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PDA Letter

November 2003

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

EMEA and WHO Draft Guidances Draw PDA Comment, pages 13 and 14

PDA Members Advancing Manufacturing Science

• PDA Viral Filtration Nomenclature Standardization Task Force Seeking To Conduct Joint Study With U.S. FDA

The PDA Viral Filtration Nomenclature Standardization Task Force has developed a test method for classifying and identifying viral-retentive filters using bacteriophage which could be used by filter manufacturers as a standard procedure to classify their products. With the cooperation of the U.S. FDA, which is offering to use one of its laboratories, the group wants to conduct a scientific evaluation of the test method.

Gail Sofer (BioReliance), Chair, Viral Filtration Nomenclature Standardization Task Force, highlighted the accomplishments of the group at the PDA/EMEA Virus Safety conference in Langen, Germany in September.

Already, the task force has gotten a number of filter suppliers to agree on a common nomenclature for identification purposes. Typically, the nomenclature for filters used for viral removal has been developed by the individual manufacturers. Additionally, various test methods are employed to evaluate the viral retention capabilities of such filters. As such, the nomenclature has been inconsistent and not informative for the pharmaceutical/biopharmaceutical industry.

The need for a common nomenclature system has been an industry concern for several years. The topic was taken up by PDA's Science Advisory Board, which then assembled the Viral Filtration Nomenclature Standardization Task Force.

To tackle the issues, the task force first formed a subcommittee to work out an agreement among viral-

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• PDA Pharmaceutical Cold Chain Discussion Group Issues Draft Guide for Member Comment

On Nov. 4, 2003, the PDA Pharmaceutical Cold Chain Discussion Group (PCCDG) issued a draft industry guide on cold chain management. The document presents a design approach to develop specialized packages and systems that will protect temperature-sensitive products during transport. It is available on PDA's Web site (www.pda.org) for review by PDA members who are encouraged to submit comments.

Environmental control throughout the distribution chain for temperature-sensitive products has been a growing area of concern among pharmaceutical manufacturers, regulators and pharmacopeial authorities. Driving this interest, in particular, has been the steady increase in the number of biopharmaceutical products under development and in the marketplace. Such products present unique shipping challenges to firms, especially those accustomed to marketing traditional chemical drug products.

In recent years, regulators worldwide have been taking a closer look at the ability of manufacturers to demonstrate product stability throughout the distribution chain. Industry, however, has seen inconsistent expectations among regulatory authorities, and sometimes among officials in the same authority.

Part of the problem has been a lack of standards for cold chain management. While some national pharmacopeial authorities—the USP in particular—have been exploring the issue, the lack of guidance served as the impetus for the formation of the PCCDG.

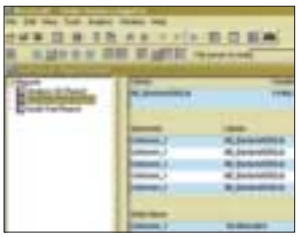
Comprised of representatives from 20 companies (see side bar, page 9), the discussion group first gathered information on current industry practices for global shipping and distribution of temperature-sensitive medicinal products. This information-gathering activity covered active ingredients, finished products, clinical products and reference standards.

With Rafik Bishara, Ph.D., Director, Quality Knowledge Management and Technical Support, Eli Lilly, at its helm, the group has completed the draft guide and is now compiling comments, which will be accepted until Dec. 1. The draft was the topic of a day-long discussion at the PDA Annual Meeting.

continues on page 9

"When other groups have a tough bug they can't identify, they bring it to us."

JOHN BARTELL
SENIOR SCIENTIST, R&D MICROBIOLOGY
AND MICROSEQ CUSTOMER SINCE 1997



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Important Dates...

- **December 4, 2003—Public Comment period closes for FDA draft guidance, see page 19.**
- **December 4–5, 2003—Blend Uniformity Workshop, see page 22.**
- **March 8–12, 2004—SciTech Summit™, see page 32**

IN THIS ISSUE...

Neal G. Koller
PDA President

PDA's Fall Conferences Bring Science and Regulation Together

September and October were remarkable months for PDA as we provided three forums for distinguished pharmaceutical scientists, senior industry executives and regulators to discuss timely scientific, technical and regulatory topics. Each forum was part of PDA's ongoing effort to meet its strategic mission of advancing pharmaceutical and biopharmaceutical science and technology internationally by promoting scientifically sound and practical technical information for both industry and regulatory agencies. The conferences significantly advanced PDA's activities of building alliances with regulators in countries around the world.

From Sept. 8–12, PDA members at the association's annual PDA/FDA Joint Regulatory Conference, Courses, and Tabletop Exhibits in Washington, D.C., heard more than 60 presentations on science, technology and regulatory issues. Lester Crawford, D.V.M., Ph.D., U.S. FDA Deputy Commissioner, provided an overview of the Agency's latest accomplishments in advancing its pharmaceutical and biopharmaceutical quality initiative. The European perspective of risk-management, quality control and regulations, as well as an update on ICH's new activities, was provided by Joyce Ramsbotham (Solvay Pharmaceuticals, The Netherlands), who has represented European industry at ICH. The meeting dovetailed with the release of four FDA draft guidances and a final guidance in early September.

Helen Winkle, Director, CDER Office of Pharmaceutical Science, Lester Crawford, D.V.M., Ph.D., and Frank Settineri (Chiron), Conference Chair and PDA Metro Chapter President, participate in a lively panel discussion at the PDA/FDA conference.

New ground was broken with the PDA/EMEA European Virus Safety Forum in Langen, Germany (Sept. 29–Oct. 1), which represented the first time PDA collaborated with EMEA to deliver scientific and regulatory information to its members worldwide. Experts from industry, academia and regulatory bodies around the world met in Langen to explore a number of key issues. Addressed were cutting-edge topics on technologies for viral removal and safety aspects of medicinal products produced via the most advanced technologies, such as transgenics and xenogeneics, as well as traditional industry concerns including regulatory requirements, source material testing, and validation.

More national and global health authorities were represented at the virus safety forum than at any other PDA forum to date. Represented were the: U.S. FDA and National Institutes of Health; EMEA; Australian Therapeutic Goods Administration; Canadian Blood Service; Belgian Scientific Institute of Public Health; British National Institute for Biological Standards & Control; Danish Medicines Agency; French Health Products Safety Agency (AFSSAPS) and Human Plasma Product Services; Finnish National Agency for Medicines; German Paul-Ehrlich-Institut; Greek National Organization For Medicines; Japanese National Institute of Infectious Diseases; Scottish National Blood Transfusion Service; Spanish Agencia Espanola del Medicamento; Swiss Agency for Therapeutic Goods; and Taiwanese Animal Technology Institute.

The PDA/EMEA conference afforded the opportunity to report to our European members the activities PDA has been pursuing around the world to increase value for our members. Our recent achievements include: initial discussions to create a new interest group on nanotechnology and new European sections of the biotechnology and filtration interest groups; exploratory meetings with European University Science Parks to bring new science to PDA; growing European and Asia Pacific member interest in the PDA Science Advisory Board and Regulatory Affairs and Quality Committee; preliminary planning of a European-based Aseptic Processing Course; and new pharmaceutical and biopharmaceutical forums for 2004. Other achievements involve expanding regulatory affairs relationships and activities in Europe, including the training program for the Italian Health Authority Inspectorate and relationship-building with the EMEA, WHO, ICH, and a number of national health authorities.

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Organizers of the 2003 PDA/EMEA Virus Safety Forum in Langen, Germany. Pictured from left to right: Dr. Georg Roessling (Schering AG) PDA Board of Directors; Neal Koller, President, PDA; Professor Johannes Löwer, Ph.D., Paul-Ehrlich-Institut; Dr. Hannelore Willkommen (Clearant), Conference Chair.

The last conference in this series of science, technology and regulatory meetings was the 2nd Taormina International Conference and Tabletop Exhibits in Taormina, Italy (Oct. 13–14), where senior executives from pharmaceutical and biopharmaceutical companies from the U.S., Europe and the Asia Pacific region met with senior regulators, senior legal experts and senior industry consultants to discuss the pursuit of quality in a cost-focused environment. Joining officials from the FDA and EMEA were executives from such companies as: Pfizer, SIFI, GlaxoSmithKline, AstraZeneca, Abbott Laboratories, Schering AG, Pharmacia, Aventis Behring, Genzyme, Eli Lilly, KMI/PAREXEL International, Chiesi Farmaceutici, Ferring Pharmaceuticals, Chiron, CTP Technol. Di Processo, Baxter, Millipore, Vectech, Novo Nordisk, Solvay, Biosol, Bausch & Lomb, Biolab, Pentapharm, Beacon Pointe Group, Pliva, LEK Pharmaceutical, Merck Sharp & Dohme, Nycomed, Chinoin, Fresenius Kabi Asia Pacific, Shire, and Pharmation.

Taormina was the ideal setting for bringing together this group of senior experts to learn about challenges and successes in pursuing quality in today's environment. With informal discussions mixed into formal presentations, conference attendees had numerous opportunities to interact and talk openly about issues *they* felt needed addressing rather than relying on a rigid conference agenda. This, along with the setting provided by the village of Taormina and the atmosphere of the 19th century Grand Hotel Timeo, made this conference a great success and an unparalleled value to attendees.

As significant as these three conferences were, they represent just a portion of the work PDA does each day to promote scientifically sound and practical technical information, to provide educational opportunities to all our members, and to strengthen its relationships with regulatory authorities around the world. ■

Dr. Antonino Giannetto, Technical Director, SIFI, SpA, Italy, receives a certificate of appreciation for his work as Chair of the 2003 Taormina Conference Program Planning Committee.

PDA Seeks New VP of Science & Technology

PDA is currently searching for an experienced, senior-level executive to serve as VP of Science & Technology. This individual will represent PDA globally on a broad range of science and technology and will focus on all aspects of planning and coordinating PDA's scientific activities. The duties and responsibilities include:

- Manage and build PDA's sci/tech program, executing the association's comprehensive global Strategic Plan
- Oversee the enhancements of the *PDA Journal of Pharmaceutical Science and Technology* and all other scientific documents
- Write and edit sci/tech papers and articles related to PDA activities
- Actively increase scientific collaboration and use of PDA science with health authorities and industry worldwide
- Identify and present emerging scientific and technical issues and opportunities to the membership and work with the PDA Planning Committee and other volunteer leaders to recommend new sci/tech initiatives
- Serve as advisor/leader for program committees regarding science and technology content and develop new scientific program initiatives
- Act as liaison with outside organizations regarding sci/tech projects of mutual interest
- Develop and implement staffing and annual plan to support task groups, organizational committees, subcommittees, and Interest Groups, and serve on these groups

The ideal candidate will have extensive experience working with multiple constituencies and committees, and must possess exceptional written and oral communication skills, strong analytical skills, natural leadership abilities, the ability to organize and lead major initiatives, and public relations skills. Candidates must possess an understanding of the complex scientific issues pertaining to the development, manufacture, and quality control of pharmaceuticals, biopharmaceuticals and related products. This position reports directly to the President; salary is commensurate with experience. Applicants should submit a letter of interest, including salary requirements, résumé, references and writing samples to John Palermo, Palo1@cox.net. ■

Meet the Scientist

Prof. Johannes Löwer

Prof. Johannes Löwer

President of the Paul-Ehrlich-Institut, Professor of Medical Virology at the University of Frankfurt (Germany)

Born on 20 November 1944 in Vienna, Austria, Prof. Johannes Löwer received a "Dr. med." (M.D.) degree from Würzburg University and a "Dipl.-Biochem." (M.Sc.) in biochemistry from Tübingen University.

