Volume XXXIX, No. 7

PDA Letter

July 2003

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

ACPS Manufacturing Subcommittee Update, page 15

PDA Provides Comments on Effectiveness of Team Biologics Program

On May 21, Russell E. Madsen, PDA Senior Vice President of Science and Technology, presented PDA's comments at an open public meeting on the effectiveness of FDA's Team Biologics Program. The comments were developed by a PDA task force led by Terry Munson, KMI, a division of PAREXEL International, LLC. Other task force members included Daniel Albrecht, ZLB Bioplasma AG; Don Baker, Baxter BioScience; Rebecca Devine, Regulatory Consultant; Russell Madsen, PDA; Amy Scott-Billman, GlaxoSmithKline; and Steve Mendevil, Amgen.

In an April 15, 2003 letter from Jesse L. Goodman, M.D., Director, Center for Biologics Evaluation and Research (CBER) and John M. Taylor, Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), FDA announced the open public meeting to obtain information regarding "specific methods, tools, criteria and metrics" to evaluate the Team Biologics program in the following areas:

1. Industry compliance with applicable laws and regulations;
2. The consistency of our inspection and compliance activities;
3. The effects of our inspection and compliance activities on product quality; and
4. The impact of our approach on public health.

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PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits—*Now in its 14th Year!*

Navigating Current GMPs: Catch the Compliance Wave

Don't let corporate budget cuts and travel restrictions get in your way! If there is only one conference you are able to attend this year, don't miss your chance to join representatives from FDA and PDA for this important conference in Washington, DC.

September 8–12, 2003

Omni Shoreham Hotel
Washington, DC

Conference: September 8–10

Tabletop Exhibits: September 8–9

Courses: September 11–12

Confirmed FDA participants include:

Lester Crawford, DVM, Ph.D., Deputy Commissioner
Murray M. Lumpkin, M.D., Principal Associate Commissioner
Jesse L. Goodman, M.D., M.P.H., Director, CBER
Mark Elengold, Deputy Director, CBER
Helen Winkle, Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Science
Ajaz Hussain, Ph.D., CDER
Joseph C. Famulare, CDER, Director, Division of Manufacturing and Product Quality
Rick L. Friedman, CDER
Nicholas Buhay, CDER
Mary Kremzner, CDER
Warren F. Rumble, CDER, Ombudsman
Yana Mille, CDER
Gary German, Office of Regulatory Affairs (ORA)
Seamus O'Boyle, CBER
Sheryl Lard Whiteford, CBER, Ombudsman
Robert Coleman, ORA
Patricia Lefler, ORA
Jean Blackston Hill, ORA
Marie T. Falcone, ORA
Mark Kramer, Director, FDA Combination Products Program
Sharon T. Risso, CBER
Pedro Piccardo, CBER
Laurie Lenkel, Office of Compliance (OC), Office of the Ombudsman
Christopher Joneckis, Ph.D., CBER
David Horowitz, CDER

continues on page 28

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- **International Technical Support**
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- **Manufacturing Engineering**
- **Microbiology**
- **Operational Excellence**
- **Packaging**
- **Process Engineering**
- **Project Engineering**
- **Process Validation**
- **Quality Assurance**
- **Quality Assurance - Auditors**
- **Quality Systems**
- **Supplier Management**
- **Tablet Coating**
- **Tablet Manufacturing**
- **Technical Investigations**
- **Technical Writing**
- **Technology Transfer**

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Director, Communications & Marketing
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Editor/Writer
Janet Raysick
Production Manager

PDA Letter

Important Dates...

- **January 31, 2004—deadline for entries for 2004 Trainer's Choice Awards—see page 27**
- **PDA/FDA Hotel Discount Deadline—August 1st or until room block is filled. *Reserve your room today!***

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Neal G. Koller
PDA President

Member Opportunities in PDA Science and Technology—Building the PDA Science and Technology Legacy

by Neal G. Koller

Science and technology are the foundations upon which PDA was built. They remain today the center of our society. PDA's reputation for delivering state-of-the-art, foundational scientific and technical information is unparalleled.

The PDA logo states "PDA, An International Association for Pharmaceutical Science and Technology" which is the core of our reason for being. The mission of PDA is to advance pharmaceutical and biopharmaceutical technology internationally by promoting scientifically sound and practical technical information and education for industry and regulatory agencies.

PDA delivers on our Science and Technology mission in a number of ways:

1. **Technical Reports**: Widely recognized by industry and regulators worldwide as foundational scientific and technical information, PDA members have been the developers, writers, and owners of 36 Technical Reports. To assure PDA stays at the leading edge in this dynamic environment, **10 new Technical Reports** are currently being developed and another **4 Technical Reports are currently being revised**. (Please see the article on page 15 for the listing of current technical report activity).
2. **The Science Advisory Board (SAB)**: Led by Dr. Jim Agalloco and based on inputs from our global membership, the SAB sets the PDA Science and Technology agenda and is supported by an army of expert working groups. (Please see the article on page 15 for a listing of current SAB Working Groups).
3. ***PDA Journal of Science and Technology***: Edited by Dr. Lee Kirsch of the University of Iowa College of Pharmacy, the *PDA Journal* has been a widely recognized peer-reviewed journal for 57 years addressing critical scientific issues facing the industry. PDA's Frederick D. Simon Award is presented annually to recognize the best paper published in the *Journal* during the previous calendar year.
4. **PDA Meetings**: Feature speakers addressing the most current science and technology topics.
5. **PDA Training and Research Institute (PDA-TRI)**: Utilizes the latest and best science for its prestigious industry and regulator training courses.

Science and technology have been PDA foundational core strengths and continue to be industry leading, fulfilling our stated goal to be stewards of our scientific mission. The opportunities for a PDA member to participate in the advancement of pharmaceutical and biopharmaceutical science and technology internationally have no equal.

Most importantly, PDA draws our strength from the technical expertise of our membership. The contributions of members, past and present, have left quite a legacy for the industry. PDA's scientific base is our membership. It is this scientific focus that sets us apart and is the basis for PDA's credibility, well earned by following the steps of the scientific process throughout the years.

The PDA Science Advisory Board forms the center of the opportunities for membership participation. Recently, members have expressed interest in establishing SABs based in Europe and the Pacific Rim to focus more deeply on regional scientific issues. Regional SABs would provide enhanced input and tie-in to the global science, and enable members to participate regionally within local business day hours. As we investigate the formation of regional SABs and how to coordinate them for a global PDA position, we encourage members who wish to participate to contact:

Russ Madsen
Senior Vice President for Science and Technology
madsen@pda.org.

This can be another opportunity for members to influence industry science and technology.

It is only through the efforts of tireless PDA members that we are able to achieve this standard of excellence. And today more than ever, the opportunity has never been greater for our members to contribute to science and technology through PDA.

Note: Future issues of the *PDA Letter* will profile the results of PDA science and technology initiatives. ■

U.S. Regulatory Briefs

FDA Announces Guidance for Industry on INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "INDs (Investigational New Drug Applications) for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls (CMC) Information." The guidance is intended to: (1) ensure that sufficient data will be submitted to the agency to assess the safety and quality of the proposed clinical studies from the CMC perspective; (2) expedite the entry of new drugs into the marketplace by clarifying the type, extent, and reporting of CMC information for Phase 2 and Phase 3 studies; and (3) facilitate drug discovery and development.

In the *Federal Register* of April 21, 1999 (64 FR 19543), FDA announced the availability of a draft version of this guidance entitled "INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format." The April 1999 guidance gave interested persons an opportunity to submit comments through July 20, 1999. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated into the guidance.

The format of the guidance has been reorganized to include the relevant headings and to follow the order recommended for an application submitted in the "Common Technical Document: Quality" format [see the Quality section of the guidance entitled "M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use" that FDA announced in the *Federal Register* on October 16, 2001 (66 FR 52634)].

Additional information has been included to explain the difference between CMC safety information, which should be submitted in an information amendment, and corroborating information that can be submitted in an annual report. As a result of the public comments and editorial changes, the guidance is clearer and more concise than the draft version. Furthermore, the scope of the guidance has been changed to exclude proteins and biologics. The agency is considering developing a separate guidance on INDs for these types of drugs.

For further information, contact:

Charles Hoiberg
Center for Drug Evaluation and Research (HFD-800)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(301) 827-5918

Copies of the guidance are available from the:
Office of Training and Communications Division of Drug Information (HFD-240)
Center for Drug Evaluation and Research (CDER)
5600 Fishers Lane
Rockville, MD 20857
(301)827-4573 or on the Web at http://www.fda.gov/cder/guidance./index.htm.

FDA Announces Guidance on Photosafety Testing This guidance is intended to help applicants decide whether they should test for photoirritation and to assess the potential of their drug product to enhance UV-associated skin carcinogenesis. The guidance describes a consistent, science-based approach for photosafety evaluation of topically and systemically administered drug products. Basic concepts of photobiology and phototesting are described, along with a process that can be used to make testing decisions or communicate risks.

Use of the principles expressed in this guidance should reduce unnecessary testing while ensuring an appropriate assessment of photosafety. The document does not recommend specific tests, but refers to some available testing methods. Sponsors may choose to use some of these tests to evaluate photoirritation, photochemical carcinogenicity potential, or the potential to enhance UV-associated skin carcinogenesis. Sponsors also can propose other assays that are scientifically sound. Tests involving biomarkers in the skin of humans receiving the drug product may clarify mechanisms of direct or indirect photoeffects seen in nonclinical studies.

Photosafety testing (testing for adverse effects of drug products in the presence of light) is only recommended when it is felt that the results of such testing would yield important safety information or would be informative for the consumer and healthcare practitioner. This guidance can be found at: http://www.fda.gov/cder/guidance/3640fnl.doc.

FDA Introduces Web Site for Postmarketing Study Commitments This new FDA Web site, http://www.fda.gov/cder/pmc/default.htm, is intended to provide information to the public on postmarketing study commitments, also called Phase 4 commitments. Postmarketing study commitments are studies—*required of* or *agreed to by* a sponsor—that are conducted after FDA has approved a product for marketing (e.g., studies requiring the sponsor to demonstrate the clinical benefit of a product following accelerated approval). FDA uses postmarketing study commit-

continues on page 6

U.S. Regulatory Briefs, from page 5

ments to gather additional information about a product's safety, efficacy, or optimal use. Agreements with sponsors to conduct postmarketing studies can be reached either before or after FDA has granted approval to a sponsor to market a product.

The Web site contains the basic information that FDA committed to make available to the public. The information currently available to search includes only postmarketing study commitments that have been reviewed for accuracy and have been made with the Center for Biologics Evaluation and Research (CBER) at any time and those made since January 1, 1991, with the Center for Drug Evaluation and Research (CDER). This site does not include commitments containing proprietary information.

The Web site will be updated quarterly (in July, October, January, and April), at which time additional commitments will be added and the status of existing commitments updated. More details about the specific information that is included on the site are provided on the search page and as part of the "Frequently Asked Questions." If you have any questions or comments related to this Web site, please send them to the Postmarketing Study Commitment Coordinator at pmcweb@cder.fda.gov.

FDA Announces Availability of Three Draft Guidances on Developing Medical Imaging Drug and Biological Products FDA is announcing the availability of three draft guidances for industry on "Developing Medical Imaging Drug and Biological Products." These draft guidances are intended to assist developers of medical imaging drug and biological products (medical imaging agents) in planning and coordinating their clinical investigations and in preparing and submitting INDs, new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to NDAs or BLAs. The draft guidances provide information on how FDA will interpret and apply certain provisions in the agency's regulations on in vivo radiopharmaceuticals used for the diagnosis and monitoring of diseases and conditions.

After considering the comments that FDA received on the revised draft guidance, the agency has decided to issue the guidance again as a draft for comment. The agency has divided the draft guidance into three parts to make it more user-friendly. These three draft guidances are intended to assist developers of medical imaging agents in planning and coordinating their clinical investigations and in preparing and submitting INDs, NDAs, BLAs, ANDAs, and supplements to NDAs or BLAs.

Part 1 of "Medical Imaging Drug and Biological Products," entitled "Conducting Safety Assessments," discusses how to conduct safety assessments of medical imaging agents. Part 2, entitled "Clinical Indications," discusses how clinical development programs for medical imaging agents can be tailored to reflect the use of these agents for the diagnosis and monitoring of diseases and conditions. Part 3, entitled "Design, Analysis, and Interpretation of Clinical Studies," discusses how to design a clinical development program for a medical imaging agent, including selecting subjects, and how to acquire, analyze, and interpret medical imaging data. Collectively, once finalized these draft guidances will provide information on how FDA will interpret and apply certain provisions in the final rule, published in the *Federal Register* of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in diagnosis and monitoring.

For further information, contact:

Kyong Kang
Center for Drug Evaluation and Research
(HFD-160)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(301) 827-7510

or

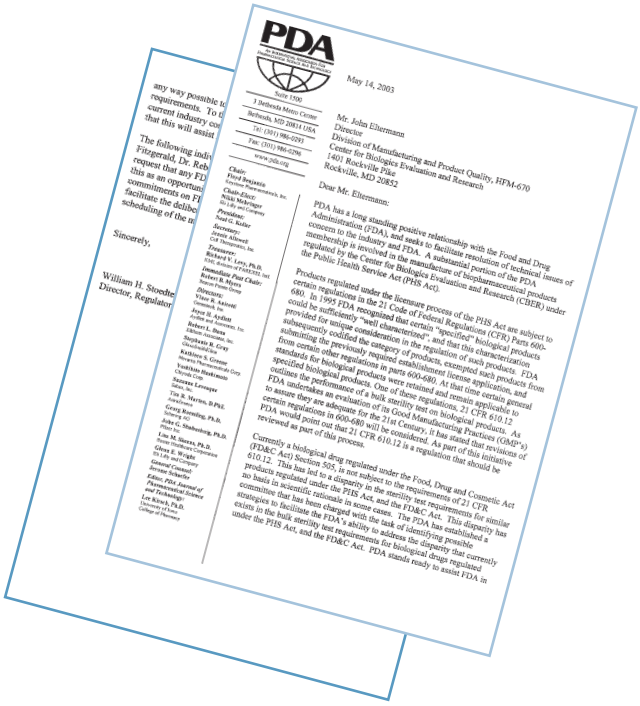
George Q. Mills
Center for Biologics Evaluation and Research
(HFM-573)
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448
(301) 827-5097.

■

—William Stoedter

On May 14, 2003 PDA sent a letter to John Eltermann requesting that CBER reconsider the requirement in 21 CFR 610.12 requiring a sterility test be performed on Bulk Biologic Materials.

May 14, 2003


PDA

May 14, 2003

Mr. John Eltermann
Director
Division of Manufacturing and Product Quality, HFM-670
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852

Dear Mr. Eltermann:

PDA has a long standing positive relationship with the Food and Drug Administration (FDA), and seeks to facilitate resolution of technical issues of concern to the industry and FDA. A substantial portion of the PDA membership is involved in the manufacture of biopharmaceutical products regulated by the Center for Biologics Evaluation and Research (CBER) under the Public Health Service Act (PHS Act).

Products regulated under the licensure process of the PHS Act are subject to certain regulations in the 21 Code of Federal Regulations (CFR) Parts 600-680. In 1995 FDA recognized that certain "specified" biological products could be sufficiently "well characterized", and that this characterization provided for unique consideration in the regulation of such products. FDA subsequently codified the category of products, exempted such products from submitting the previously required establishment license application, and from certain other regulations in parts 600-680. At that time certain general standards for biological products were retained and remain applicable to specified biological products. One of these regulations, 21 CFR 610.12 outlines the performance of a bulk sterility test on biological products. As FDA undertakes an evaluation of its Good Manufacturing Practices (GMP's) to assure they are adequate for the 21st Century, it has stated that revisions of certain regulations in 600-680 will be considered. As part of this initiative PDA would point out that 21 CFR 610.12 is a regulation that should be reviewed as part of this process.

