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PDA Letter

April 2001

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

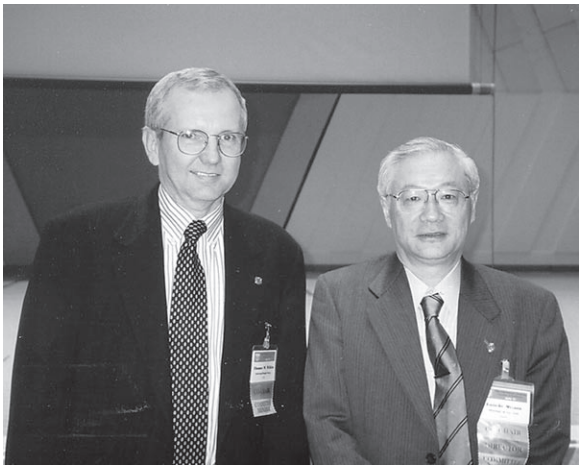
PDA Conferences on Viral Clearance and Extractables are Planned, page 24

# Kyoto International Congress a Success

Over 300 people attended the 2001 PDA International Congress and Exhibition, "Bridging the Healthcare and Pharmaceutical Worlds in the New Millennium," which was held February 19–23. The venue for the meeting was the magnificent International Conference Hall in the scenic northern part of Kyoto, Japan. The conference, presented in cooperation with PDA's Japan Chapter, drew registrants from Japan, Korea, Taiwan, Australia, the United States and other countries around the world.

The meeting covered a full range of important topics including quality assurance, process validation, new technologies, international harmonization, regulatory affairs, contract manufacturing and drug development. It also featured a comprehensive exhibit of pharmaceutical production and testing equipment from over 60 companies. Several

*continued on page 4*



Kyoto Congress Co-chairs Thomas W. Wilkin, Ed.D., Schering-Plough Corp., and PDA Board Member Taiichi Mizuta, Ph.D., Shionogi & Co., Ltd.

Featured Speakers Robert W. Tribe, Therapeutic Goods Administration (Australia) and PDA Board Member Stephanie Gray, GlaxoSmithKline.

# PDA to Update Aseptic Processing Survey

PDA's Board of Directors has approved a plan to conduct a survey on aseptic processing practices in the pharmaceutical industry. The survey is intended to update PDA aseptic processing practices surveys that were conducted in 1992 and 1996. The survey instrument to be used will be patterned on the 1996 survey to allow for easier comparison and to gauge changes in practice. The survey instrument should be completed by late spring of 2001. The results of the survey should be available to the membership by late 2001. ■

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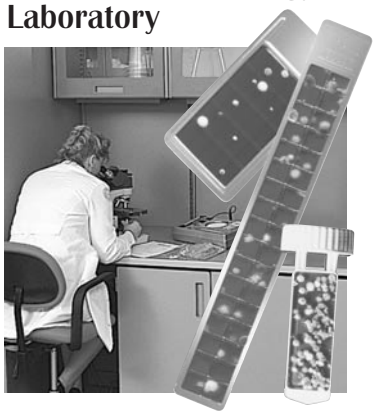

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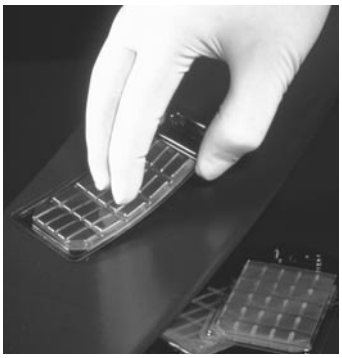

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## Deadlines...

- **June 8 — Call for Papers deadline, PDA/FDA Viral Clearance Forum, page 24**

## IN THIS ISSUE...

PDA President
Edmund M. Fry

# FDA Invites PDA's Madsen to Speak at Quality Systems Seminar

FDA invited Russell Madsen, PDA's Senior VP Science and Technology, to attend one of their regularly scheduled Quality Systems Seminars to present his paper "Real Compliance and How To Achieve It" and to participate in a question and answer session following the presentation. The seminar, which took place on February 15 at FDA's Office of Compliance facilities in Rockville, Maryland, is one in a series of regularly scheduled meetings for FDA staffers to discuss quality issues that affect the pharmaceutical industry. The seminar was attended by over 20 individuals, including Joseph Famulare, Director, Division of Manufacturing and Product Quality; Fred Blumenschein, Chief, Case Management & Guidance; Richard Friedman, Compliance Officer; David Hussong, Microbiology Reviewer; and Paul Stinavage, Senior Review Microbiologist. Topics discussed following the presentation included Part 11, aseptic processing, media fills, environmental monitoring and quality systems. ■

*— Edmund M. Fry*

*Kyoto International Congress a Success from cover*

"special session" programs on diverse topics such as computer validation, education and training, freeze drying technology, visual inspection and particulate matter definitions and pharmaceutical water systems. These special sessions ran in conjunction with the regular program and added tremendous value to Congress participants.

The Congress featured key regulatory speakers from the Ministry of Health, Labor and Welfare (Japan), Food and Drug Administration (USA), Therapeutic Goods Administration (Australia), and the Pharmaceutical Inspection Convention as well as the Japan Pharmacopeia, European Pharmacopeia and the United States Pharmacopeia.

If you were unable to attend this important event and would like more information, complete proceedings from the Congress are available from PDA. ■

PDA Board Member Jennie Allewell, Cell Therapeutics Inc. with Hirohito Katayama, Fujisawa Pharm. Co., Ltd. and two assistants who provided a demonstration of the Japanese tea ceremony for visitors to the exhibition hall.

Leaders of Japan, Korea and Taiwan PDA Chapters met at the Kyoto Congress to discuss PDA Asia strategy with PDA Board Member Jennie Allewell, Cell Therapeutics Inc. and PDA President Edmund Fry.

# USP UPDATE

*by Roger Dabbah, Ph.D.*

The Fourth Supplement of USP 24-NF 19 is in preparation and will tentatively be published in June 2001 with a tentative Official Date in August 2001. Further information of the content of the 4th Supplement will be included in next month's column.

Eric Sheinin, Ph.D., has joined USP as Vice-President, Standards and Information Development. Sheinin retired from FDA-CDER and will be in charge of the Scientific Departments at USP. Sheinin had a distinguished career at FDA and will bring his considerable knowledge of the regulatory process to USP.

All divisions of the Council of Experts have met and have developed work plans for the balance of the current revision cycle. These work plans will be published at a later date in PF. In the Analytical Microbiology area, harmonization is still the main thrust of the Committee. In addition, a variety of information chapters that have been published as Previews will be moved to In-Process and we expect a speedy publication as Official Texts. Of interest to PDA readers is the completion of a draft on "Validation of Alternative Microbiological Methods." USP has presented the draft at a number of seminars and meetings in order to obtain early feedback. It is essentially a counterpart to chapter <1225> Validation of Compendial Methods, but applies to microbiological methods, qualitative as well as quantitative. Plans for the development of information chapters on Validation of Sterilization Processes and for Aseptic Processing, and for Barrier Technologies are being prepared.

In the Biotechnology and Natural Therapeutics/Diagnostics Expert Committee, an information chapter on "Process Validation For Biotechnological-derived Products" that was started at the end of the last revision cycle will be reactivated. In the same vein, "Process Validation for Blood and Blood Products" will also be considered as a candidate for an information chapter. In the area of Toxicology, the feasibility of developing information chapters on a variety of toxicological tests is being considered. In the Cell and Gene Therapy area an initiative on the development of standards for ancillary products — products used in manufacturing but that will not remain in the product — is underway. In the Vaccines area, general information chapters on immunological methods and in collaboration with other Expert Committees the development of methods for viral adventitious agents are also underway.

These plans are ambitious but doable and the various Committees look to PDA members for active participation on all these initiatives. As these initiatives evolve we will keep PDA readers aware of developments and progress. ■

# TR-32 UPDATE

*by Harvey Greenawalt, Audit Repository Center*

Errata

Last month's 'TR-32 Update' incorrectly bylined Harvey Greenawalt as the author. We apologize for this oversight. Following are the authors for that article:

**Torsten Wichmann**, Program Director-Global Quality Management, SAP

**Dr. Joseph S. Cardarelli**, SAP Pharmaceutical Segment Manager

**Paul Hopkins**, Global Quality Management, SAP

Industry participation in the PDA Process for Auditing of Suppliers Providing Computer Products and Services for the Regulated Pharmaceutical Operations, defined in PDA Technical Report #32, continues to increase.

