submissions in Electronic Format–Postmarketing Expedited Safety Reports." FDA has cooperated with industry associations and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. Under the auspices of the ICH, standards for electronic submission of safety information for human drug and biological products have been developed, including a standard medical terminology for regulatory purposes, ICH M1; electronic standards for the transfer of regulatory information, ICH M2; and standardized data elements for transmission of individual case safety reports, ICH E2B and E2BM formats. The FDA's intent is to provide industry with the guidance they need to submit postmarketing expedited safety reports to FDA electronically using the standards established by the ICH. FDA believes the changes recommended by the ICH will result in more effective and efficient safety reporting to regulatory authorities worldwide. This draft guidance is being issued consistent with FDA's good guidance practices

regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the Agency's current thinking on providing postmarketing expedited safety reports in an electronic format. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. The announcement was made in the *Federal Register* on May 4, 2001 (Volume 66, Number 87, Page 22585). The draft guidance can be found at www.fda.gov/cder/guidance. Submit written comments on the draft guidance (Docket No. 01D-0185) to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, RM 1061, Rockville, MD 20852. For further information contact: Deborah Yaplee, CDER, (HFD-400), FDA, 5600 Fishers Lane, Rockville, MD 20857, (301) 827-3237, aersesub@cder.fda.gov, or, Michael Fauntleroy, CBER, (HFM-588), FDA, 1401 Rockville Pike, Rockville, MD 20852, (301) 827-5101, Fauntleroy@cber.fda.gov.

The FDA has announced the availability of a Guidance for Industry entitled, "E10 Choice of Control Group and Related Issues in Clinical Trials." This guidance was developed within the Expert Working Group (Efficacy) of the International Conference on Harmonization (ICH) for Technical Requirements for Registration of Pharmaceuticals for Human Use and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This document has been endorsed by the ICH Steering Committee at step 4 of the ICH process. At step 4 of the process, the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and the US. The guidance is intended to assist applicants in choosing a control group for clinical trials intended to demonstrate the efficacy of a treatment. The document also discusses related trial design and conduct issues and describes what trials using each design can demonstrate. This guidance does not address the regulatory requirements of any region. The document can be found at: www.fda.gov.cber/guidelines.

CBER Defines Major and Minor Amendments to Applications. The manual of Standard Operating Procedures and Policies, SOPP 8402, version #2, dated April 16, 2001 defines license application amendments as Major or Minor. An amendment to a pending application is considered Major if it contains one or more of the following:

- A substantial amount of new data not previously submitted to, or reviewed by, the Agency;
- A substantial amount of new manufacturing or facility information not previously submitted to, or reviewed by, the Agency; or
- A new analysis of studies previously submitted to the pending application.

Any amendment not meeting the criteria for major amendments above is a minor amendment. Any amendment to a supplement is a minor amendment. The full document can be found at www.fda.gov/cber/regsopp/8402.htm.

FDA and the Reuse of Single Use Devices, Policy Now Established. Larry Kessler, Director of the Office of Surveillance and Biometrics at CDRH, reported the FDA's position on April 23, 2001. It is the Agency's position that reprocessing single use devices (SUDs) is the equivalent of manufacturing. FDA research shows that reprocessing may be feasible, but that it is difficult and possibly dangerous. SUDs are designed and validated for one use. The materials are selected for a single use, biocompatibility is ensured for the intended environment and the manufacturer's validation and performance testing is limited to an initial failure. Some technical concerns expressed by the FDA are: how is the raw material (used device) controlled and cleaned, what changes to the device occur during reprocessing and how can the functionality of the reprocessed device be assured? The FDA plans to inspect all third party reprocessors in Fiscal Year 2001 to assure that they comply with the GMPs and Quality System requirements. Hospitals that reprocess SUDs will be inspected with the early inspections focusing on education rather than enforcement. More information can be found at www.fda.gov/reuse.

Results of Medical Device Inspection Survey Available from CDRH. This report presents an analysis of the 559 surveys returned from the beginning of March 1999 through the end of April 2000. The report consists of (1) an introduction, (2) the tabulated responses to each survey question and a few comparisons between questions, (3) a comparison of responses across FDA Regions, (4) a comparison of responses between firms with shorter versus longer inspections, (5) a comparison of responses between larger and smaller firms, and (6) a comparison of responses according to inspection outcome, NAI, VAI or OAI. The Medical Device Industry Initiatives Grassroots Task Force, composed of representatives from the FDA and medical device industry organizations, sponsored this survey. The survey's purpose was to determine how satisfied medical device firms are with the current FDA inspection process, discover if and where there are any problems with the process and to foster communication between industry and the FDA. When asked how this inspection compared with previous inspections, slightly more than half (52%) of those who had experi-

enced inspections previously thought this inspection was better, 40% thought it was about the same and only 8% thought this inspection was worse than previous inspections (question 18). Respondents who said this inspection was better or worse were asked to explain why. From the tabulated responses of those who said this inspection was better, the most often cited reason was the investigator's attitude, approach or personality. The QSIT method of inspection and good communication between the investigator and the firm were also frequently mentioned. The full survey is available at: www.fda.gov/cdrh.

International Briefs

Harmonization of Medical Devices. The Global Harmonization Task Force (GHTF) issued a draft document on April 26, 2001 defining the term "Medical Device." The GHTF was conceived in 1992 in an effort to respond to the growing need for international harmonization in the regulation of medical devices.

Chairmanship of the GHTF is rotated among the regulatory representatives of the five founding member countries: Australia, the US, the European Union, Japan and Canada. Australia's Therapeutic Goods Administration is the current Chair. For more information visit www.ghtf.org.

EMEA Press Release Announces Appointment of New Head of Unit for Human Medicines. Thomas Lonngren, EMEA Executive Director, announced on March 1st the appointment of Patrick Le Courtois, M.D., Ph.D., as the new Head of Unit for the pre-authorization evaluation of medicines for human use. Le Courtois was previously Head of Sector for scientific advice and orphan drugs at the EMEA. This position was established following the creation of two operational units: one dealing with pre-approval aspects of medicines and the other with postmarketing issues.

EMEA Issues a Note for Guidance on Limitations to the Use of Ethylene Oxide in the Manufacture of Medical Products. Ethylene oxide is a substance which, due to its structure, is counted among the very reactive compounds. This reactivity includes organic structures within cells, cell nuclei, DNA, RNA and proteins. Cytotoxicity, carcinogenicity and mutagenicity of ethylene oxide have been demonstrated by many *in vitro* and *in vivo* tests. In view of the known potential of ethylene oxide for genotoxic carcinogenicity, it is recommended that the use of this material is acceptable only when pharmaceutically absolutely necessary. When used, residual ethylene oxide in the product should not exceed a limit of 1 part per million (ppm). This limit is based on the current limit of detection for ethylene oxide residues. Any deviation upwards from this limit must be justified with supporting data and defended. Ethylene oxide is used in the synthesis of pharmaceutical raw materials and as a sterilant. Since it is effective only as a surface sterilant, it should be used only when justified and validated on an individual basis. The use of ethylene oxide as a sterilant should only be used where a safer alternative cannot be used. Due to the above mentioned considerations, the limits are fixed on a mass/mass basis and not on a daily intake basis. This guidance was adopted by the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) on March 1, 2001 and came into operation on April 1, 2001. The full guidance can be found at www.emea.eu.int.