Since 1981, Prof. Löwer has been working at the Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines in Germany. The Paul-Ehrlich-Institut is the German competent authority for licensing and batch control of biological medicinal products for human and veterinary use. The institute also performs research in its sphere of competence.

From December 1987 to January 2002, Johannes Löwer was Head of the Division of Human Virology. In April 1991, he was also appointed Deputy Director of the Paul-Ehrlich-Institut. In his capacity as Deputy Director, he was responsible for the institute's ongoing business from October 1996 to October 1999. In October 1999, he was appointed Acting Director of the Paul-Ehrlich-Institut. In June 2001, he was appointed President of the Paul-Ehrlich-Institut.

Prof. Löwer is a member of various scientific societies and works for a number of scientific committees. He has been chairman of the Scientific Committee for Medicinal Products and Medical Devices at the European Commission since 2000, being a member since 1998. He was also a member of the Scientific Steering Committee at the European Commission from 2000 until the end of its term in 2003. His work on these committees is principally focused on the safety of immunobiological medicinal products.

Prof. Löwer performs basic research in retrovirology and in transmissible spongiform encephalopathies and applied research in the field of infection safety of blood and other biological products.

The Paul-Ehrlich-Institut (PEI) was established as the 'Institute for Sera Research and Serum Control' on 1 June 1896, in Steglitz near Berlin. Its first director was Paul Ehrlich, after whom today's institute is named. The principles underlying the work of the modern PEI and the criteria for verifying efficacy, quality and safety can be traced back to Paul Ehrlich. In the beginning, Paul Ehrlich and his staff members were only concerned with testing diphtheria immune sera, with between 10 and 60 test samples being received by the institute each month. Today the employees of the PEI deal with approximately 9,000 batches annually, and the number of applications for (and renewals of) marketing approvals ranges between 400 and 500 per year. ■

The Paul-Ehrlich-Institut, Steglitz, Germany.

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Shifting Sands—Computer Validation

Good System Practices: An Educational Beginning

by George J. Grigonis, Jr., Sr. Consultant, QA Edge

Software Engineering Institute is a federally-funded research and development center operated by Carnegie Mellon University. For more information, go to: www.sei.cmu.edu.

The phrase "Good System Practices" refers to the collection of activities that ensure confidence that computing environments are fit and remain fit for their intended purposes as business solutions.

Education in current Good System Practices (GSP) is the first step in changing the 'classic computer validation' paradigm to suit today's technologies and emerging IT concepts. Education is also essential in creating a common scientific basis for understanding and communication between regulators, industry practitioners, and suppliers, thus avoiding the invention of new language to describe concepts already defined by computing disciplines. Collaborative work for GSP between the Software Engineering Institute (SEI) and PDA has taken its first step in pursuing this educational path. Robert Mello, Ph.D., VP PDA Training & Research Institute, and George Grigonis, Sr. Consultant, QA Edge, met with Patricia Oberndorf, Director of Dynamic Systems, SEI, and Chuck Chrissis, Manager Business Development, SEI, on October 1, 2003 to explore some collaborative educational opportunities.

It was agreed that the SEI educational program is an ideal supplement to current PDA Training & Research Institute courses dealing with GSP issues. SEI courseware have a focus on commercial off-the-shelf (COTS) software practices and related topics for systems engineering, computing architectures, and computer security practices. Courseware related to COTS practices range from executive level briefings on concepts, through management and developer workshops designed to provide practitioners with technical knowledge of how to use marketplace products in computing solutions while meeting validation expectations. Tutorials also are offered that provide education in the evaluation of COTS products, risk evaluation in using COTS, and formal processes for integrating commercially available systems.

SEI's offerings also seem to support the foundations of the PDA Supplier Audit Program (TR-32). The design intention of the PDA Supplier Audit Program (TR-32) is to work with the COTS principles articulated in the SEI's COTS work.

Courseware relating to security and survivable systems is geared toward management and technology practices that help organizations identify the risks and engineer mitigation strategies that ensure secure computing environments. Knowledge in this domain is becoming very important with the increased usage of Internet technologies, web-based applications, and now utility computing services, all in the context of 21 CFR Part 11 issues and information assurance.

The FDA, regulated establishments and industry organizations have recognized SEI as a leading, government-funded, research-oriented institution in the field of current systems engineering. Through the PDA Training & Research Institute conduit, SEI's courseware can present GSP to the industry, thus refreshing classic validation thinking with contemporary IT concepts and systems engineering predicated on current good science.

PDA will work to develop a framework for a GSP curriculum that satisfies both regulatory and business needs in meeting the goals for correct and reliable computing environments in the context of predicate regulations. Two PDA Interest Group sessions were held at the PDA annual meeting this year that helped with the next steps:

1. On Monday, November 10, 2003, an Interest Group discussed "Computer Validation Modernization." During the session, the PDA initiative to modernize computer validation thinking was introduced. The goal of the initiative is to evolve computer validation from a "document-centric" activity to a "process-centric" activity that harmonizes compliance expectations with business computing needs through the use of state-of-the art IT concepts and tools that define current "good system practice" (cGSP).
2. On Tuesday, November 11, 2003, an Interest Group met to discuss "Part 11 Compliance Alternatives." This interest group session largely focused on an alternative approach to complying with information assurance rules from an e-information perspective. The common denominator is GSP, applying modern methods for implementing computing environments that collectively enable information assurance.

Armed with a needs assessment and curriculum framework, PDA plans further meetings with SEI early in 2004 to refine a collaborative work and education arrangement that are mutually beneficial to all stakeholders. Later, courseware that marries GSP to expectations of predicate regulations when computing tools are involved in regulated activities needs to be devised. ■

Cold Chain Management, from cover

After reviewing the comments and updating the document as appropriate, the PCCDG will solicit the opinions of regulators and pharmacopeial authorities from various countries. The goal is to have the document published as a PDA technical report, and, eventually, used as the basis for either an FDA guidance or a USP Stimuli Article and/or General Information Chapter.

Below is an excerpt from the draft document. To access the entire document go to: www.pda.org. To comment, contact Rafik Bishara at bishara_rafik_h@lilly.com or Sopita Lapsomphop at lapsomphop@pda.org. ■

Component Specification (CS)

This section of the guidance outlines general principles that apply to product impact components for the transport process. Product impact components are those, which may have a direct effect on the performance of a transportation system. Examples of product impact components include insulated containers and refrigerants. The component specification establishes confidence that components are capable of consistently performing within established limits and tolerances.

A specification should be generated to outline component requirements as applicable. This specification may include, but is not limited to:

- Material requirements
- Mechanical requirements
- Dimensional requirements
- Printing requirements
- Storage requirements
- Sampling requirements
- Weight requirements
- Calibration limits
- Fragility limits
- Shock and Vibration limits

Design Testing

Design Testing should be performed prior to Qualification testing. Design testing is performed to assure that functional requirements are met by the proposed package or system. Design testing process parameters typically include, but are not limited to:

- Process Duration
- Quantity, temperature conditioning and location of Refrigerant
- Type of insulating material
- Minimum and Maximum Loads

The outcome of design testing assures a high confidence for successful OQ testing of a specific package or system. The results of design testing should be formally documented in a report.

1. Shipping temperature (2 to 8 or Frozen)
2. Shipping duration (48 hr. 72 hr or 96 hr.
3. Primary package (vial, syringe or carboy)
4. Secondary packaging

1. Temperature mapping
2. Thermal testing Profile
3. Air / product relationship
4. Duration
5. Develop specification

Companies Participating in the PCCDG

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Astra Zeneca
Bausch & Lomb
Baxter
Boehringer Ingelheim
Centocor
Genentech
Genzyme
Jansen
Eli Lilly
Merck
Novartis
Organon
Ortho
Pfizer
PSGA
Schering-Plough
Wyeth

Recent Sci-Tech Discussions

Analytical Cleaning Limits for Weighing Isolators

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

This month's posting...

Question 1

What is consensus on cleaning limits for potent drug weighing isolators? Should they be cleaned to product contact surface limits as determined by MAC equation even though they are not direct product contact and carryover is not the major issue? Or should they be visual clean only like most filler line isolators are since there is no direct product contact. Or is there a middle ground here? Just wanted to find out the Forums thoughts on this.

Response 1

If the drug was NOT potent I would use the visibly clean argument. As the drug type quoted here indicates potent compounds I would go for a more stringent cleaning limit. It is difficult to say exactly what without knowing the potency detail i.e. cytotoxic, hormonal etc. In either of these cases I would go for a very low TOC as determined by sampling post cleaning. One thing to consider is the ability of the compound to "stick" to the filters and then get blown off to contaminate other materials. Could happen if clouds are formed during dispensing and one can not realistically sample filter surfaces.

Response 2

I think the cleaning goal with a potent drug weighing process is to reduce the residue to something that is safe for the operator to open the unit, remove the materials and introduce the next material to be weighed. The key driver in setting limits would be acceptable worker exposure levels to the materials being weighed.

Response 3

What are considered to be very low TOC levels? I am assuming this is to be determined through swab sampling.

Response 4

As it is a potent drug, you should set up a low limit for TOC value after cleaning, and consider the key point, which is the sampling. The final result should be no contamination of the operator or cross contamination.

Response 5

Right now the only major equipment that is not product contact for which cleaning validation is required is lyophilizers. If the concept of requiring cleaning validation were extended to other non-product contact surfaces, my guess is that manufacturing isolator surfaces would be next. Define in your higher level master plan what should be done for these surfaces. If you choose to do cleaning validation, then I doubt if "visually clean" is appropriate for potent drugs. If you choose to set residue limits for the active, you might consider cleaning it to the same limit as other manufacturing equipment for the same active. The logic here is that if direct product contact surfaces are acceptable at that level, then non-direct product contact surfaces should also be acceptable at the same level. For clarification, I 'm not saying do a MAC calculation on the isolator surfaces. I'm saying using the same limit for isolator surfaces as for other equipment where you perform a MAC type calculation.

Response 6

Remember, this is a weighing isolator, not a drug manufacturing isolator. Weighing isolators are designed to protect people from contamination, not subsequent drug from contamination. All "direct product contact" surfaces are removed each time (i.e.: weigh bags, weigh boats, scoops, utensils, weighing containers, etc.) and cleaned elsewhere. Usually, only the scale remains in the isolator, and it is sometimes even removed. This is different from the drug manufacturing isolator or lyophilizer where product exposed parts are normally cleaned in place by a process of wipe down, modified CIP, etc. It would appear that there is very little likely hood that the following weighing of another drug would be contaminated by even the most potent of previous drug (0.5mcg/day carryover limit in our case) if all the previous drugs weighing utensils and containers were removed prior to a wipe down with bleach or some other denaturing agent followed by a wet wipe with water or alcohol. If this is true, why would not visual cleanliness of the box be adequate? We will be doing air testing of the isolator each time to assure that Employee Exposure Limits (EEL) for dust exposure are not exceeded. As another writer noted, a swab near the exhaust filter area in a weighing isolator would probably "fail" must potent drug cleaning level requirements (due to air flow pulling in dust), but such a swab would also not represent the weighing area directly around or above the scale. Once we say that the weighing isolator internal surface must be cleaned to product contact surface analytical limit, how can we not use

"worst case MAC"? Wouldn't the EEL air test establish adequate cleanliness in combination with visual clean?