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

## MEMBERSHIP

Four major Pharmaceutical/Chemical companies, one Biotechnology Company and three Suppliers of computer products to the industry have become members of the Audit Repository since June of 2000.

In February of 2001, ARC entered into subscription agreements with three major suppliers of computer products and services to voluntarily place their audit data in the repository for distribution to the pharmaceutical industry.

## AVAILABILITY OF AUDITS

Currently, 30 audits are either available for distribution, in process or planned to be completed within the next six months.

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

## AUDITOR RESOURCES

Eighty-two auditors have been trained and qualified by PDA during the year 2000. Forty-two percent of these auditors are from pharmaceutical industry companies, with seven percent coming from the European Union. Nine independent consulting firms have placed agreements in effect to provide qualified auditors to the industry.

## SERVICE TO INDUSTRY

PDA and ARC recognize that the quality of computer products is a function of the processes used to create them. Independent assessments of technology processes are an important asset to Suppliers as it helps them in their process improvement initiatives to improve their software products and reduce cost for their clients. PDA Technical Report #32 is designed to provide Suppliers with the maximum benefit of audits, which are based on assessment practices, while using a global industry endorsed program for audit sharing.

Regulatory inspections of how well Health Care industry firms qualify application software and validate computer systems are assessed on a case-by-case basis. Technically sound systems practices for evaluating and implementing computer technology is a key part of computer validation today. The PDA Process is designed to provide good data to document the technology practices and quality systems involved to bring computer products to the marketplace.

With the process defined in Technical Report #32, suppliers now have a vehicle through which they can provide audit data to their Pharmaceutical industry clients. The audit data is generated with a minimum impact to the supplier community and is retained in a secure repository for the industry by ARC as licensed by PDA.

Technical Report #32 also provides a mechanism for the pharmaceutical industry to reduce their audit burden by sharing standardized audit results via a secure and recognized repository.

In November of 2000, ARC introduced a new pricing schedule for Suppliers who wish to have their PDA Technical Report #32 audit data on file with the Repository.

This pricing schedule:

- Reduces financial risk to the Supplier;
- Eliminates up-front subscription fees;
- Provides access to the repository and PDA Process for all Suppliers; and
- Reduces the cost of the Suppliers' products to Pharmaceutical clients by providing reliable audit data at no cost to the client.

To date, four suppliers of computer products have taken advantage of the new pricing schedule. A profile of the first of these suppliers, SAP, was featured in last month's *PDA Letter*. Profiles of the other suppliers will be published in future issues.

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) | Batch Recipe Management System |
| Etrails.com, Inc. | Electronic Data Capture - EDC<br>Electronic Patient Diaries - EPD<br>Electronic Trail Management- ETM |
| Fanuc Robotics North America | Robotic Controllers & Communications |
| First Consulting Group, Inc. | Custom information based strategy software, operations improvements management and integration services |
| 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<br>Custom Software Programming |
| Qumas, Ltd. (Participating Supplier) | Qumas-Doc: Electronic Records Document Management Systems |

# International Calendar

## 2001

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

**May 17–18**
PDA-TRI Course at R3-Nordic: **Computer Products Supplier Auditing Process Model: Auditor Training**
Stockholm, Sweden

Send Registration for Symposium and Course to:
Nordiska R3 Föreningen
Box 65
S-240 13 Genarp
Sweden
Tel: +46 (0) 40 50 01 18
Fax: +46 (0) 40 50 01 48
E-mail: r3nordic@algonet.se
Web site: www.r3nordic.se
For Information: Berit Reinmüller
E-mail: berit@bim.kth.se
Tel: +46 (0) 8 790 7537

Note: An Application must be submitted to Russell Madsen at PDA to qualify for the **Computer Products Supplier Auditing Process Model: Auditor Training** course. Download Application from www.pda.org.

Send Course Application to:
Russell Madsen
PDA
7500 Old Georgetown Rd., Ste. 620
Bethesda, MD 20814
USA
Fax: (301) 986-0296

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

## 2002

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

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

# Regulatory Briefs

## Clarification to the standardized content and format requirements for the labeling of OTC drug products

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

In the *Federal Register* of March 17, 1999 (64 FR 13254), the Food and Drug Administration (FDA) published a final regulation establishing standardized content and format requirements for the labeling of OTC drug products. Standardized labeling for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use such products safely and effectively.

This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products marketed under ANDAs (abbreviated new drug applications) and the manufacturer of the corresponding Reference Listed Drug (RLD) to implement the Agency's regulation on standardized content and format requirements for the labeling of OTC drugs. The guidance contains recommendations on how RLD and ANDA holders can update their labeling in a timely manner consistent with the regulation on OTC drug labeling (21 CFR 201.66).

The new labeling regulation in 21 CFR 201.66 covers all OTC drug and drug-cosmetic products, whether marketed under a new drug application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph). The implementation dates are the same for products that were legally marketed under an NDA or ANDA before the date of the final rule.

Section 201.66(c)(1) through (c)(9) of the labeling regulation provides the content requirements for labeling information, including information about active ingredients, their purpose, use, warnings, directions, other information and inactive ingredients.

Questions have been submitted to the Agency asking whether products marketed under an ANDA can use the new labeling content and format requirements prior to the RLD, or must the ANDA holder wait for the RLD holder to submit revised labeling and then submit labeling that is the same as that of the RLD. These questions have been raised because under the Federal Food, Drug, and Cosmetic Act, a drug product marketed under an ANDA must bear the same labeling as that approved for the RLD (21 USC 355(j)(2)).

The "same labeling" requirement does not require an ANDA's labeling to be identical to that of the RLD. Among permissible differences, FDA regulations (21 CFR 314.94(a)(8)(iv)) allow an ANDA holder to include labeling that is different from that of the RLD where the ANDA labeling revisions are made to comply with current FDA guidelines or other guidance. In this case, the new Drug Facts labeling changes to be made in ANDA labeling would result from a regulation (21 CFR 201.66). In addition, the preamble to the OTC drug product labeling final regulation states that the adoption of the new labeling format for most OTC drug products marketed under an NDA or ANDA would be considered editorial or minor changes and that the majority of the changes required by the final regulation could be submitted to the Agency in an annual report to the application under 21 CFR 314.70(d)(3).

The Agency believes manufacturers of ANDA products need not wait to implement the new labeling format until after the RLD holder has submitted its labeling.

To facilitate the implementation of the new Drug Facts labeling for ANDA products, the Agency is developing labeling examples for manufacturers to follow. Manufacturers of OTC ANDA products for which FDA does not currently plan to develop labeling examples may implement labeling changes before their RLD's and may use these labeling examples to guide their own effort to comply with 21 CFR 201.66.

Two labeling examples, which show specific product labeling in the new format, are included in this draft guidance: One for Ibuprofen 200 milligram (mg) in a tablet/capsule dosage form; and one for Minoxidil topical solution 2% for men and women. These labeling examples may also be found on the OTC Web site at www.fda.gov/cder/otc/. The agency intends to develop the additional labeling examples referenced above, and they, too, will be made available before the close of the comment period at the same OTC Web site.

When using the labeling examples, it should be noted that interchangeable terms can be used in certain places (see 21 CFR 330.1(i) and (j)). For example, although the Agency uses the word doctor in its labeling examples, the term physician can also be used where appropriate.

Manufacturers can submit their ANDA labeling changes in their annual reports according to 21 CFR 314.70(d)(3) and need not submit a supplemental application to the Agency for preapproval under several different circumstances:

- If they use the Agency's labeling examples to make their changes
- If they do not use the Agency's labeling examples, but change their labeling in accordance with 21 CFR 201.66 and 21 CFR 330.1(i) or (j)
- Where the Agency has not provided any labeling examples, if they change their labeling in accordance with 21 CFR 201.66 and 21 CFR 330.1(i) or (j)

Manufacturers should submit preapproval supplements to the NDA or ANDA, as appropriate, if they make changes to the content of the labeling or wording changes that go beyond those provided for in 21 CFR 330.1(i) or (j).