Currently a biological drug regulated under the Food, Drug and Cosmetic Act (FD&C Act) Section 505, is not subject to the requirements of 21 CFR 610.12. This has led to a disparity in the sterility test requirements for similar products regulated under the PHS Act, and the FD&C Act. This disparity has no basis in scientific rationale in some cases. The PDA has established a committee that has been charged with the task of identifying possible strategies to facilitate the FDA's ability to address the disparity that currently exists in the bulk sterility test requirements for biological drugs regulated under the PHS Act, and the FD&C Act. PDA stands ready to assist FDA in any way possible to address the scientific and technical issues of the bulk sterility test requirements. To this end the PDA is requesting an opportunity to meet with the FDA to present current industry concerns, and to offer possible strategies for solutions to the issues. It is hoped that this will assist FDA in their review of the regulation under the GMP initiative.

The following individuals could attend the meeting for PDA: William Stoedter, Dr. Edward Fitzgerald, Dr. Rebecca Devine, Mr. Martin Van Trieste, and Mr. Chris Masterson. We would request that any FDA staff involved in the review of this issue attend the meeting. PDA views this as an opportunity to provide input to FDA's deliberation process, and does not expect any commitments on FDA's part, but looks forward to providing technical information that could facilitate the deliberation process. Please contact me at your earliest opportunity to discuss the scheduling of the meeting.

Sincerely,

William H. Stoedter, RAC
Director, Regulatory Affairs

Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach:

Questions and Answers

The following information consists of frequently asked questions that have been posed to FDA regarding their initiative, "Pharmaceutical CGMPS for the 21st Century: A Risk-Based Approach." This information also can be found on the FDA Web Site at: http://www.fda.gov/cder/gmp/gmp_q&a.htm#q1.

Questions Regarding the Center Review of CGMP Warning Letters

What is Direct Reference Authority? What does the "rescission" of "direct reference" authority for GMP warning letters mean?

FDA district offices have had the authority to issue Warning Letters to firms after inspections of manufacturers of human and animal drugs when the inspectional observations demonstrate that the firm does not meet the requirements of the regulations concerning Current Good Manufacturing Practices (21 CFR, Parts 210 and 211). They also have the authority for Type A medicated articles (21 CFR, Part 226), and medicated feeds (21 CFR, Part 225).

When does the rescission of Direct Reference Authority begin?

FDA District Offices are being advised that Direct Reference Authority for issuing Warning Letters will be rescinded on February 28, 2003. In March 2003, the Centers began reviewing warning letters proposed by the District Offices.

Why are all drug CGMP Warning Letters now going to be reviewed by the Centers?

This will help identify possible program inconsistencies and resolve them before warning letters are issued.

Will the Centers/FDA be doing any kind of evaluation of the inspectional information supporting proposed Warning Letters?

Yes, regular analysis of these data will aid the Centers in identifying trends used to further develop a risk-based strategy towards CGMP enforcement practices. FDA can also use this knowledge to enhance policy, provide guidance, and establish training for the FDA field staff and regulated industry.

What are some of the inconsistencies that the FDA is trying to eliminate and why?

As innovative manufacturing and control technologies are adopted in the pharmaceutical industry, it is important that FDA regulate them in a consistent way. Some of these technologies will be first encountered in FDA's inspection program, and Center review of Warning Letters will help assure that FDA responds to any deficiencies in a consistent manner.

Questions Regarding the Dispute Resolution Process

How would improving the transparency help the regulatory process for resolving disputes?

A more transparent process should be more easily understood and used. Such a process should make it easier to raise scientific and technical issues early on to avoid misunderstandings and reduce inconsistent agency action. In addition, sharing the outcome of technical and scientific issues/disputes should provide greater clarity about regulatory requirements and should facilitate the development and revision of guidance documents. Further dissemination of the results, both internally and externally, should preclude future disputes on the same and related subjects.

Questions Regarding Effective Communications (FDA Form 483)

What reaction does the FDA anticipate in response to the added language clarifying the status of observations on the FDA Form 483?

We anticipate a positive reaction because it clarifies what the document represents. For the firm undergoing inspection, it illustrates that the Agency has a regulatory process and that the FDA-483 is only one aspect of that process. Further, it decreases the likelihood that inspectional observations will be misused or misunderstood.

Is this effort in response to industry complaints about how the press and public perceive the FDA Form 483 they obtain through the FOIA process?

The external and internal interviews we conducted demonstrated a general lack of understanding as to what the FDA Form 483 represents. It is only one piece of the overall inspection process that the Agency employs to make its decisions on the compliance status of the inspected firm. ■

Meet the Regulator

Peter H. Cooney, Ph.D.

Peter H. Cooney, Ph.D.

Peter H. Cooney, Ph.D., is the Associate Director for New Drug Microbiology in the Office of Pharmaceutical Science with the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA.) He has worked in this Office since 2002. In this position, he directs and coordinates product quality microbiology review functions for new drugs within the Office of Pharmaceutical Science. He coordinates the scientific and regulatory components of microbiology reviews for New Drug Applications, Investigative New Drug Applications, and their Amendments and Supplements. Part of his duties also include formulating and implementing policies related to the microbiological review of applications and to issues related to product quality microbiology across CDER. Cooney coordinates the participation of staff and personally participates in non-review activities related to product quality microbiology at the Center, Agency, national and international levels.

Cooney started his career as a Staff Fellow and Microbiologist for the National Institutes of Health in the National Institute of Neurological and Communicative Disorders and Stroke, Laboratory of Molecular Biology, where he worked from 1972 to 1978. He then worked as a Manager of Operations Development in Biological Indicator Production and Control for the Medical Products Division of the American Sterilizer Company. From 1979 to 1982 Cooney served as Chief of the Biological Quality Research Section in the Drug Biocontaminants Branch, National Center for Antibiotics Analysis, Bureau of Drugs, FDA.

Cooney then moved to the Antimicrobial Drugs Branch, Division of Drug Biology in the Office of Drugs of FDA to serve as a Research Microbiologist. After this position, from 1984 to 1988 he was one of two Review Microbiologists for the Division of Surgical–Dental Products for the Center for Drugs and Biologics, FDA. He then acted as the Supervisory Microbiologist for the Division of Surgical–Dental Drug Products for CDER from 1988 to 1995. Before obtaining his current position, he was the Chief and Associate Director for Microbiology in the Office of New Drug Chemistry of CDER, where he worked from 1995 to 2002.

Cooney graduated from Hobart College in New York, where he majored in Biology and minored in Chemistry. He attended graduate school at Syracuse University where he earned his Ph.D. in Microbiology and Molecular Biology. His thesis was entitled "Isolation and Characterization of a New Bacteriophage of Bacillis megaterium: its Relationship to the Study of Sporulation."

Cooney and his wife Adele (a biologist at NIH) have two sons who are completing doctoral degrees in astrophysics at the University of Florida and in biomedical engineering at the University of North Carolina, respectively. He enjoys fishing, both salt water and fresh water, hunting, and golf. ■

—Evelyn Heitman

Associate Director for New Drug Microbiology
Office of Pharmaceutical Science
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

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cooney@cder.fda.gov

Calendar of Events, from page 46

AUGUST

August 16–20, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

SEPTEMBER

September 13–17, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

OCTOBER

October 4–8, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

NOVEMBER

November 1–5, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

European Regulatory and GMP Briefs

EMEA News

Guidance on Chemical Warfare Agents

At the request of the European Commission (the Pharmaceuticals Unit, Enterprise Directorate General), the European Agency for the Evaluation of Medicinal Products (EMEA) and its Scientific Committee, the Committee for Proprietary Medicinal Products (CPMP) have produced a guidance document on the use of medicinal products for the treatment of patients exposed to terrorist attacks with chemical agents. The chemical warfare agents are classified as: blisters and vesicant agents; nerve agents; blood agents; lung-damaging agents; incapacitating agents; lachrymators; and toxins. For each of these classes the information on toxicity, clinical symptoms, treatment management, and medicinal treatment are described.

For further insight into this guideline, please visit the following Web site: http://pharmacos.eudra.org/F2/pharmacos/docs.htm#news.

Guidance on Clinical Trials

DG Enterprises released the Detailed Guidance for the Request for Authorization of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authorities, Notification of Substantial Amendments and Declaration of the End of the Trial as required by Article 9 (8) of Directive 2001/20/EC. This detailed guidance will be included in the Notice to Applicants in the new Volume 10 relating to information on clinical trials. For details, please visit http://pharmacos.eudra.org/F2/pharmacos/docs.htm#news.

CPMP has released for comments a draft Annex II to the Note for Guidance (NfG) on Process Validation–Non-Standard Processes. This draft document is an annex to the March 2001 CPMP/CVMP (Committee on Veterinary Medicinal Products) Note for Guidance on Process Validation. The March 2001 NfG describes the process validation data to be included in marketing authorization applications (as distinct from those validation data that more properly fall under the remit of GMP inspection). The April 2003 draft Annex is intended to further help define "non-standard manufacturing processes" in the context of the NfG on process validation. A brief overview of the draft Annex is provided below.

The March 2001 NfG includes specific data requirements relating to "non-standard methods of manufacture," in particular, an expectation that validation data on production scale batches should be included in the dossier (in contrast to other products, where a validation scheme may be submitted). The March 2001 NfG also includes some examples of "non-standard methods of manufacture" (e.g., "non-standard methods of sterilization," aseptic processing, and, in some cases, lyophilization, micro-encapsulation, and "certain mixing and coating processes and other specialized processes.")

The April 2003 draft Annex is intended to further help define "non-standard manufacturing processes" in the context of the NfG on process validation, and for which production scale validation data may be needed in the MAA. Four main categories are described, with illustrative examples of each (comments should focus on the appropriateness of these categories and the examples given in the Annex):

- The manufacture of specialized dosage forms;
- Specialized processing involving new technologies;
- The incorporation of new technology into conventional processes;
- An established process known or likely to be problematic.

Additionally, processes not previously approved for pharmaceuticals in the European Union are usually considered "non-standard." Manufacturers' experience in "non-standard" processes will be taken into account, and exemptions from the above requirements may be justifiable. More details can be found on the following Web site: http://www.emea.eu.int/pdfs/human/qwp/205403en.pdf. ■

—Gautam Maitra

Executive Meetings

PDA President Koller Advances PDA Science through Meetings with Global Health Authorities and Key Industry and Chapter Executives

Health Authorities

Adding to the successful FDA meeting in April with David Horowitz, Esq., Director, Office of Compliance, Helen Winkle, FDA, CDER, Office of Pharmaceutical Science, and Gary J. Buehler, FDA, CDER, Director, Office of Generic Drugs, Neal G. Koller, PDA President, traveled to Europe in May 2003 and visited with the World Health Organization (WHO), the Switzerland National Health Authority, Swissmedic and the Italian Health Authority Inspectorate. These meetings are part of a continuing effort to advance PDA's science and technology-based relationship with global health authorities.

Koller and Gautam Maitra, PDA Director, Europe, met with the following senior management of WHO: Jonathon D. Quick, M.D., M.P.H., Director, Essential Drugs and Medicines Policy, WHO; Lembit Rägo, M.D., Ph.D., Coordinator, Quality and Safety of Medicines (QSM), Essential Drugs and Medicines Policy, WHO; and Sabine Kopp, Ph.D., QSM, Good Manufacturing Practices (GMP), Guidelines and Inspection. These WHO executives expressed an interest in PDA offering its science, technology and education programs focusing on the needs of developing countries, and offered the potential for PDA to become an official organization invited to comment on WHO guidances.

Koller and Maitra also met with top officers of Swissmedic, including: Klaus-Jörg Dogwiler, Executive Director, and Dr. Rolf Spang, Head of International Affairs. Dogwiler expressed interest in the activities of PDA and pointed out that it would be beneficial for PDA to offer courses on GMP and GCP for the EU candidate countries.

Subsequent to these meetings, Koller traveled to Italy to meet with Carlo Pini, Ph.D., Director, Laboratory of Immunology of the Italian Health

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News from EFPIA Annual Conference

"Europe must do more to encourage innovation for the benefit of patients," says Sir Tom McKillop Athens, GREECE—May 27, 2003—At the Annual Meeting of the European Federation of Pharmaceutical Industries and Associations (EFPIA), Sir Tom McKillop, EFPIA President and Chief Executive of AstraZeneca, reviewed progress on issues of priority for the pharmaceutical industry in Europe. Sir McKillop stressed the need to strike the right balance between health, social and industrial policies. He stated, "Patients in Europe today have increasingly come to expect new and better medicines that will help them live longer, better quality and more productive lives than ever before. Through our intensive research, the pharmaceutical industry can offer them tremendous opportunities and choices in their personal healthcare and well-being. As the European Commission acknowledged in 1994, the legitimate concern to limit public expenditure and healthcare costs—of which it must be remembered that medicines represent only a small fraction—must not be allowed to jeopardize the future of pharmaceutical research in Europe. Public health and healthcare systems have nothing to gain from a weakening of Europe's research-based industry. On the contrary, as one of the key contributors to scientific and medical progress, Europe's economy, and society, the success of the pharmaceuticals sector is crucial to the wealth and health of Europe."

Competitiveness: European Pharmaceutical Industry at Risk Data for 2002 confirm that the European pharmaceutical industry remains one of Europe's best high-technology sectors. It performs well on most standard measures, such as employment (with 582,500 qualified people); production (worth 160bn EURO at ex-factory prices); R&D (19.8bn EURO invested); and trade surplus (with a positive balance of 40bn EURO). However, key benchmarking indicators also highlight the vulnerability of the pharmaceutical industry in Europe and its steady decline in competitiveness compared to the US, which has increased its dominance as an attractive site for R&D and as a 'locus of innovation.'

The European pharmaceutical industry, which has for many years been the world's leading inventor of new medicines, seems to be marking time as its share of R&D investment declines under economic and regulatory pressure. High failure rates, the significant cost of clinical trials and the amount of time needed to get approval by the regulatory authorities are the primary reasons for the exponential increase in pharmaceutical R&D costs. It would be too simplistic to attribute the deterioration of the European pharmaceutical environment to a single factor. As a whole, Europe remains less attractive for R&D investments than other regions, the US in particular. The economic and healthcare environments, the science base, the investment conditions, the regulatory framework, and societal attitudes towards new technologies all contribute.

"US patients are willing to embrace innovation—they want to be informed and to have the benefits of new approaches to healthcare," said Sir McKillop. "In Europe, research shows that patients seek increased access to healthcare information—people also want greater participation in healthcare policies. But Europe's healthcare systems are reluctant to adopt new technologies—they do not seem prepared for the current and future healthcare needs of an aging European population."

G10 and Review of the EU Pharmaceutical Legislation: The Way Forward As a response to the general concern caused by the deterioration of the industry's competitiveness, the G10 process marks an important first step by establishing a discussion platform that involves and commits the various interested parties (Commission, member states, industry, patients, and mutualities) to a set of 14 recommendations. EFPIA now expects the upcoming communication from the European Commission to convert these recommendations into practical steps that will positively contribute to a pro-research environment in Europe.

"G10 gives us a foundation for the way forward to improve the European market environment and address issues raised by the enlargement of the European Union. The review of medicines legislation offers the chance to consolidate progress towards a world class European regulatory framework," declared Sir McKillop. "For the first time in many years, there is a glimmer of hope that the issues really affecting the pharmaceutical industry are being discussed openly and constructively."