The EMEA has Announced the Issuance of Volume 2 B, Presentation and Content of the Dossier/Common Technical Document (CTD). The Commission, in conjunction with the Notice to Applicants Working Party is currently working on the incorporation of the International Conference on Harmonization (ICH) Common Technical Document (CTD) into a revision of Volume 2 B of the Notice to Applicants. A schematic representation of the correspondence between the five modules of the CTD and the four parts of the European registration dossier has been prepared in order to facilitate the transition from the old application format to the new application format. The full revised text of the Notice to Applicants Volume 2 B is expected to be available in June 2001. The revised provisions, which take into account the ICH agreements, are ultimately intended to replace the previous structure of the European marketing authorization dossier described in the 1998 edition of the Volume 2 B. However, in order to take into account the fact that the marketing authorization holders may need some time to adapt their current procedures, it has been agreed that both the previous edition 1998 Volume 2 B and the new edition expected to be published in June 2001 will coexist for some time. Therefore from July 1, 2001, the legal requirements governing the particulars, and documents to accompany an application for marketing authorization, may be fulfilled either by reference to the 2001 edition or to the previous 1998 edition of Volume 2 B. More information can be found at www.emea.eu.int. ■

—Bill Stoedter

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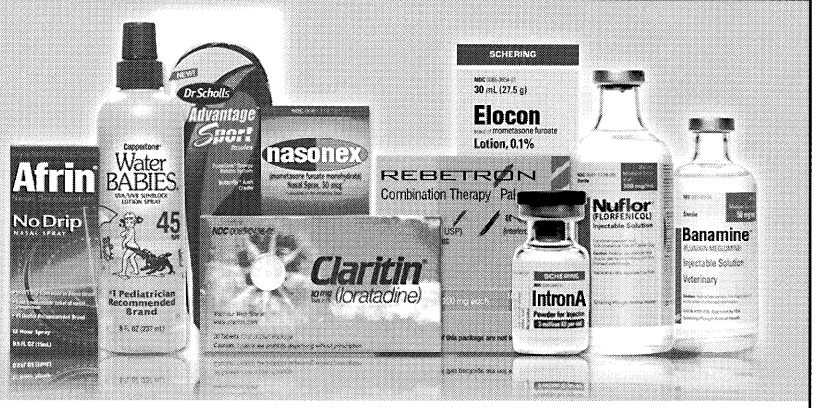

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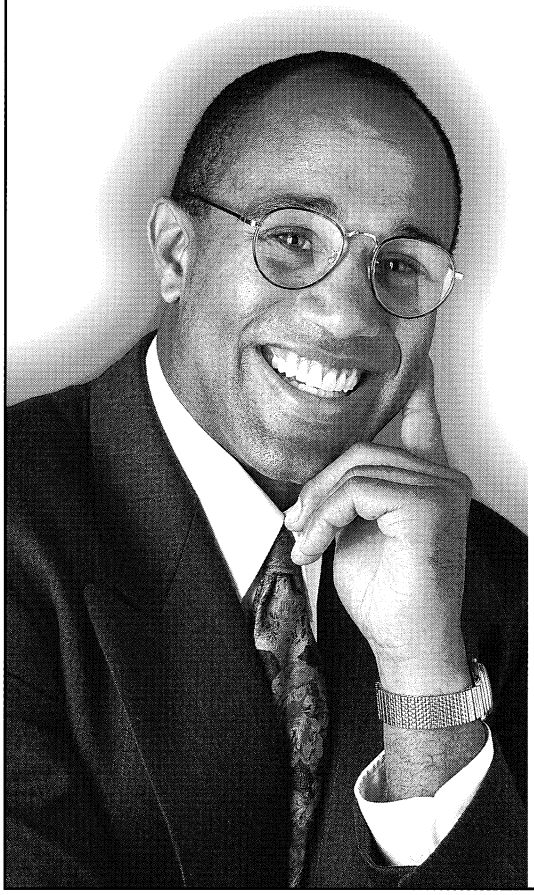
BS/BA/MS/ED.D are preferred with a minimum of 10 years of experience in employee training, curriculum development and needs assessment. Experience with GMP/GLP, SIH, SOP, and/or environment training is required. Excellent verbal and written communication skills as well as process and creative problem-solving skills are needed. Outstanding facilitation skills and a background in e-learning, CBT and other alternative training methods are key. **Job Code: PAD/ONW/SRI/1242HS**



Development Operations Technical Training Manager

Supporting multiple locations domestically and internationally, you will be responsible for the design, delivery and evaluation of curriculum-based training for one or all of the key training areas. In addition, you will be responsible for the identification and selection of any outside vendors/resources and managing the delivery of that vendor from briefing to evaluation. You will be required to keep current with and implement cutting edge technologies and training techniques to ensure knowledge transfer and learning to various learning styles. In this position, you will work with Subject Matter Experts in preparing various training presentations and documentation of the training as well as identify appropriate seminars and establish a schedule for delivery of these sessions.

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Taormina Conference Highlights

World Class Program, Great Weather, Good Time

PDA's conference "Global Pharmaceutical Manufacturing & Quality Strategies," April 5–6, 2001, was a true success with a world-class program, good weather and a strong complement of Italian hospitality. Evaluations from the attendees reflected satisfaction with the program and the venue. Highlights of the program included the opening presentation by James Kamienski, Baxter Healthcare, and presentations by Prof. Frank Hallinan, Irish Medicines Board; Dr. Carlo Pini, CPMP and Istituto Superiore Sanita, and Prof. Michael Vivion, F. Hoffmann-La Roche. Of particular interest was the presentation by Dr. Brian Matthews, Alcon Laboratories, on the BSE–TSE situation in Europe and the potential effects on the healthcare industries.

If you missed this very special conference, you may have another chance in 2003. PDA and the Italy Chapter will consider a biennial scheduling of the conference with the first repeat in early 2003. Watch the *PDA Letter* for details. PDA extends sincere appreciation to the following companies and individuals for their support of this conference:

Administrative support and conference dinner:

Dr. Giuseppe Benanti, Dr. Antonino Giannetto, and Ms. Ludmilla Lo Stimolo, S.I.F.I., SpA, Catania, Italy.

Administrative and promotional support:

Vincenzo Baselli, Pall Italia, Milan, Italy.

Conference binders:

Wyeth-Lederle SpA, Catania, Italy.

Reception:

IPRA SpA, Palermo, Italy.

Sponsorship:

CTP Technologie Di Processo, Poggibonsi, Italy
KMI, Div. of Parexel International, Arlesheim, Switzerland
Phil Ellis Associates, Wilmington, NC, USA
Nicomac srl, Milan, Italy
Millipore SpA, Milan, Italy
M.A.R. srl, Milan, Italy
Serail Division of S.G.D., Argenteuil, France ■

—James C. Lyda

Opening Session (L-R): Robert Myers, VP Schering Plough, PDA Chair and Conference Co-Chair; James R. Kamienski, VP Manufacturing, Baxter Healthcare Corporation (Keynote address); Antonino Giannetto, Technical Director, S.I.F.I. and conference Co-Chair.

Regulatory Environment and International Compliance (L-R): Tim R. Marten, Vice President International Compliance, AstraZeneca; Prof. Frank Hallinan, Chief Executive, Irish Medicines Board; Stephanie Gray, VP Worldwide Quality Strategy and Policy, GlaxoSmithKline; Georg Roessling, Head CMC Ultrasound, Schering AG.

Manufacturing of Biotechnological Drug Products (L-R): Dr. Carlo Pini, Head, Laboratory of Immunology, Istituto Superiore di Sanita & member of EMEA Biotechnology Working Party (BWP); Professor Giuseppe Vicari, Ministero della Sanità, past member of CPMP & Past Chair BWP; Dr. Enzo Bucci, Technical Director, Kedrion SpA.

Quality Challenges in International Business Growth (L-R): Phil Budahewitz, Government Affairs, Elan Pharmaceuticals; Joyce Aydlett, Aydlett and Associates, Immediate Past Chair, PDA; Robert Myers, Schering Plough, PDA Chair.

Photo 5
Information Strategies for Optimizing What You Know (L-R): Edmund M. Fry, PDA President; Prof. Michael Vivion, Director Special Communications, F. Hoffmann-La Roche; James C. Lyda, PDA Europe.

International Technology Issues (L-R): Antonino Giannetto; Vincenzo Baselli, Pall Italia and President of PDA Italy Chapter; Jim McKiernan, Partner and Leader of Pharma SCM Practice, Pricewaterhouse Coopers.

Presentation to Dr. Giuseppe Benanti, President and CEO S.I.F.I., in appreciation of generous support of the conference (L-R): Edmund Fry, Bob Myers, Giuseppe Benanti, Antonino Giannetto.