**The Supreme Court recently ruled that people cannot sue companies for allegedly defrauding the federal government in order to get approval of a new medical device.**

By a unanimous vote, the Court threw out a lawsuit by more than 5,000 people who accused a company of fraudulently winning Food and Drug Administration approval to market a device for use in spinal injuries.

These types of lawsuits in state court are preempted by the Federal Regulatory Plan for medical devices as outlined in the Food, Drug and Cosmetic Act, Chief Justice William H. Rehnquist wrote for the court.

The court determined that existing federal regulatory powers are sufficient for the FDA to punish and deter fraud against the FDA and the agency's objectives can be skewed by allowing lawsuits against companies in state court.

Thousands of people who contend they were injured by the device sued the manufacturer, alleging that it perpetrated a fraud against the FDA. The lawsuits, consolidated into one case, sought monetary damages.

**In February, the Sierra Club filed a lawsuit in an effort to block construction of the new Food and Drug Administration headquarters complex on an 800-acre military site in suburban Maryland.**

The proposed two million square foot complex in White Oak would serve as FDA headquarters, housing 6,000 employees. FDA offices at 18 sites would be consolidated there and at two other locations in Maryland.

The attorney for the Sierra Club stated that this is a perfect example of wide open areas that should be preserved rather than developed with sprawl projects. The Forest Conservation Council also is a plaintiff.

The lawsuit, filed in US District Court in Washington names the General Services Administration and the Acting Commissioner of the Food and Drug Administration as plaintiffs.

An agency spokeswoman said that lawyers for the Department of Justice have not yet had a chance to review the complaint and therefore, would not comment.

Construction was to begin in March at the former weapons testing facility, located on largely undeveloped land about one mile north of the Capital Beltway.

While an environmental impact statement has been approved, the lawsuit called it legally inadequate because alternative sites were not considered. If necessary, the Sierra Club intends to file for an injunction to block construction.

## Clinical trial race, age and gender requirement

Drug and biotechnology companies either do not know, or are not fully reporting the gender, racial and age make-up of subjects in their clinical trials to the Food and Drug Administration.

The FDA issued a rule in 1988 requiring companies to tabulate age, race and gender of subjects enrolled in clinical trials in order to gauge participation of minorities and women. Companies are to submit the record to the FDA in annual Investigational New Drug (IND) reports.

The IND reports are a first look at the early phases of a company's clinical trial, and may be the best place to intervene to ensure gender, age and racial balance of the trial. Even if the data is eventually tabulated, the agency wants to review it during the early stages to assess the design of the trial.

## Postmarketing studies for approved human drug and licensed biological products; Status reports; Delay of effective date

A *Federal Register* notice published on February 20, 2001 (volume 66, Number 34) temporarily delays for 60 days the effective date of the rule entitled Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports, published in the *Federal Register* on October 30, 2000 (65 FR 64607). The effective date moves from February 27, 2001, to a new effective date of April 30, 2001.

The rule concerns the requirements for annual postmarketing status reports for approved human drug and biological products, and requires applicants to submit annual status reports for certain postmarketing studies of licensed biological products. The rule describes the types of postmarketing studies covered by these status reports, the information to be included in the reports and the type of information that the Food and Drug Administration would consider appropriate for public disclosure. The temporary 60-day delay in effective date is necessary to give Department of Health and Health and Human Services officials the opportunity for further review and consideration of new regulations.

## Device third party review, expansion of pilot program

In an effort to encourage greater use of the Accredited Persons Program, FDA implemented an expansion pilot in January 2001 that allows Accredited Persons to review many Class II devices that were not previously eligible. The pilot allows, subject to certain conditions, Accredited Persons to review Class II devices for which there are no device-specific guidance documents. Information on the expansion pilot, including criteria allowing for the review of these Class II devices, can be found in a guidance document entitled, *Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997*.

This guidance is a revision of the October 30, 1998 guidance document with the same title. Accredited Persons and other interested parties should refer to Section II.B., Purpose and Nature of the Program, for the criteria that would allow for the review of the Class II devices in the expansion pilot.

## International Briefs

### EMEA announces appointment of new Head of Unit for Human Medicines

Thomas Lonngren, EMEA (European Medicines Evaluation Agency) Executive Director announced on March 1, 2001, the appointment of Patrick Le Courtois as the new Head of Unit for the Pre-authorization evaluation of medicines for human use. Previously, Le Courtois was the Head of Sector for scientific advice and orphan drugs at EMEA.

The position was established following the creation of two operational units: one dealing with pre-approval aspects of medicines and the other with post-marketing issues. The Head of Unit for post-marketing evaluations of medicines for human use is Noel Wathion, whose appointment was effective September 1, 2000.

Le Courtois is a French national, born on August 9, 1950. He qualified as a medical doctor from the University of Paris and holds a Ph.D. in public health from the University of Bordeaux. His postgraduate degrees include tropical medicine, clinical research and epidemiology.

From 1977 to 1986, Le Courtois worked as a general practitioner and as director of a medical center in Paris. In 1986 he joined the University of Bordeaux and was involved in research areas in public health including epidemiology, clinical research, pharmacovigilance, tropical and infectious diseases, health economy and education. In 1990, he joined the Pharmacy Directorate of the French Ministry of Health and in 1993 the French Medicines Agency as CPMP rapporteur, Head of Unit of European Procedures. Since 1995, Le Courtois has served as a French CPMP delegate.

In September of 1997, Le Courtois joined the EMEA and was appointed as Head of Sector for new chemical substances in June of 1998. He was appointed Head of Sector for orphan drugs and scientific advice in January 2001.

For further information telephone Martin Harvey at: (44-20) 74 18 84 27.

### MCA launches revamped Web site www.open.gov.uk/mca

The Medicines Control Agency (MCA), the government body responsible for monitoring and licensing drugs, has relaunched its Web site to offer a more user-friendly service for professionals and consumers alike.

The new layout is designed with a focus on the user. Clear identification of different sectors of the Web site such as "Frequently Asked Questions", "What's New?" and "Our Work" enables users to quickly move to their area of interest.

For visitors to the site who require more assistance, the Web site now has a comprehensive help section, a search engine, sitemap and an A–Z index.

A new "About the Agency" section draws together the aims and objectives of the MCA, its Annual Report, the Business Plan for the coming year, the structure and organization of the Agency and job vacancies with an option to e-mail the Human Resources Unit for further information.

The new Web site also has a page of links to related sites such as the Committee on Safety of Medicines (CSM), the General Practice Research Database (GPRD), the British Pharmacopoeia Commission Laboratory, other government sites, and regulatory bodies such as the European Medicines Evaluation Agency (EMEA).

Monitoring the safety and quality of medicines is an important function of the MCA and the new site has a dedicated section which features important safety messages, new drugs under intensive surveillance, adverse drug reaction (ADR) schemes and the work of the Agency's Defective Medicines Report Center.

Users also have the opportunity to comment on the site and suggest improvements by using the Web site feedback form.

The health minister with responsibility for the MCA, Lord Philip Hunt, said the new development was further evidence of the agency's commitment to openness and freedom of information. ■

*— William Stoedter*

# Guidance for Industry on BACPAC I

## Intermediates in drug substance synthesis; Bulk actives post-approval changes: Chemistry, manufacturing, and controls documentation; Availability

In the *Federal Register* on February 16, 2001 (Volume 66, Number 33) the Food and Drug Administration (FDA) announced the availability of a guidance for industry entitled "BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation." This guidance provides recommendations to holders of new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications and drug master files or veterinary master files who intend, during the postapproval period, to change the site of manufacture, the scale of manufacture, the equipment, the specification(s) and/or the manufacturing process of intermediates in the synthetic pathway leading to the drug substance.