Response 7

As far as cleaning validation limits for a weighing isolator, I would suggest that in addition to a risk analysis for potential exposure of your operators to the potent compound is there any risk for exposure of other products to the potent compound. For either risk, you will need to mitigate the risk. The cleaning validation limits should be based on the risk analysis.

Response 8

I assume this isolator is used to weigh out actives for drug manufacture. If the isolator surfaces are not product contact surfaces, then how do they get "dirty"? Is it just dust from the air? Or are you truly concerned about residues of the potent actives on the surfaces? My recommendation would be for you to consider doing a calculation initially assuming a visually clean limit of 1 to 4 micrograms per square centimeter, and assume as a worst case—and I will readily admit it is an unreasonable or improbable worst-case—what would happen if all the potent active at that level on surfaces got into the next potent active weighed in the same isolator. If you do such a calculation, and it is significantly below a 0.001 carryover, then go with visually clean. As I stated earlier, cleaning validation for such non-product contact surfaces is not a regulatory requirement at this time. However, once you bring up the issue, I would recommend addressing it in a logical way. It may be that visually clean is adequate; however, once you've gone as far as you have, I would suggest a simple calculation to demonstrate that. ■

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 **www.pda.org** to sign up via the Web or send an e-mail to *requests@www2.pharmweb.net*.

Viral Filtration Nomenclature Standardization, from cover

retentive filter suppliers on which standard they would use to classify and identify their products.

Led by Kurt Brorson, a biologist at the U.S. FDA Center For Biologics Evaluation and Research (CBER), representatives from a number of filter companies—including Millipore, Asahi, and Clearant—joined with representatives of the pharmaceutical industry, including officials from Schering and Bayer, and reached an agreement to use bactierophage as the standard. The reference standard agreed on—PR772 for main rating—can be obtained from a standard reference collection (e.g., American Type Culture Collection (ATCC), the United Kingdom National Collection of Type Cultures or the Canadian Felix d'Herelle Reference Center for Bacterial Viruses, Laval University). Bacteriophage was selected because it is smaller than most retroviruses.

This agreement is a significant achievement. Initially, filter manufacturers were concerned that the use of a standard classification system could make their filters appear inferior to others. However, the task force has emphasized that the use of the common nomenclature is for information only and that the drug manufacturers are ultimately responsible for determining the suitability of filters for their specific processes. Standardization is not intended to test filters at maximum or worst case operating conditions nor to compare filters from one supplier to the other. The proposed testing is not a substitute for the common process validation procedures drug manufacturers perform for regulatory purposes.

The task force wants to analyze the classification/identification method that they have developed. CBER's Brorson has volunteered to oversee the project at an FDA laboratory in Maryland. If the results are acceptable, filter manufacturers involved with the project have agreed to assess the method in their own facilities. The task force is now looking at how to fund the project.

The study is to focus specifically on large virus nanofilters. If successful, the task force anticipates that a similar study for small virus nanofilters could follow. The group views small virus nanofilters to be the "greatest challenge" in this effort.

The agreement to focus on large virus filters was reached because all such filters appear to work under optimized conditions. The brackets defined for the procedure are throughput volume, trans-membrane pressure, flux, and wash volume. To prepare the bacteriophage stock, broth cultures or agar overlay methods could be used. The stock can be run through the filter only or can be further purified. Titers should be in excess of 10^{12} pfu/ml if a pure concentrate method is used. The titer determination method is: *E. coli* host suspension and score plates for pfu.

The goal is to eventually publish the study results and the preparation method in the *PDA Journal of Pharmaceutical Science and Technology* and to publish a PDA Technical Report on virus filtration, modeled on *PDA TR No. 26: Sterilizing Filtration of Liquids*.

The task force is meeting with filter manufacturers in Atlanta, Georgia, following the PDA annual meeting to further discuss the study and the technical report.

Those interested in participating in the task group or learning more about the study should contact Gail Sofer via e-mail at gsofer@bioreliance.com. ■

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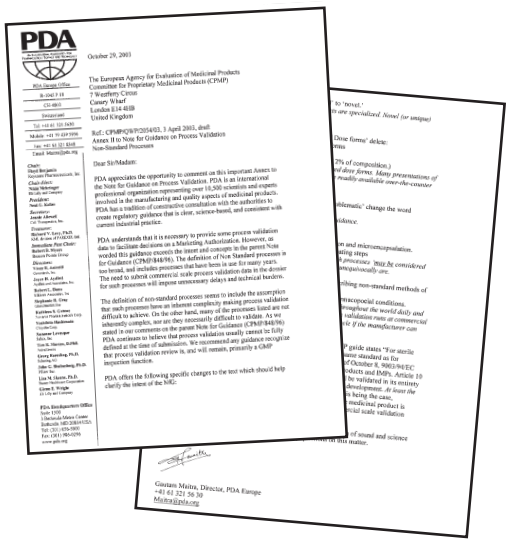
EMEA Draft Guidance Could Cause Delays, Pose Unnecessary Burdens

October 29, 2003


PDA

October 29, 2003

The European Agency for Evaluation of Medicinal Products
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Ref.: CPMP/QWP/2054/03, 3 April 2003, draft
Annex II to Note for Guidance on Process Validation
Non-Standard Processes

Dear Sir/Madam:

PDA appreciates the opportunity to comment on this important Annex to the Note for Guidance on Process Validation. PDA is an international professional organization representing over 10,500 scientists and experts involved in the manufacturing and quality aspects of medicinal products. PDA has a tradition of constructive consultation with the authorities to create regulatory guidance that is clear, science-based, and consistent with current industrial practice.

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PDA understands that it is necessary to provide some process validation data to facilitate decisions on a Marketing Authorization. However, as worded this guidance exceeds the intent and concepts in the parent Note for Guidance (CPMP/848/96). The definition of Non Standard processes is too broad, and includes processes that have been in use for many years. The need to submit commercial scale process validation data in the dossier for such processes will impose unnecessary delays and technical burdens.

The definition of non-standard processes seems to include the assumption that such processes have an inherent complexity making process validation difficult to achieve. On the other hand, many of the processes listed are not inherently complex, nor are they necessarily difficult to validate. As we stated in our comments on the parent Note for Guidance (CPMP/848/96) PDA continues to believe that process validation usually cannot be fully defined at the time of submission. We recommend any guidance recognize that process validation review is, and will remain, primarily a GMP inspection function.

PDA offers the following specific changes to the text which should help clarify the intent of the NfG:

A. Throughout the text change the word 'specialized' to 'novel.'
Rationale: Many aspects of medicinal products are specialized. Novel (or unique) better captures the intent of the guidance.

B. Under '1. Specialized [now Novel] Pharmaceutical Dose forms' delete:
a. Suspension, emulsions or other dispersed forms
b. Prolonged release preparations
c. Products containing drugs in low content (< 2% of composition.)
Rationale: These are not novel or even specialized dose forms. Many presentations of a, b, and c have been produced for years and are readily available over-the-counter around the world.

The need to submit commercial scale process validation data in the dossier for such processes will impose unnecessary delays and technical burdens.

C. In the title in '4. Established processes known to be problematic' change the word problematic to 'complex'.
Rationale: This better describes the intent of the guidance.

D. Under '4. Established processes….' Delete:
- Processes with critical steps such as lyophilization and microencapsulation.
- Process including certain types of mixing and coating steps

Rationale: The parent NfG (CPMP/848/96) says such processes 'may be considered non-standard.' The existing wording states that they unequivocally are.

continues on page 15

WHO Document Contrary to Established U.S. & EU GMPs

October 15, 2003

Dr S. Kopp
Quality Assurance & Safety: Medicines (QSM)
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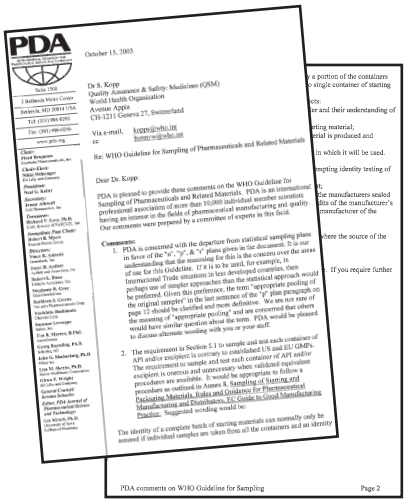
Via e-mail, kopps@who.int
cc bonnyw@who.int

Re: WHO Guideline for Sampling of Pharmaceuticals and Related Materials

Dear Dr. Kopp:

PDA is pleased to provide these comments on the WHO Guideline for Sampling of Pharmaceuticals and Related Materials. PDA is an international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical manufacturing and quality. Our comments were prepared by a committee of experts in this field.



Comments:

1. PDA is concerned with the departure from statistical sampling plans in favor of the "n", "p", & "r" plans given in the document. It is our understanding that the reasoning for this is the concern over the areas of use for this Guideline. If it is to be used, for example, in International Trade situations in less developed countries, then perhaps use of simpler approaches than the statistical approach would be preferred. Given this preference, the term "appropriate pooling of the original samples" in the last sentence of the "p" plan paragraph on page 12 should be clarified and more definitive. We are not sure of the meaning of "appropriate pooling" and are concerned that others would have similar question about the term. PDA would be pleased to discuss alternate wording with you or your staff.

2. The requirement in Section 5.1 to sample and test each container of API and/or excipient is contrary to established US and EU GMPs. The requirement to sample and test each container of API and/or excipient is onerous and unnecessary when validated equivalent procedures are available. It would be appropriate to follow a procedure as outlined in Annex 8, Sampling of Starting and Packaging Materials, Rules and Guidance for Pharmaceutical Manufacturing and Distributors, EC Guide to Good Manufacturing Practice. Suggested wording would be:

The identity of a complete batch of starting materials can normally only be assured if individual samples are taken from all the containers and an identity test is performed on each sample. It is permissible to sample only a portion of the containers where a validated procedure has been established to ensure that no single container of starting material has been incorrectly labeled.

The validation should take into account at least the following aspects:

- The nature and status of the manufacturer and of the supplier and their understanding of the GMP requirements of the pharmaceutical industry;
- The quality assurance system of the manufacturer of the starting material;
- The manufacturing conditions under which the starting material is produced and controlled;
- The nature of the starting material and the medical products in which it will be used.