Taking a break, lunch on the terrace of the Grand Hotel Timeo.

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New PDA Task Force Developing Aseptic Processing Guidance

The FDA is currently in the process of revising the 1987 Aseptic Processing Guideline. The PDA Special Scientific Forum on Environmental Monitoring and Aseptic Processing, held August 21, 2000, at the Hyatt Regency Bethesda, Bethesda, Maryland, provided an excellent opportunity for a discussion among FDA and industry experts on several key aseptic processing issues—the location of airflow measurements in critical areas, surface monitoring of sterile product contact surfaces, how to handle alert and action level excursions during environmental monitoring in aseptic areas, identification requirements for sterility test and environmental monitoring isolates, media fill acceptance criteria and incubation conditions and requirements, and gowning qualification. The current regulatory expectations for these issues have been an ongoing source of confusion even though the revised FDA guidance has not yet been finalized.

Panelists at the Forum were in general agreement over many of the issues yet sharply divided over others. The creation of the PDA Task Force Developing Aseptic Processing Guidance—the subject of this article—came about because it was recognized that further study and evaluation of these guidelines was needed. The Task Force intends to develop scientifically-based positions on each of these issues and publish a technical document containing "best practices" for use by the pharmaceutical industry. Once the initial draft is complete, it will be made available for review and comment by a larger technical audience to ensure it accurately addresses the concerns of PDA's membership, as well as other industry groups.

The Task Force is headed by David J. Miner, Ph.D., *Eli Lilly & Company*. Other members are: Joyce H. Aydlett, *Aydlett and Associates, Inc.*; William R. Frieben, Ph.D., *Pharmacia Corporation*; Nigel Halls, Ph.D., *GlaxoSmithKline*; Richard M. Johnson, *Abbott Laboratories, Inc.*; Carol M. Lampe, *Baxter Healthcare Corporation*; Russell E. Madsen, *PDA*; Ken Muhvich, Ph.D., *The Validation Group*; Terry Munson, *KMI/PAREXEL, Inc.*; Richard N. Prince, Ph.D., *Richard Prince Associates*; Dr. Andreas Sachse, *Schering AG*; Martin Van Trieste, *Abbott Laboratories*; Richard T. Wood, Ph.D., *Pfizer, Inc.*; Glenn E. Wright, *Eli Lilly & Company*; and Jeffrey T. Yuen.

The Task Force intends to make the draft technical report available for comment as quickly as possible. Its availability will be announced in a future issue of the *PDA Letter* and on the PDA Web site, www.pda.org. Additional information about any of the issues discussed at the Forum, and mentioned at the top of this article, appears in the November 2000 issue of the *PDA Letter*. ■

—Russell E. Madsen

International Calendar

2001

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

September 17–18, 2001
PDA Canada Chapter/A$_3$P International Conference and Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec, Canada

2002

February 11–15, 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

Interest Groups Update

Many of the PDA Interest Groups met at the Spring Conference in Las Vegas, Nevada, in March 2001. Following are summaries sent to PDA on behalf of three IG sessions held at the meeting. Summaries of the Microbiology/Environmental Monitoring and Filtration IG sessions were submitted to PDA and published in the May issue of the *PDA Letter*. More information about PDA Interest Groups can be found on the PDA Web site at www.pda.org.

Sterilization/Aseptic Processing

by Charles D. Anderson (for James P. Agalloco)

In keeping with the Spring Conference theme of Microbiology, much of the discussion revolved around issues of setting and meeting microbiological requirements, and in responding to situations in which microbiological limits are exceeded.

Aseptic Processing

The session opened with a challenging question from the floor about the role of equipment vendors in helping operations people to meet microbiological limits requirements. In particular, what design features are vendors providing to promote and maintain good aseptic practice in filling operations? The ensuing discussion included comments on media fills and environmental monitoring during media fills and production runs. It was clear from the discussion that equipment vendors have an opportunity to come forward and explain the design principles that are used to support aseptic operations, especially for filling and closing machines.

The session continued with some general discussion of the following issues:

Bulk Sterile Liquids

What criteria should be used in establishing policies and practices for sterile testing of bulk prior to fill? What criteria should be used for review and retest in the event of high bio-burden in bulk? Comments from attendees indicated that there is considerable variation in dealing with these issues in the industry.

Qualification and Training for Aseptic Filling

The discussions of this topic indicated that there was considerable sensitivity among the attendees of the role of operators in successfully meeting environmental and media fill requirements. There was particular concern about establishing clean room entry procedures, and then training and testing the operators in good clean room practice.

Re-certification of HEPA Filters and Air Flow Patterns

Some attendees expressed an interest in obtaining guidance for the re-certification of HEPA filters and air-flow patterns.

Terminal Sterilization

The session ended with a short but lively discussion of the role of Biological Indicators in cycle development and qualification. There is a growing awareness of "cycle creep" in the industry. In this context, the inappropriate application of Sterility Assurance was pointed out. Principles in the selection of Biological Indicators and the development and qualification of sterilization parameters, in some cases, is leading to the selection of excessively severe sterilization conditions. The result is unnecessary degradation of product and packaging components, and, in some cases, leading to decisions to select (higher risk) aseptic processing over terminal sterilization.

Inspection Trends/ Regulatory Affairs

by Robert L. Dana

A number of topics were addressed with input provided by several of those in attendance. Significant points covered included:

Quality Systems Drug Product Inspections

An overview of the FDA program to pilot a systems approach for inspections of drug product manufacturers was provided by PDA's Bill Stoedter. This program is currently underway for a six-month trial in the Dallas, Texas; Los Angeles, California; Newark, New Jersey; New York, New York; Philadelphia, Pennsylvania; and San Juan, Puerto Rico districts. The goal is to improve inspection efficiency for FDA. Systems slated for coverage include the quality system, and those governing facilities and equipment, materials, production, packaging and labeling and laboratory operations. A full inspection will include the quality system and three other systems; whereas an abbreviated inspection will include the quality system and one other system. Under the systems approach, FDA will consider a system out of control if there is evidence of a pattern of failure, however, single isolated non-compliances will not be considered a pattern of failure. If one system is found out of control, the firm will be considered out of control. This could have significant impact on pending applications, government contracts, etc.

None of the attendees had experienced an inspection conducted using this approach.

The pilot program is described in more detail in FDA's draft Compliance Program Guidance 7356.002, Drug Manufacturing Inspections. FDA's Fred Blumenschein also discussed this program in detail at the QC/QA Interest Group meeting during the PDA 2000 Annual Meeting. Copies of his slides may be found at the QC/QA Interest Group Web site. A copy of Bill Stoedter's overhead entitled *System Based Inspections, FDA Pilot Program*, is attached to the end of this summary (Inspection Trends/Regulatory Affairs).

Current Inspection Trends

- Warning Letter issues

Participants noted that topics appearing recently in Warning Letters include aseptic processing, laboratory operations, including failure investigations, manufacturing operations and process validation, computerized systems, facility and cross contamination issues, stability and data integrity. One recent letter cited the failure of the QC Unit to fulfill their responsibilities. In some cases, FDA is making use of the practice of disgorgement and is holding up NDA approvals until they are satisfied with a firm's corrective actions.

• Hot topics

Based on discussion at the meeting and participants experiences; Part 11, OOS investigations and aseptic processing issues remain hot topics during FDA inspections.

FDA Administrative Actions

The FDA programs which provided for pre-inspection notification, annotated FDA-483s and the post-inspection close out letter are no longer required for drug product inspections. Pre-inspection notification is now at the discretion of district management, and use of annotated FDA-483s are left to the discretion of the investigator. The close out letter is no longer needed, since FDA now automatically provides a copy of the Establishment Inspection Report when an inspection is considered closed.

Interest Group Administration

Participants discussed the idea of forming a steering committee to help plan future meetings, as well as determine other activities which the group might consider. These could include, for example, publication of a periodic newsletter, developing a "quality system punchlist" and developing guidance for training analysts and operators in the interactions of the inspection process. Those interested in participating in such a Steering Committee are asked to contact Bob Dana by e-mail at elkhornassoc1@aol.com. Other ideas and suggestions for future IG meetings or activities are also solicited from the general membership and should also be forwarded to Bob Dana by e-mail.