This guidance describes chemistry, manufacturing, and controls information and documentation in support of each change and provides recommendations on reporting categories. The guidance applies to synthetic drug substances and the synthetic steps involved in the preparation of semisynthetic drug substances. It is limited to structurally well-character-

ized drug substances where impurities can be monitored at the levels recommended. The guidance covers changes as follows: (1) site, scale and equipment changes involving the synthetic steps up to, and including, the step that produces the final intermediate; (2) specification changes for raw materials, starting materials and intermediates, excluding the final intermediate; and (3) manufacturing process changes involving the synthetic steps up to and including the final intermediate. The guidance does not cover postapproval changes affecting: (1) synthetic peptides, (2) oligonucleotides, (3) radiopharmaceuticals, (4) drug substances derived exclusively by isolation from natural sources or produced by procedures involving biotechnology, or (5) nonsynthetic steps for semisynthetic drug substances. Also excluded from this guidance are certain changes in specification and process associated with the use of raw materials or starting materials derived from natural sources or biotechnology.

In the *Federal Register* of November 30, 1998 (63 FR 65793), FDA announced the availability of a draft version of this guidance. The November 1998 guidance gave interested persons an opportunity to submit comments through March 31, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version. The guidance document can be found at www.fda.gov/cder/guidance/index.htm. Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch, refer to Docket No. 98D 0994. ■

*— William Stoedter*

# Thompson Takes Helm at Health and Human Services

Newly sworn Health and Human Services (HHS) Secretary Tommy G. Thompson addressed a gathering of HHS staff on February 2nd. About 1,000 employees crowded in the Great Hall of the Hubert H. Humphrey Building to hear Thompson, while others watched by videoconference and on the Internet.

Tommy G. Thompson, Health and Human Services Secretary

Thompson, who stepped down as longest-serving governor in Wisconsin history and longest-serving current US governor, is the 19th person to hold the Cabinet-level office heading the department. Prior to 1980, HHS was known as the Department of Health, Education and Welfare.

"I took this job because there is no other job in America where you have a greater opportunity to help people—to actually make a difference in people's lives and improve the quality of life they lead," Thompson said. Photos of the welcome are at http://www.hhs.gov/news/photos/.

Thompson said that he plans to bring an innovative spirit to HHS and its more than 300 programs. "I'm here to persuade you to do things just a little differently on the national level. I believe so passionately that the issues faced by this department are among the most important facing us as a nation. And I believe that we need to find innovative, creative ways to face these challenges," Thompson said.

"We need to reach out to states and local governments. We need to look at successful models and best practices from all over this country, because there are no one-size-fits-all solutions to the challenges we face."

Thompson's "aggressive agenda" includes:

- Modernizing Medicare;
- Enacting a Patient's Bill of Rights;
- Acting to provide access to affordable health insurance for the more than 43 million Americans who are uninsured;
- Continuing welfare reform to help those who go to work to "have the opportunity to continue to move up the ladder of economic success";
- Taking action to establish an office of faith-based and community initiatives;
- Improving foster care and adoption programs around the country;
- Taking a leadership role in women's health;
- Supporting biomedical research; and
- Continuing vigilant protection of the safety of the nation's food and drug supply.

He also announced that he would move in the first 100 days of his tenure to "launch a national campaign to raise awareness of organ donation."

A copy of Thompson's speech is available at http://www.hhs.gov/news/speech/2001/010202.html.

Thompson has dedicated his professional life to public service, most recently serving as governor of Wisconsin since 1987. He gained national attention for his leadership on welfare reform. As governor, he focused on revitalizing Wisconsin's economy, expanded access to health care for low-income people and education. His biography is at http://www.hhs.gov/about/bios/dhhssec.html.

*continued on page 14*

# BSE: Background, Current Concerns, and US Response

## From Information on the FDA Web Site

The recent increase in cases of bovine spongiform encephalopathy (BSE) found in some European countries has revived public concern about the safety of eating beef and using other animal-derived products. The largest increase of this fatal neurological disorder in cattle (commonly called "mad cow disease") occurred in France, which reported 99 cases in 2000, compared to 31 cases in 1999. The incidence of BSE-infected cattle is also rising in Belgium and Ireland. Some countries that have not previously seen BSE in their native cattle, including Germany, Spain, Denmark, and Italy, reported their first cases in 2000.

First identified in the United Kingdom (UK) in 1986, BSE peaked in the UK in January 1993 at almost 1,000 new cases per week. The UK has reported more than 180,000 total cases of BSE, and about 1,800 cases have been found elsewhere in the European Union (EU).

Because of the UK's aggressive actions to eradicate BSE since it was first identified, the number of BSE cases is falling sharply in that country. The sudden rise in reported BSE cases in other European countries may, in part, reflect increased testing by some countries, particularly Switzerland and France. In addition, because of the long incubation period of BSE (two to eight years), cows being identified now with BSE may have become infected several years ago.

No cases of disease in humans or livestock caused by BSE have ever been detected in the United States. BSE has thus far been kept out of this country largely through the combined efforts of the Food and Drug Administration (FDA), the US Department of Agriculture (USDA), the Centers for Disease Control and Prevention (CDC), other federal organizations, and state regulatory and health agencies. These organizations have taken aggressive actions to reduce the risk that BSE could be introduced and spread in this country. These actions build on a continuing program of prevention, education, surveillance, testing, and emergency preparation.

## BSE in Cattle Linked to Disease in People

In 1996, British scientists traced a link between a new variant of Creutzfeldt-Jakob disease (CJD), a rare but fatal disease in humans, and BSE in cattle. Both the new variant CJD and the classic CJD are slow degenerative diseases of the central nervous system whose symptoms include dementia and loss of motor skills. There is no known treatment and the outcome is ultimately death. Only the new variant—not the classic—CJD is believed to be caused by exposure to the BSE agent, most likely through certain foods.

CJD and the new variant CJD (nvCJD) belong to a family of diseases known as transmissible spongiform encephalopathies (TSEs). These diseases, so named because of the spongy appearance of the infected brain tissue, are caused by a transmissible agent that is not yet fully understood.

On March 20, 1996, the UK reported 10 cases of nvCJD. As of Feb. 2, 2001, 98 cases of nvCJD have been suspected or confirmed in the EU. With the exception of three cases in France and one case in Ireland, all have occurred in the UK.

No cases of nvCJD have been detected in the United States through CDC's surveillance program. In fact, no illnesses in livestock or humans caused by BSE have ever been diagnosed in the United States, despite 10 years of active surveillance.

## Transmission and Testing

Current research suggests the agent that causes BSE and other TSEs is a "prion," an abnormal protein with a novel mode of replication and transmission. Cattle may contract the disease from feed containing animal byproducts contaminated with this protein.

The BSE agent is highly resistant to most disinfectants that normally inactivate viruses or bacteria, such as heat, ultraviolet light, and ionizing radiation. BSE agents do not appear to stimulate an immune response, and so, as yet, cannot be detected with a blood test for antibodies or prevented with a vaccine. No evidence exists to indicate that BSE spreads through routine contact between cattle or from routine contact between cattle and humans or other species.

Currently, no test can readily detect BSE in a live animal or detect TSEs in healthy humans. The main laboratory method used to confirm a diagnosis is to examine brain tissue after death. Researchers are working to develop new test methods to detect TSEs in live animals and humans.

## The US Response

The United States has aggressive BSE surveillance and prevention programs in place. FDA's restrictions on certain animal feed ingredients and its import alerts on cattle products are a critical part of this program. In addition, USDA has an import ban on certain cattle and cattle products, and CDC has established surveillance and investigation programs for suspected human TSE cases.

USDA's Animal and Plant Health Inspection Service (APHIS) introduced import restrictions in 1989, when it banned the import of all live ruminants (cud-chewing animals, such as cows, sheep, and goats) from the UK.

On Dec. 12, 1997, APHIS expanded its prohibition on certain imports to include live ruminants and most ruminant products from all of Europe.

USDA's Food Safety and Inspection Service (FSIS) inspects cattle before they go to slaughter if they show signs of BSE or other central nervous system impairment. Any animals displaying these signs are condemned, and the meat is not allowed to be used in human food. The animal brains are submitted to USDA's National Veterinary Services Laboratories for analysis. Approximately 12,000 cattle brains from nearly every state and Puerto Rico have been examined, with no evidence of BSE or other TSE found to date.

FDA is responsible for ensuring that animal feeds are safe and produce no human health hazards when used in food-producing animals. On June 5, 1997, FDA published a final regulation that prohibits the use of most mammalian protein in the manufacture of animal feeds given to ruminants. The regulation, which became effective on Aug. 4, 1997, also requires manufacturers to use appropriate process and control systems to ensure that feed for ruminants does not contain the prohibited mammalian tissue.