"We need to maintain a high level of intellectual property protection, as well as an efficient and world-class regulatory system in Europe, allowing patients to reap the benefits of therapeutic progress more quickly. We need less bureaucratic government intervention which stifles competition, discourages innovation, and creates significant inequity among European patients' access to new therapies. All of us—governments, regulators, industry, healthcare providers, and above all patients—have an opportunity to work together to deliver a vibrant pharmaceutical industry for

the benefit of the 450 million citizens in an enlarged Europe," concluded Sir McKillop.

EU Enlargement; Innovative Medicines Can Significantly Improve Public Health in Accession Countries Also at the annual meeting of EFPIA, a workshop was organized on Economic Union (EU) enlargement entitled "European Healthcare in 2010," bringing together over 180 EU and accession countries' policy-makers as well as senior pharmaceutical industry delegates. Although EU enlargement is just around the corner—with 10 countries set to join the EU on May 1, 2004, EFPIA Director General Brian Ager pointed out that accession countries still face enormous public health and healthcare challenges. The standard of healthcare provisions in accession countries actually has not been part of the accession negotiations, which concentrated on candidate countries' capability to implement the acquis communautaire.

The EU enlargement workshop had focused instead on the issues that would matter most for the citizens of the new members—the evolution of healthcare needs, the reform of healthcare systems, the empowerment of patients, and the role of the EU. Recent European Commission analysis had suggested that it might take the new members 40 years to "catch up" with the existing members, both in GDP and in healthcare investment. Mr. Ager questioned whether more could be done to bridge the "health gap." Referring to a recently observed trend of some accession countries to respond to external financial disciplines by reducing the share of their budget dedicated to healthcare, Friedrich Breitenstein, Chair of EFPIA's Enlargement Action Team, challenged the assumption that this was cost-free, arguing that increased investment in healthcare is absolutely critical to the longer-term success of enlargement.

Health and Enlargement—The Role of the Pharmaceutical Industry It must be clear that innovative medicines can play a significant role in improving the quality and efficiency of healthcare delivery as well as improving overall socio-economic welfare. "Our priority therefore is to ensure that our research-based industry is rightly seen and valued in the enlarged Europe as an important and positive contributor to public health," said Mr. Breitenstein. "The success of the EU enlargement project in the pharmaceutical area will depend on guaranteeing the flow and availability of innovative medicines in newly acceding EU states, without jeopardizing the foundations and legitimate interests of European research-based companies," stated Mr. Breitenstein.

Regulatory News

Review of EU Pharmaceutical Legislation: EFPIA calls on Member States to Adopt World Class Regulatory Framework for Innovative Medicines Ahead of the EU Health Council (2–3 June), the European Federation of Pharmaceutical Industries and Associations (EFPIA) reminded EU Member States that a key objective for the review is to help the pharmaceutical industry find new and better treatments for the benefit of patients.

"EU Member States have an opportunity to set a more favorable legal framework for research and patients for the next 10–15 years," said Brian Ager, EFPIA Director General. "The Commission's initial proposal presented a balanced package. There is growing evidence of the relative decline of European industry's competitiveness in the pharmaceutical sector. This review is an opportunity to contribute to improving the situation."

Key priorities for EFPIA are:

- Regulatory Data Protection—Industry supports 10+1 years data protection as endorsed by G10—This will be an essential driving force for research in Europe;
- Regulatory Procedures—Industry supports improvements to ensure a strong and effective EMEA/Centralized Procedure, together with improvements to facilitate business operations;
- Business Flexibility—Industry supports legislation to facilitate business operations;
- Pharmacovigilance—Industry strongly supports the strengthening of the EU market surveillance and pharmacovigilance system;
- Added Therapeutic Value—Industry believes that the introduction of the concept of "added therapeutic value" as a criterion for product registration would have a negative impact on public health;
- Information to Patients—EFPIA welcomes steps that allow patients and consumers better access to information regarding medicine.

"If these points are not addressed, Europe will take a serious step backwards. We support the Commission's initial proposal on regulatory data protection (10+1 years), a strong and effective EMEA, and improvements in the Centralized Procedure to allow business flexibility," declared Sir Tom McKillop, EFPIA President and CEO of AstraZeneca. "We call on EU Member States to encourage pharmaceutical innovation. In the light of current and future disease threats (e.g., SARS), it is clear that patients and Europe in general can only benefit from industry's capacity to innovate to defeat disease. In any event, the future of Europe will not be secured by its ability to copy." ■

—Gautam Maitra

The 27th International Exhibition—

Report: Congress on Chemical Engineering, Environment Protection, and Biotechnology

The world's biggest chemical exposition of its kind, ACHEMA, was held in Frankfurt from May 19–24, 2003. More than 5,000 companies and research institutions from 55 countries representing chemical engineering, environmental protection and biotechnology were present this year in Frankfurt. ACHEMA 2003 is also the Year of Chemistry in Germany. ACHEMA is a unique event that demonstrates to a broad public just how indispensable chemistry and all its products have become to our technological civilization. Many of the special events, study courses, panel discussions on chemical companies of the future, trends in industrial research, functional food and molecular medicine, along with the new Recruitment Forum are measures to ensure the future of chemistry and thus, the basis of our existence.

I had the honor to be invited by Sartorius to one of their seminars entitled, "Discover How to Increase the Efficiency of your Biotech Production Process," where I was asked to speak about the "Evaluation of the Regulatory Environment in Biotech Manufacture—A PDA Perspective." It was a very good platform for knowledge exchange. The subjects covered included: integrated manufacturing in pharmaceutical biotechnology; validation and scale-up concepts for membrane absorbers for viral removal; and the purification, automation, and validation of bioprocess equipment.

Over 1,500 exhibitors presented the latest processes and services in the areas of air pollution control, water and waste water treatment, waste technology and recycling, soil remediation, noise abatement, environmental measurement techniques and analysis, pharmaceutical analysis technique, and energy conservation. The new policy for the environment of the European Union has given added impetus to the development of integrated solutions for environmental protection and for efficient purification processes. Best available technologies (BAT), ecoefficiency, and green chemistry have become the buzz words in integrated environmental protection and in the merging of ecology with business. The exhibition and congress in ACHEMA 2003 reflected this development.

It was apparent at ACHEMA that pharmaceutical analytical technology was undergoing a rapid transformation in light of the new GMP initiative involving Process Analytical Technology. There were numerous seminars where NIR, among others, was discussed as the appropriate technique. ■

—Gautam Maitra

2003–2004 INTERNATIONAL CALENDAR

September 29–October 1, 2003
PDA/EMEA European Virus Safety Forum
Hosted by the PDA Central Europe Chapter in collaboration with EMEA and the Paul-Ehrlich-Institut
Frankfurt, GERMANY

October 13–14, 2003
2003 Taormina International Conference
Managing for Quality in a Cost-Focused Environment—An International Conference featuring Global Health Authority Experts and Senior Level Executives from the Pharmaceutical Manufacturing Industry
Conference: October 13–14
Tabletop Exhibits: October 13–14
Grand Hotel Timeo & Villa Flora
Taormina, Sicily, ITALY

December 15, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

2004

February 16–20, 2004
2004 PDA International Congress—Basel
Messe Basel Convention Center
Basel, SWITZERLAND

May 17–21, 2004
2004 PDA Pacific Rim Congress—Singapore
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
The Ritz Carlton Millenia, SINGAPORE

Stay tuned to **www.pda.org** for the most up-to-date calendar information.

PDA
An International Association For Pharmaceutical Science And Technology

ACPS Manufacturing Subcommittee Update

At the May 21–22 meeting of the newly created Manufacturing Subcommittee of FDA's Advisory Committee for Pharmaceutical Science (ACPS), Ajaz S. Hussain, Ph.D., outlined the goals of the subcommittee and defined the "desired state" envisioned by FDA as the "GMPs for the 21st Century" initiative takes shape. Dr. Hussain is Deputy Director, Office of Pharmaceutical Science, at the Center for Drug Evaluation and Research (CDER). The subcommittee is chaired by Judy P. Boehlert, Ph.D. [See the June 2003 issue of the *PDA Letter* for additional information.]

Hussain defined the "desired state" for pharmaceutical manufacturing and regulatory processes under the "GMPs for the 21st Century" as:

- Product quality and performance achieved and assured by the design of effective and efficient manufacturing processes;
- Product specifications based on a mechanistic understanding of how formulation and process factors impact product performance;
- Continuous "real time" assurance of quality;
- Regulatory policies tailored to recognize the level of scientific knowledge supporting product applications, process validation, and process capability;
- Risk-based regulatory scrutiny related to the:
  —Level of scientific understanding of how formulation and manufacturing process factors affect product quality and performance;
  —The capability of process control strategies to prevent or mitigate the risk of producing a poor quality product.

Topics and priorities set forth for consideration by the Manufacturing Subcommittee included (1) defining "Quality" and "Risk;" (2) evaluating various risk models and risk management approaches; (3) reviewing manufacturing and process control strategies, including process understanding, process validation and process capability; and (4) continuous improvement through the use of prior knowledge (development information) for risk mitigation and justification for less burdensome reporting (e.g., "make your own SUPAC.")

The next meeting of the subcommittee is tentatively scheduled for September 17, 2003. Additional information may be found on the FDA Web site at: http://www.fda.gov/ohrms/dockets/ac/cder03.html#PharmaceuticalScience. ■

—Russell Madsen

PDA Science Advisory Board Moving PDA Science and Technology

PDA's scientific activities provide an unparalleled opportunity for you to be involved. Currently, PDA members are participating in the following **17 active Science and Technology Working Groups** to pursue their science and technology interests:

1. Gas Filtration Task Force
2. API Task Force
3. Aseptic Processing Task Group
4. Biological Indicators Task Force
5. Glass Defects Task Force
6. Audit Repository Center Industry Advisory Board
7. Isolation Technology Task Group
8. Validation of Lyophilization Task Force
9. Microbiology OOS Task Force
10. Packaging Task Group
11. Part 11 Task Group
12. Pharmaceutical Water Task Group
13. Sterile Bulk Processing Task Group
14. Steam Sterilization Task Force
15. USP Packaged Water Committee
16. Viral Filtration Nomenclature Standardization Task Force
17. Visible Inspection Task Force

The following projects are underway within the current 17 Science & Technology Working Groups:

❖ **14 PDA Technical Reports in the pipeline**
- 4 Revisions in process
  - TR No. 22: Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals
  - TR No. 28: Simulation Testing for Sterile Bulk Pharmaceutical Chemicals
  - TR No. 1: Validation of Steam Sterilization Cycles
  - TR No. 3: Validation of "Dry Heat Processes Used for Sterilization and Depyrogenation
- 10 NEW Technical Reports in process on:
  - Filtration of Gases
  - Validation of Plasma Fractionation Processes
  - Standardized Integrity Test and Labeling for Virus Removal Filters
  - Glass Defects
  - Lyophilization
  - Visual Inspection
  - Aseptic Processing of Biologically Derived Materials
  - In-Process Bioburden Concerns for Biologics
  - In-Process and Finished Products Extractables
  - Inspection of Labeling

❖ **7 NEW Technical Bulletins**
- Enclosed with this newsletter
  - Incubation of Damaged Media Fill Units
  - Incubation of Intervention Units in Aseptic Process Simulation Tests (Media Fill)
- In Process
  - Freezing of Microbial Samples Prior to Testing
  - Testing of HEPA Filters in Ovens/Tunnels

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Team Biologics, from cover

Other organizations that made presentations were the Plasma Protein Therapeutics Association (PPTA), the National Hemophilia Foundation (NHF) and the Immune Deficiency Foundation (IDF). A transcript of the meeting will be posted on the Food and Drug Administration's Web site, www.fda.gov/.

PDA made the following points in its presentation and submitted detailed, written comments to the Docket.

Industry Compliance with Applicable Laws and Regulations

- Issues
  – The majority of companies want to comply with applicable laws and regulations;
  – Firms and regulators sometimes have different interpretations of the requirements;
  – Individual inspector interpretations are sometimes a factor in FDA 483 observations.
- Suggestions for Change:
  – Analyze and identify top areas of non-compliance;
  – Develop a guidance to improve compliance in these areas;
  – Measure "repeat findings" as a metric to determine the effectiveness of the compliance programs;
  – Categorize observations as "critical," "major," and "minor;" measure compliance by the number of critical observations per year divided by the number of inspections.

Consistency of Inspection and Compliance Activities

- Issues:
  – Some investigators appear to focus on building a case rather than objectively analyzing the facts of a situation;
  – Inspectional outcomes are often the result of how individual inspectors interpret the GMPs;
  – Inspectors are sometimes not adequately prepared; they have not reviewed the Biologics License Application (BLA) or sBLA or are not aware of agreements between CBER reviewers and the company.
- Suggestions for Change:
  – Provide comprehensive investigator training and certification for areas of competence;
  – Develop mechanisms for the oversight of investigators;
  – Review issues that investigators are citing and make decisions about which should be policies underlying Team Biologics inspections; communicate these to investigators;
  – Develop an effective dispute resolution program.

Effects of Inspection/Compliance Activities on Product Quality

- Issues:
  – The goal of FDA inspections and compliance activities is to protect the public health;
  – Over time this should result in improvements in product quality;
  – Metrics include increased customer satisfaction, a reduction in non-conforming product, and reduced cost;
  – The association between inspection, compliance activities, and product quality is indirect and difficult to measure.
- Suggestions for Change:
  – Develop a methodology that can more accurately measure the effects of inspection/compliance activities on product quality, e.g.,:
  » Evaluate the number of recalls due to known product defects;
  » Evaluate the number and type of complaints and identify related inspection findings.

Impact of Approach on Public Health

- Issues:
  – Effective products almost invariably have an associated potential for harm;
  – Significant adverse effects and contraindications are identified on the approved product insert;
  – Post approval serious and unexpected adverse experiences (SAEs) associated with the use of a therapeutic agent reflect a previously unidentified risk;
  – SAEs may be associated with the product, a user error, or a quality defect;
  – The Team Biologics program can have a negative effect on public health if it inappropriately raises the compliance bar resulting in increased production costs and possible product shortages.
- Suggestions for Change:
  – A reduction of serious unexpected adverse events, normalized to the amount of product distributed could be a measure of the effectiveness of agency inspection and compliance programs;
  – As the agency currently captures both product distribution data and SAE reports, this metric could be tracked using existing FDA systems;
  – This metric also is consistent with the Team Biologics goal of "… an operational and policy approach that fits within FDA's existing structures and systems." ■

—Russell Madsen

Differential Pressure between Isolator and Cleanroom

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 at www.pda.org and join.

This month's posting...

Question

Our site is installing a filling isolator that connects to a class 5 lyophilizer loading room. The isolator is a full isolator, while the Class 5 lyophilizer loading room is a conventional Class 5 cleanroom with conventional gowning. One of the questions we are debating is what the differential pressure between the Class 5 isolator and the Class 5 lyophilizer loading room should be.

One argument is that the isolator is inherently cleaner than the lyophilizer loading room, and that product is more exposed inside the isolator, as the vials are partially stoppered as they exit the isolator. Therefore, the isolator should be positive to the lyophilizer loading room.

The opposing argument is that both the isolator and lyophilizer loading room are Class 5 environments and that there is no requirement for positive pressure between two adjoining rooms of the same classification. Making the isolator positive to the Class 5 cleanroom could possibly introduce turbulence at the isolator/conventional cleanroom interface.

I would like to hear from the members of the Sci-Tech Discussion Group what their experience with interfacing isolators to conventional cleanrooms has been.

Response 1

Keep the isolator positive. I think guidance says minimum 12.5 Pa? This is to keep the isolator as clean as possible between transfers and sterilization cycles. If you sterilize each time, once the transfer is complete you have a rationale for the environment not being compromised by the air change over and therefore you could keep them the same. If you are not sterilizing, there is a possibility that organisms could be transferred, i.e., I would expect the isolator Class 5 to be a higher level of cleanliness than the room Class 5 because the room has operators in it.