Under such a system, it is permissible that a validated procedure exempting identity testing of each incoming container of starting material could be accepted for:

- Starting materials from a single product manufacturer or plant;

continues on page 15

PDA Comments on EMEA Guide, from page 13

E. Under the second half of '4. Established processes…' describing non-standard methods of sterilization delete:
   • Terminal sterilization by moist heat using non-pharmacopoeial conditions.
   Rationale: Processes fitting this description are used throughout the world daily and have been proven effective. We see no reason that three validation runs at commercial scale will be necessary to show the efficacy of such a cycle if the manufacturer can provide adequate data.

Comment: Paragraph 17 of the final text of Annex 13 to the GMP guide states "For sterile products, the validation of sterilizing processes should be of the same standard as for products authorized for marketing." Similarly, the new directive of October 8, 9003/94/EC lays down principles and guidelines of GMP for both marketed products and IMPs. Article 10 Production, # 4 states: "For IMPs the manufacturing process shall be validated in its entirety in so far as is appropriate, taking into account the stage of product development. *At least the critical process steps, such as sterilization, shall be validated.*" This being the case, significant validation work will already be accomplished before the medicinal product is ready to be the subject of a marketing application, and three commercial scale validation batches are not necessary.
PDA appreciates the opportunity to support the CPMP in preparation of sound and science based guidance. Please contact me if you have any questions on this matter.

Sincerely,

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Note—Copies of PDA comments on regulations and regulatory guidances can be found at www.pda.org.

PDA Comments on WHO Guide, from page 14

• Starting materials coming directly from a manufacturer or in the manufacturers sealed container where there is a history of reliability and regular audits of the manufacturer's quality assurance system are conducted by the purchaser (the manufacturer of the medicinal product) or by an officially accredited body.

It is improbable that a procedure could be satisfactorily validated for:
• Starting materials supplied by intermediates such as a broker where the source of the manufacturer is unknown or not audited;
• Starting materials for use in parenteral products.

PDA thanks you for the opportunity to comment on this draft guideline. If you require further information, please feel free to contact me at the e-mail address below.

Sincerely,

William Stoedter, RAC
PDA Director of Regulatory Affairs
e-mail: stoedter@pda.org
Web site: www.pda.org

It is improbable that a procedure could be satisfactorily validated for:
• Starting materials supplied by intermediates such as a broker where the source of the manufacturer is unknown or not audited;
• Starting materials for use in parenteral products.

European & Australian Regulatory and GMP Briefs

EMEA

First Parallel EMEA-FDA Scientific Advice: The EMEA has given its scientific advice in the first parallel EMEA-FDA scientific advice procedure. The advice was adopted by the Agency's Committee for Proprietary Medicinal Products (CPMP) on 22 October 2003. This is the first such parallel procedure following the 12 September 2003 signature of a confidentiality agreement with the FDA.

The parallel procedure was initiated at the request of the sponsor company and relates to protocol assistance for a designated orphan medicinal product. It is the first in a pilot exchange of views between the two agencies. While the two agencies will continue to adopt their advice independently of each other, the aim of the parallel procedure is to maximise the exchange of information, allow discussion on common issues and to avoid as far as possible unnecessary study replication in the two regions.

Discussions regarding the proposed product development were held between EMEA and FDA assessors during the parallel procedures for protocol assistance (EMEA) and investigational new drug application (FDA). A videoconference allowed regulators from both agencies to discuss common scientific issues on the proposed development plan. It took place after an oral explanation with the company at the EMEA and before the 'End-of-Phase II' meeting at the FDA.

The videoconference was chaired by Prof. Markku Toivonen, chair of the Scientific Advice Working Group and a member of the CPMP. The meeting was observed by Thomas Lönngren, EMEA Executive Director, and Dr. Murray Lumpkin, FDA Principal Associate Commissioner.

The advice was adopted by the CPMP as part of its monthly meeting 21–23 October 2003.

The confidentiality agreement allows the EMEA, FDA and the European Commission to exchange information as part of their regulatory process, both pre- and post-approval. Types of information covered include regulatory issues, scientific advice, orphan drug designation, inspection reports, marketing approvals and post-authorization surveillance information.

The exchange of letters took place as part of the regular cycle of EU-FDA bilateral meetings that have taken place since 1989. The meeting, at EMEA headquarters in London on 12 September 2003, addressed a number of other topics including the implementation of the agreement and areas for future cooperation between the two agencies.

The agreement builds on close cooperation over the years between European and US pharmaceutical regulators. Its primary aim is to strengthen communication between these public authorities and reinforce public health promotion and protection.

The agreement will be implemented in a stepwise manner. One priority area for the two agencies that is likely to have immediate benefit from this agreement is the possibility of parallel scientific advice from both regulators to companies as they develop new medicines.

Therapeutic Goods Administration, Australia

Amendments to Schedule 4 of the Therapeutic Goods Regulations Concerning New Substances Approved for Inclusion in Listed Medicines: A number of new substances that have been approved for inclusion in listed medicines are now included in the latest consolidation of Schedule 4 of the Therapeutic Goods Regulations, following their gazettal on 16 October 2003. The new substances are as follows:

- Azadirachta indica (Neem) is permitted for topical application only at concentrations up to 1%, and at concentrations greater than 1% when in a container fitted with a child resistant closure and labelled with the statements:
  —"Not to be taken",
  —"Keep out of the reach of children", and
  —"Do not use if pregnant or likely to become pregnant.";
- Borax, Borax pentahydrate, Boric acid and Sodium perborate (limited to a maximum daily dose of 3 mg of boron);
- Calcium sodium caseinate (products must be supplied with a label that includes a statement to the effect "contains cow's milk protein");
- Magnesium phosphate dibasic trihydrate;
- Molybdenum trioxide (limited to a maximum daily dose of 125 μg of molybdenum);
- Quercetin; and
- Trametes versicolor in the form of powdered aqueous extracts of the hyphae.

In addition, the entry for "bioflavonoids (except quercetin)" has been removed, and replaced by the new Australian Approved Name (AAN) of "Citrus Bioflavonoids Extract", to better reflect the Therapeutic Goods Administration's (TGA) definition of bioflavonoids as an extract derived from citrus. An updated compositional guideline has been prepared for "citrus bioflavonoids extract", and will soon be available on the TGA website, where it will be available for public consultation for six weeks.

Sponsors are to be allowed two years, or until the next label run, to update the AAN product labels for medicines containing bioflavonoids, but no charge will be made for updating ARTG entries.

Australian Regulatory Guidelines for OTC Medicines: These Guidelines describe the infor-

mation to be supplied with an application for registration of OTC (over-the-counter) medicines in the Australian Register of Therapeutic Goods. These medicines will be subject to evaluation by the Non-prescription Medicines Branch of the Therapeutic Goods Administration, in accordance with Section 25 of the Therapeutic Goods Act 1989.

This information will enable the determination of the application for registration and, accordingly, the Guidelines are approved for the purposes of subsection 23(2) of the Therapeutic Goods Act 1989 with effect from 1 July 2003.

The Guidelines also give guidance on the information required to be submitted for consideration of applications to vary information about therapeutic goods included in the Register, which are made under subsection 9D(1), (2) or (3) of the Therapeutic Goods Act 1989.

Blood Banks Get Qualified All-Clear from TGA: The TGA has now audited all the major Australian Red Cross Blood Service (ARCBS) sites that undertake manual testing and manual entry of data and have found a general degree of adequate training, processes and procedures in place.

Last week the TGA placed restrictive conditions on the manufacturing licence held by the South Australian ARCBS, requiring them to use only fully automated tests for blood donor screening. These tests must be interfaced with the National Blood Management System and not require human interpretation or manual entry.

This follows an audit of the Adelaide blood bank during which the TGA found a number of breaches of the Good Manufacturing Practice Licence held by the Blood Bank. The most serious breach was the release of some blood products labelled as negative to cytomegolovirus (CMV) when in fact these were CMV positive.

The TGA is also investigating other breaches at the Adelaide blood bank including the release of a unit of blood before it was adequately tested for syphilis. Subsequent follow up by the ARCBS has shown that all of the blood released was in fact negative to the disease.

TGA audits undertaken last Friday and during this week of blood bank sites in Brisbane, Sydney, Melbourne, Perth and Darwin found that adequate training, processes and procedures are in place to protect public health and safety at these facilities.

However, auditors have expressed some concerns about training records for the manual entry of test data at the Alice Springs site. As a result, the Alice Springs ARCBS has agreed that all their manual entry of test data will cease, until they have had the opportunity to address these concerns following receipt of the written audit report.

The TGA is expecting to finalise all the written audit reports early next week. ■

—compiled by Gautam Maitra and Walter Morris

U.S. Regulatory Briefs

KEY REGULATORY DATES: Dec. 4—Public comment period closes for FDA draft "Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information."

FDA Issues Draft Guidance on Pharmacogenomics Data: The guidance is intended to ensure that evolving policies are based on the best science and provide public confidence in this new field. The document is intended to encourage drug and biologic developers to conduct pharmacogenomic tests during drug development and clarifies how FDA will evaluate the resulting data.

"Pharmacogenomics holds great promise to shed scientific light on the often risky and costly process of drug development, and to provide greater confidence about the risks and benefits of drugs in specific populations," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "Pharmacogenomics is a new field, but we intend to do all we can to use it to promote the development of medicines. By providing practical guidance on how to turn the explosion of pharmacogenomic information into real evidence on new drugs, we are taking an important step toward that goal."

This is FDA's first step towards integration of this new field into the process of demonstrating that new drugs are safe and effective, and thus the regulatory guidance is intended to facilitate this integration. This guidance is intended to ensure that evolving regulatory policies and study designs are based on the best science; provide public confidence in this new field where scientifically appropriate; facilitate the use of such tests during drug development; and clarify for industry what types of pharmacogenomic data to submit to FDA.

The guidance provides specific criteria and recommendations on submission of pharmacogenomic data to investigational new drug applications (INDs) and New Drug Applications (NDAs) and Biological License Applications (BLAs). This includes information on what data is needed, and how FDA will or will not use such data in regulatory decisions.

Because there is a need for scientific exchange, the agency is asking for voluntary submissions of research information. This data will help FDA gain experience as the field evolves. In these cases, FDA advises sponsors to clearly label voluntary submissions; and the agency advises

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U.S. Regulatory Briefs, from page 17

that it will not use information from voluntary reports for regulatory decisions. If a sponsor subsequently develops additional data that meet the criteria for submission for regulatory purposes, the Agency advises sponsors that such data should be submitted as explained in the guidance.

FDA's Science Board recently (April 2003) endorsed FDA proposals to move forward with this guidance on assisting industry in deciding whether a submission is needed. In addition, FDA held public meetings and workshops in which the key issues for drug development were identified.

FDA plans to issue further guidance on co-development of pharmacogenomic tests and pharmaceuticals in the near future. The draft guidance on display today is available on FDA's Web site at: http://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0497-nad0001vol1.pdf.

Biological Therapeutic Products Transfer to CDER, Web site Launches: On October 1, 2003, FDA transferred certain product oversight responsibilities from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This consolidation provides greater opportunities to further develop and coordinate scientific and regulatory activities between CBER and CDER, leading to a more efficient, effective, and consistent review program for human drugs and biologics. FDA believes that as more drug and biological products are developed for a broader range of illnesses, such interaction is necessary for both efficient and consistent agency action. Under the new structure, the biologic products transferred to CDER will continue to be regulated as licensed biologics.