To ensure that industry was complying with the animal feed regulation, FDA, with assistance from state feed control officials, has conducted nearly 10,000 inspections since January 1998. Inspected firms include feed mills, ruminant feeders, dairy farms, renderers, protein blenders, feed haulers, and distributors. More than three-fourths of all of the inspected facilities were found to be in compliance with the regulation, and nearly 85 percent of the 180 renderers handling prohibited materials were in compliance. The compliance of rendering plants is particularly important because they are the source of most domestic MBM. Sites initially found not to be in compliance have shown a high percentage of compliance upon re-inspection.

Using an innovative, education-oriented partnership program, FDA continues to enforce its 1997 feed regulation. FDA has sponsored workshops for state veterinarians and feed control officials from all 50 states, Puerto Rico, the US Virgin Islands, and Canada. In addition, a joint satellite teleconference with the Association of American Feed Control Officials, the American Feed Industry Association, and the National Grain and Feed Association was broadcast in 1998 throughout the United States and Canada to describe the requirements of the regulations and answer questions from callers. FDA has also developed an interactive CD-ROM that provides information on the regulation and what is expected of those to whom the regulation applies.

To continue its comprehensive efforts to try to head off a BSE problem in the United States, FDA is conducting additional inspections, and is re-inspecting facilities that were found non-compliant upon initial inspection. Based on the evaluation of the inspections conducted from 1998 through 2000, FDA will revise its compliance strategy to try to assure its goal of 100% compliance with the feed regulation.

FDA and USDA recently took further emergency action to prevent potentially cross-contaminated products from entering the United States. On Dec. 7, 2000, APHIS banned all imports of rendered animal proteins, regardless of species, from 31 countries listed as BSE-positive or as presenting an undue risk of introducing BSE into the United States. Prohibited products include MBM, meat meal, bone meal, blood meal, tankage (dried animal residues), and offal (organs, such as brain and liver, and trimmings, such as tails and hooves). FDA has also announced an import alert, allowing its inspectors to detain shipments from these 31 countries of animal feed (including pet food), animal feed ingredients, and other products of animal origin intended for human or animal use.

## Protecting Medical Products

In addition to protecting the American cattle herd from BSE, FDA also has taken steps to protect medical products (such as drugs, blood, vaccines, and medical devices) for human use. In 1990, FDA intensified its review of new product applications for human medical products derived from or containing bovine (cattle) sources. FDA recommended to manufacturers of these new products that they not purchase as components animal tissues or products that originated in a country where native cattle have been diagnosed with BSE.

In 1993, and again in 1996, FDA issued letters to the manufacturers of drugs, biologics and medical devices advising them that in the manufacture of FDA-regulated products intended for human use, they should not use materials derived from cattle born, raised or slaughtered in countries where BSE is known to exist. Again in 2000, FDA reissued the same advice to vaccine and other biological manufacturers regarding bovine materials from countries listed as having BSE or with an undue risk of introducing BSE into the United States.

FDA will continue its close collaboration with the scientific community and with public health officials, at home and abroad, to take the appropriate preventive actions in response to the growing and changing knowledge concerning TSEs in its ongoing effort to protect the health of Americans and of US cattle herds. ■

*— William Stoedter*

**For More on TSE, see related article on page 20**

*Thompson Takes Helm from page 11*

Thompson takes over one of the federal government's largest departments.

At $429 billion, HHS has the largest budget among Cabinet-level departments, representing 23% of all federal outlays. The department has 63,000 employees. It includes:

- Medicare, the nation's largest health insurer, serving 40 million elderly and disabled Americans;
- Medicaid, the joint federal-state program providing health care for low-income Americans;
- National Institutes of Health, the world's premier biomedical research institution;
- Food and Drug Administration, which has responsibility for safety of products representing 25 cents out of every dollar in US consumer spending;
- Centers for Disease Control and Prevention, maintaining a nationwide and global public health network;
- Administration for Children and Families, working with states to provide services especially to low-income families; and
- Six other primary agencies providing services to Americans.

A summary of HHS activities is at http://www.hhs.gov/about/profile.html. ■

*— William Stoedter*

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# PDA Forms Science Advisory Board

James P. Agalloco

PDA's Board of Directors has approved the formation of a Science Advisory Board (SAB), chaired by James P. Agalloco, Agalloco and Associates. The SAB establishes the strategic perspective and provides oversight for the association's scientific and technical activities through development of guidelines, technical monographs and interaction with regulatory authorities.

Responsibilities of the SAB include:

- Identifying current scientific issues and developing strategy for addressing them (e.g., Forum, major meeting topic, white paper, technical report, research project, meeting with FDA);
- Proactively identifying scientific trends requiring PDA's attention;
- Assuring consistency of scientific and technical positions with the PDA Strategic Plan; and
- Reviewing technical documents and providing in-process oversight and guidance as needed. ■

*—Russell E. Madsen*

The Science Advisory Board will add important new dimensions and strength to the association's scientific and technical activities.

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# Class 100,000 Fermentation Suite and Pseudomonas and Rubber

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 explores the requirements for controlled environments around closed systems, such as fermentation processes and whether Pseudomonas sp. bacteria can "colonize" rubber and plastic sometimes used in pharmaceutical industry piping systems.

## Question 1

If you have a closed fermentation process is there any regulatory or industry standard that requires a 100,000 or better classification for that room or is a controlled unclassified environment acceptable for the process?

### Response 1.1

The EU regs allow the environment to be adapted to the product and production step. Theoretically fermentation in a closed vessel can take place in an unclassified area. The problem is having a truly closed system, additions, sampling and inspection after cleaning are the problem.

### Response 1.2

As long as it is truly closed you do not need a class 100,000 room, it can be unclassified.

### Response 1.3

Sterile filtration of additions and off-gas (exhaust) can aid in further isolation.

## Question 2

I had a comment from an auditor the other day while he was looking at our non-sterile purified water system (which is fairly "organic" and mainly plastic pipes). He mentioned something about Pseudomonas sometimes growing into the structure of certain rubbers and therefore being out of the firing line of any sanitising agents. He couldn't provide any references on the spot but he was fairly certain he'd read it somewhere. Does anyone know if this is the case, and indeed have any references or ideas about this?

### Response 2.1

There was a very famous case back in the early '80s involving a Povidone/Iodine solution manufacturer where the product was contaminated with *Pseudomonas aeruginosa*. There were several cases of infection of patients by the organism and upon investigation the Povidone/Iodine solution was identified as the source of the organism. When the FDA investigated the manufacturer, the source of the organism was determined to be the process piping which was sanitized using a bleach solution before being used in the processing of a batch. The process piping was made of PVC. It was determined that the interior of the PVC had "crazed" (developed micro-cracks and fissures) which the *P. aeruginosa* had colonized and was not being eliminated by the bleach sanitant or by the povidone/iodine product solution. Therefore, the FDA took issue with PVC piping system or any other kind of material which would craze like PVC and provide areas for organisms to colonize. This led to the current CGMP standard of stainless steel tubing with welded joints and sanitary clamp connections for piping systems. I can see a similar scenario occurring with elastomeric compounds that are porous or ones that can crack or craze. I do not know of any specific references that describe this problem outside of any of the watchdog journals (*Gold Sheet*, *Pink Sheet*, *Microbiological Trends*, etc.) that reported on the incident that I described above.

### Response 2.2

The auditor was referring to the phenomenon of biofilm build-up. This is not restricted to plastic pipes but these are more prone to the problem, especially at joins and, of course, any "dead" flow areas of the system.

What happens is that the organisms settle/attach to the substrate (pipe surface) and grow producing exopolysaccharide that forms a protective film around them. Over time they can develop to be quite substantial. In such cases any sanitizer applied to the system the surface-associated bugs get killed but not all the organisms in the biofilm, such that when the sanitizer is rinsed out, they simply regrow.

For more information check out references on biofilms (there has developed a vast literature on the subject in recent years and recently there was a UK SGM symposium in Exeter on the subject which is available as proceedings) or wait to hear of other forum members' personal experiences. I might add that I have seen perfectly adequate micro results from well maintained PVC-based water systems. However, the potential micro problems associated with them have driven the move towards stainless steel systems. You don't say whether the comments by the auditor were related to actual micro problems with the system or not.