Following is William Stoedter's System Based Inspections, FDA Pilot Program:

• The pilot program runs from January 1, 2001 through June 30, 2001.
• All drug inspections performed in this time period should use the systems approach.
• This pilot program is for drug inspections only, not CBER, CDRH, or DVM.
• The pilot program is taking place in the following districts: New York, New York; Newark, New Jersey; Philadelphia, Pennsylvania; Dallas, Texas; Los Angeles, California; and San Juan, Puerto Rico.
• The goal of System Based Inspections is to make inspections more efficient for the FDA.
  – To have a more systematic approach to drug establishment inspections;
  – To increase the focus of the inspection;
  – To improve the organization of FDA 483s;
  – To improve the organization of the EIR;
  – To improve efficiency in processing regulatory actions; and
  – To assure the updating of all profile classes.
• The systems that the FDA will look at are: the Quality System, Facilities and Equipment System, Materials System, Production Systems, and the Labeling and Packaging System.
• A full inspection will consist of the quality system and three other systems.
• A full inspection would 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, or as a follow-up to a warning letter.
• There is an option for an abbreviated inspection which would include the Quality System and one other system. This would be used for surveillance inspections or to satisfy the biennial inspection requirement.
• **If one system is out of control, the firm is out of control!** This could halt the approval of new products, prevent shipments on US government contracts and essentially is the equivalent of an injunction.
• A system is out of control if there is evidence of a **pattern of failure** to:
  – Establish and follow a control system for implementing changes;
  – Document investigations of discrepancies;
  – Follow analytical and OOS procedures;
  – Validate analytical methods;
  – Establish stability indicating methods; or
  – Perform at least one identity test on raw materials.
• A single non-compliance does not mean the system is out of control.

The pilot program can be found at: www.fda.gov/cderldmpqlindex.htm. Compliance Program Guidance Manual for FDA Staff, 7356.002 draft: DRUG MANUFACTURING INSPECTIONS (Pilot Program) (1/g/01) or at www.fda.gov./oralcpqm; look for 7356.002.

Vaccines

by Frank S. Kohn, Ph.D.

Topics discussed were environmental monitoring issues, reprocessing and rework in vaccine manufacture, process validation for vaccine processes, corrective/preventive action investigations, training and plans for upcoming meetings.

Several topics surrounding environmental monitoring were discussed, beginning with "what needs to be investigated?" The group agreed that investigating alert/action level excursions is a hot issue. The consensus was that companies do not uniformly define what alert and action means as well as whether they are levels, limits, or specifications. This lack of consistency leaves companies open to FDA scrutiny of their investigation practices. For example, most com-

panies do agree that alert/action excursions are warnings that the environment is trending out of control. However, some companies label these excursions as specifications or limits. So, if your SOP states that you will investigate out of spec (OOS) situations in a formal and in depth manner, then you best do it. Of course, most everyone treats product contact excursions in a thorough manner to support their justification for product release, but do not expect that this thoroughness be performed for an excursion on a back wall far from the process activities. Most thought that there was a benefit to harmonize practices on how they treat excursions and investigate them, as well as how to handle multiple excursions around product contact situations. It was also agreed that there should be differentiation between what are critical areas for drug manufacturing and vaccine manufacturing as these areas are distinctly different (i.e., cell propagation and seed propagation areas in vaccine manufacturing pose interesting environmental situations).

The next question posed was "What needs to be monitored?" A discussion of who monitors the monitor ensued. Several people responded that the monitors are a potential source of contamination and errors too. One person stated that they do monitor—the monitor who is present—in critical process areas.

Process validation issues in vaccine manufacturing were discussed briefly with most of the focus on establishing operating parameters. Several people stated that biological products are not as tightly consistent as chemical products, so it is very difficult to address their inherent variability when it comes to establishing parameters that must be met.

Most vaccine companies use the root cause analysis tool and other method for investigating and resolving problems. Finding the root of a problem will provide the information needed to design a preventive action to ensure that the problem will not return.

Reprocessing and rework was discussed and many at the meeting stated that there was much confusion and difference of opinion about this topic with Team Biologics inspectors. A guidance document on this topic is expected in 2001, but companies are dealing with this now and want input. A recommendation was made to form a PDA task force to collect industry input and provide discussion on the forthcoming guidance for FDA. ■

—Russell E. Madsen

Autoclave Empty Chamber Temperature Mapping

The following remarks are taken from an exchange in the Pharmaceutical Sci-Tech Discussion Group, a PDA-sponsored Online Forum held on the Internet at www.pda.org. PDA Online Forums are free of charge and open to the public. They serve as a platform for exchanging practical, and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. If you are not currently a member of a discussion group, we encourage you to visit our Web site and join.

This month's posting...

Question

During an autoclave validation–empty chamber mapping, it was observed that the chamber come-up time varied considerably and was longer than expected (Range was four minutes, eight minutes, ten minutes, eleven minutes). There was no change in the autoclave settings between the four runs. Fourteen TCs were introduced into the chamber via a feedthru attached to the drain line where the autoclave controller RTD is also located. The normal come-up time for the same settings is 1.5–2.5 minutes. After reviewing the data, it was concluded that the observations were probably due to the TC bundle affecting the ability of the autoclave RTD to detect the correct temperature and initiate the sterilization cycle. The insulation on the TCs must be having an insulating effect on the RTD, the space in the drain line is limited.

This inconsistent come-up time due to the thermocouples will make F_0 calculations meaningless later in the validation study. The only solutions I have come up with are:

1) Reduce the number of thermocouples until there is no effect on the chamber RTD.
2) Find another way of introducing the TCs into the chamber.

Neither of these solutions really appeals to me. Making a new access port in the chamber wall by welding on a fitting has been ruled out by one contract engineering firm due to chamber integrity and pressure certification issues. That leaves me with adapting the steam inlet piping to take the thermocouple feedthru, but how do I know that the TC bundle is not going to affect the delivery of the steam into the chamber in a critical way? Any advice from the forum on this problem would be appreciated.

Response 1

Does the autoclave have a port for another RTD? For a recorder perhaps? If so, you can use it for introducing TCs. The recorder is not going to be necessary for this run.

Response 2

It is not normal to install test thermocouples via the drain or steam inlet lines because of the reasons you have discovered. If there is not a dedicated test port provided then look for a suitable port that is used for a pressure sensor, even an air admission line or the chamber pressure relief valve; anything, provided it is not going to affect the functioning of the critical aspect of the sterilizing cycle.

Insert a Tee connector as near as possible to the chamber at the chosen port and insert the test thermocouples into that port. Sometimes purely for the purpose of thermal validation it is possible to remove an instrument or sensor connected to a chamber and use its port for the test probes. If there is absolutely nowhere then consider using stand alone sterilizable data logging units such as the Datatrace.

Response 3

Was the air removed effectively from the chamber?

Response 4

Wow, tough situation. I am surprised that the autoclave manufacturer didn't put in a T/C access port. I can't help but think of your bigger problem of placing penetration and distribution thermocouples in the chamber during PQ (26+).

I have, periodically, run thermocouples in through the door. I use 30 gauge wire (pretested

Omega wire). If you separate the wires enough so there is no overlapping you should have a pretty good shot at getting your thermocouples in without having too much steam leakage. I would put tape under and over the T/Cs wherever the door will compress the T/C against the chamber to avoid breakage, but again, not too much otherwise you will get leakage. Also, be sure to have a couple extra T/Cs distributed in the chamber in case you break a T/C.

Response 5

Kaye recently introduced some small temperature measuring devices that can store the recorded data. So you can use those things as a wireless RTD, reading the obtained values after ending the sterilization cycle.

Response 6

Does the autoclave have a port for another RTD? For a recorder perhaps? If so, you can use it for introducing TCs. The recorder is not going to be necessary for this run.