On the same day that the transfer was official, FDA launched a Biological Therapeutic Products section to the CDER Web site. Users can link to the following information from the new page covers:

- Approval Information (Labels and Reviews)
- Letters to Industry, Healthcare Providers, and Clinical Investigators
- Prescription Drug User Fee Act (PDUFA) Billable Products
- Recalls and Withdrawals
- Research Divisions and Investigators
- Talk Papers
- Safety Information
- Violative Advertising and Promotional Labeling Letters
- Important Addresses
- Required Postmarketing Adverse Experience Information
- Advertising and Promotional Labeling
- Reports of Biologic Product Deviations

Guidance for Industry on Investigational New Drug Application, Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer: FDA has announced the availability of a guidance for industry entitled "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer." Exemption from IND regulation of certain studies of marketed drugs is allowed under 21 CFR 312.2(b)(1). Along with other criteria outlined in the regulation, investigations that involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product are not exempt from the requirements for an IND. This guidance discusses the pertinent regulations relating to exemption of INDs, the risk/benefit determination in the practice of oncology, FDA's policy for determining exemption status based on risk, and specific examples of studies generally considered exempt. The guidance can be found at: http://www.fda.gov/cber/gdlns/indcancer.htm

For further information contact: Grant A. Williams, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, +1 301-594-5758, or Patricia Keegan, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, +1 301-827-5093.

FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments: A recent series of spot examinations of mail shipments of foreign drugs to U.S. consumers conducted by the Food and Drug Administration (FDA) and U.S. Customs and Border Protection (CBP or Customs) revealed that these shipments often contain dangerous unapproved or counterfeit drugs that pose potentially serious safety problems. These "blitz" exams were conducted in the Miami and New York (JFK) mail facilities from July 29–31, 2003, and the San Francisco, and Carson, Calif., mail facilities from August 5–7 2003, to obtain a representative picture of products entering the United States.

Although many drugs obtained from foreign sources purport, and may even appear to be, the same as FDA-approved medications, these examinations showed that many are of unknown quality or origin. Of the 1,153 imported drug products examined, the overwhelming majority, 1,019 (88%), were violative because they contained unapproved drugs. Many of these imported drugs could pose clear safety problems.

FDA Anti-Counterfeiting Task Force Interim Report Focuses on High-Tech Weapons and Other Promising New Counter Measures: FDA's Counterfeit Drug Task Force has issued its interim report containing potential options for a multi-pronged approach to combat counterfeit drugs. In recent years, the FDA has seen an increase in the number and sophistication of efforts to introduce counterfeit drugs (i.e., drugs which, or the container or labeling of which, is purported to be something that it isn't). The task force's final report is due in early 2004.

The potential options contained in the interim report are premised on three interim conclusions reached by the task force:

- There is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method. It could also be less costly, because a 'one-size-fits-all' approach is unlikely to work for all parts of the complex prescription drug supply system.
- Although drug counterfeiters today are more sophisticated and better organized than ever before, there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats.
- Because many of these promising ideas have not been fully developed, the task force believes that an opportunity for broad public comment is essential to guide its further work.

Commissioner McClellan established the task force in July 2003 as part of FDA's heightened battle against counterfeit drugs. Commissioner McClellan specifically charged the task force with developing recommendations for achieving four fundamental goals: (1) preventing the introduction of counterfeit drugs into the U.S. market, (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure of consumers to counterfeit drugs, and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs. ■

—compiled by Bill Stoedter and Walter Morris

Highlights from the
2003 PDA/FDA Joint Regulatory Conference

A delegation of PDA Japan Chapter members met with Robert Coleman, National Expert Investigator, FDA, Office of Regulatory Affairs, and Robert Dana, Elkhorn Associates, PDA Board of Directors and Leader of the Regulatory Affairs and Inspection Trends Industry Group.

Customers discuss the latest in products and services in the industry with PDA exhibitors.

Stephen Stachelski, Sr., Compliance Consultant, KMI a Div of PAREXEL Int'l LLC moderates a panel discussion on "engineering issues" with Richard M. Johnson, Director, Quality Center of Excellence Drugs, Abbott Laboratories and Robert Coleman, FDA, ORA.

Joseph C. Famulare, Director, Division of Manufacturing & Product Quality, FDA, CDER, discusses publicly for the first time the new Part 11 Guidance document. The document had been released just 4 days prior to the PDA/FDA conference.

The interactive exhibition provided key opportunities for conference delegates to learn about new technologies.

More highlights from the
PDA/FDA Joint Regulatory Conference
featuring the exhibits, sessions and
the "luncheon with the FDA."

Blend Uniformity Workshop December 4-5, 2003, Bethesda, MD

Venue:
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This workshop is managed by PDA.

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PQRI
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You are invited to attend the 1 1/2 day **PRODUCT QUALITY RESEARCH INSTITUTE'S (PQRI) BLEND UNIFORMITY (BU) WORKSHOP**, which was originally scheduled for September 2003, to discuss the Blend Uniformity Working Group's recommendation and the subsequent draft FDA guidance document.

These changes in FDA's draft BU guidance are expected to be issued prior to the workshop.

Speakers from academia, industry and FDA will discuss the contents of the draft FDA BU guidance with workshop participants. The workshop will include breakout sessions, which will offer the opportunity to provide feedback to FDA and PQRI regarding PQRI's recommendation and FDA's succeeding draft guidance document. Attendees will gain an understanding of:

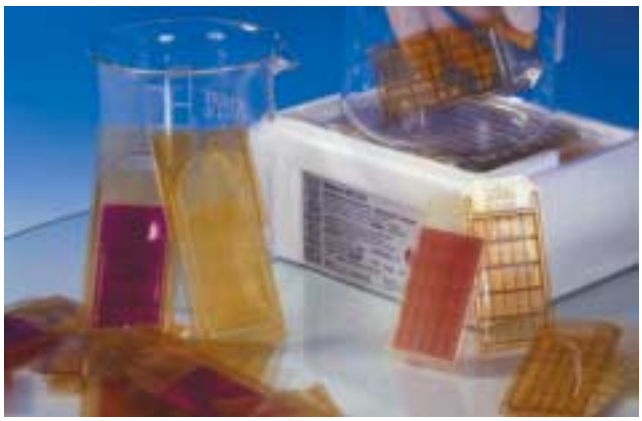
- The contents of the PQRI recommendation and the draft FDA guidance document;
- How to apply the recommendation to new and existing products;
- The economic benefits of instituting the BU guidance;
- FDA experiences with submissions using the PQRI approach;
- Detecting and resolving issues related to content uniformity; and
- Addressing mixing and segregation issues.

If you have already registered for this workshop in September, you will automatically be registered for the December workshop, unless you request a refund.

To register, visit http://www.pda.org/OnlineReg/index.html

For more information about the Workshop, visit http://www.pqri.org/events/workshops/Blend2003/RevisedWkshpInfo.pdf today.

We hope to see you in Bethesda!



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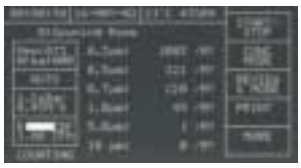

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PDA Training & Research Institute Director's Message

Of Damaging Storms, Dedicated Staff, and Generous Donations

Bob Mello, Ph.D.

It's the Autumn Season and I love it. Originally from New England, I can't help looking forward to the explosions of color in late September and October, which is truly magnificent in the Northeast. The more rain that falls during the summer, the more vibrant the autumn leaf colors are. For a number of years now, I've taken up residence in the Mid-Atlantic region. Autumn is nice here, too, and this year, we have had more than our share of rain to assist the leaf coloration. However, sometimes that rain comes as a result of another autumnal event—hurricanes, like Isabel. (Now, I know the purists will say that it was a "tropical storm" that hit the Baltimore–Washington area this past September 18th, but it really didn't matter what it was called if your home was flooded, damaged, or worse, lost completely.)

This year has been a challenge for PDA sponsored events—war (Iraq), pestilence (SARS), famine (some of the catered lunches for our courses were of "less than expected quality"-my apologies), and record winter snows followed by record Spring rains. And then the hurricane, which came right in the middle of PDA's busiest time of year, the third quarter. Sounds almost Biblical, doesn't it? I am often asked, "How do you manage dealing with all of this?" Well, to put it simply, "I" don't. "We" do. "We", the staff of PDA. "We", the membership of PDA. "We", the contributors to PDA. If you think this is just some marketing line, you don't know me yet (or you have not been reading my column each month). So read on and I hope to explain what I mean.

First, our supporters. Let me thank some of our most recent contributors. GE-Kaye Instruments has donated the ValProbe™ System to assist the PDA Training & Research Institute in offering courses on the use of state of the art wireless temperature monitoring and sterilization process monitoring systems. Sartorius Corporation responded to our request for an MD8 Portable Airscan unit and specialized gel filters to assist in demonstrating sampling of compressed air for GMP compliance. Millipore Corporation's Lab Systems unit responded immediately with a donation of service support for the PDA Training & Research Institute's MilliQ lab water system. As I have mentioned previously, ongoing donations of supplies and service make PDA Training & Research Institute operations viable and contribute to sustaining our laboratory course offerings throughout the year.

Next, PDA staff. Where do I begin? When 'Isabel' struck the area late Thursday, September 18th, I was in Woodstock, Illinois, at the Blow-Fill-Seal workshop. Although I was safe from the storm, I was more than somewhat anxious because of the family, friends, and facility back home. I was on my cell phone quite a bit that day and the next (exceeded my cellular plan's "minutes" by four-fold that month!). The PDA Training & Research Institute lost all power as a result of the storm. Normally, service is restored rapidly in such situations, but Isabel knocked out power to over 1 million people in this region, overwhelming the repair crews. The estimates for power restoration to the PDA Training & Research Institute ranged from 12 hours to 'indeterminate.' To make matters more interesting, the following Monday was to be the start of the second week of our Aseptic Processing course. Ten faculty and twenty-two attendees were calling for updates. PDA Training & Research Institute staffers Janet Kearney and Juner Torres returned to a very dark facility, flashlights in hand, to handle these phone calls and to assess damage (minimal, except for no power) and prepare contingency plans including possible offsite lectures as well as backup generators to power our facility. Such efforts often are transparent to our membership, yet I could not have managed this event without their help. Thanks, also, to Lance Hoboy, VP, Finance & Strategic Planning, who literally cut his way through the downed trees to get to the Bethesda PDA office and help with our coordination efforts. We did get lucky at the PDA Training & Research Institute—power was restored late Friday and the Institute facility and equipment were made operationally ready for the course to begin Monday morning.

Last, but certainly not least, I must acknowledge the efforts of our membership and attendees. While making for interesting discussions and stories at the start of the course on Monday morning, the storm interfered with the delivery schedule of some necessary consumable items, most notably a shipment of sterile, disposable 'wipes.' Those in aseptic processing know that this is a must-have commodity. After all, it is difficult to demonstrate proper techniques while using non-sterile materials in the aseptic filling area. Our rescue came from one of our attendees: Jeffrey Rugg of Gilead Sciences (San Dimas, CA) contacted his colleague, Jose Rodrigez (also of Gilead and former Aseptic Processing student), to have a supply of 'wipes' express shipped to the Institute's facility in Baltimore. I specifically wanted to thank these members in this column, for it was the support of our membership pulling together with our faculty and staff that overcame the storm related problems of the autumn of 2003.