Hope this clarifies the audit comment.

Response 2.3
I believe that the auditor was misinformed. Vulcanized rubber, due to the complexity of the polymeric material, cross-linkaging, residues of accelerators with antimicrobial activity within the rubber, is not susceptible to microbial degradation. It is possible that the auditor was thinking that different materials may support varying amounts of biofilm formation. A thick biofilm would be less sensitive to sanitizing agents.

Response 2.4
Teflon tubing could be a possible source of the same problem. Eventually the plasticizer is dissolved and the inside of the tubing, particularly if exposed to any lipophilic substance/solvent, will crack, forming areas that might also harbor organisms. Documentation for the cracking phenomena can be found in the NIEHS literature related to the milking industry.

Anyone who has worked in the lab with Teflon tubing knows how hard it eventually becomes, losing its flexibility. The micro-cracking occurs much sooner than you can easily detect it.

Response 2.5
Thanks for the supporting remark. I did my Ph.D. thesis on the determination of DEHP in Tygon tubing which is widely used and if re-used, as for example in milking machines, could cause this same problem, as evidenced by DEHP levels.

Too many people readily accept advertising remarks and then find out in reality they are not always truthful, because they avoided doing the testing and relied on anecdotal evidence that probably was unjustified for their particular application.

Response 2.6
I believed you missed an important point, the fact that the rubber could crack, form fissures (dead-legs) and eventually lead to resident colonies of the organism(s). The equivalent of dead-legs in a water system. ■

*—compiled by Russell E. Madsen*

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

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

## PDA/IABs Conference on

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


**Berlin Hilton Hotel, Berlin, Germany**
**September 6–7, 2001**
**Co-Sponsored by PDA and the International Association for Biologicals (IABs)**

**Program Committee Co-Chairs:**
**Vincent Anicetti, Ph.D., Genentech, Inc.**
**Brendan P. Hughes, GlaxoSmithKline, UK**

Pursuant to the jointly sponsored PDA/FDA meeting on this topic last September, PDA is hosting a follow-up conference on process validation for biologics in Europe.

The purpose of the European meeting will be to provide a forum for open dialogue between European regulatory agencies and industry representatives and to gain comparative perspectives on the European and US platforms.

Discussions will focus on appropriate practices, and discussions will serve as a good basis on which to connect issues of comparability and process validation. PDA will work in conjunction with regulatory agencies to put together scientifically and technically sound approaches to reuse and cleaning. IABs will publish the conference proceedings.

The program for this meeting is currently in development. Details will be posted at www.pda.org when available.

# Latest EMEA Quality Guidance

## Process Validation, Parametric Release, Pharmaceutical Water

The EMEA and EC have recently released a burst of guidance documents which will affect the industrial pharmaceutical manufacturing sector. Following is a summary of the guidances and where they can be found. Look for more information in upcoming *PDA Letters*.

- *Annex 15, Qualification and validation - Final*. This is the revision, and apparently final version, of the original draft of Annex 15 to the GMP released for consultation in late 1999. PDA submitted comments on this draft in February 2000 based on an evaluation by an international group of GMP experts. The revision is much shorter and concise and has been re-titled. The revision was approved by the Inspectors Working Party in December 2000, and will come into effect June 2001. For copy go to http://dg3.eudra.org/pharmacos/gmp_doc.htm.
- *CPMP Note for Guidance on Process Validation - Final* (CPMP/QWP/848/96) - The companion to Annex 15 which describes the dossier requirements associated with validation. PDA also submitted comments on this document. The final was adopted by the CPMP in February 2001, and will come into effect September 2001. For copy go to www.emea.eu.int/pdfs/human/qwp/084896en.pdf.
- *CPMP Note for Guidance on Parametric Release - Final* (CPMP/QWP/3015/99) - The companion to draft Annex 17 of the GMP which was the subject of extensive PDA comments based on a task force of international experts and submitted September 2000. This guidance was adopted by the CPMP in February 2001, and comes into effect September 2001. At press time the status of draft GMP Annex 17 was unclear. For copy go to www.emea.eu.int/pdfs/human/qwp/301599en.pdf.
- *CPMP Note for Guidance on Water for Pharmaceutical Use - Draft* (CPMP/QWP/158/01draft) - Released for comment on March 1, 2001, this guidance offers guidance to the industry on the pharmaceutical use of different grades of water: Potable water; WFI; Purified Water, and Highly Purified Water. Comments are to be submitted by end of August 2001. For copy go to www.emea.eu.int/pdfs/human/qwp/015801en.pdf. ■

*—James Lyda*

# More on TSE

## On February 28 the EMEA issued additional guidance in the TSE risks for medicinal product:

Joint CPMP/CVMP Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

*Explanatory Note for Medicinal Products for Human Use on the Scope of the Guideline* (EMEA/CPMP/BWP/498/01) - This explanatory note, which should be read along with the referenced NfG, addresses the scope of the TSE guideline and also the status of ruminant derived materials used in master seed lots of master cell banks. For copy: www.emea.eu.int/pdfs/human/bwp/049801en.pdf.

*Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE) risk via the use of Materials of Bovine Origin in or During the Manufacture of Vaccines* (EMEA/CPMP/BWP/476/01). For copy: www.emea.eu.int/pdfs/human/press/pus/047601en.pdf.

In early March the European Directorate for the Quality of Medicines (EDQM) published the expedited proceedings from the TSE risk conference, January 11, 2001, Strasbourg. Those interested in the proceedings can find them on the EDQM (European Pharmacopoeia) Web site, www.pheur.org. ■

*—James Lyda*

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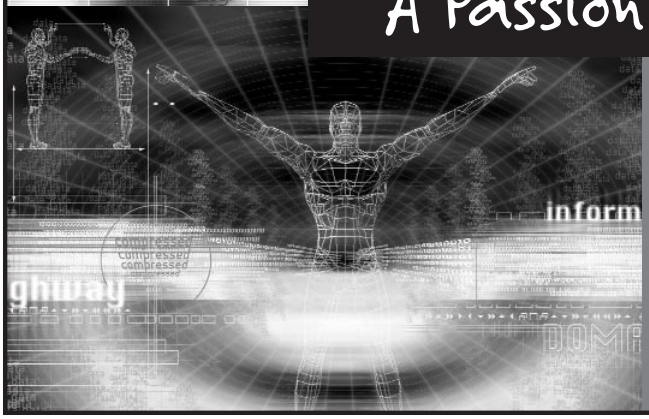


More than anything, the name Baxter Healthcare Corporation is synonymous with innovation characterized by the relentless pursuit of brilliant ideas. It is this passion for excellence that makes a real difference in the careers of our dedicated professionals. These valuable individuals receive access to the latest technology and corporate support within a setting where creative thinking is encouraged, and accomplishments are recognized and rewarded. If you're a highly innovative professional in your own right, here's your chance to prove it. Our Round Lake, Illinois, facility is seeking dedicated individuals who possess excellent verbal/written communication skills to join us in the following capacities:

## Microbiologist, Lab Supervisor

- BS with 5+ years experience, MS preferred
- Supervisory experience preferred
- Biotechnology
- Lyophilization
- Aseptic Processing
- Isolator/Barrier Technology
- Sterility and Bioburden Test Method Validation
- 20% Domestic and International Travel Required

## Microbiologist

- BS Microbiology with 2 years experience, MS preferred, exceptional advanced degreed new graduates will be considered
- Biotechnology
- Lyophilization
- Aseptic Processing
- Isolator/Barrier Technology
- Sterility and Bioburden Methods
- 15% Domestic and International Travel Required

## Engineer

- BS Engineering with 2 years experience
- Biotechnology
- Lyophilization
- Aseptic Processing
- Isolator/Barrier Technology
- Familiar IQ/OQ/PQ Process
- 15% Domestic and International Travel Required

## Microbiologist

- PhD in Microbiology with 5+ years experience in Pharmaceutical Industry
- Experience with Regulatory Authorities
- Terminal Sterilization
- Aseptic Processing
- Mycology a plus
- 20% Domestic and International Travel Required

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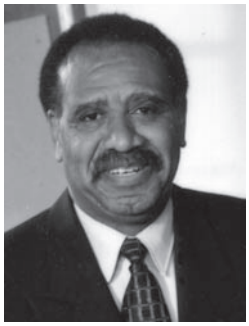
# Company, Colleague & Product Announcements

**Akorn, Inc.** recently announced that Floyd Benjamin, PDA Chair-Elect, who has served as Akorn's Chief Executive Officer and Director for the past three years, assumed the new position of Vice Chairman of the Board. He will continue to have day-to-day responsibility for regulatory affairs and quality control. Benjamin commented, "In my ongoing role at the Company, my goal will be to ensure that Akorn remains on the cutting edge of all regulatory affairs and quality control matters -- making certain that our products and standards are maintained at the highest levels as new products come to market. I believe that emphasis on these key areas will enable us to build the strongest company going forward." Akorn, Inc. manufactures and markets sterile specialty pharmaceuticals, and markets and distributes an extensive line of pharmaceuticals and ophthalmic surgical supplies and related products. (See also www.akorn.com.)