Response 7

Another alternative would be wireless sensors. Kaye Instruments just came out with a new system of preprogrammable, self-contained sensors that can be placed in the autoclave, the study run, sensors retrieved and data downloaded. Sensors are then reprogrammed and run again and again. They can be used in banks of ten (10), but you just need to program the sensors in groups and use as many as you can afford. Next best thing to having a "Tricorder". Don't have any specific details immediately available, but Kaye Instruments is readily available for comment.

Response 8

Maybe you can try to distribute your TCs, in a way that they are not affected significantly. Maybe four in your drain connection, and some of them in the steam inlet, some of them in the vent, etc.

Response 9

I have seen this problem before. What is most likely is that the 14 thermocouples in the drain are restricting condensate removal. Therefore the drain temperature probe is in more condensate than usual so affecting the temperature that it reads. However, this does not generally cause poor chamber temperature distribution since most autoclaves control on chamber pressure (to give the required temperature) rather than actually using the drain probe to control steam input. Therefore the only problem would be erratic readings from the drain probe but not poor temperature distribution in the chamber. What type of autoclave is this? What did the pressure trace look like? Is it an air steam cycle or a saturated steam cycle?

Fourteen thermocouples is not a lot for chamber and then load mapping, so I don't think it's an option to reduce the number of thermocouples you are using. Therefore the best way forward is to get the thermocouples in through another port. Modifying the pressure vessel is not practical as you say. Is there a separate port for the chamber vent or pressure transducer that you could modify for thermocouple access? If there is only a small port available you could look at using thinner thermocouples (0.3mm solid), if you can afford it there is a company I know of that will epoxy seal your thermocouples into an entry port which is a lot smaller than a normal thermocouple entry gland. This would probably get your thermocouples down a ½ inch port.

The least elegant solution would be to try to get the thermocouples through the door seal. This will only work with small thermocouple wire (0.3mm solid) and on a fluids machine where air leakage through the door seal is less of a problem.

Response 10

In an empty chamber you should get come up time of seconds not minutes. I don't understand how your autoclave is working and what kind of pre-sterilization process have you done.

In a vacuum-steam pulses process the low vacuum values will give notice to you that something is wrong. I would not use the drain pipe for inserting the thermocouple at all. The steam inlet pipe is better. It is not the perfect solution but the steam will find its way in. The heat up rate will be slower and if it is not too slow comparing regular cycle you can use it. Try to use thinner thermocouples or using seven thermocouples and repeating the cycle twice.

Response 11

Your guess that you impeded the condensate flow out of the autoclave sounds like a good one. Your problem remains to find a place to insert all the thermocouples. The most sensible way would be to make up a 'T' piece on one of the other inlets for your validation. The steam inlet/outlets are a no-no, as you will interfere with the steam flows, and you'll be back to the original problem. I would try one of the others—safety valve pipework, pressure gauge or transducer, but be careful to refit whatever you remove back into the T-piece before starting the cycle. I would be reluctant to remove the chart recorder altogether during validation, as it will provide additional data for your validation file.

Response 12

From your description I'm guessing that there are only two ports on your autoclave, steam in and drain. If there are any other ports into your chamber use them for TC access. Look inside and outside the chamber to try to find more ports, sometimes they can be hard to locate due to insulation.

If you have no other ports then you have two choices. 1) Get hold of (I don't know of anyone who rents them—but would be interested myself)

wireless data/temperature recorders either from Kaye or Datatrace. These units can withstand the heat and pressures of an autoclave cycle and are very accurate. Not cheap but your best solution. The only other option (short of welding a new port onto the unit, having the pressure testing repeated and getting a new stamp) would be to purchase a door gasket specifically for validation, drill holes through it and use a thin gauge thermocouple wire. There are a lot of problems with this method. The door gasket may leak, the TC wires may break when you close the door.…It's not my first choice but I have done it and if you are careful you can make it work for validation.

Response 13

The chamber of a steam sterilizer is a pressure vessel. As a pressure vessel, it needs at least one safety valve or rupture disc connected directly to the chamber (the pressure vessel standards prevent the installation of any element between the safety valve and the chamber). Then, this port is excellent to put through the TC's. You only need to remove the safety valve (it is correct to work without it for validation purposes).

Response 14

I am planning to use wireless data loggers such as HT120 or HT100 from Dickson. They can withstand high temperatures (121EC or higher) and they are submersible (according to the manufacturer). In this way I would avoid the problem of inserting thermocouples or RTD's in the autoclave chamber (it is always difficult to find a port for wires).

Do you have experience with those data loggers (or does anybody in the group)?

Response 15

This is most likely a gravity steam sterilizer, where there is no prevacuum cycle. Steam is lighter than air. In a gravity cycle, air is pushed out of the drain at the bottom of the autoclave by the steam entering at the top of the chamber. Baffles on the steam inlet help to the chamber help to minimize the turbulence and resulting mixing caused by the steam entering the chamber. The come up time for this type of autoclave depends on a number of factors including the size of the autoclave. Several minutes is not a cause for concern as long as air removal is complete and the process is repeatable.

Response 16

Ellab also makes wireless data loggers (http://www.ellab.com).

Response 17

I have used the Datatrace units quite successfully for a few years now for validating a washer/sterilizer used for rubber stoppers. The stoppers are in a rotating drum in the autoclave chamber so there is no way you can introduce fixed thermocouples into the load. I still place some fixed probes within the chamber for reference purposes. The datatrace accuracy is good, normally better than 0.5EC. The calibration can be checked by immersing them in an oil bath.

Response 18

Learn something new every day. In the past I never even considered removing the safety valve or adding a T connection (now it seems so obvious I can't imagine why not). Thanks, much better solution than using the door gasket.

Response 19

Although it may be quicker and cleaner, as a safety measure to yourself and/or personnel in the immediate area, I would NOT or NEVER recommend removing the safety valve or rupture disc. Especially if the autoclave is being initially validated. How do you know the safety valves and rupture disc work when the system was never validated. I recommend purchasing an additional door gasket, thread thin TCs through. After post calibrating the TCs, remove the TCs from the temperature recorder, and dedicate the gasket and threaded wires to this autoclave, for future revalidation testing. It may be a little messy with steam autoclaves, but disregarding safety, in any circumstance, will cost more in the long run.

Response 20

When we are validating steam sterilizer, we follow the next steps:

* Verify that the calibration of all the control and display elements are correct (including safety elements, as pressure switches, safety valves, pressure and temperature transducers, etc.)
* Verify that the functioning of all the safety elements is correct. In Europe the regulation about 'Machinery safety' is very strict, and we need to verify things as 'the door can not be closed and locked if there is any object in their displacement (for sliding doors)'
* When we are sure that everything is correct, we go to the chamber mapping. The European norms force to have (at least) two validation ports: one for temperature elements (TCs, RTDs) and the other one for pressure elements (it is important to verify pressure as well!).
* Usually, the big chambers have two or more safety valves. If yes, there is no problem to remove one of them to install the TCs (if you do not have temperature validation port). Obviously, if you only have one safety valve, or there are no more safety elements in your machine (in fact, this only happen in old or very small machines), you can simply install a T in the safety valve port: connect the TCs in one side and the safety valve in the other side.
* More, I only want to remark that TCs readings are very sensitive to cold working, hot junction, etc. Kaye has an excellent Web site (www.kayeinc.com) where almost everything is explained!

Response 21

The HTM 2010 demands 15–30 seconds for come up time. This is a criterion for the air removal process. I know that in the US the HTM is not considered and the 15–30 seconds is a draconic criterion, but several minutes are too much. And one more thing: **Don't run the autoclave without a safety valve!** Using a T piece is accepted as long as it is installed close to the autoclave chamber.

Response 22

You are correct that the safety valve should not be removed. Upon initial reading I liked the idea of putting a T in line with the safety valve and using the port for thermocouple introduction to the chamber. Your response got me thinking about the subject a little further. Safety valves are sized for the chamber they are intended to relief. In order to effectively relieve the pressure in a chamber, the contents of the chamber must be bled off, in the case of an autoclave steam/air must be released. Inserting numerous thermocouples into the port to which the safety valve is attached will restrict the flow of steam should the valve open due to overpressure (in the same manner that the drain was restricted in the original posting). This would prevent proper venting of the chamber and could lead to serious safety hazards.