So now, when I am asked, "How do you manage dealing with …?" I remember the line from a song by the Beatles: "I get by with a little help from my friends." My Thanks to you all. ■

—Bob Mello

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2004 Aseptic Processing Course Dates

The 2004 dates for the PDA Training & Research Institute (PDA-TRI) laboratory course on Aseptic Processing have been established. 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. This extremely popular two-week course sells out rapidly, so we urge you to register early. Check our Web site at www.pda.org; the registration information will be available soon.

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 ■

—Bob Mello, Ph.D.

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Upcoming PDA Training & Research Institute Education Courses

Courses listed in chronological order

Environmental Mycology Identification Workshop—Lab December 4–5, 2003; February 12–13, 2004; May 13–14, 2004; December 2–3, 2004; $2,000 members/$2,195 nonmembers; *Faculty:* John Brecker

Cleaning Validation—Lab April 19–21, 2004

Advanced Environmental Mycology Identification Workshop September 2–3, 2004

Ensuring Measurement Integrity in the Validation of Thermal Processes November 11–12, 2004

Aseptic Processing 2004 Training Program—Lab **Option 1**: January 26–30, 2004 and February 23–27, 2004; **Option 2**: March 22–26, 2004 and April 26–30, 2004; **Option 3**: May 24–28, 2004 and June 14–18, 2004; **Option 4**: August 16–20, 2004 and September 13–17, 2004; **Option 5**: October 4–8, 2004 and November 1–5, 2004; $7,800 members/$9,300 nonmembers; *Faculty:* John Lindsay and David Matsuhiro ■

These courses will be held at the PDA Training & Research Institute (PDA-TRI) in Baltimore, MD, unless otherwise noted. **For course content information,** call PDA-TRI directly at +1 (410) 455-5800.

For registration information, call PDA's world headquarters in Bethesda, MD at +1 (301) 656-5900.

PDA Training & Research Institute Location/Lodging Information

Unless otherwise noted, PDA Training & Research Institute courses are held at: PDA Training & Research Institute, UMBC Technology Center, 1450 South Rolling Road, Baltimore, MD 21227, Tel: +1 (410) 455-5800; Fax: +1 (410) 455-5802.

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

Baltimore Hilton & Towers Inner Harbor
+1 (410) 539-8400
+1 (410) 625-1060 - fax

Baltimore Marriott Inner Harbor
+1 (410) 962-0202
+1 (410) 625-7892 - fax

Courtyard Baltimore Downtown/Inner Harbor
+1 (443) 923-4000
+1 (443) 923-9970 – fax

Courtyard by Marriott–BWI
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+1 (410) 859-5068 – fax

Embassy Suites BWI
+1 (410) 850-0747
+1 (410) 850-0816 – fax

Holiday Inn—BWI ***
+1 (410) 859-8400
+1 (410) 684-6778 – fax

Holiday Inn Inner Harbor **
(*Special Rates for our course attendees*)
+1 (410) 685-3500
+1 (410) 727-6169 – fax

Homewood Suites BWI*
+1 (410) 684-6100
+1 (410) 684-6810 – fax

Hyatt Regency Baltimore Inner Harbor
+1 (410) 528-1234
+1 (410) 605-2870 – fax

Sheraton International Hotel BWI
+1 (410) 859-3300
+1 (410) 859-0565 - 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 www.baltconvstr.com, the Baltimore Convention and Visitors Bureau's Web site.

Transportation to the PDA Training & Research Institute:
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.

Registration Form

R

PDA Training & Research Institute Courses

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

Preferred Address: ❑ **Business** ❑ **Home**			
❑ Mr. ❑ Ms. ❑ Dr. First Name	Middle Initial	Last Name	
Job Title		Membership Number	
Company/Organization			
Address			
City	State/Province	ZIP+4/Postal Code	
Business Phone	Fax	E-mail	

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

2. **Indicate the session you wish to attend and indicate appropriate fee category.** **Not a current PDA member?** Join today and … Save up to 50% on PDA training courses, conferences, and publications; Gain access to expert, peer reviewed information relevant to *your career*; Connect to global and regional science and regulatory expertise; Become a part of the world's leading international network of pharmaceutical and biopharmaceutical professionals. For more details on PDA membership and the many benefits of becoming a member, visit www.pda.org!

Course Title/Course No.	Date	Current Member	Join PDA and Attend Course	Attend Course Only; Do Not Join PDA	Government/Health Authority Employee *
				TOTAL	

** You must be an employee of an official government agency or health authority to qualify for this rate.*

3. **Payment Options** (please check one).

❑ A. By **Credit Card** (VISA, MasterCard/EuroCard, American Express), clearly indicating account number and expiration date. **Proceed to Item 4 below.**

❑ B. By **Bankers' Draft** forwarded together with the registration form PAYABLE IN US DOLLARS ONLY to:

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Please mark here to request a **PROFORMA INVOICE** from PDA to process your company payment.[1] ❑

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4002 Basel, Switzerland

[1] You are not considered registered for a PDA course until payment is received and a confirmation letter is issued by PDA. Should you attend a course without a formal confirmation or receipt of payment you will be required to provide a credit card as guarantee of payment at the time of the course.

4. **Please check the appropriate box:** ❑ Check Enclosed ❑ Wire Transfer Charge: ❑ MastercardCard/EuroCard ❑ VISA ❑ AmEx

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Signature:_____ Date:_____

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5. **Return completed form with payment made to:** PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA **FAX:** +1 (301) 986-1093 (credit cards only)

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 up to the time of the course. 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 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. **For more details, call PDA at (301) 656-5900.**

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Chapter Focus on Southern California

Based in Irvine, Calif., the PDA Southern California Chapter has two to three major seminars annually. The seminar subjects vary from the latest U.S. FDA regulatory initiatives and guidances to common FDA-483 observations and how to avoid them. The Chapter leaders meet monthly to discuss seminar dates, subjects, and guest speakers.

The Chapter was conceived by PDA Chairman Floyd Benjamin and former PDA President Edmund Fry. Following their lead, a group of Southern California PDA members formed the Chapter in 1996. Among the founders was Glenn Wright, Global Regulatory Affairs Director, Eli Lilly and Company, who has since become a member of the PDA Board of Directors. From Dec. 2002 through March 2003, Glenn chaired the PQRI Aseptic Processing Working Group, the work product of which helped shape the FDA draft guidance for aseptic processing, published Sept. 3.

The Southern California Chapter currently is led by President Kikoo Tejwani, Corporate VP, Quality/Regulatory Compliance, B. Braun Medical, Inc. Under his watch, the chapter's membership grew by 25%. Kikoo is a candidate in the 2003 PDA Board of Directors election.

The Chapter's latest offering is "An Evening with FDA at the Disneyland Hotel" on "Pre-Approval Inspections: How to Prepare for a Successful PAI" in Anaheim, Calif. (Nov. 20). There will be no "mousing" around at this event as FDA Los Angeles District Office Consumer Safety Officer Caryn McNab and industry consultant Jeff Yuen (President of Jeff Yuen & Associates) address challenges involved with preparing for a preapproval inspection.

For more information about the PDA Southern California Chapter, please visit its Web site at www.pdasc.org. More information on this and other PDA chapters, including PDA Chapter News (the association's monthly, Web-based communication for members specifically targeted towards those active in our chapters) can be found on at www.pda.org. ■

—Kiki Coffman

Monthly Chapter News Update—November

Australia

The PDA Australia Chapter hosted a special holiday meeting on November 27 in Melbourne. Neal Koller, president of PDA, spoke about "PDA and the Future" and Tony Gould, chief auditor of the Therapeutic Goods Association (TGA), spoke about "Regulatory Changes in Australia." The event was held at the Ascot House in Melbourne. For more information, please contact Chapter President Ken Dibble by E-mail at ken_dibble@millipore.com.

Canada

PDA Canada Chapter has wrapped up its meetings for the year. Individuals interested in helping out within the Canadian Chapter, please contact Chapter President Grace Chin by telephone at +1 (416) 422-4056, ext. 230, or E-mail at grace.chin@snclavalin.com.

Capital Area

The PDA Capital Area Chapter held a dinner meeting titled, "Current Technologies Applied to Biopharmaceutical Analysis" presented by Charles L. Soliday, Ph.D., Director of BioMolecular Analysis for Biopharmaceutical Group MDS Pharma Service. The meeting was held October 1 at the Gaithersburg Holiday Inn in Gaithersburg, Md. For more information on the Chapter's activities, please contact Chapter President Robert Mello, Ph.D., by telephone at +1 (410) 455-5981, or E-mail at rjmello1@aol.com.

Central Europe

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Delaware Valley

PDA Delaware Valley Chapter presented "Sterile Drug Product Manufacturing Processes—The New Drug Application Review Perspective" on September 17. The event's featured speaker was Peter Cooney, Ph.D., of the FDA. The Chapter's next scheduled meeting was held on November 19. The meeting focus was "CAPA Investigations in GMP Environments," presented by Terry Munson of KMI Consulting Services. For more information, visit the Delaware Valley Chapter's Web site at www.pdadv.org.

Israel

PDA Israel held a one-day meeting on Microbiological issues in September. The Chapter's annual meeting is scheduled for December 14. For more information, please contact Israel Chapter Liaison Karen S. Ginsbury by telephone at +972-3-921-4261, or E-mail at kstaylor@netvision.net.il.

Italy

PDA Italy Chapter presented "A Comparison of Experiences: The Approach of the Pharmaceutical Companies in Italy Towards the 21 CFR Part 11" a 2-day conference held in Milan—on the 11 and 12 of November, 2003. This was a joint conference with the Italian Affiliate of ISPE and with AFI (Italian Pharmaceutical Association), following the issuance of the "Good Practice and Compliance for Electronic Records and Signature - Part 1 and Part 2" documents, produced jointly by ISPE and PDA—and the latest revision of the Code of Federal Regulations by FDA.

About 20 qualified speakers—coming from different pharmaceutical companies (both Multinational and local ones which have one or more manufacturing plants in Italy)—will show their company's strategy and actual plan implementation to address the requirements of 21 CFR Part 11—and there will be adequate room for debate.

Sion Wyn, member of the GAMP council , will participate in the conference. Wyn will talk about the new "risk based" approach of FDA, in regard to computers and software validations. For more information, please contact Chapter President Vincenzo Baselli by telephone at +39-02-477-96217, or E-mail at vincenzo_baselli@pall.com.

Japan

PDA Japan Chapter held a meeting titled, "How to Receive FDA Inspection" on September 30. The PDA Japan Chapter Annual Meeting was held on October 28–29. For more information, contact Hiroshi Harada by telephone at +81-3-3815-1681, or E-mail van@bcasj.or.jp.