Floyd Benjamin

**Abbott Laboratories** recently named Richard M. Johnson as their new Director, Information and Policy. Johnson's most recent position was Director, Corporate Quality Technology for Alcon Laboratories, Inc. Known widely in PDA circles, Johnson has assumed many responsibilities in his association with PDA. He is leader of the PDA Ophthalmics Interest Group, member of the PDA Aseptic Processing Task Group, which is developing a technical report on sterile pharmaceutical products produced using aseptic techniques and a member of PDA's Science Advisory Board. Johnson was also a member of the PDA committee that developed the program for the Environmental Monitoring Aseptic Processing Forum which was held at the Hyatt Regency Bethesda, Bethesda, Maryland, in 2000. Johnson may be reached at Abbott Laboratories, Dept. 03-QA, 100 Abbott Park Road, Abbott Park, IL 60064-6091, (847) 938-1750.

Vic Edy has recently founded **Newland GxP Consultancy**, focusing on aiding start-up and development-phase biotech and pharmaceutical companies to establish appropriate QA and GMP compliance systems. The move is viewed as particularly relevant now that the European Union Directive on Clinical Trials will soon require GMP compliance inspections of manufacturers of materials used in clinical trials. Prior to establishing Newland, Edy was Head of Quality for British Biotech Pharmaceuticals Ltd. He may be contacted at +44 (0)1993 709550, or edy@newland-gxp.co.uk.

**Magellan Laboratories** has appointed Robert N. Woodhouse, Ph.D. its new Senior Vice President and General Manager of Analytical Chemistry. His responsibilities will center on overseeing analytical chemistry operations within Magellan Laboratories. In his senior leadership role, the company's Inhalation and Analytical divisions will report to him.

Woodhouse joins Magellan after two decades of working in the highest levels of management with international pharmaceutical companies. Most recently, he served as Director, Worldwide Inhalation Pharmaceutical Development for GlaxoWellcome Research and Development—a company with which he enjoyed a 15-year affiliation. During his career, Woodhouse was instrumental in the launch of many prescription drugs in both the U.S. and Europe, including Zantac®, Imitrex®, Zofran®, Flovent® (metered dose inhaler) and Serevent® (CGC metered dose inhaler and Diskus). For more information contact Magellan's East Coast headquarters at 919-481-4855 or info@magellanlabs.com. (See also www.magellanlabs.com.)

Robert N. Woodhouse, PhD

**Pall Corporation** announced the formation of its **Life Sciences Group** to harness the Company's resources across the spectrum of life sciences. The move will allow Pall to better support the demanding needs of researchers and developers of drugs and diagnostics in the biotechnology market place. "By bringing together all of our life sciences technologies, we are in step with the convergence taking place in biotechnology," said Eric Krasnoff, Chairman and CEO. "Our customers will work with a focused core of technologists and researchers within **Pall Life Sciences** that can harness our vast resources." In the past few weeks, Pall made several other announcements. Pall entered into a strategic alliance with Genetix Group Plc. to develop and commercialize novel membranes to optimize robotic high-density array printing and detection methods for DNA and proteins. According to Krasnoff, "This alliance is an important fit in our Life Sciences market segment as the sciences of genomics and proteomics are among the most dynamic and fastest growing business oppor-

tunities in life sciences today." Pall provides leading-edge products for use in high-growth applications such as genomics, proteomics and biotechnology; transfusion medicine; semiconductor; water; aerospace and a host of other industries. In another accord, Pall and Genicon Sciences Corporation have agreed to apply Pall's membrane technology and Genicon's ultra-sensitive RLS™ technology toward the development of an enhanced system for the labeling, detection and study of biological analytes for the pharmaceutical, biotechnology, genomics and diagnostics industries. Pall provides many of the tools used for molecular biology and drug discovery and currently offers many membrane choices for these applications. Pall's portfolio of filtration, purification and separations technologies spans the full spectrum of life sciences applications. Its products are used from the earliest stages of discovery and development of new drugs and diagnostics, through the production and delivery of therapies for the detection, diagnosis and treatment of disease states. As part of the Company's Life Sciences mission, it is actively developing partnerships with companies that provide complementary technologies. Pall's business is organized around two broad markets: Life Sciences and Industrial. For more information contact Patrice Radowitz at (516) 484-3600 x6111 or pat_radowitz@pall.com. (See also www.pall.com.)

**VWR Scientific Products** has published two new full-color guides: one detailing VWR Signature™ laboratory equipment, the other detailing VWRbrand™ product lines. The Signature line is designed to deliver high quality and superior performance and includes baths, circulators, chillers, dry block heaters, freezers, refrigerators, hot plate stirrers, humidity test chambers, incubators, microscopes, ovens and shakers. The 28-page guide includes color photos, descriptions, specifications, ordering information and pricing for each product. The 56-page VWRbrand Product Guide details the full line of chemicals, equipment, lab supplies, liquid handling products and safety products available. Complete product descriptions, ordering information, pricing and color photos are included. VWR Scientific Products is an international distributor of chemicals, equipment, supplies and cleanroom products that meet the performance and productivity needs of university, government, industrial, life science, pharmaceutical and other laboratories. For more information contact Megan Devin at 610-429-5577. (See also www.vwrsp.com.)


The Tri-Mix Turbo-Shear, introduced by **Lee Industries, Inc.**, is a combination of a scraped-surface, counterrotating, double-motion agitator and an independent, bottom-center mounted, high-speed homogenizer head. The counterrotating scraped-surface agitator can be designed to handle products up to 2,000,000 CPS. The Turbo-Shear head has been modified to accept several disperser designs and the "can" design of the Turbo-Shear has been improved to handle a wider range of high-viscosity products. The Turbo-Shear can handle products up to 10,000 CPS alone and viscosities to 50,000 CPS and beyond with the aid of the high-intensity scraper agitator. This new more versatile design has been incorporated into the company's existing 25-gallon lab Tri-Mix Turbo-Shear unit and is available for customer testing and product analysis. For additional information contact Lee Industries at 814-342-0461 or leemis@netphd.net. (See also www.leeind.com.)

**MKS, Inc.** recently published a new HPS® Pirani Gauge Brochure. The Brochure includes information on the Series 945 LED digital controller, the Series 917 analog controller, the Series 315 Pirani sensor and the Series 345 Pirani sensor. Standard on the Series 945 and 917 controller are two adjustable setpoints with LEDs and analog output. The Series 945 will measure from 10-4 to 100 Torr, and can be CE marked. The lower-cost Series 917 measures from 10-3 Torr to atmosphere. The series 345 and Series 315 sensor tubes will operate with the Series 945, 917, 937 and 953 gauge controllers. They have a measurement range of 10-4 Torr to atmosphere. The sensor can be installed in any orientation. Tubes are interchangeable without user calibration. The robust design and construction of the sensor make it reliable and give it a long life. Since the Series 345 sensor is shielded for RF immunity, it can be used in conjunction with CE marked gauge systems, allowing the Series 945 and the Series 937 to be CE marked with Pirani sensors. For more information contact the Vacuum Products Group at 800-345-1967 or 303-449-9861. (See also www.mksinst.com.)