Guess I responded too quickly and I'm going to have to reverse myself on this one. Even with a T using the safety valve port can be unsafe. ■

—compiled by Russell E. Madsen

Chapter News

PDA-TRI Courses Will Be Held at PDA Southeast Chapter Meeting

Location:
Sheraton Chapel Hill
Phone:
(919) 968-4900
Fax:
(919) 942-3557

Make your room reservations no later than June 26 to receive the special PDA rate!

July 18–19, 2001
Sheraton Chapel Hill
Chapel Hill, NC

July 18, 2001
- **Using INFOSEC Technology and Procedures 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** ■

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

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

If you would like to attend the Southeast Chapter Summer dinner meeting on July 18, 2001, contact Diane S. Williams of the Southeast Chapter at (919) 859-6277. The featured speaker is Frank J. Golden of the Third Party Contract Management Group at GlaxoSmithKline. Golden was an FDA investigator and compliance officer for 13 years and routinely provides quality-oriented training to company staff, contractors and other industry personnel. A social will take place from 6:00–6:30 pm, dinner from 6:30–7:15 pm with the presentation from 7:15–8:00 pm. $50.00 per person.

Southern California Chapter Election Results

The Southern California Chapter recently held a new election. We are pleased to announce the chapter's new Board Members:

Kikoo Tejwani, President
(Kikoo.Tejwani@bbmus.com)

John D'Angelo, Vice President
(John.D'Angelo@bbmus.com)

Dan Klassen, Treasurer
(dan_klassen@allecure.com)

Maria Wagner, Secretary
(mariaw@ims-limited.com)

■

Company, Colleague & Product Announcements

John Geigert recently founded **BioPharmaceutical Quality Solutions**, a consultancy company focused on assisting start-up and clinical development phase biopharmaceutical companies establish appropriate Quality and GMP compliance systems and develop appropriate CMC strategies. Prior to this venture, Geigert was Vice President of Quality at IDEC Pharmaceuticals Corporation and Immunex Corporation. In his 25 years in the pharmaceutical industry, he has been instrumental in bringing five recombinant and monoclonal antibody drug products to the market in both the US and Europe. Geigert is a past member of the PDA Board of Directors and current member of the USP Expert Committee on Biotechnology & Natural Therapeutics/Diagnostics. He may be contacted at (760) 943-0198 or BPQS@aol.com.

United States Pharmacopeia (USP) announced that **Barbara B. Hubert** has been appointed Director of USP's Pharmacopeial Education Programs. This new program was initiated to support the appropriate use of the United States Pharmacopeia and the National Formulary (USP-NF). Hubert will work with a curriculum committee comprised of individuals from academia, industry, the FDA, USP's Council of Experts, and others as appropriate, to develop curricula for courses. USP senior scientists and other experts will serve as instructors. Hubert joined USP in 1980 as a scientific liaison for the USP-NF. She has held progressively responsible positions including scientific associate, scientist, and assistant director, Scientific Administration in the Drug Standards Division. From January 1999 through March 2001, she was director of the Executive Secretariat Department, which provided support to the USP Council of Experts. Hubert can be reached at (301) 816-8333 or bbh@usp.org. USP also announced that **P. Steven Lane** has joined the organization as Director, Quality Assurance. Lane will be responsible for providing professional and scientific leadership to continue to ensure that USP Reference Standards are of superior quality and meet customer requirements. He also will be responsible for developing and implementing comprehensive quality assurance programs for all USP operations. Lane comes to USP from Osiris Therapeutics, Inc., in Baltimore, Maryland, where he served as Associate Director, Quality Assurance/Quality Control. He was responsible for all quality control testing and all equipment and facility validation activities. Lane has extensive experience in CGMP document and material management systems as well as department-specific training programs. Before joining Osiris, Lane held quality assurance management and training positions with Alpharma's US Pharmaceutical Division in Baltimore, Naska Pharmacal, Inc., in Lincolnton, North Carolina, and Baxter Pharmaseal Division in Johnson City, Tennessee. Lane can be reached at USP at (301) 816-8337 or psl@usp.org.

Tularik Inc. announced the formation of **Tularik GmbH**, a wholly owned subsidiary located in Regensburg, Germany. The subsidiary will develop new assays and implant high-throughput screening for the identification of small molecule drugs that act to regulate gene expression. Over the last two years biotech in Europe has blossomed, with interest and activity especially strong in Germany, yet "…relatively few US biotech companies have so far taken advantage of the enormous opportunities and resources in Europe," said Ulrike Schindler, Ph.D., Managing Director of Tularik GmbH. A 2,000-year-old Bavarian City on the banks of the Danube, Regensburg has become a hotbed of German biotechnology and other high-technology business activity in recent years. For more information, visit www.tularik.com. ■

—Joe Bury

The Extractables Puzzle: Putting the Pieces Together

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

November 12–13, 2001, Doubletree Hotel, Rockville, Maryland

Reserve your hotel room now!

The Doubletree Hotel, Rockville, Maryland.

Registration information for the conference will be posted soon to PDA's Web site, at www.pda.org.

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

Materials Presentations:

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

Analytical Presentations:

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

Toxicology Presentations:

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

Regulatory Presentations:

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

—Leslie Zeck

Regulators, regulatory affairs professionals, analytical chemists, toxicologists, material and component suppliers, formulators, and materials and packaging scientists should plan to attend this important conference.

PDA Calendar continued...

from back cover

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

See Back Cover for Beginning of Calendar

2002

FEBRUARY

February 11–15, 2002
PDA International Congress, Courses and Exhibition
Basel Congress Center
Basel, Switzerland

MARCH

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

SEPTEMBER

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

OCTOBER

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

DECEMBER

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

PDA and FDA Will Cosponsor Viral Clearance Forum

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

Sessions will focus on the following topics:

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

Upon completion of the conference attendees will have gained an understanding of:

- Current and new viral removal technologies, including filtration, chromatography and inactivation technologies;
- Issues related to the reuse of chromatographic columns with an emphasis on viral clearance requirements;
- Current opinion on the need to standardize quality attributes of viral preparations as controls in spiking and infectivity assays;
- Current methods used to standardize or validate traditional infectivity assays;
- Implementation and acceptability of PCR, PERT and real-time PCR-based viral assays standardization and validation of these new assays; and
- The potential of and issues related to bracket/matrix studies defining generic virus inactivation conditions.

A networking reception and poster presentation will be held on Monday, October 1, 2001. PDA is soliciting poster presentations of research related to viral clearance topics. ■

—Leslie Zeck

Hyatt Regency Bethesda
One Bethesda Metro Center
Bethesda, MD 20814
Phone:
(301) 657-1234 or (800) 233-1234
Fax:
(301) 657-6453
Rates:
$185.00 single/double

For additional information or to register for this conference, visit PDA's Web site at www.pda.org.

2001 PDA/FDA Joint Regulatory Conference from cover

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

VIII. Tabletop Exhibits

- Featuring the latest technologies, products and services.

IX. Networking "Dine-Around" at some of Washington's most exclusive restaurants

X. PDA-TRI Courses

Attendees will be afforded the opportunity to interact with all levels of FDA staff, including Division Directors, Local Inspectors and Scientists. ***PDA is pleased to announce that the following FDA Officials have confirmed their participation at the conference***: Frederick Blumenschein, Chief, Case Management and Guidance, CDER, Office of Compliance; Robert Coleman, Local District Inspector; John Dietrick, Compliance Officer, CDER; Marie T. Falcone, Small Business Representative, Central Region, Office of Regulatory Affairs; Joseph C. Famulare, Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER; Richard L. Friedman, Compliance Officer, Division of Manufacturing and Product Quality, Office of Compliance, CDER; Jean Blackston Hill, Chemist, ORA; Brenda Kiliany, Consumer Safety Officer, CDER; Steven A. Masiello, Director, Office of Compliance and Biologics Quality; Lorrie Harrison McNeill, Public Affairs Specialist, CBER; Sharon O'Callaghan, Office of Compliance and Biologics Quality, CBER; Helen N. Winkle, Acting Director, Office of Pharmaceutical Sciences, CDER. ■

—Leslie Zeck

Plan to attend this important conference.