Korea

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+82-2-560-7822

Metro

The PDA Metro Chapter hosted a meeting titled, "A Critical Review of FDA's Draft Aseptic Processing Guidance: Implications for Compliance," presented by Jim Agalloco, Agalloco & Associates. The event was held on October 8th, at Crown Plaza Hotel in Clark, NJ. For more information on upcoming events, please contact Frank R. Settineri by telephone at +1 (908) 730-1222, or E-mail at frank_settineri@chiron.com.

Midwest

The PDA Midwest Chapter held a meeting on September 25. The meeting's topic focused on endotoxin and served as a kickoff for a Midwest Chapter interest group headed by Peter Lee, Ph.D. The Chapter's next meeting was held November 20. For more information, please contact Amy Gotham by telephone at +1 (847) 564-8181 x263, or E-mail at PDAMidwest@northviewlabs.com.

Mountain States

The PDA Mountain States Chapter hosted a successful vendor night on September 11.

The Chapter also held a speaker dinner on November 13. The speaker for the November dinner was a former Denver FDA Director. For more information, please contact Jeff Beste by telephone at +1 (303) 832-8100, or E-mail at cmdjeff@aol.com.

New England

The PDA New England Chapter held a dinner seminar September 24. The presentation addressed CFR 11. The Chapter will have another meeting in December and also held for a social event in conjunction with the PDA-TRI Boston Course Series in October. For more information, please contact Mark A. Staples, Ph.D., by telephone at +1 (617) 456-9290, or E-mail mstaples@glycogenesys.com.

Southeast

The PDA Southeast Chapter held its "Fall Exhibitor Show & Meeting" on September 23. The Chapter is planning a "Joint Meeting with the North Carolina Pharmaceutical Discussion Group and the PDA Southeast Chapter" to be held January 13, 2004. For more information, please contact Mary Carver by telephone at +1 (919) 474-2149 or E-mail at mary_carver@eisai.com.

Southeast Asia

For more information about the PDA Southeast Asia Chapter, please contact K.P.P. Prasad at Prasadk@labs.wyeth.com.

Southern California

The Southern California Chapter held a meeting on September 18. The topics were "Isolator Design & Validation" and "Aseptic Guidelines."

The Chapter also hosted another meeting in November. The Chapter held "An Evening with FDA at the Disneyland Hotel" on the following topic: "Pre-Approval Inspections: How to Prepare for a Successful PAI."

The presenters were Caryn McNab, a Food & Drug Administration Investigator with the Los Angeles District Office; and Jeff Yuen, President of Jeff Yuen & Associates. The event was held November 20, at the Disneyland Hotel in Anaheim, Calif. For more information about the PDA Southern California Chapter, please visit the Chapter's Web site at www.pdasc.org.

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Monthly Chapter News Update, from page 31

Taiwan

The PDA Taiwan Chapter announced a new listing of officers: As of July 25, 2003, the PDA Taiwan Chapter new president elect is Mr. Shin-Yi Hsu; Secretary General is Tuan-Tuan Su; and Chapter Liaison is James T.S. Tu. The Chapter is planning to host their next event in 2004. For more information, please contact Tuan-Tuan Su by telephone at +8862-2550-9301, or E-mail at pdatc@ms17.hinet.net.

UK & Ireland

The PDA UK & Ireland Chapter's next meeting will be held in March 2004. For more information about the Chapter, please contact John Moys by telephone at +44-1372-737-140, or E-mail at john.moys@sartorius.com.

West Coast

The PDA West Coast Chapter hosted a Chapter Dinner Meeting on October 9. The title of the programs was "Applications of Failure Mode and Effect Analysis in Bioprocesses." Dr. Robert J. Seely, Corporate Validation, Amgen, Inc. presented at the meeting. For more information visit the Chapter's Web site at www.istep.com/~randallt/wccpda/. ■

—compiled by KiKi Coffman

Important, new and timely information. Pertinent and useful tools for all levels of expertise. Keep your company ahead of the curve. Attend the SciTech Summit™.

PDA SciTech Summit™

March 8–12, 2004 • Orlando Convention Center • Orlando, Florida

Plan now to attend PDA's "new" annual meeting—the 2004 SciTech Summit™. A week-long series of scientific sessions and training courses is now being planned to provide those in the industry with a one-stop "shop" for all training and education needs.

The most critical issues facing industry in science and technology, production and manufacturing, QA/QC and regulatory science and biopharmaceutical science will be debated and discussed. Industry and regulatory experts will: explain process analytical technologies; rapid microbial methods; aseptic processing that meets regulatory expectations; new manufacturing technologies; isolation technologies and user issues; interpreting and complying with new regulatory guidances; understanding the Annex 13 clinical trials directive; and Part 11 issues, updates and answers.

What is new about this conference? Expanded discussion time with scientific experts and regulatory representatives. A focus on new science and new technologies such as nanotechnology, chemometrics and the design of experiments. More opportunities for discovery, discussion and networking are being offered.

With the strategic co-location of the 2004 SciTech Summit with the CleanRooms East Exposition, professionals will discover cutting-edge expertise and state-of-the-art technology for contamination control and drug manufacturing.

Over 300 leading companies in Contract Services, Cleanrooms, Environmental Monitoring, Filtration, Validation, Training Materials & Services, Software and more will be represented in the exhibit hall. This is your opportunity to benefit from face-to-face interaction with decision-makers and leaders of domestic and international pharmaceutical and biopharmaceutical science and technology industries from companies large and small.

This coming year, the CleanRooms East Exposition 2004 conference will offer the perfect complement to the PDA SciTech Summit, offering three days of sessions geared toward facility design and construction, cleanroom ISO standards, HVAC and air filtration engineering issues, proper gowning techniques as well as panel discussions aimed to help end users find proper retrofit and construction solutions.

Exhibitors: Take advantage of this exciting event in Orlando, Florida and increase your brand recognition along unbeatable visibility for your products and services—and set time aside for a family vacation during the best season of the year in Disney World.

Reserve your space today!

Delegates: Take advantage of all that Orlando has to offer—including a fun-filled reception at Universal Studios—part of your full conference registration. Special discounts will apply to three or more individuals registering from the same corporate site. Chances to win a free conference registration are being offered to each chapter.

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

New member contact information is forwarded to Chapters on an ongoing basis. For immediate notification of Chapter events, please contact your local representative and ask to be placed on the Chapter mailing list.

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PDA
An International Association For Pharmaceutical Science And Technology

2003–04 Premium Technology Providers™ Named By Audit Repository Center (ARC)

World Renowned Technology Companies Recognized for Most-Commonly Requested Product Audits In Compliance with FDA Regulations

A list of Premium Technology Providers™, including several of the most well-known and respected vendors, was released today by the Audit Repository Center. ARC is a unique clearing-house for standardized industry evaluations of commercial off-the-shelf (COTS) software and hardware products used by firms engaged in FDA-regulated industries.

According to Harvey Greenawalt, ARC President, "The ARC organization is pleased to announce that Agilent Technologies, Documentum, Inc., Fisher Rosemont Systems, MERANT, Inc., Mercury Interactive, and Sparta Systems, Inc. are 2003–04 Premium Technology Providers. Audits of their software and systems in compliance with FDA regulations, including 21 CFR Part 11, continue to be the most popular requested by ARC subscribers."

"Members of ARC," explained Mr. Greenawalt, "include Bristol-Meyers Squibb Company, Eli Lilly & Co., Novartis Pharmaceuticals Corporation, Pfizer, Schering-Plough and dozens of other leading pharmaceutical companies.

Pharmaceutical industry members now—at 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 the industry standard process defined in PDA Technical Report #32 between and among participating companies.

About ARC and PDA

PDA—An International Association for Pharmaceutical 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 #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.

The Audit Repository Center is headquartered in Pottstown, PA, 19464; phone 610-970-1083; fax 610-970-4272; or www.auditcenter.com. ■

Company, Colleague & Product Announcements

Cambrex to Preview Breakthrough On-line System to Measure Endotoxin: Cambrex Bio Science Walkersville, Inc. has announced that it will preview its new on-line PyroSense™ endotoxin detection system at the PDA Annual Meeting. PyroSense will allow in-process monitoring of fever-causing gram-negative bacterial endotoxin in "water for injection" (WFI) systems used for the production of injectable drugs, medical devices, and other therapeutic products.

PyroSense automatically monitors endotoxin levels in WFI and high purity water systems. This robust and reliable system is designed to test round the clock—seven days per week. Companion 21 CFR Part 11 compliant host software stores raw data and test results, provides immediate feedback on water quality across a company network, and provides an efficient tool for trending endotoxin levels.

This new technology moves endotoxin testing from the lab bench to the water loop and replaces the manual collection and testing of samples with an automated process. PyroSense provides consistent testing techniques using robotics and an easy-to-use snap-in reagent cartridge for replenishing supplies. It allows for more frequent WFI testing at key points in the process without increasing labor and reduces the risk to finished products by providing test results when you need them where you need them.

This advanced and innovative endotoxin detection system supports the FDA's Process Analytical Technology initiative aimed at improving the current level of quality assurance for products manufactured by the pharmaceutical and medical device industries through improved technology and automation.

Cambrex, East Rutherford, NJ, USA, is a global, diversified life science company dedicated to providing high quality products and services to accelerate drug discovery, development, and manufacturing processes for customers focused on health and the prevention of disease. The Company employs approximately 2200 worldwide. For more information, please visit our Web site at http://www.cambrex.com.

Agilent Technologies' New Software for Agilent 2100 Bioanalyzer Features Compliance Support, Enhancements: Agilent Technologies has introduced new software with compliance features that enable the Agilent 2100 bioanalyzer to be used for the development and manufacture of protein-based therapeutics in regulated environments, such as the pharmaceutical and biotechnology industries. It also offers significant improvements in usability, data analysis, results handling and reporting.

The new Agilent 2100 expert software is the first element of Agilent's plan to further develop the Agilent 2100 bioanalyzer system into a compliance solution for customers in regulated environments, specifically those involved in the QA/QC and manufacturing of antibodies and other protein pharmaceuticals. Since 2000, regulators in Europe and North America have approved 64 protein-based drugs (1), comprising more than a quarter of all new drug approvals. The Agilent 2100 bioanalyzer, combined with the Protein 50 or Protein 200 Plus LabChip® Kits, provides a fast and easy method of analyzing protein size, concentration, purity and integrity.

As part of this introduction, Agilent is providing software support for installation qualification (IQ) and operational qualification/performance validation (OQ/PV) in a dedicated validation context. Agilent is also introducing IQ and OQ/PV services and "Declarations of Conformity" for reagents and chips. Declarations of Conformity state that during final verification, a product's functional characteristics are individually tested for conformance with the manufacturer's internal specifications.

Agilent next plans to introduce a security software pack, which will enable full 21 CFR Part 11 compliance for electronic signatures, audit trails and user authentication.

The software introduced today also provides a consolidated platform for all Agilent 2100 bioanalyzer assays. These assays, used to assess the quality and quantity of DNA, RNA and proteins, as well as monitor cell parameters, had previously required two dedicated software modules. The software's other enhancements include:

- improved integrator and manual integration capabilities;
- normal and advanced user modes;
- color-coded result flagging tool;
- enhanced reporting, export and printing functions; and
- customizable result tables and gel-like images.