**American Pharmaceutical Partners, Inc.** (APP), a specialty pharmaceutical company, has received a patent for aqueous Acyclovir Sodium Injection in a plastic vial. This innovative packaging provides health care professionals with a combination of high-quality product in a safety-enhanced package. APP offers aqueous Acyclovir in 500mg/10mL and 1 g/20mL vials, as well as a 500mg/10mL vial in powder form. The aqueous solution of Acyclovir helps to ensure correct dosing and saves time and labor for busy medical professionals. In comparison, the lyophilized products require constitution and should be used within 12 hours to ensure solution stability. APP's aqueous Acyclovir, however, remains shelf-stable for months, prior to being opened. For more information contact Kerry L. Garman at 847-330-1372. (See also www.appdrugs.com.) ■

*—Joe Bury*

# PDA and FDA to Jointly Host Viral Clearance Forum

PDA, in collaboration with the US Food and Drug Administration (FDA), will host a Viral Clearance Forum on October 1–3, 2001 in Bethesda, Maryland. This three-day workshop 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 FDA and international regulatory agencies, academicians, pharmaceutical/biotechnology manufacturers, manufacturers of enabling technologies, and contract testing organizations (CTOs). The goals of the conference are to:

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

A networking reception and poster presentation will be held on Monday, October 1, 2001.

Abstracts and outlines for 30-minute presentations are sought on the following topics:

Viral Filtration
Viral Preparation
Viral Assays
New Technologies
Validation of Processes — Biotech Products
Validation of Individual Steps — Biotech Products
Virus Removal Validation — Natural Products
Filtration
Chromatograph

PDA is soliciting poster presentations of research related to viral clearance topics.

Presenters whose abstracts are accepted for presentation will receive full complimentary conference registration. Presenters will be advised in writing of the acceptance of their abstract by August 1, 2001. ■

*—Leslie Zeck*

**Abstracts and Outlines must be received by June 8, 2001 for consideration.**

- Include title, objectives, topics to be discussed; and
- Include bio with abstract.

Send your abstract of approximately 200 words in length and your bio to:

**Leslie Zeck**, PDA, 7500 Old Georgetown Road, Suite 620, Bethesda, MD 20814 USA, Tel: (301) 986-0293 x 129, Fax: (301) 986-0296, **E-mail: zeck@pda.org**.

**E-mail submissions are preferred.**

# The Extractables Puzzle: Putting the Pieces Together

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

As a follow-up to the 1996 Special Forum on Container/Closure Extractables, PDA will conduct a national conference entitled *The Extractables Puzzle: Putting the Pieces Together*. The conference will explore analytical, material, regulatory and toxicology issues.

The purpose of the conference will be to assess the state-of-the-art in extractables science. Information on interpreting new regulations, such as the Packaging Guidance issued May 1999, and how to implement them will be provided. A comparison of extractables issues for drugs, devices and biologics will be drawn. Presenters will explore national and international regulations and compendial standards and identify commonalties and differences. Case studies will be provided. All conference participants will be surveyed and survey results will be analyzed at the conference.

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

- Discuss national and international regulations and guidelines;
- Benchmark what companies are doing related to extractables in drugs, biologics and devices;
- Learn how to write and execute an Extractables Protocol;
- Gain a better understanding of FDA expectations; and
- Influence policy development in extractables regulation.

A source book providing a compendium of international regulatory information will be provided. ■

*—Leslie Zeck*

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*PDA Calendar Begins on Back Cover*

September 6–7, 2001
**PDA/IABs Conference on Process Validation for Manufacturing of Biologics 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 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 Value Analysis**
Baltimore, MD

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

## OCTOBER

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

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

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

October 15–17, 2001
**PDA Isolation Technology Conference**
Hilton New Brunswick
New 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 15–16
**PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training**
Baltimore, MD

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

## DECEMBER

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

## 2002

## FEBRUARY

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

See page 29 to sign up for PDA-TRI courses.

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

# New Contamination Control Course Presented at PDA-TRI

A new one-day laboratory course was recently presented at the PDA Training and Research Institute in Baltimore, Maryland. Entitled "Contamination Control Basics" the course addressed the issues associated with contamination of sterile products in controlled environments by human operators.

The types and sources of contamination, as well as methodologies for control and elimination of it in pharmaceutical processing areas, were demonstrated for the participants through interactive lecture and discussion sessions. The operator as the major cause of Cleanroom contamination is a central theme throughout the course. Additional topics covered include:

- Basic Microbiology;
- Contamination Control Measures;
- Aseptic Processing; and
- "The People Factor".

The course took full advantage of the laboratory and Aseptic Processing facilities located at the PDA Institute. Participants were able to view and interact with equipment and supplies used in critical environments.

"Contamination Control Basics" is designed for anyone who enters a Cleanroom or Aseptic Processing Area. The course pertains to line operators, setup personnel, support personnel, mechanics, supervisors/managers, environmental monitoring personnel, quality auditors, etc.

The course is taught by Sandra Lowery, President of Quality Systems Consulting, Inc. Lowery has spent 25 years in injectable pharmaceutical manufacturing, specializing in the areas of Contamination Control, validation, quality assurance, regulatory affairs, and research and development. Her expertise includes development and validation of aseptic processes, environmental monitoring, process, systems and equipment validation, specialization in drug GMPs, and extensive interaction with FDA.

Lowery also recently joined the faculty for our Aseptic Processing Training Program, a comprehensive two-week program in manufacturing sterile products.

Sandra Lowery, President of Quality Systems Consulting, Inc.

**"Contamination Control Basics" will be held at the PDA Training and Research Institute on the following dates:**

- April 30, 2001
- June 29, 2001
- September 7, 2001
- November 30, 2001

For more information about this course or any other PDA-TRI course, please contact PDA-TRI at (410) 455-5800 or info-tri@pda.org. ■

*—Casey Weininger*

# Upcoming PDA-TRI Education Courses

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

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

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

**Computer Products Supplier Auditing Process Model: Auditor Training (PDA #474)**, May 10–11, October 11–12, and November 15–16, 2001 in Baltimore, Maryland; May 17–18, 2001 in Stockholm, Sweden; June 6–7, 2001 in East Brunswick, New Jersey; $950 PDA members/$1100 nonmembers. *For more information, vist our Web site,* www.pda.org. ■

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

# PDA-TRI Location/Lodging Information

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

*** indicates no on-site restaurant*

- **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.

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

## PDA-TRI Thanks the Following...

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# Capital Area Chapter to Hold Vendor Exposition May 9, 2001

The PDA Capital Area Chapter will hold a Vendor Exposition at the University of Maryland, Shady Grove Center in Rockville on May 9, 2001 from 5:00 p.m. to 8:00 p.m. The event will be free to attendees. There will be door prizes (attendees must preregister to win) and free hors d'oeuvres. Former FDA employees, now consultants, will give presentations on current regulatory issues and answer your regulatory questions. Vendors and attendees can find registration forms and additional information in the chapter section of the PDA Web site at www.pda.org. ■

*— William Stoedter*

**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

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❑ 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 ❑).

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**USA Fax: (301) 986-1093 (credit cards only)**

Payment must be included to be considered registered.

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***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 04/01**

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## FDA Documents Available

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## PDA Books Available

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

## PDA Technical Reports Available

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

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

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

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

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# Calendar of Events

See page 26 for the continuing list.

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

## APRIL

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

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

## MAY

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

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

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

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

May 17–18, 2001
**PDA-TRI Course: Computer Products Supplier Auditing Process Model: Auditor Training**
(*at the R3-Nordic Annual Symposium; see page 7 for contact information*)
Stockholm, Sweden

## JUNE

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

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

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

## JULY

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

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

## AUGUST

August 6–8, 2001
**PDA-TRI New Orleans Course Series**
New Orleans, LA
August 6, 2001
**- Understanding the Regulatory Compliance Requirements of the US Pharmacopeia**
August 6–7, 2001
**- A System Based Approach to an FDA Inspection**
August 6–8, 2001
**- Tablet Formulation**
August 7, 2001
**- Good Documentation Practices**
August 8, 2001
**- Conducting Compliant Deviation Investigations for the Pharmaceutical Industry**
**- Everyday Compliance**
**- Designing Regulatory Training that Works**

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

## SEPTEMBER

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

*continued on page 26*