Do you have a question for FDA relating to one of the forums? Submit your question in confidence to PDA via e-mail to royal@pda.org. Please reference PDA/FDA and the forum topic in the subject line. Your questions will help moderators and presenters focus on issues important to you and allow regulators and industry experts to prepare answers to your questions in advance of the conference.

2001 PDA/FDA Joint Regulatory Conference Exhibitors

- Amersham Pharmacia Biotech, Inc.
- Audit Repository Center
- Carlisle Barrier Systems
- CompuPharma, Inc.
- Genesis Machinery Products
- Learnwright, LLC
- Millipore Corporation
- Novatek International
- NuGenesis Technologies
- Optical Image Technology, Inc.
- Pacific Scientific Instruments
- Pall Corporation
- Phoenix Imperative, Inc.
- RCM Solutions
- Sensitech, Inc.
- SL Pharma Labs, Inc.
- The Biologics Consulting Group
- The Validation Group, Inc.
- VelQuest Corporation
- West Pharmaceutical Services

PDA and IABs to host International Conference from cover

es for Biologics" in Washington, DC. This benchmarking conference drew over 500 attendees for three days of discussions. During the closing summaries it became clear that process validation, still undergoing both technical and regulatory evolution, also needed to be discussed in Europe. As a result, representatives from FDA, the EMEA and Health Canada, will dialogue with affected industry representatives, at this important event.

Conference highlights will include discussions on:

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

Today's expectations for process validation are varied and complicated. Bulk biopharmaceuticals pose a particular challenge for process validation due to the numerous process parameters that need to be controlled and monitored. Manufacturing processes for the removal of process-related impurities and adventitious agents pose additional concerns that require validation. In addition, interpreting the available regulatory guidance can be confusing.

If you are a Process Scientist, Manufacturing and Quality Professional, Regulatory Affairs Professional, Analytical Chemist, Process Engineer or Virologist, to name a few, then this conference will be of significant value to you!

For a conference brochure and registration information, please visit our Web site at www.pda.org.

Many thanks to our Program Planning Committee for the development of this important international program:

Brendan Hughes,
GlaxoSmithKline, UK
(Co-Chair)

Vincent Anicetti,
Genentech, Inc. USA
(Co-Chair)

Enzo Bucci, Ph.D.
Kedrion SpA, Italy

Rodolfo Franceschini, Ph.D.
Kedrion SpA, Italy

Norbert Hentschel
Boehringer Ingelheim Pharma AG, Germany

Christopher Joneckis, Ph.D.
CBER, FDA

James Lyda
PDA, Switzerland

Anthony Lubiniecki, Ph.D.
GlaxoSmithKline, USA

Mary Malarkey,
CBER, FDA

Genesio Murano
Genentech, Inc., USA

John Purves, Ph.D.
Head of Sector, Quality of Medicines
European Medicines Evaluation Agency

Anthony Ridgway, Ph.D.
Bureau of Biologics, Health Canada

Georg Roessling, Ph.D.
Schering AG, Germany

Giuseppe Vicari, M.D.
Italy

Leslie Zeck
PDA, USA

—Leslie Zeck and James C. Lyda

Plan Now to Attend!

Compliance—
Challenges and Pragmatic Solutions

The 2001 PDA Annual Meeting, Courses and Exhibition

The Exhibit Hall is Nearly SOLD OUT so Reserve Your Space Now by Contacting Nahid Kiani at (301) 986-0293 ext. 128 or kiani@pda.org.

2001 PDA Annual Meeting, Courses and Exhibition
December 3–7

Marriott Wardman Park, Washington, DC

Stayed tuned to the *PDA Letter* and www.pda.org

2001 Annual Meeting Exhibitors

- AAI International
- Abbott One 2 One
- ABC Laboratories
- Acculab/Accuqenix
- Akron, Inc./Taylor Pharmaceuticals
- American Pharmaceutical Partners, Inc.
- American Stelmi
- Amersham Pharmacia Biotech, Inc.
- Anatel Corporation
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- Chemunex, Inc
- Chesapeake Biological Labs, Inc.
- CimQuest, Inc.
- Collaborative Quality Systems Consultants, Inc.
- Compliance Software Solutions
- CompuPharma
- Contract Pharma
- Cook Pharmaceutical Solutions
- Covance
- CRB Consulting Engineers, Inc.
- Cryovac Sealedair
- Decon Labs
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- Duoject Medical Systems, Inc.
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- Eisai USA, Inc.
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- Formatech, Inc.
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- Gavin Pharmaceutical Services
- General Econopak, Inc.
- Genesis Machinery Products, Inc.
- George Uhe Company
- HyClone Labs, Inc.
- Irvine Analytical Laboratories, Inc.
- Kaye Instruments, Inc.
- KMI
- La Calhene
- Lancaster Laboratories
- Learnwright, LLC
- Lives International
- Matrix Contract Services
- MECO
- Meissner Filtration Products, Inc.
- Meridian Medical Technologies
- Microcheck
- Millipore Corporation
- Minntech
- Nicomac Inc.
- Nikka Densok USA, Inc
- Novaseptic America
- Novatek International Inc.
- Orbisphere
- Osmonics
- Pacific Scientific Instruments
- Pall Biopharmaceuticals
- Patheon, Inc.
- PDA
- Pharma - Technik Smeja
- Pharmaceutical Development Center
- Pharmaceutical Processing
- Pharmaceutical Systems
- Pharmaceutical Technology
- Phoenix Imperative Inc.
- PML Microbiologicals
- Powderject Pharmaceutical
- PTI
- Q-One Biotech
- Raven Biological Laboratories
- RCM Solutions
- Remel, Inc.
- RommeLag
- Russell Publishing LLC
- Safety Syringes Inc.
- Saint-Gobin Desjonqueres
- Sartorius Corporation
- Schering-Plough, Third-Party Business
- Schott PharmaceuticalPackaging, Inc.
- Schott Scientific Glass, Inc.
- Seidenader Equipment Inc.
- Sensitech Inc.
- Sera Care Life Sciences
- Serail Div. of S.G.D. North America
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- West Pharmaceutical Services
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- Wimmer Systems, LLC

2002 Training Conference Announced

"Charting a Course for Success"

PDA's Training Conference Committee is making plans for the 4th biennial PDA Training Conference. It will be held October 7–11, 2002 in Tampa, Florida.

PDA's Training Conferences have provided CGMP trainers with access to scores of professional presentations and networking, and in just a few short years have become recognized as the preeminent conference for CGMP trainers in the pharmaceutical, biotech, medical device and related industries. The first biennial Training Conference under PDA sponsorship was held at Tyson's Corner, Virginia in September 1996. Two years later the venue was Baltimore's Inner Harbor and last year the conference was held in New Orleans, Louisiana.

According to Conference Committee Chairman Rob Wachter of Eli Lilly & Company in Indianapolis, Indiana, the program for the Tampa conference will be one of the most ambitious to date. The 2002 conference will incorporate a number of changes. First, the conference is going to be expanded to three full days of activities from the two-and-one-half day format employed previously. Second, the three-day conference will be followed by two full days of PDA-TRI training courses focusing on CGMP training. Last year's conference was the first to offer PDA-TRI training courses following the meeting. Finally, Program Vice-Chair Bill O'Connor of DuPont Pharmaceuticals in N. Billerica, Massachusetts announced the addition of the "Trainers' Choice" Awards in 2002. In short, nominations will be voted on by the trainers in attendance at the conference to pick the best CGMP and Safety/Technical training course produced by non-commercial trainers in several different formats. Details about these awards will be published in future editions of this newsletter.