Response 2

I would expect the isolator Class 5 to be a higher level of cleanliness than the room Class 5 because the room has operators in it. ISO 14644-1 Class 5 (corresponds to 100 particles in cubic feet equal to or above 0.5 micron in operation) have the same cleanliness whether it applies to a filling isolator or to a manned conventional Class 5 cleanroom.

Response 3

The isolator is still considered a step cleaner than an ISO Class 5 room. I recommend the isolator to be positive to the ISO Class 5 room. In FDA's "2002 DRAFT revision to the 1987 Guideline on Sterile Products Produced by Aseptic Processing," Appendix 1: Aseptic Processing Isolators, (Sec B) Design, Sub-sec.3—Pressure Differential, lines # 1385 and #1387 state that the "Positive pressure differentials from the isolator to the surrounding environment have largely ranged in pressure differentials from approximately 0.07" to 0.2" water gage." In Sub-sec. 4—Clean Area Classifications, lines #1400 to #1405 state "the interior of the isolator should, at a minimum, meet Class 100 standards…A Class 10,000 or Class 100,000 background is appropriate…An isolator should not be located in an unclassified room."

In Annex 1 of the EC GMPs Guideline (found in "The Orange Guide,") item 7—"Isolator Technology" states "The air classification required for the background…should be controlled and for aseptic processing it should be at least grade D."

Response 4

Perhaps I did not explain my rationale adequately. My concern is not simply particulate contamination, but all forms of contamination, including micro and the impact that micro contamination may have on the perception of isolator performance.

If the Class 100 cleanroom is occupied, which no doubt it is—but that is not clear from the original scenario—some of the particulate matter may be due to shedding from operators, and that shedding could also include microbiological contamination. As a Class 100 environment is not sterile, and as such isolated cases of micro contamination in non-critical locations may be of no concern regarding product quality.

Here is my scientific rationale for the presence of a differential between isolator and cleanroom. If there is no pressure differential between the isolator and the cleanroom, there exists the possibility for air exchange, and therefore the possibility for micro contamination also exists arising from the fact that the isolator is not protected. Now, if during routine micro surveillance of the isolator envi-

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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. Visit PDA's Web site at **www.pda.org** to sign up via the Web or send an e-mail to *requests@www2.pharmweb.net*.

USP Update

by Roger Dabbah, Ph.D.

The Second Supplement of USP 26-NF 21, which is to be official on August 1, 2003 (unless otherwise indicated,) has been released. It contains 17 new USP new monographs. These are: Bisoprolol Fumarate; Ceforoxime Axetil for Oral Suspension; Cephalexin Tablets for Oral Suspension; Dextran 1; Fludarabine Phosphate; Fludarabine Phosphate for Injection; Loperamide Hydrochloride Oral Solution; Methadone Hydrochloride Tablets for Oral Suspension; Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution; Pentazocine Injection; Pentazocine and Aspirin Tablets; Pentazocine and Naloxone Tablets; Perflutren Protein-Type A Microspheres Injectable Suspension; Phytonadione Injectable Emulsion; Sotalol Hydrochloride; Sotalol Hydrochloride Tablets; and Tiamulin Fumarate. Four new NF monographs are also included; these are: Coriander Oil; Lemon Tincture; Maritime Pine; and Martime Pine Extract. There are also five current USDP titles that are being changed, effective February 1, 2005, and two titles that are being changed, effective June 1, 2005.

The Second Supplement includes a harmonized chapter on Bacterial Endotoxins Test 85, indicating that the chapter has been published in the three pharmacopeias (USP, EP, JP). Additional information introduced by USP in this chapter is marked by a lozenge sign. Under Chapter 1047: Biotechnology Articles-Tests, two additional tests are published. These are: Capillary Electrophoresis and Isoelectric Focusing, which are harmonized with EP and JP as a Stage 6 document (Adoption).

Also included in this Supplement is the status of the harmonization documents, which appears in Chapter 1196 entitled Pharmacopeial Harmonization. This Chapter discusses the process of harmonization and will be updated on a continuous basis as harmonization proceeds. A number of changes have been introduced to Chapter 2750, Manufacturing Practices for Dietary Supplements, as well.

The USP Conference on Biological and Biotechnology has been rescheduled; it will be held November 18–21, 2003 at the Marriott Crystal Gateway, Crystal City, VA. This three-day conference is composed of plenary sessions and workshops, as well as an interesting panel discussion on the "Equivalence of Biological and Biotechnological Products and Ingredients." ■

Differential Pressure, from page 17

ronment one were to identify a human borne organism in the isolator, one has an extremely difficult time explaining that away, i.e., it may (no doubt will by FDA) be attributed to a breach in isolator integrity, e.g., glove rupture/half suit pin hole, etc.

So, in order to eliminate that possibility and potentially compromise the isolator system, maintain it at positive pressure to all environments irrespective of the classification of the surrounding environment.

Response 5

There is an EU requirement that the room surrounding the isolator is no more than 2 categories higher in contamination level, so an ISO Class 9 (US Class 100) isolator would be expected to be in a room of ISO Class 7 (US Class 10,000).

Response 6

Is this a "scientific rationale" or a "touchy–feely" rationale? It sounds more like you are worried about the quality of your operators than the semantics surrounding the pressure differentials. Note comments, "ranged in pressure differentials from approximately 0.07" to 0.2"," these values are with respect to a Class 10,000 or 100,000 environment. You are dealing with a Class 100 isolator in a Class 100 room with operators that are certified—they are certified, right? Be careful not to box yourself into an expensive corner when it is unnecessary. Don't go for broke, go for quality. I think everyone here would agree that it is necessary for the isolator to be positive compared to the environment, however, in the environment you are discussing, "good" or "should" are words I would begin to think about. Think about how much energy it takes to get your core to the pressures, temperature, and humidity levels where they are; now you want to add an additional level of pressure differential over your core? Good luck getting enough air to accomplish this while not disrupting your core pressure and temperature.

Suppose you can jump through these engineering hoops, what value did you add? You still have an aseptic process good to, what, a three to six log reduction? You will still need to have the full complement of validation, retains, and micro work. Your process is only as good as the weakest link.

If you can have your isolator really positive, great, but I wouldn't push the specification too high.

Response 7

After reading this discussion with interest, I agree that the isolator should be positive to the Class 5 cleanroom, as stated. There is no necessity to be 0.07" to 0.2" positive between two areas with the same classification. The 0.07" to 0.2" specification is more appropriate to connecting an isolator to a room of lower classification. In fact, we follow this specification between the isolator and the surrounding Class 8 room in which the vials are washed and depyrogenated. When vials are exiting from a Class 5 isolator into a Class 5 cleanroom, a high differential pressure will most likely cause more problems, such as horizontal airflow over partially stoppered vials, vial handling problems, etc. A pressure of 0.02" to 0.05" is most likely adequate. ■

Audit Repository Center Provides Instant Access to Completed Audits of Software Providers for Clients in FDA-Regulated Industries

Eliminates "Re-Inventing the Wheel" When Pharmaceutical Manufacturers Require Vendor Compliance and Validation

by Harvey Greenawalt

The Audit Repository Center (ARC) announces the launch of Audit Repository Services, an innovative approach to providing completed audits of software applications used by FDA-regulated pharmaceutical and biotech manufacturers. According to Harvey Greenawalt, ARC president, "The prerequisite for validation under 21 CFR Part 11, companies providing computer products and services including Commercial Off-the-Shelf (COTS) products are required to undergo audits for compliance and validation of the regulations for development of their products. Both software providers and their clients spend great amounts of time and money on audits, when, in reality, they are going over plowed ground again and again. The ARC concept is to provide a safe, secure repository of completed audits, available on a subscription basis. For significantly less investment, a pharmaceutical or biotech company can obtain a variety of completed and FDA-approved audits performed by highly qualified auditors within a standardized industry process."

Mr. Greenawalt explained, "For example, recent surveys of suppliers of computer products and services to the pharmaceutical industry show that the average cost for a provider to support an audit is approximately $9,000. This is only the direct cost for personnel and facilities to support the actual performance of the audit. It does not include costs due to lost productivity while personnel are involved in audit activities. The true cost of an audit can run from $13,000 to more than $20,000 for an audit that most likely has been completed and can be used over and over again."

ARC and PDA Join Forces to Provide Structural Integrity for Computer Products

PDA—recognized as the authoritative voice and leading technical organization in the field of pharmaceutical and biopharmaceutical science and technology—has teamed up with ARC to provide the industry with audits that prove good evidence of the structural integrity of computer products and services used by the regulated industry. PDA Technical Report No. 32 (TR-32) "Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations" (PDA Process) is designed to provide pharmaceutical and biotech companies with the maximum benefit of that verification using a global industry-endorsed program." Pharmaceutical industry members now—at a significantly reduced cost—can obtain this data for the computer services and products they use. The PDA Process repository administrated by ARC for PDA provides the means to share data collected in accordance with TR-32 between and among participating companies.

Benefits of ARC at a glance:

Subscribers to ARC Repository Services report the following benefits:

- 80% reduction in time to obtain and evaluate audit data;
- 50% reduction in cost of doing audit;
- 400% increase in number of audits that can be managed by a single person;
- Enterprise-wide sharing of audit information;
- Standardization of method for analysis and consistent look and feel to reports;
- Seamless integration with acquisition and existing System Life Cycle practices;
- Fulfillment of Part 11 expectations of computer validation and use of COTS products;
- Substantial reduction in employee travel.

Participating Software providers benefit from:

- Audits performed in an expedient, positive and professional manner by experienced personnel;
- Data Collection Tool providing a clear and thorough examination, probing the supplier's practices and determining if they meet industry expectations;
- Time efficient method to reduce cost, satisfy regulatory requirements and provide shareable data, reducing impact on development;
- Reduced product cost to clients;
- Reduction of upfront cost to clients by eliminating duplication,offering continuous improvement of the audit process;
- Secure environment for sharing audit data with pharmaceutical and biotech clients.

To ensure that the ARC Repository Services and the PDA Process are meeting industry needs and keeping pace with emerging technologies, PDA has established the Industry Advisory Board (IAB). The IAB is comprised of representatives from the pharmaceutical industry, PDA, suppliers, and auditors. The IAB is responsible for ensuring that the ARC is functioning in accordance with the PDA Process and industry standards, as well as is providing continuous improvement of the PDA Process.

The Audit Repository Center is headquartered in Pottstown, PA, 19464; phone (610) 970-1083; fax (610) 970-4272; or www.auditcenter.com. PDA is located at 3 Bethesda Metro Center, Suite 1500, Bethesda, MD 20814; phone (301) 656-5900; fax (301) 986-0296; or www.pda.org. ■

Company, Colleague & Product Announcements

Oakwood Laboratories, L.L.C. recently announced the appointment of **Antonio R. Pera** to Executive Vice President and Chief Commercial Officer. In this newly created position he will be responsible for sales, marketing, business development, operations, and administrative functions for the company, which develops and manufactures long-acting dosage forms of pharmaceuticals. Most recently **Pera** was President/COO and Director of Akron, Inc., where he led turnaround efforts for the company, a publicly-held opthamalic and parenteral drug manufacturer. **Pera** holds a B.S. degree from the University of Illinois and an M.B.A. from DePaul University. To find out more about Oakwood Laboratories, please visit their Web site at www.oakwoodlaboratories.com.

Agilent Technologies, Inc. and **Csol plc** announced an agreement to develop and market the integration of **Csol's** Link for LIMS (laboratory information management systems) software products and **Agilent's** networked data systems (NDS), a series of products which include the Agilent ChemStation Plus and Agilent Cerity NDS for Pharmaceutical Quality Assurance/Quality Control. The Link for LIMS software is expected to provide a seamless, bi-directional interface between Agilent networked data systems and any LIMS by using plug-in drivers for all major commercial LIMS. This would allow users of Agilent networked data systems to integrate their chromatography data with their enterprises' LIMS in accordance with common regulatory standards such as GMP or the U.S. Food and Drug Administration's ruling on electronic records and signatures (21 CFR Part 11.) For more information about Agilent Technologies, Inc., visit their Web site at www.agilent.com; information regarding **Csol, psl** can be obtained at: www.csols.com.

BioReliance Corporation has released it Biologics Testing Services Reference Guide.

This is a comprehensive reference source and includes the most recent information concerning biosafety testing requirements for biopharmaceutical products. It includes detailed assay descriptions, testing procedures, and regulatory requirements for biosafety tests offered at BioReliance. The Reference Guide also includes easy-to-use tables outlining testing requirements based on the type of product being tested. The guide describes assays for Cell Line Characterization, Lot Release, Viral Clearance, Raw Material Testing, and Analytical Support. To receive BioReliace's latest news and to review other corporate developments, please visit their Web site at: www.bioreliance.com.

Mettler Toledo introduced its new regulatory assistance packages named Equipment Qualification for titrators, density meters and refractometers. These services are designed to address GxP, A2LA, ISO17025 and FDA 21 CFR Part 11 requirements, and they also support ongoing compliance obligations with re-certification requirements. **Mettler Toledo** factory-trained technicians use certified test equipment and traceable standards to guarantee their instruments are performing to their standards. **Mettler Toledo** is a global supplier of precision instruments and is the world's largest manufacturer and marketer of weighing instruments for use in laboratory, industrial and retailing applications. Additional information can be found at www.mt.com.

Integrated Service Solutions, Inc. announced the launch of its latest service, chromatography, which will provide its customers with flexible, customized services for liquid and gas chromatography. This new service will provide: (1) fixed fee services to eliminate high travel and hourly rate costs; (2) fast on-site response-within 24 hours; (3) scheduled preventive maintenance and emergency services; (4) IQ/OQ/PQ (installation, operational and performance qualifications); and (5) SOP Development. Says President Joseph Uricchio, "[this] enables the company to deliver unparalled service, fast turnaround and complete documentation trails to satisfy regulatory requirements." For more information, go to www.integratedservicesolutions.com. ■

—compiled by Evelyn N. Heitman

Send announcements on personnel changes and new products . . .

. . . to Evelyn Heitman via e-mail at heitman@pda.org or mail a hard copy to PDA headquarters at 3 Bethesda Metro Center, Suite 1500, Bethesda, MD 20814.

PDA/EMEA European Virus Safety Forum

Hosted by the PDA Central Europe Chapter in collaboration with EMEA and the Paul-Ehrlich-Institut

by Georg Roessling

September 29–October 1, 2003

Frankfurt, Germany

This joint PDA/EMEA conference will discuss current issues relating to the viral safety of recombinant proteins, monoclonal antibodies and plasma-derived medicinal products.

The conference will cover regulatory requirements for these products, aspects of testing source materials for viruses, several aspects of virus validation, such as the model virus approach, as well as virus assays and their standardization. Virus inactivation/removal technologies and special aspects of their validation will be discussed.

A separate session will focus on the virus safety aspects of advanced technology medicinal product (gene therapy, cell therapy, xenogeneic cell therapy and products from transgenic animals) and will summarize the current knowledge.

The conference is intended for participants from Regulatory Authorities, Industry, and Academia; participation is limited.

Watch the PDA Web site at www.pda.org for additional information on this important conference. ■

ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

August 20–22, 2003

San Francisco, CA

The Historic Fairmont Hotel

Benefit from Training by the Members of the ICH Q7A Expert Working Group!

This exclusive training workshop has sold out in seven locations in North America and Europe. Register today to ensure that you can benefit from training by regulators and industry representatives who were members of the International Conference on Harmonization (ICH) Expert Working Group. After this session, the training workshop will move to Asia.

FDA, in collaboration with PDA, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA) developed a workshop training series on the ICH Q7A Guidance. The ICH Q7A document, the first GMP guidance jointly developed between regulators and industry, is intended for use worldwide. It impacts any manufacturer who manufactures in, or intends to supply into, the ICH regions (US, Europe, Japan).

This three-day workshop will provide training of regulatory personnel alongside industry participants. Substantial time has been allotted for interactive question and answer sessions.

Highlights

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

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

http://www.fda.gov/cder/guidance/index.htm;

http://www.emea.eu.int/pdfs/human/ich/410600en.pdf;

www.ifpma.org/ich5q.html#gmp.

Who Should Attend

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

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

Learning Objectives

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

Participation is limited; to register, visit PDA's Web site at www.pda.org. ■

—Leslie Zeck

Building on Our Strengths: Quality, Science and Innovation

THE annual conference you can't afford to miss!

2003 PDA Annual Meeting, Courses and Exhibition

Janet Woodcock, M.D., FDA, Director of CDER to Keynote

November 10–14, 2003

Downtown Hilton Atlanta on Courtland NE
Atlanta, GA

Annual Meeting:
November 10–12

Courses:
November 13–14

Exhibition:
November 10–11

Join PDA as we chart the progress of pharmaceutical research, technology, manufacturing and compliance over the past decade. Identify emerging trends and discuss how to effectively and efficiently respond to the growing demand on pharmaceutical production in an evolving regulatory environment. Attend the 2003 PDA Annual Meeting in Atlanta.

Keynote and plenary session presentations will feature:

- An update on FDA (CDER) initiatives and activities;
- A dialogue on the impact of SARS and emerging diseases on the pharmaceutical industry and an exploration of industry's response to these crises;
- A five-year forecast of the industry.

Three distinct session tracks, Compliance Issues, Manufacturing, and Science and Development will feature case studies and presentations from industry experts.

Critical discussion topics include Part 11: the new guidance, quality systems, the aseptic processing guidance document, clinical, biotech and disposable manufacturing, outsourcing, and visual inspections. Presentations on environmental monitoring, process development and cleaning validation are just a few of the featured science and development track topics.

An interactive exhibition will provide information on new concepts, products and services in pharmaceutical science and technology.

Don't miss this unique opportunity to network with colleagues and health authorities. Learn how to effectively respond to changing regulatory expectations, and become better-equipped to embrace the future of the industry. Register today for the 2003 PDA Annual Meeting at: www.pda.org. ■

—Leslie Zeck

PDA-TRI Lecture Courses

November 13

Designing, Monitoring & Validation of Pharmaceutical Manufacturing Ventilation Systems

Auditing Techniques for CGMP Compliance

November 13–14

Basic Concepts in Cleaning and Cleaning Validation

Computer-Related Systems Validation

A Practical Approach to Aseptic Processing and Contamination Control

November 14

Managing in a GMP Environment

Change Control & Documentation

2003 Taormina International Conference and Tabletop Exhibits

Managing for Quality in a Cost-Focused Environment

October 13-14, 2003

Grand Hotel Timeo & Villa Flora
Taormina, Sicily
ITALY

Sponsored by the PDA Italy Chapter

Decision makers responsible for strategy, implementation and management of quality assurance and regulatory compliance will convene in Taormina to benefit from the information exchange and industry case study presentations at this exclusive conference focusing on Managing for Quality in a Cost-Focused Environment. Regulatory representatives and industry experts from around the world will participate in this high-level interactive conference.

The design of the conference, including formal presentations, informal discussions and social events, is specifically designed to enhance interaction among delegates and speakers.

Highlights include:

- Expert executives from leading pharmaceutical firms presenting industry experiences, perspectives and solutions;
- Outside technical experts;
- Legal and regulatory perspectives on consent decrees and other consequences, and how to avoid them;
- Discussion on the development, implementation and execution of a new quality management system;
- Identification of the key elements of building an effective quality system;
- Discussion on supply chain management and strategic contracting.

Participation in this conference is very limited. Please review the official brochure and registration information for this conference, now available online at www.pda.org. A representative from your company should attend. ■

—Leslie Zeck

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Disinfectants & Sporicides

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What is SimpleMIX?

The convenient, patent pending SimpleMIX System provides a sealed multi-chamber container that when activated mixes the two solutions. The top part contains the sterile concentrate disinfectant or sporicide and the bottom part contains the sterile USP WFI Quality Water. Just pull the tab and they instantly mix together.

US and Foreign Patents Pending

Features of SimpleMIX:

- All chemical agents and the WFI Quality Water are filtered at 0.2 microns and manufactured in a Class 100 filling operation.
- Eliminates regulatory concerns for mixing and sterility of the solution.
- No more concerns for mixing concentrate phenolics, quaternary ammoniums or peracetic acid & H_2O_2 with sterile water in aseptic manufacturing operations.
- The contents of the double bag package are sterilized through a validated gamma radiation cycle.
- Lot sterility tested per current USP compendium.
- The system assures the appropriate dilution is made each time in a closed, sterile system.
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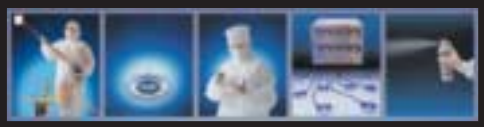

INNOVATIVE CLEAN ROOM PRODUCTS

Visit us at the PDA/FDA Joint Regulatory Conference—Table #29

2004 PDA International Congress—Basel

Product Life Cycle Management for the 21st Century

Messe Basel Convention Center

Congress and Tabletop Exhibition
February 16–18, 2004
Courses
February 19–20, 2004

Congress Overview

Convene in scenic Basel, Switzerland for this prestigious three-day Congress which has annually attracted nearly 500 international professionals and scientists in the parenteral, sterile products, biotechnology and related fields. Participate in high-level education and dialogue among industry and regulatory experts. This is the eighth International Congress PDA has hosted in Europe since 1992.

Who Should Attend?

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

Confirmed FDA Speakers Include:
- » Mark Elengold, Deputy Director, CBER
- » Ajaz Hussain, Ph.D., CDER

PDA Interest Groups

Take advantage of the informal discussion groups to meet with colleagues to discuss specific questions and ideas on such issues as aseptic processing, isolation technology, inspection trends, and visual inspections of parenterals. Interest groups will be offered each day in the morning and afternoon in conjunction with the scheduled program. More detailed information will be available on our Web site at: www.pda.org.

Exhibits

Exhibits provide a great opportunity to see the latest in pharmaceutical and biopharmaceutical science, technology products, and services. Tabletop exhibits will be strategically located in the foyer area outside the main meeting rooms. Three receptions, two lunches and daily refreshments breaks are also scheduled in the exhibit area, maximizing your opportunity to meet with vendors. Exhibitors are encouraged to invite prospective clients to attend the "exhibits only" time period, on Wednesday February 18, from 8:30 am to 12:00 pm., during which time clients will be provided with a complimentary pass. For more information on exhibiting, please contact Nahid Kiani at (301) 656-5900 or via e-mail at: kiani@pda.org.

Congress Highlights

21st Century FDA Initiatives Improving the Control and Effectiveness of Drugs
- GMP Changes
- Regulatory Changes
- Inspections
- Clinical Trials Development

From Current to Future Manufacturing & Technology Trends
- PAT Initiatives
- Contract Manufacturing
- Biotechnology
- Isolation Technology or What?
- Membrane Absorbing Technology
- Standardization of Nano (Virus) Filters
- New Drug Delivery Technologies—Combination Products
- Rapid Development of Vaccines vs. Emerging Global Diseases

Future Trends of Information and Control System Technology in the Pharmaceutical Industry
- Interpretation of Evolving Regulations
- Electronic Common Technical Documents (ECTD)
- Electronic Process Assurance and Control.

Educational Courses

The PDA Training and Research Institute (PDA-TRI) provides unprecedented education, training, and applied research in pharmaceutical sciences and associated technologies. Courses providing in-depth education on technology topics relating to the Congress will be held on February 19–20 following the Congress.

About Basel

Basel, a city of nearly 200,000 people and 2,000 years of history, is located at the elbow of the Rhine on the borders of France and Germany. It is the center of the pharmaceutical industry and the site of major trade fairs. Attendees of this Congress will be staying at the Swissotel Basel, which is conveniently located adjacent to the Messe Basel Convention Center and is accessible by tram, bus, and train. Detailed reservation information will be furnished in future announcements.

The program for this conference is still in development. Visit our Web site at www.pda.org for up-to-date information. ■

—Wanda Neal

Possessing all but super hero powers,

the Environmental Monitoring Software System™ (EMSS™) is here to transform the way you handle environmental and water sampling data. EMSS can collect, document and trend data effortlessly, plus give you complete control of all your sampling and testing.

You may not be able to leap tall buildings in a single bound with EMSS, but you'll feel like the hero when you can comply with regulatory requirements ***and*** exceed industry guidelines.

For a copy of your 21CFR Part11 assessment, contact your local BD representative today.

Visit Booth #31 at the PDA / FDA Joint Conference, September 8-9, 2003, to learn how EMSS can bring the future of data management to your microbiology lab!

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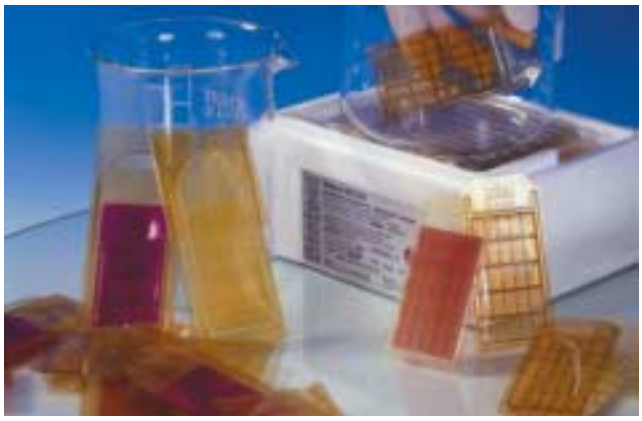
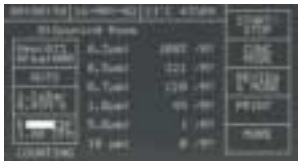


Complete Cleanroom Contamination Control.

Monitoring air quality is the first step to complete contamination control. Biotest designs and manufactures a distinctive line of environmental monitoring products including RCS microbial air samplers, APC airborne particle counters, and contact slides for surface monitoring.

NEW

Cleanroom Champion: The APC Portable.



Touchscreen keypad allows direct access to all settings. All relevant sample information is on screen at all times.

Now you can put another powerful Cleanroom Champion to work for you: The battery-powered, lightweight APC Portable Model P3610. With 0.3 µm sensitivity it measures six particle sizes simultaneously and features a backlit LCD touchscreen keypad for easy readout and programming.

Find more information and how to set up a trial evaluation at *www.APCportable.com*

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PDA SciTech Summit™

March 8–12, 2004, in Orlando, Florida

Experience PDA as you never have before with a newly reformatted conference; collaborative exhibition; a wider variety of educational courses, poster sessions; and networking opportunities galore!

Join PDA at the 2004 SciTech Summit™—an interactive week of activities of interest to those involved in pharmaceutical and biopharmaceutical manufacturing, featuring tracks and sessions on: Science and Technology, Regulatory/Compliance, GMPs in Development, Part 11 Issues, and Biopharmaceuticals. Industry experts, FDA officials, and international health authority representatives have been invited to participate.

Budget today to attend this landmark conference! Plan to bring the entire family to experience the excitement of all that Orlando has to offer.

Biopharmaceutical Track—Call for Papers

Research papers and educational presentations of high quality are sought in the areas of worldwide viral trends, multi-product facilities, costs of quality, transportation validation and related biopharmaceutical fields through the submission of abstracts. Accepted abstracts are scheduled as either poster or oral presentations. By submitting an abstract, the author or authors agree that, if accepted, the paper will be presented as scheduled.

Accepted abstracts of papers must not have been previously published or presented at scientific meetings, must be non-commercial in nature and must contribute to the body of knowledge of biopharmaceutical science and technology.

Proposed abstracts must be received by July 18, 2003 for consideration.

Each abstract submission must be related to one of the conference subject categories listed below. The formats and categories will assist PDA conference planners in organizing the program and in constructing an index of sessions for use by conference participants. If the presenting author prefers a poster presentation, that preference must be indicated at the time of submission.

Topics being considered for the biopharmaceutical track are:

- Worldwide Viral Trends
  - — Viral control issues
  - — TSE, MVM, testing
- Cost of Quality
  - — Risk assessment tools
- Multi-product Facilities Design
  - — Cleaning validation
- Microbiology Monitoring and Validation
- Transportation Validation
- Process Characterization

Other biopharmaceutical topics may be considered. See the enclosed Call for Papers for further details and instructions.

Contact PDA if you are interested in exhibit or speaking opportunities. Watch the PDA Web site at www.pda.org for updated information on the PDA 2004 SciTech Summit™, THE conference to attend in 2004. ■

—Leslie Zeck

2004 PDA Trainer's Choice Awards

Have you developed an innovative approach to delivering a training program or materials? If so, get recognized for your achievement and submit your entry to the Trainer's Choice Awards.

"No Trainer is an Island—Developing and Leveraging Your Training Network for Success" the theme for the biennial professional conference for trainers and human performance technologists once again presents the Trainer's Choice Awards. Established by the PDA Training Task Force, The Trainer's Choice award is presented to trainers by their peers for outstanding achievement in design, development, and delivery of CGMP training programs or materials. There are four categories from which you may make submissions:

- Best Multimedia Presentation
- Best Classroom/Training Manual
- Best E-learning program/Web Page Design
- Best Experiential/Interactive Training

You may submit an entry for each category.

Consideration for this award is open to all trainers currently employed in the pharmaceutical, biotechnology, medical device or biologics industry. Consultants or vendors to such industries are not eligible. Internal training staff must have developed the training programs and materials. **All entries must be submitted by January 31, 2004.**

Preliminary judging is conducted by the PDA Training Conference Committee and final voting will be conducted onsite by training conference attendees. The awards will be presented at the conference closing Awards Luncheon, May 19, 2004 at the Westin Rio Mar, Puerto Rico. ■

—Lisa Wade

PDA/FDA, from cover

What is your return on investment at the PDA/FDA Joint Regulatory Conference?

- Participate in interactive sessions with the FDA and industry experts on a wide variety of compliance-focused sessions.
- Discuss the FDA's new aseptic processing guidance, corrective and preventative actions, inspection trends, legal issues and the new Part 11 guidance.
- Several optional breakfast sessions will be offered to help enhance your knowledge and interaction with the FDA.
- "Meet the FDA" at a luncheon for all full conference registrants, providing an additional opportunity to facilitate discussion on critical issues.
- Meet the FDA Ombudsmen in a special luncheon session (previously scheduled as a breakfast session, this session has been enhanced and moved to a later time on the agenda.)

Enjoy a private performance by The Capitol Steps, a troupe of current and former Congressional staffers who claim to be the only group in America that attempts to be "funnier than the Congress." The Capitol Steps monitor events and personalities on Capitol Hill, in the Oval Office, and in other centers of power and prestige around the world and then take a humorous look at serious issues while providing a laughs for the entire audience.

Individuals of all expertise levels who are involved in pharmaceutical, biopharmaceutical product development, regulatory approval, production and quality assurance including those associated with drug product manufacture, service providers, contract services and US and international regulatory authorities will benefit from participation in this important conference.