All of the conferences have been well attended and last year the conference attracted 250 trainers from across the US and 11 foreign countries. Trainers flock to these meetings because they know they can expect to find a variety of presentations targeted to their needs. Papers, presented at these conferences, are reputed to include every aspect of the training process: from curriculum design to the latest compliance issues, to classroom involvement techniques and much more. One hallmark is that professionals in the CGMP training community submit the vast majority of these papers. Only a small percentage of the presentations are solicited from consultants in the training industry. **If you are a CGMP trainer, thinking about making a contribution to your peer group at the 2002 conference, go to www.pda.org and download the "Call for Papers" information under the 2002 Training Conference. The Conference Committee is already seeking papers and you are asked to participate. The deadline for submissions is December 14, 2001.**

The Training Conference Committee is a subcommittee under the Training Interest Group, chaired by Tom Wilkin of Schering-Plough in Kenilworth, New Jersey. The Training Interest Group meets an average of twice a year. The next meeting of the Training Interest Group is currently scheduled for the Annual Meeting this coming December in Washington, DC. ■

—Rick H. Rogers

Call for papers deadline
December 14, 2001

PDA's Rogers to Speak on the Future of CGMP Training

PDA Vice President of Education Rick H. Rogers has accepted an invitation to address the New England Chapter of PDA on July 26,2001 at the Marriott Hotel in Cambridge, Massachusetts. Rogers will update the group on the current status of CGMP training in the pharmaceutical and related industries, and preview the new millennium with his own outlook and prescription for CGMP training in the years to come. His presentation will also offer a short history of the CGMP training function, covering the last 20 years or so, and will discuss the state-of-the-art in pharmaceutical training, as well as current inspection trends and recommendations directed at improving the organization's compliance posture from a training perspective.

CGMP trainers have been tremendously impacted by recent events in the pharmaceutical industry. Numerous consolidations have reduced the number of practicing CGMP trainers and the overall standing of trainers among manufacturers has been diminished. What does this mean for CGMP trainers? What does this mean for the affected industries? And what does the future hold for this vital function? If you will be visiting the New England Chapter area, which covers Massachusetts, New Hampshire, Vermont, Rhode Island, Maine and parts of Connecticut, you are invited to attend their quarterly meeting and get the answers.

For additional information, contact the New England Chapter President, Bob Pazzano, at (508) 870-0007 ext. 140 or robert_pazzano@vtsinc.net. Registration begins at 5:15 p.m., dinner is at 6:00 p.m. and the presentation starts at 7:00 p.m. ■

PDA-TRI New Orleans Course Series

August 6–8, 2001
Hyatt Regency New Orleans
New Orleans, LA

August 6, 2001
- **Understanding the Regulatory Compliance Requirements of the US Pharmacopoeia**

August 6-7, 2001
- **A Practical Approach to Aseptic Processing and Contamination Control**
- **A System Based Approach to an FDA Inspection**

August 6-8, 2001
- **Tablet Formulation**

August 7, 2001
- **Good Documentation Practices in the Pharmaceutical Industry**

August 8, 2001
- **Everyday Compliance: Introduction to the CGMPs & Drug Regulation**
- **Conducting Compliant Deviation Investigations for Pharmaceutical Industry**
- **Identification of Microorganisms Using Comparative DNA Sequencing** ■

Location:
Hyatt Regency New Orleans

Reservations:
(800) 233-1234

Fax:
(504) 587-4141

Make your room reservations no later than July 16 and mention PDA to receive the special rate of $109 single occupancy!

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

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

PDA-TRI Thanks the Following...

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Upcoming PDA-TRI Education Courses

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

To register, call PDA headquarters in Bethesda, Maryland at (301) 986-0293.

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

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

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

PDA-TRI Location/Lodging Information

For additional hotel information, please visit www.baltconvstr.com, the Baltimore Convention and Visitors Bureau's Web site.

Transportation to PDA-TRI: All listed hotels are no more than a 15–20 minute taxi ride to the Training and Research Institute. All hotels can assist you with taxi arrangements. Registrants may prefer to rent a car for easier access to and from the Institute.

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

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

***no on-site restaurant*

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

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

Membership Number

Job Title Company

Business Address

City State/Province ZIP/Postal Code

Tel Fax E-mail

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

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

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

3. Please check the appropriate box:

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

Account Number_____ Exp. Date _____

Name _____
(exactly as on card)

Signature_____ Date _____

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

4. Return completed form with payment made to:

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

Payment must be included to be considered registered.

Federal Tax I.D. #52-1906152

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

LTR 06/01

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

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Delaware Valley Chapter
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Fax: (616) 833-5195
E-mail—
john.g.shabushnig@pharmacia.com

FDA Documents Available

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

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

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

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

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

FDA 53 **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 108 **Review Guidance, Validation of Chromatographic Methods;** November 1994; CDER; 33 pp; $25 members/$40 nonmembers.

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

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

FDA 158 **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 187 **General Principles of Software Validation Guidance for Industry**; June 1, 1997; CDRH; 20 pp; $25 members/$40 nonmembers.

FDA 220 **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 229 **Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production**; Draft Guidance; September 1998; CDER; 11 pp; $15 members/$30 nonmembers.

PDA Books Available

Change Control; *S. Schwartze*; 2001; 40 pp; $80.00. **Item No. 17189**

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

Electronic Records and Electronic Signatures; *C. Reid and B. Mullendor*; 2001; 50 pp; $99.00. **Item No. 17177**

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry; *J. Vesper*; 2001; 224 pp; $119.00. **Item No. 17191**

Microbiology for Pharmaceutical Manufacturing; *R. Prince, ed.*; 2001; 900 pp; $279.00. **Item No. 17185 — Available mid July 2001**

Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections; *L. Clontz*; 2001; 175 pp; $119.00. **Item No. 17176**

The Internal Quality Audit; *M. Grimaldi and J. Gough*; 2001; 100 pp; $119.00; **Item No. 17179**

Understanding GMP: An Expert's View on Merging Global Regulatory and Manufacturing Perspectives; *M. Becker*; 2001; 224 pp; $119.00. **Item No. 17174**

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PDA Technical Reports Available

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

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

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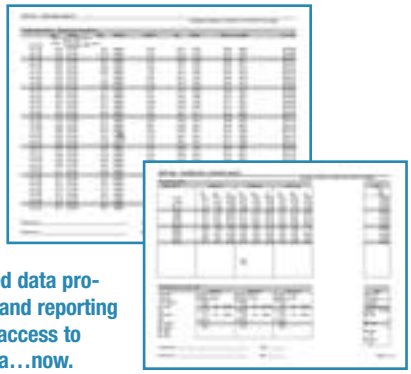

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July 18–19, 2001
PDA Southeast Chapter Meeting & PDA-TRI Courses
Sheraton Chapel Hill
Chapel Hill, NC

July 18, 2001
- **Using INFOSEC Technology and Procedures 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

AUGUST

August 6–8, 2001
PDA-TRI New Orleans Course Series
New Orleans, LA

August 6
- **Understanding the Regulatory Compliance Requirements of the US Pharmacopoeia**

August 6–7
- **A System-Based Approach to an FDA Inspection**
- **A Practical Approach to Aseptic Processing and Contamination Control**

August 6–8
- **Table Formulation**

August 7
- **Good Documentation Practices in the Pharmaceutical Industry**

August 8
- **Conducting Compliant Deviation Investigations for the Pharmaceutical Industry**
- **Everyday Compliance: Introduction to the CGMPs & Drug Regulation**
- **Identification of Microorganisms Using Comparative DNA Sequencing**

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

SEPTEMBER

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

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

September 10–14, 2001
PDA/FDA Joint Regulatory 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/A_3P International Conference and Exhibition
Holiday Inn Montreal Midtown
Montreal, Quebec, Canada

OCTOBER

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

October 1–5, 2001
PDA-TRI 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 Isolation Technology Conference
Hilton East Brunswick
East Brunswick, NJ

October 16–18, 2001
PDA-TRI Palm Springs Course Series
Palm Springs, CA

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 12–13
The Extractables Puzzle: Putting the Pieces Together—Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Answers
Doubletree Hotel
Rockville, MD

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