Register early on the PDA Web site, www.pda.org, to guarantee your participation in this popular and important regulatory conference. PDA looks forward to welcoming you to Washington, D.C. this September. ■

—Leslie Zeck

PDA-TRI Lecture Courses at PDA/FDA Joint Regulatory Conference:

September 11

Biopharmaceutical QA/QC for Senior Management

September 11–12

Cleanroom Management

CGMP & Compliance

Preparing for an FDA Pre-Approval Inspection

Validation of Sterilization Processes

September 12

Application of CIP to the Pharmaceutical Process

2004 PDA Education and Networking Opportunities

With corporate budget cycles now underway for 2004, make plans to invest in the critical education and training of your employees. Your return on investment will be unmatched as your staff is exposed to credible scientific and technical presentation, networking opportunities with industry leaders, roundtable discussions and access to international regulators.

Benefits of participating in PDA conferences and meetings include:

- CD-ROMs of presentations and conference materials for your company archives;
- Interactive Q&A with FDA, EMEA and industry colleagues;
- Group and early registration discounts to help you maximize your education dollars.

PDA recognizes that you have many opportunities to participate in training and educational conferences being offered by a variety of companies around the world. We encourage you to take a good look at the credibility of what PDA has to offer and the value to your company that will prove profitable for years to come.

PDA has the following opportunities available:

2004 PDA International Congress—Basel, Switzerland
February 16–18, 2004

PDA SciTech Summit™—Orlando, Florida
March 8–12, 2004

Senior Executives Networking Conference—Resort Location, USA
April 22–23, 2004

2004 PDA Pacific Rim Congress—Singapore
ICH Q7A Workshop offered in conjunction with Congress
May 17–21, 2004

2004 PDA Biennial Training Conference, Courses and Vendor Exhibit—Puerto Rico
May 17–21, 2004

PDA/FDA Joint Regulatory Conference—Washington, DC
September 20–22, 2004

We look forward to your participation! ■

—Leslie Zeck

2004 PDA Pacific Rim Congress—Singapore

The Singapore Congress will bring together experts from international health authorities and the pharmaceutical manufacturing industry to discuss critical scientific and compliance issues, new regulatory guidances and emerging worldwide trends. The conference will provide unique opportunities for PDA members and non-members in Singapore and nearby Asian countries to convene to discuss all that PDA has to offer.

Education courses offered by the PDA Training and Research Institute will provide additional opportunities for unprecedented worldwide training and applied research in pharmaceutical sciences and associated technologies. An interactive exhibition will feature the latest advances in technology and services in the industry.

Singapore has been Southeast Asia's most culturally diverse and modern city for more than a century. Easy to explore independently, visitors will discover small shops, a special house, or a temple, or enjoy observing the daily scene. The average daily temperature is 80°F (26.6°C).

Direct, one-stop flights are offered from Los Angeles, New York, San Francisco, and Seattle to Singapore. The Singapore Tourism Board frequently works with travel trade partners worldwide to provide special value-added travel packages to make your visit to Singapore even more memorable.

Individuals engaged in manufacturing, production, quality assurance/quality control, engineering and maintenance operations, facility design, product and process development, scale-up, validation, compliance and regulatory affairs, and research and development will derive significant value from participation in this unique educational and networking opportunity.

A limited number of tabletop exhibits are being offered. Please contact Nahid Kiani at (301) 656-5900 or via e-mail at Kiani@pda.org for details on how to provide information on your company's products and services.

When planning your company's budget, remember that this conference is a must attend. PDA looks forward to your participation in 2004! ■

—Leslie Zeck

The Ritz Carlton Millenia Singapore
May 17–21, 2004

Congress:
May 17–19
Courses:
May 19–21
Tabletop Exhibits:
May 17–19

Meet Your Objectives with PDA

Selecting the right event that can provide opportunities for valuable face-to-face contact with your key clients and prospects, and that can also reinforce your corporate brand/message is a powerful sales and marketing tool. PDA conferences do just that; they are carefully planned and conducted so that you will be able to meet your objectives by delivering:

- quality scientific information;
- coverage of the most timely topics; and
- unique networking opportunities with customers, regulators and health authorities.

The summer is here, so before you leave for vacation, make sure to sign up for your exhibit space at the upcoming PDA shows! PDA has planned a variety of conferences for you to showcase your product and services. Following is a list of these upcoming shows, along with a few reminders:

Be a sponsor *& build recognition for your company throughout the pharmaceutical and biopharmaceutical industries.*

PDA/FDA Joint Regulatory Conference, Courses and Exhibition

September 8–12, 2003, Washington, DC

With extensive participation from FDA this is a MUST exhibit. By now you have received the exhibitor service kit, which includes timely information. Please check the deadlines for submittal of your company description, category listing and number of booth personnel who will be attending.

2003 PDA Annual Meeting, Courses and Exhibition

November 10–14, 2003, Atlanta, GA

PDA is going to Atlanta for the first time!! Take advantage of this unique opportunity to mix business with pleasure. Come to meet new prospects and network with old clients but also set aside time with your family to enjoy the scenery and shopping.

The exhibitor service kit will be mailed by the end of July and keep in mind that the September/October issue of the PDA Journal is the show issue, the September and October issues of the *PDA Letter* are the pre-show and show issues for the PDA Annual Meeting.

Please contact me at (301) 656-5900 ext. 128 to reserve your space! ■

—Nabid Kiani

2003 PDA/FDA Joint Regulatory Conference Exhibitor Listing

Alphabetical by company name with booth location

Accugenix 21
BD Diagnostic Systems 31
bioMerieux Inc. 24
BioReliance 41
Bioscience International, Inc. 30
Brock Solutions 45
Cambridge AccuSense, Inc. 40
Carlisle Life Sciences 34
Charles River Laboratories 25, 26
CIMCON Software 20
CimQuest Inc. 38
Compliance Software Solutions 55
Document Control Systems, Inc. 14
DVT 44
Eli Lilly & Company 19
FOSS NIRSystems 32
Genesis Machinery Products 28
Getinge 8
Grace Engineering and Validation, LLC 37
INTELITEC Corporation 5
KMI, a division of PAREXEL International, LLC 46
La Calhene, Inc. 7
Lansmont Corporation 36
LearnWright, LLC 1
Millipore Corporation 39
NovaTek International 58
Pall Life Sciences 15
Phoenix Imperative Inc. 56
PML Microbiologicals 4
Propack Data Corporation 33
PSI 42
RCM Technologies, Inc. 27
Sartorius Corporation 47
Sparta Systems, Inc. 3
Vectech Pharmaceutical Consultants 22
Veltek Associates Inc. 29
Veriteq Instruments, Inc. 35
West Pharmaceutical Services 6
Working Words 2

VISIT THE EXHIBIT HALL FOR FREE!

Chapter News from the
PDA Taiwan Chapter

by Tuan-Tuan Su, Secretary General

The PDA Taiwan Chapter (TPDA), founded in 1997, has now been in operation for six years. Currently the Chapter has 483 members, 80 percent of which are from the pharmaceutical industry sector. Over the past six years, TPDA has helped the Industrial Development Bureau Ministry of Economic Affairs and the Bureau of Pharmaceutical Affairs of the Taiwan government implement CGMP validation. TPDA has demonstrated its invaluable role as a provider of technical support and training for the pharmaceutical industry, and has, in the process, gained a recognizable presence and reputation in the pharmaceutical community.

In 2001, TPDA accomplished "The Standardization of Chinese Pharmaceutical Terminology," which broadcasts 4,900 pharmaceutical terms on the TPDA Web site, www.pdatc.org.tw. This broadcast contains English terms with their equivalent Chinese terms.

As for the future, TPDA plans to develop relations with the pharmaceutical industry on mainland China, with the goal of assisting in the implementation CGMP validation there. In addition, the Chapter anticipates that the Taiwanese pharmaceutical industry will be at a turning point due to: (1) the continuing decrease in the prices of drugs as a result of the regulation from the Bureau of National Health Insurance; (2) the potential challenges in finance; and (3) the fast growth of biotech companies in Taiwan. These changes mean that TPDA will likely be requested to take an active role in these developments, which in turn, will ensure the continued growth of the Chapter. ■

Upcoming Chapter Events—2003

SEPTEMBER

September 3, 2003
UK & Ireland Chapter Meeting
Training Strategies
Royal Pharmaceutical Society, UK

September 25–26, 2003
UK & Ireland Chapter Meeting
What to Do When Things Go Wrong
Britannia International, Canary Wharf, UK

September 29–October 1, 2003
PDA/EMEA European Virus Safety Forum
Hosted by the PDA Central Europe Chapter in collaboration with EMEA and the Paul-Ehrlich-Institut
Frankfurt, GERMANY

OCTOBER

October 28–29, 2003
PDA Japan Chapter
Annual Meeting
Location: TBA

NOVEMBER

November 20, 2003
UK & Ireland Chapter Meeting
Impact of FDA's Revised Guidelines on Aseptic Manufacture
Keele University Management Centre, UK

See page 43 for PDA Chapter Contacts

Robert Mello, Ph.D.

PDA-TRI Director's Message

Timing is Everything

Actually, in the scheme of life, timing is NOT everything … it just *seems* like everything. Time points, time lines, time cards, time zones, time piece, peace time, dinner time, bed time, plenty of time, not enough time … *time*. Something we all want more of, and something that slips away all too easily.

I thought that today I would bring up the subject of timing as it relates to our PDA-TRI courses and you, our membership.

The timing of world events has had an impact on our PDA-TRI course offerings. Economies world-wide are down and so are training dollars within companies. The Iraq war impacted travel globally, and SARS has had a direct effect on PDA-TRI course events in Singapore (postponed to 2004) and Toronto (rapidly moved to Charleston this past June). Be advised that we *will* be back in Singapore and Toronto in 2004!

Those are the obvious "timing" issues. Here are a few timing issues you may not be aware of, but should know about. First, some courses that are initially offered by PDA-TRI get cancelled. Some course registration figures are too low to warrant the expense of holding the course. That was "Economics 101" in my undergraduate college days. What you may not realize is that the decision to cancel a course can occur two to four weeks before the course is scheduled to start. I have decisions to make about producing the course notes, faculty and staff travel arrangements, hotel room guarantees, and a host of other issues that are (and should be) transparent to you, the course attendee. But you should be aware that they exist. Therefore, it is advisable to you, the attendee, to register as early as possible for those courses that are of interest to you.

So, why not wait until the course date nears? Long before I joined the PDA staff, I was a PDA member, and I attended many previous PDA courses. I always felt that if the course was offered, then it would actually take place. And for me, it did. (For the record, I did register early.) For a variety of reasons though, others may have experienced the disappointment of a course cancellation. Most likely, *time* slipped by in that work-a-day world of ours, and the speed and convenience of fax or online registration can lull us into a last minute sense of "plenty of time." Sometimes it's out of our control since our management hasn't had the time to approve the request. As a result you may miss out on a chance to add to your professional development because too many of your colleagues had similar problems with "timing." That is not to say that you cannot wait until the "last minute" to register. You absolutely can. I would advise, however, that you first check course availability information with our registrar.

So don't delay registering for that PDA-TRI course. Check this newsletter or the PDA Web site (www.pda.org) for the schedule of upcoming PDA-TRI course offerings. Sometimes, "timing is everything." ■

—Robert J. Mello, Ph.D.

Auditors, Trainers, Engineers, Lend Me Your Ears

PDA-TRI August Courses

Auditors, Trainers, Engineers, lend me your ears;
We come to offer knowledge, not stifle your potential.
The training that you gain lives on in your facilities;
The good need not be interred with your bones.
With my humblest apologies to William Shakespeare;
(Julius Caesar, Act 3, Scene 2).

Coming this August to the PDA Training and Research Institute (PDA-TRI) Baltimore facility are three outstanding course offerings of benefit to all personnel—not just those listed above—in the pharmaceutical, biopharmaceutical, medical device and contract manufacturing industries.

Rick Rogers brings his 28 years of experience as a training and development professional to PDA-TRI on August 11–15, 2003, as our faculty for the **CGMP Trainer's Qualification Course**. Not simply a lecture course, this hands-on training course requires participants to first set up their organization's training curriculum, then design training courses to meet these requirements, and finally, to actually deliver classes. Don't miss out on the opportunity to develop your skills as a trainer.

On August 14–15, 2003, **Anne Marie Dixon**, internationally recognized as an expert on cleanroom management, environmental monitoring, and ISO standards, will offer a course on **Compliance Auditing of Cleanrooms and Controlled Environments**. This course is designed to sharpen the skills of auditors required to assess the regulatory compliance of operations conducted in highly specialized cleanrooms and controlled environments. Manufacturing/engineering and QA/QC personnel can learn about critical environments and what internal and external auditors will be looking for during their "time in the plant." Learn from the best, as Anne Marie Dixon's experience in this field is unparalleled!

continues on page 34

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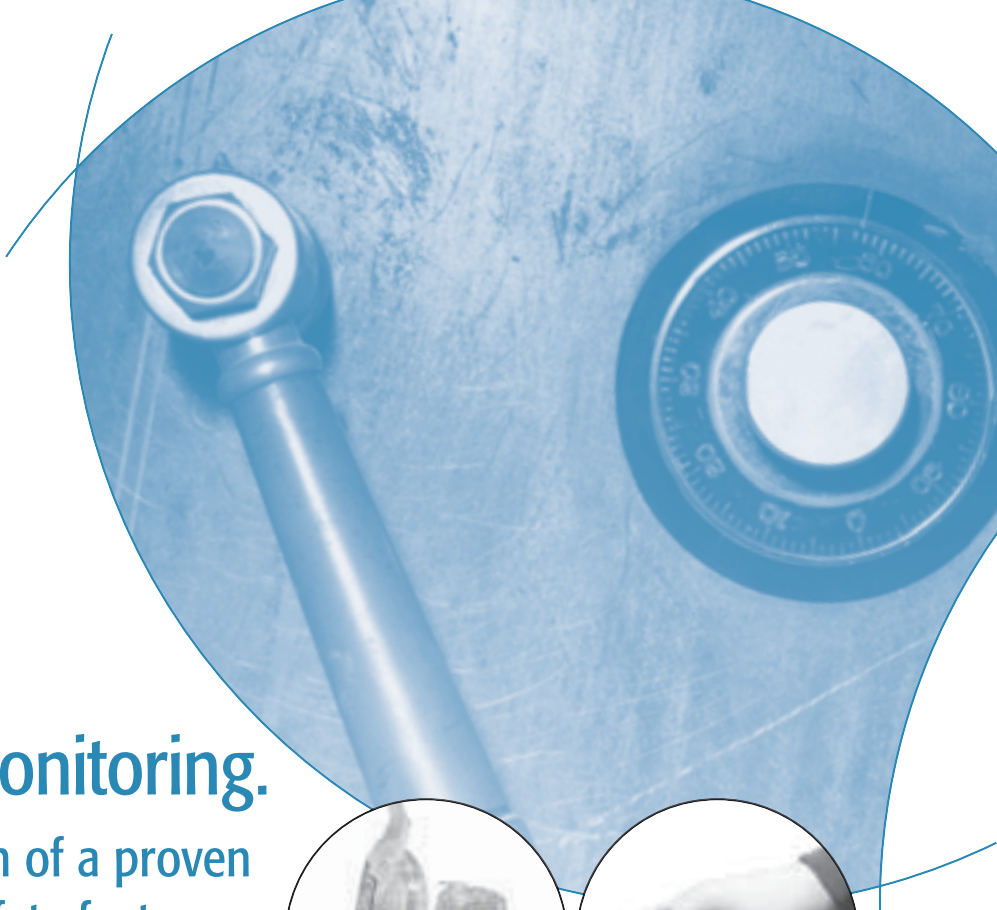

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- Improved storage stability
- Easier transport

Easy to Use

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- No change in methodology
- Secure and easy to open

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BIOMÉRIEUX INDUSTRY

Visit us at the PDA/FDA Joint Regulatory Conference—Table #24

Compliance/Regulatory Training

San Francisco, CA

PDA-TRI San Francisco Course Series August 19–21, 2003

Register now for the training you need to address the compliance and regulatory issues you face each business day. The location is the Fairmont Hotel, San Francisco, California. The dates span August 19–21, 2003.

PDA-TRI, known for providing the industry's most reputable course content, will be presenting a series of nine outstanding courses during this period. Home to the Golden Gate Bridge, cable cars, Chinatown, and more, San Francisco is the perfect setting to expand both your professional and cultural development. Choose from a selection of one-, two-, or three-day courses covering general and advanced compliance and regulatory topics. Here's a brief synopsis of the offerings:

In Jim Vesper's interactive "GMP Fundamentals" course you will learn the five central values found in the CGMPs. Gayle Dolecek, formerly on staff at CDER's Policy and Guidance Branch will discuss the elements of QA/QC and CGMPs in "CGMP & Compliance."

To help you identify several ways to improve your validation efficiency, A. Samuel Clark and Jon Voss will present "Computer-Related Systems Validation." If you need a solid overview of sterile manufacturing, formulation development, microbiology and compliance training, Mike Akers and John Ludwig team up to bring you "Sterile Pharmaceutical Dosage Forms: Basic Principles."

Corporate trainers developing internal training programs for multi-disciplinary personnel will benefit greatly from "Introduction to Competency-Based Training" taught by David Gallup and Richard Sands, experts in "training the trainers." Jim Vesper also will be presenting "Managing in a GMP Environment," a workshop-style course for pharmaceutical industry managers who are responsible for GMP implementation in their organization.

Individuals who must quickly resolve problems need to learn advanced skills in root cause analysis and problem prevention. Ken Peterson will train you in these skill sets in "Analytical Problem-Solving for CAPA Systems."

Dr. Alan Smith combines lecture, workshop and question/answer sessions during his course on "Annual Product Reviews: How to Comply with FDA and ICH Requirements." The course covers both drug product and drug substance (APIs/active pharmaceutical ingredients) issues.

Attend Jeff Masten's course on "Good Documentation Practices in the Pharmaceutical Industry" and be introduced to the fundamental documentation principles and industry standards that are required to produce high-quality records that will support the manufacture and testing of pharmaceutical products.

As you can see, the lineup is packed with high-quality training content to assist your pharmaceutical professional development. AND, it's being held in a great city!

For further details on content as well as registration information, obtain a copy of the PDA-TRI San Francisco brochure, available at info@pda.org, or download a copy of the brochure now at http://www.pda.org/PDF/TRI-SanFranSeries-Bro.pdf.

Use the URL https://store.pda.org/events/registration/registration_start_choose_type.asp to register online NOW and secure your spot at one or more of the courses.

Don't miss this outstanding opportunity. Register now! ■

——Robert J. Mello, Ph.D.

PDA-TRI August Courses, from page 32

If you are employed at a sterile processing facility and are looking for training in sterilization technology, then join us on August 21–22, 2003 when **John Shirtz** teaches the **two-day** laboratory element course on **Fundamentals of D, F, and z Value Analysis**. Learn the meaning of this often misunderstood terminology and understand the history of biological indicator technology. In the laboratory, develop actual data by performing test cycles in the PDA-TRI laboratory BIER vessel.

Finally, if you feel the need to just "get away" for training, check out one of the nine course offerings of the **PDA-TRI San Francisco series** being held in the Golden Gate city on August 19–21, 2003 (see additional information in this issue).

So, come to PDA-TRI in Baltimore this August for the best in professional development training. I promise—no more Shakespeare. ■

——Robert J. Mello, Ph.D.

The brochure for the upcoming PDA-TRI course "Fundamentals of D, F, and z Value Analysis" being held August 21–22, 2003, contains an error in the faculty description section. The correct affiliation for John Shirtz is as follows:

This course is taught by Mr. John Shirtz. Mr. Shirtz is Director of Quality at American Pharmaceutical Partners in Grand Island, New York. Prior to this he was Manager of Quality Control Microbiology at Catalytica Pharmaceuticals in Greenville, North Carolina. His career also includes quality management positions with Glaxo Wellcome, Burroughs Wellcome and Bristol-Myers Squibb. He has experience with all compendial microbiological and chemical requirements, and has been involved with both sterile and non-sterile product validation for many years. He has authored several journal articles and book chapters on various aspects of microbiological testing, served as a PDA member and publication reviewer since 1982, and served as the Treasurer of the PDA Southeast Chapter. Mr. Shirtz holds a B.S. in Biology from the State University of New York at Albany, and an M.S. in Molecular Biology/Biotechnology from East Carolina University.

We apologize to John Shirtz and all of the membership for this error and regret any inconvenience it may have caused.

2004 Aseptic Processing Course Dates

The 2004 dates for the PDA Training and Research Institute (PDA-TRI) laboratory course on Aseptic Processing have been established. This extremely popular 2-week course sells out rapidly, so we urge you to register early. Due to the intensive hands-on nature of this course, class registration must be limited to 20 students per offering (or Option, as it is called). In response to the overwhelming registration requests for the four Option dates in 2003, PDA-TRI has added a fifth Option date to this series in 2004 in order to accommodate our members' requests. The 2004 dates are as follows:

Option I
Week 1 January 26–30, 2004
Week 2 February 23–27, 2004

Option II
Week 1 March 22–26, 2004
Week 2 April 26–30, 2004

Option III
Week 1 May 24–28, 2004
Week 2 June 14–18, 2004

Option IV
Week 1 August 16–20, 2004
Week 2 September 13–17, 2004

Option V
Week 1 October 4–8, 2004
Week 2 November 1–5, 2004

——Robert J. Mello, Ph.D.

Registrations for the 2004 series are being accepted. Visit www.pda.org for more information, or contact info@pda.org.

Upcoming PDA-TRI Education Courses

Courses listed in alphabetical order

Aseptic Processing 2003 Training Program—Lab **Option 3**: August 25–29, 2003 and September 22–26, 2003; **Option 4**: October 27–31, 2003 and November 17–21, 2003; $7,500 members/$7,695 nonmembers; *Faculty:* John Lindsay and David Matsuhiro SOLD OUT SOLD OUT

CGMP Trainer's Qualification Program—Lecture August 11–15, 2003; October 20–24, 2003; $3,450 members/$3,645 nonmembers; *Faculty*: Rick Rogers

Compliance Auditing of Cleanrooms and Controlled Environments—Lecture August 14–15, 2003; $1,350 members/$1,545 nonmembers; *Faculty*: Anne Marie Dixon

Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance—Lab October 8–10, 2003; $2,500 members/$2,695 nonmembers; *Faculty:* Bob Livingston

Ensuring Measurement Integrity in the Validation of Thermal Processes—Lab November 6–7, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* Göran Bringert

Environmental Mycology Identification Workshop—Lab October 2–3, 2003; December 4–5, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* John Brecker

Fundamentals of D, F, and z Value Analysis—Lab August 21–22, 2003; $2,000 members/$2,195 nonmembers; *Faculty:* John Shirtz

Rapid Microbiological Methods December 8–12, 2003; $4,500 members/$4,695 nonmembers; *Faculty:* Jeanne Moldenhauer

Cleaning Validation—Lab October 13–15, 2003; $3,000 members/$3,195 nonmembers; *Faculty:* Jon Voss and Bob O'Brien ■

These courses will be held at PDA-TRI in Baltimore, MD unless otherwise noted.

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

For registration information, call PDA headquarters in Bethesda, MD at **(301) 656-5900**.

PDA-TRI Location/Lodging Information

Unless otherwise noted, PDA-TRI courses are held at: PDA Training and Research Institute, 1450 South Rolling Road, Baltimore, MD 21227, Tel: (410) 455-5800; Fax: (410) 455-5802.

PDA has not secured any specific room blocks for participants attending courses at the Training and Research Institute. There are several hotels in the Inner Harbor (downtown Baltimore) and BWI airport areas. These include, but are not limited to:

Baltimore Hilton & Towers Inner Harbor
(410) 539-8400
(410) 625-1060 - fax

Courtyard by Marriott–BWI
(410) 859-8855
(410) 859-5068 – fax

Baltimore Marriott Inner Harbor
(410) 962-0202
(410) 625-7892 - fax

Embassy Suites BWI
(410) 850-0747
(410) 850-0816 – fax

Homewood Suites BWI*
(410) 684-6100
(410) 684-6810 – fax

Holiday Inn Inner Harbor **
(*Special Rates for our course attendees*)
(410) 685-3500
(410) 727-6169 – fax

Hyatt Regency Baltimore Inner Harbor
(410) 528-1234
(410) 605-2870 – fax

Sheraton International Hotel BWI
(410) 859-3300
(410) 859-0565 - fax

Courtyard Baltimore Downtown/Inner Harbor
(443) 923-4000
(443) 923-9970 – fax

Holiday Inn—BWI ***
(410) 859-8400
(410) 684-6778 – fax

* no on-site restaurant

** **A discounted rate** is available for **Holiday Inn Inner Harbor of $99**. To receive this rate call the number above and mention the PDA-TRI Corporate Rate (ID# 100196574) when making your reservations. **Rooms are based on availability**.

*** **A discounted room rate** is also available from the **Holiday Inn—BWI**. You must call the number above and mention the PDA Corporate Rate (3-PDA) when making your reservations.

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

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

PDA-TRI Thanks the Following...

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Kaye Instruments, Inc.
National Instrument Co., Inc.
Neslo, Inc.
Perfex Corporation
Pfizer, Inc.
Sievers Instruments, Inc.
Technovation

R

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

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

Membership Number

Job Title Company

Business Address

City State/Province ZIP+4/Postal Code

Telephone Fax E-mail

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

LTR 07/03

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

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

3. Please check the appropriate box:

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

Account Number_____ Exp. Date _____

Name _____
(exactly as it appears on credit card; please print clearly)

Signature_____ Date _____

Payments must be made to PDA in US dollars by a check drawn on a US bank, or by American Express, MasterCard, EuroCard, or VISA.

Payment must be included to be considered registered.

4. Return completed form with payment made to:

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

Federal Tax I.D. #52-1906152

Deadline*: Enrollment is limited for the benefit of all attendees; this necessitates early registration. Paid registrations must be received one week prior to the event.*
Confirmation*: Written confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter.*
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 the start of an event (course series, conference, etc.), a full refund, minus a $55.00 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 an 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.*

PDA USE:
Date:_____ Check:_____ Amount:_____ Account:_____

PDA Science Advisory Board from page 15

- – Validation of Biologic Manufacturing Processes
- – Elimination of Sterility Testing for Steam Sterilized Products
- – Microbiological OOS Issues
- • In Development
  - – Chemical OOS Results
- • Other
  - – USP Packaged Water
  - – Aseptic Processing White Paper

❖ **Scientific Comments on Regulation**

- – PDA Member Companies on FDA Aseptic Processing Concept Paper
- – PDA Comments on EC Guide to Good Manufacturing Practice - Revision to Annex 1 (Sterile Products)

❖ **6 Surveys**

- • In Process
  - – Visual Inspection Practices
  - – Extractables
  - – Environmental Control/Facility Design for Tablet and Capsule Operations
- • In Development
  - – Terminal Sterilization Practice
  - – Pharmaceutical Water Systems
  - – Cleaning Validation Practices

❖ **Ongoing Liaison**

- – Blow/Fill/Seal Points to Consider (Blow/Fill/Seal International Operators Association)
- – FDA Manufacturing Technology Subcommittee
- – Inhaler Dosing Project Work Plan (in association with PQRI)
- – Blend Uniformity Working Group (in association with PQRI)

The 24 **PDA Interest Groups** are another key way for PDA members to pursue and influence science and technology. A complete list of Interest Groups and contact persons for members interested in participating in this PDA Science and Technology activity appears on page 45.

Each and every member has an opportunity to participate in PDA Science and Technology activities. Working group members are selected from our corps of PDA volunteers. If you are interested in lending your talent and time to the scientific initiatives at PDA, please send your resume along with a statement of area(s) of expertise to:

Russ Madsen, Sr. VP, Science and Technology madsen@pda.org.

Science and Technology is a PDA legacy, stronger than ever and growing. We are working on new and more ways for members to participate to strengthen PDA's science core. ■

Executive Meetings, from page 11

Authority Inspectorate. Pini and Koller discussed the science and technology work, the SAB and RAQC process within PDA, as the basis for PDA's Training and Research Institute courses, including the current PDA six-module course in Italy to train the Italian Health Authority pharmaceutical and biopharmaceutical inspectors.

In a related meeting on June 5, 2003, Maitra visited the Finland National Agency for Medicines, meeting with Dr. Jussi Holmalahti, Head of the Marketing Authorization section of the Agency, along with Holmalahti's departmental team. The group discussed science and technology points as they relate to regulatory issues specific to the Nordic countries. In particular, Holmalahti and Maitra focused on packaging and labeling of pharmaceuticals and biopharmaceuticals. It was decided that a collection of such topics will be organized and discussed with other Nordic Health Authority experts.

PDA looks forward to becoming an important partner in science and technology, a strong vehicle of communication and to developing greater working relationships with global Health Authorities.

Industry

Koller and Maitra added to the effort to strengthen ties with industry in Europe by scheduling a meeting with R. Stuart Heir, Head of Global Quality Operations at Novartis Pharma AG, Basel. Heir and Koller discussed the value of PDA developing programs for top-level executives from pharmaceutical and biopharmaceutical companies and health authorities, allowing these executives to avail themselves of the association's unbiased position as a forum to advance science and technology. The two determined that it may be beneficial to have a World Pharmaceutical and Biopharmaceutical Forum, similar to the PDA Taormina Conference for industry executives. (This year's Taormina Conference, entitled "Managing for Quality in a Cost-Focused Environment" will be held October 13–14, 2003 in Taormina, Italy.) Heir and Koller suggested critical issues addressed by such a World Forum should focus on return-on-investment for topics ranging from science, technology, education and regulation.

Another valuable meeting was held with the following senior executives and PDA Chapter members in Basel: R. Stuart Heir, Head of Global Quality Operations at Novartis Pharma AG, Bernard Kronenberg, Chairman, Bakrona AG, Annemarie Moeritz, Novartis Pharma; Oliver Schläfli, Head of Quality, Novartis Pharma, Roger Seiler, Production Manager, Sartorius; Finley Skinner, Skinner Pharma-Assist and Carlo Voellmy, Production Launch Manager, Novartis Pharma AG. The group discussed the future direction of PDA, possible plans to further PDA's scientific work and reputation, an enhanced scientific relationship with world health authorities, an effort to provide more opportunity for volunteers to pursue their scientific interests within PDA and the opportunities to help chapters better provide for the PDA members.

Koller will continue developing these working relationships with chapters and executives in industry in Europe as well as around the world. The *PDA Letter* will update you on additional trips planned to Europe in early July and to the Pacific Rim in late July. ■

—Gautam Maitra

NEW BOOKS

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The Essence of GMPs: A Concise Practitioner's Guide U.G. Barad; "The Essence of GMPs: A Concise Practitioner's Guide is a practical book…an immensely readable and engaging book for busy executives and managers of today's competitive pharmaceutical business. U.G. Barad's insight into the makeup of quality system requirements gives pharmaceutical personnel at each stage of their work a vision for developmental needs for systems and procedures."—Hamad A. Al-Khamees, M.S., Ph.D., Professor of Medicinal Chemistry, King Saud University—College of Medicine, Saudi Arabia; This book is a compilation of more than 20 years of experience working with multinational pharmaceutical manufacturing companies and with various regulatory authorities. It incorporates and addresses the essence of GMPs prevailing around the world. It is organized in four sections. The principal section, entitled Essentials, covers policies that are expected to prevail in any pharmaceutical industry. The second section covers policies (prevention of contamination) that are the requirements of non-sterile pharmaceuticals. This section is followed by complete coverage of sterile products, and the book culminates with a complete glossary in part four.

Written for a global audience, it provides readers with excellent practices/standards based on a comparison of the following:

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Supply of Chemicals in the Pharmaceutical Industry: Regulatory Guidelines and Rulings Mark Selby; Although the supply of healthcare products is subject to strict regulatory requirements, only those products in their finished form for supply to the end user are exempt from basic chemical legislation. This basic level of legislation covers workplace health and safety, transport, packaging and disposal of the chemicals used. Chemical supply legislation therefore impacts the production and transport of intermediates, excipients and bulk material, and a failure to comply with this legislation may be a rate-limiting step for the introduction of a new healthcare product.

This informative guide highlights the areas of legislation that suppliers of all chemicals involved in the synthesis and supply of healthcare products should be aware of, and offers details and comparisons of current issues in Europe, the United States, Canada, Australia, Japan and other countries worldwide. Topics include help in deciding how the legislation may apply to you if you manufacture chemicals, pharmaceuticals, or medical devices or are engaged in R & D related to these efforts. The book describes the chemical supply in global terms, discusses the supply of new substances, offers specific cases such as export only, R & D, and clinical trials, provides information about worker health, communication of hazard, and control of pollution, and provides details about lab testing, complete with examples of test guidelines. The book also contains a useful glossary. If you supply any type of healthcare product, it is very likely that at some stage chemical supply legislation has an impact; failure to recognize the importance of such legislation may delay or prevent supply. 160 pp; $185 member/$229 nonmembers; hardcover **Item # 17204**

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Filtration Handbook—Integrity Testing Maik W. Jornitz and Theodore H. Meltzer; This complete guide explains the proper performance of filter integrity testing by clarifying its relationship to bioburden concerns and assessing its role in filter validation. It offers practical approaches to the appropriate use of integrity testing, wetting and temperature requirements, the Bubble Point test, diffusive airflow testing, and much more. Numerous regulatory citations and references complete this invaluable book. 150 pp; $185 members/$229 nonmembers Item # 17197

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, 3rd edition James Vesper; A quick guide to GMP, designed to simplify and enhance the understanding of most of the current GMP expectations and how they apply to ongoing tasks in any given pharmaceutical manufacturing situation. 252 pp; $105 members/$129 nonmembers Item # 17199

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Introduction to Environmental Monitoring in Pharmaceutical Areas Michael Jahnke; Topics discussed include all aspects of cleanrooms, air handling systems, HAACP and risk analysis along with numerous useful charts, tables and figures. 104 pp; $90 members/$109 nonmembers Item # 17182

Media Fill Validation Environmental Monitoring During Aseptic Processing Michael Jahnke; The second in this series of four books. This edition provides current, practical techniques that focus on considerations in the preparation and monitoring of aseptic manufacturing, taking into account the national and international requirements as well as guidelines concerning the validation of aseptic processing. Topics include: Risk analysis, HAACP, Documentation and qualification; Qualification and training of personnel; Scope of validation; Overall requirements; Release requirements; Documentation; and Authorization. The guide also includes an excellent Manufacturing and Testing Master Batch Record, and 25 extremely valuable charts, graphs, and figures. 108 pp; $90 members/$109 nonmembers Item # 17181

Microbiological Monitoring of Pharmaceutical Process Water Michael Jahnke; This quick guide discusses effective microbiological monitoring strategies for testing the quality of process water used in the pharmaceutical industry. 70 pp; $90 members/$109 nonmembers Item # 17193

Microbiology in Pharmaceutical Manufacturing Richard Prince, Editor; Providing valuable knowledge for the novice and the expert alike, many of the world's greatest pharmaceutical microbiologists and engineers, as well as other prestigious thought leaders, have invested their considerable talents in developing this comprehensive collection of timely information on this critically important subject. This book encapsulates current knowledge in a truly wide array of microbiological applications for the reader. It is hoped that this book will demystify the field of microbiology by describing it plainly and systematically from various scientific, technical, and functional perspectives. 900 pp; $240 members/$299 nonmembers Item # 17185

Rapid Analytical Microbiology: The Chemistry and Physics of Microbial Identification Wayne P. Olson, Editor; The old, dendritic methods of identifying microbes can be found in the most recent edition of Bergey's Manual (Holt 1993). The issues with this approach to microbial identification (ID) include the time required to make a critical ID and the accuracy and reliability of IDs. Hence, the introduction and success of automated, rapid methods. This book focuses on the numerous new, efficient, and effective methods currently available and serves as both guide and reference to readers interested in improving performance and accuracy in a timely manner. 2003; 354 pp; ISBN 1-930114-36-2; $195 members/$239 nonmembers. Item # 17184

Steam Sterilization—A Practitioner's Guide Jeanne Moldenhauer, Editor; Contains pragmatic details on how to accomplish the tasks necessary for a sterility assurance program for steam sterilization processes. Each chapter author is a subject matter expert and has a minimum of 10 years of hands-on experience in the topics discussed. The authors use this experience to identify practical ways to perform research, development, validation, and production activities associated with steam sterilization. Many of the chapters include sample standard procedures or protocols that may be used as templates to generate documents for your facility. Other chapters outline and explain the requirements. The book also provides guidance for those individuals who are responsible for the oversight of these processes or those who wish to update their knowledge. While written primarily for the pharmaceutical industry, much of the content may be applicable to the food and cosmetic industries as well. While this book does not specifically address the bulk drug industry, certain information may be applicable to bulk drug manufacturers. Whether your organization is small or large, this book contains insights and techniques that will prove invaluable in your effort to develop and maintain a sterility assurance program for steam sterilization processes. 740 pp; $215 members/$269 nonmembers
Item # 17183

For a full listing of documents available, please contact PDA at (301) 656-5900 or visit our Web site, www.pda.org.

Selected PDA Technical Reports and Supplements

TR 36 Current Practices in the Validation of Aseptic Processing—2001; The validation of aseptic processing continues to be a major area of interest within the pharmaceutical industry. Five years have passed since the last PDA survey on this subject. While there have been no new broadly applicable regulations or regulatory guidance since that time, there has been continued controversy over the details of aseptic processing and process simulation practice. Industry practices largely adhere to current regulations and guidelines on aseptic processing by the European Union, ISO, and FDA. The impact of PDA's TR 22: Process Simulation Testing for Aseptically Filled Products, is also apparent. Over time industry methods, practices and limits have been modified to adapt to the changing circumstances. The Pharmaceutical Manufacturers Association (now PhRMA) in 1979 and PDA in 1986, 1992 and 1996 conducted surveys on this subject that have provided a clearer understanding of contemporary industry practice. This survey addresses the continuing need to track industry practice in the validation of aseptic processing as it evolves. One of the major benefits of surveying on a regular basis is the opportunity to follow the evolution of concepts and practices over time. To that end, this survey instrument used many questions that were nearly identical to those asked in 1992 and 1996. 2001; 34 pages; $75 members/$125 nonmembers. **Item # 01036**

TR 13 Revised Fundamentals of an Environmental Monitoring Program; The purpose of this document is to identify microbiological and particulate control concepts and principles as they relate to the manufacture of sterile pharmaceutical products. This document serves as a source on cleanroom environmental test methods, and although some non-viable particulate and endotoxin testing data are included, its primary focus is microbiological control. The concepts for sterile product manufacturing are the most stringent application, but these concepts can also be applied to non-sterile product manufacture. The focus is environmental monitoring as it relates to facility control and compliance. This document was compiled to aid in setting up a program that is meaningful, manageable, and defendable. 2001; 37 pages; $75 member/$125 nonmember. **Item # 01013**

Points to Consider for Aseptic Processing Volume 57 Number 2 Supplement This document represents over 18 months of dedicated work by the Task Force members. It presents the issues framed as problem statements with both a recommendation and a rationale for the recommendation provided. Some of the topics included in this 72-page report are: airflow velocity and patterns; critical area environments; differential pressures; HEPA filter testing and patching; setting environmental monitoring alert and action levels; the relationship of environmental monitoring results to batch release; investigation of environmental monitoring excursions; critical surfaces; process simulation acceptance criteria; incubation of normally excluded units; interventions; duration of process simulation tests; number of media-filled units. 2003, 72 pp; $75 members/$125 nonmembers **Item # 03004**

TR 32 Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations; Developed in response to an FDA challenge to develop a standard way to assess the structural integrity of acquired software, TR 32 was written by the PDA Supplier Auditing and Qualification (SA & Q) Task Group, which included pharmaceutical companies, suppliers, auditors and FDA members who used their experiences with supplier audits and performed research to draft a common practice to satisfy industry needs. The scope of the project included audits of computer products and services and describes how the SA & Q Task Group, led by George J. Grigonis, Jr., Merck and Co., Inc., developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. December 1999; 277 pp; $90 members/$140 nonmembers (paper copy **Item # 01032**); CD-ROM—$50 members/$75 nonmembers (CD-ROM format **Item # 01132**).

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Calendar of Events, from back cover

October 22
Achieving CGMP Compliance during Development of a Biotechnology Product
Z1.4 Attribute Inspection Sampling in a CGMP Environment
Analytical Problem Solving for CAPA Systems
Annual Product Reviews: How to Comply with FDA & ICH Requirements

October 20–24, 2003
PDA-TRI Lecture Course:
CGMP Trainer's Qualification Program
PDA-TRI Baltimore, MD

October 27–31, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

October 28–29, 2003
PDA Japan Chapter
Annual Meeting
Location: TBA

NOVEMBER

November 6–7, 2003
PDA-TRI Laboratory Course:
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA-TRI Baltimore, MD

November 10–14, 2003
2003 PDA Annual Meeting, Courses and Exhibition
Building on Our Strengths: Quality, Science and Innovation
Annual Meeting: November 10–12
Courses: November 13–14
Exhibition: November 10–11
Downtown Hilton Atlanta on Courtland NE, Atlanta, GA
PDA-TRI Lecture Courses:
November 13
Designing, Monitoring & Validation of Pharmaceutical Manufacturing Ventilation Systems
Auditing Techniques for CGMP Compliance
November 13–14
Basic Concepts in Cleaning and Cleaning Validation
Computer-Related Systems Validation
A Practical Approach to Aseptic Processing and Contamination Control
November 14
Managing in a GMP Environment
Change Control & Documentation

November 17–21, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

November 20, 2003
UK & Ireland Chapter Meeting
Impact of FDA's Revised Guidelines on Aseptic Manufacture
Keele University Management Centre, UK

DECEMBER

December 4–5, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

December 8–12, 2003
PDA-TRI Laboratory Course:
Rapid Microbiological Methods
PDA-TRI Baltimore, MD

December 15, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

2004

JANUARY

January 26–30, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

FEBRUARY

February 16–18, 2004
2004 PDA International Congress—Basel
Messe Basel Convention Center, Basel, SWITZERLAND

February 23–27, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

MARCH

March 8–12, 2004
PDA SciTech Summit™
Orlando County Convention Center, Orlando, FL

March 22–26, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

APRIL

April 26–30, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

MAY

May 17–21, 2004
2004 PDA Biennial Training Conference, Courses and Vendor Exhibit
The Westin Rio Mar Beach Resort & Golf Club, Puerto Rico

May 17–21, 2004
2004 PDA Pacific Rim Congress—Singapore
Congress: May 17–19
Courses: May 19–21
Tabletop Exhibits: May 17–19
The Ritz Carlton Millenia, SINGAPORE

May 24–28, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

JUNE

June 14–18, 2004
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

Information on these conferences and courses will be posted on the PDA Web site as they become available.

Visit often to get the latest information!

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Calendar of Events

2003

AUGUST

August 11–15, 2003
PDA-TRI Lecture Course:
CGMP Trainer's Qualification Program
PDA-TRI Baltimore, MD

August 14–15, 2003
PDA-TRI Lecture Course:
Compliance Auditing of Cleanrooms and Controlled Environments
PDA-TRI Baltimore, MD

August 19–21, 2003
PDA-TRI San Francisco Course Series
The Fairmont Hotel, San Francisco, CA
PDA-TRI Lecture Courses:
August 19
GMP Fundamentals
August 19–20
Sterile Pharmaceutical Dosage Forms: Basic Principles
Computer-Related Systems Validation
CGMP & Compliance
August 19–21
Introduction to Competency Based Training
August 20
Managing in a GMP Environment
August 21
Good Documentation Practices in the Pharmaceutical Industry
Analytical Problem Solving for CAPA Systems
Annual Product Reviews: How to Comply with FDA & ICH Requirements

August 20–22, 2003
ICH Q7A Workshop
Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
The Fairmont Hotel, San Francisco, CA

August 21–22, 2003
PDA-TRI Laboratory Course:
Fundamentals of D, F, and Z Value Analysis
PDA-TRI Baltimore, MD

August 25–29, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 1
PDA-TRI Baltimore, MD

SEPTEMBER

September 3, 2003
UK & Ireland Chapter Meeting
Training Strategies
Royal Pharmaceutical Society, UK

September 8–12, 2003
2003 PDA/FDA Joint Regulatory Conference, Courses and Tabletop Exhibits—Navigating Current GMPs: Catch the Compliance Wave
Conference: September 8–10
Courses: September 11–12
Tabletop Exhibits: September 8–9
Omni Shoreham Hotel, Washington, DC
PDA-TRI Lecture Courses:
September 11
Biopharmaceutical QA/QC for Senior Management
September 11–12
Cleanroom Management
CGMP & Compliance
Preparing for an FDA Pre-Approval Inspection
Validation of Sterilization Processes
September 12
Application of CIP to the Pharmaceutical Process

September 18–19, 2003
PDA-TRI Laboratory Course:
PDA-BFS Joint Workshop on Blow/Fill/Seal Processing
Cardinal Health Facility, Woodstock, IL—Metro Chicago

September 22–26, 2003—**SOLD OUT!**
PDA-TRI Laboratory Course:
Aseptic Processing Training Program—Week 2
PDA-TRI Baltimore, MD

September 25–26, 2003
UK & Ireland Chapter Meeting
What to Do When Things Go Wrong
Britannia International, Canary Wharf, London, UK

September 29, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum, Basel, SWITZERLAND

September 29–October 1, 2003
PDA/EMEA European Virus Safety Forum
Hosted by the PDA Central Europe Chapter in collaboration with EMEA and the Paul-Ehrlich-Institut
Frankfurt, GERMANY

September 30–October 1, 2003
PDA-TRI Lecture Course:
PDA Computer Products Supplier Auditor Process Model: Auditor Training
PDA-TRI Baltimore, MD

OCTOBER

October 2–3, 2003
PDA-TRI Laboratory Course:
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

October 8–10, 2003
PDA-TRI Laboratory Course:
Designing, Operating and Controlling High Purity Water Systems for Regulatory Compliance
PDA-TRI Baltimore, MD

October 13–14, 2003
2003 Taormina International Conference
Managing for Quality in a Cost-Focused Environment
Conference: October 13–14
Grand Hotel Timeo & Villa Flora, Taormina, Sicily ITALY

October 13–15, 2003
PDA-TRI Laboratory Course:
Cleaning Validation
PDA-TRI Baltimore, MD

October 20–22, 2003
PDA-TRI Boston Course Series
Radisson Hotel Boston, Boston, MA
PDA-TRI Lecture Courses:
October 20
Beyond the GMP/ISO Basics—Practical Strategies for Everyday Compliance
Bioassay Development & Validation
October 20–21
Parenteral Packaging: Rubber, Glass, Plastic and Metal Seals
Everything you Wanted to Know about Environmental Monitoring, but were Afraid to Ask
October 20–22
GMP Training Manager Workshop
October 21
Maximizing SOPs—An Untapped Resource of Training
Assay Validation

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Be sure to watch
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