The Agilent 2100 bioanalyzer is the market-leading microfluidics-based system for automated quality control, sizing and quantification of nucleic acids or proteins, and simple flow cytometric analyses. The system uses micro-fabrication technology to transfer laboratory processes onto miniature glass chips. Integrating sample preparation, fluid handling and biochemical analysis, the system offers several advantages over traditional gel electrophoresis in terms of speed, automation, sample use and data quality.

Agilent Technologies Inc. (NYSE: A) is a global technology leader in communications, electronics, life sciences and chemical analysis. The company's 30,000 employees serve customers in more than 110 countries. Agilent had net revenue of $6 billion in fiscal year 2002. Information about Agilent is available on the Web at www.agilent.com.

Cambrex Announces New Chiral Technologies: Cambrex Corporation has announce new pathways to chiral molecules used in active pharmaceuticals ingredients (APIs) and ad-

continues on page 36

Send announcements on personnel changes and new products . . .

to **Walter Morris** via e-mail at morris@pda.org or mail a hard copy to PDA global headquarters at 3 Bethesda Metro Center, Suite 1500, Bethesda, MD 20814.

Company & Colleague News, from page 35

vanced intermediates through a business alliance agreement with Dextra Laboratories Ltd. located in Reading, UK.

Dextra specializes in the early development of unique sugar and carbohydrate technologies used to produce chiral pharmaceutical building blocks including the synthesis of carbohydrate building blocks, carbohydrate based libraries, oligosaccharides, monosaccharides, aza sugars, and locked nucleosides.

Carbohydrates are components of many drugs and drug intermediates and can be derived from the carbohydrate pool. Carbohydrates provide a means to achieve multiple contiguous chiral centers that can be chemically manipulated to form the desired drug intermediate. Using Dextra's technology, Cambrex can generate more complex molecules using their proprietary enzyme technologies coupled with Dextra building blocks to support combinatorial drug discovery with complex, chiral materials of known structure and configuration.

"Our collaboration with Dextra will enhance our in-house capabilities with unique technologies to produce multiple chiral centers and generate more complex molecules with enhanced functionality through the addition of carbohydrate side chains," commented Gary Mossman, President Cambrex Pharma Business Unit, "We believe the alliance will enhance our portfolio of enabling technologies for novel new drugs from a single source."

"For some time at Dextra, we have been excited about the potential of carbohydrates as chiral building blocks. We believe that this alliance can pave the way to new classes of drug candidates through the provision of hitherto unavailable chiral structures in quantities suitable for practical development work," commented Dr. Andrew Hacking, Joint Managing Director, Dextra Laboratories Ltd.

Dextra Laboratories specializes in all areas of carbohydrate research, synthesis and analysis for the pharmaceutical industry. The Company provides over 250 catalogue products plus carbohydrate building blocks and combinatorial libraries. At Dextra, we retain a flexible approach to tackling new projects and challenges in the areas of carbohydrate chemistry and biology. For more information, please visit the Dextra Web site at http://www.dextralabs.co.uk. ■

Calendar of Events, from back cover

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

June 15–17, 2004
PDA Training & Research Institute
Toronto Course Series
The Westin Harbour Castle
Toronto, CANADA

◆ June 28, 2004
PDA Presents
Basel Pharmaceutical and Biopharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

August

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

◆ August 30, 2004
PDA Presents
European Rotational Forums
Location TBA
Berlin, GERMANY

September

September 2–3, 2004
PDA Training & Research Institute Laboratory Course
Advanced Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

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

◆ September 27, 2004
PDA Presents
Basel Pharmaceutical and Biopharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

October

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

November

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

November 11–12, 2004
PDA Training & Research Institute Laboratory Course
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA-TRI Baltimore, MD

◆ November 29, 2004
PDA Presents
European Rotational Forums
Location TBA
Lisbon, PORTUGAL

December

December 2–3, 2004
PDA Training & Research Institute Laboratory Course
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

◆ December 13, 2004
PDA Presents
Basel Pharmaceutical and Biopharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

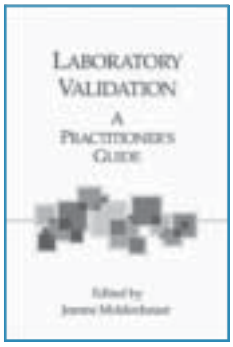
NEW BOOKS & TRAINING CDs

at PDA ... your source for scientific, technical, and regulatory information.

Just Released New Book!

Laboratory Validation: A Practitioner's Guide

Edited by Jeanne Moldenhauer



In recent years, regulatory inspections have focused on laboratory testing performed to assess the quality attributes of a product. In many cases, the testing is so specialized or complex, that the entire responsibility for validation has been transferred to the laboratory personnel. This excellent guide and reference provides an overview of validation from a laboratory perspective.

Divided into three parts, Part 1 includes an overview of many of the laboratory support systems and equipment common to both microbiology and chemistry laboratories. Part 2 is dedicated to systems applicable specifically to the chemistry laboratory, and Part 3 covers the systems applicable to microbiology laboratories. Where the laboratory predominantly performs the test, for example, cleaning and disinfection, requirements are included within the text. While the book offer validation details representative of the most common types of laboratory systems, should you have a system that is not included, the information in these 38 chapters will likely be of great assistance in providing resources for compilation of requirements for other systems. 1,224 pp; hardcover; $250 member/ $309 nonmember **Item No. 17201**

NEW TRAINING CDs

(All of the programs have been developed for pharmaceutical and biopharmaceutical operations: programs may be used for individual or group training.)

A Training Program for a System Audit of the Operation, Control, Qualification, Validation and Design of a WFI System $500 member/$1,495 nonmember **Item No.11012**

Control of Ray Materials for Pharmaceutical and Bio-Pharmaceutical Operations $300 member/$895 nonmember **Item No.11001**

Cross-Contamination in the Production of Pharmaceuticals and Bio-Pharmaceuticals $300 member/$895 nonmember **Item No.11002**

Finishing Operations in the Production of Pharmaceuticals and Bio-Pharmaceuticals $300 member/$895 nonmember **Item No.11004**

Good Manufacturing Practice Regulations, 21 CFR Parts 210-211, Sub-Parts B thru K $300 member/$895 nonmember **Item No.11005** (single program); $1,500 member/$4,500 nonmember **Item No.11014** (Set of 10 programs)

Managing an FDA Inspection in Your Facility-Establishing a Proactive System for Managing an FDA Inspection–A Quality and Compliance Training Program $300 member/$895 nonmember **Item No.11006**

Quality Assurance Standards for the Manufacture and Control of Injectable Products—A Quality and Compliance Training Program $300 member/$895 nonmember **Item No.11007**

Quality Indicator Reports—A Proactive Management System $300 member/$895 nonmember **Item No.11008**

Shep's Systems Audits© $300 member/$895 nonmember **Item No.11009** (single program); $1,500 member/$4,500 nonmember **Item No.11015** (Set of 10 programs)

Team Biologics Inspection Program for Bio-Pharmaceutical Operations, FDA Compliance Program 7341.001 $500 member/$1,495 nonmember **Item No.11010**

Technology Transfer Process for Pharmaceuticals and Bio-Pharmaceuticals $300 member/$895 nonmember **Item No.11011**

The Development Report—A Discussion and Outline for a Development Report $300 member/$895 nonmember **Item No.11003**

Using the FDA Pre-Approval Inspection Compliance Program in Preparing for an Inspection $300 member/$895 nonmember **Item No.11013**

For complete descriptions, visit our Web site, www.pda.org.

PDA-DHI Press Best Sellers

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Commercial Off-The-Shelf Software Validation for 21 CFR Part 11 David Nettleton and Janet Gough; Validation clearly is a requirement for regulatory compliance. Every indication is that the regulations will focus more and more on the electronic generation of data, data control, and data transfer. The goal of this book is to provide guidance for validating commercial, off-the-shelf (COTS) computer software that generates data or controls information about products and processes subject to binding regulations. This book provides the practical information needed to ensure an understanding of the FDA-issued guidance as they develop systems that will enable them to go partially or fully electronic; hardcover; 118 pp; $185 members/$229 nonmembers **Item No. 17200**

JUST RELEASED

The Essence of GMPs: A Concise Practitioner's Guide U.G. Barad; 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.

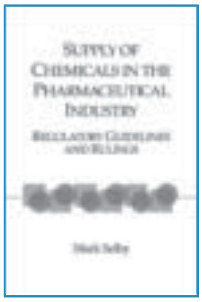
The purpose of the book is to enable novices, busy executives, and hard-pressed colleagues to quickly gain access to excellent global GMP practice and expectations. Beginners will find that it provides a solid prescription in preparation for the constantly expanding global GMPs. Experienced readers will find this book invaluable as a tool for assistance in the preparation and design of common practices worldwide by enabling them to speak on common quality language regardless of location. 280 pp; $185 members/$229 nonmembers; hardcover **Item No. 17203**

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; hardcover **Item No. 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; hardcover **Item No. 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; hardcover **Item No. 17183**

Supply of Chemicals in the Pharmaceutical Industry: Regulatory Guidelines and Rulings Mark Selby; 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 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, also complete with examples of test guidelines. The book 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 members/$229 nonmembers; hardcover **Item No. 17204**



Good Practice and Compliance for Electronic Records

Published jointly with ISPE

Part 1—Good Electronic Records Management (GERM): Electronic Information Assurance for the Regulated Industry—Guide to Current Good Practice for Electronic Records and Signatures 2002; 104 pages; $95 PDA members/$190 nonmembers **Item No. 19003**

Part 2—Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures 80 pages; $95 members/$190 nonmembers (English) **Item No. 19001**

Also available in German and Spanish. For more information, visit www.pda.org.

Selected PDA Technical Reports

Item No.	Title	Price Member	Price Nonmember
03004	Points to Consider for Aseptic Processing	$75	$550
01036	Technical Report No. 36	$75	$550
01034	Technical Report No. 34	$75	$550
01033	Technical Report No. 33	$75	$550
01030	Technical Report No. 30	$75	$550
01029	Technical Report No. 29	$75	$550
01026	Technical Report No. 26	$75	$550
01013	Technical Report No. 13	$75	$550
01011	Technical Report No. 11	$75	$550
01001	Technical Report No. 1	$75	$550
01032	Technical Report No. 32	$100	$575
01132	Technical Report No. 32 CD version	$75	$550

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Cleaning & Cleaning Validation: A Biotechnology Perspective Authors: Roger Brunkow, David DeLucia, George Green, Shane Haft, John Hyde, John Lindsay, Jill Myers, Robert Murphy, John McEntire, Karen Nichols, Ray Prasad, Brenda Terranova, Jon Voss, Caroline Weil, and Edward White; This book is intended to serve as a source of practical technical information for those persons in the biotechnology industry. Case studies and/or actual industry examples are used to support the text wherever possible. While much of the material contained within this text is equally applicable to non-biopharmaceutical processes, the emphasis has been focused directly upon biopharmaceutical manufacturing. 1995; 190 pp; $125 members/$320 nonmembers **Item No. 13002**

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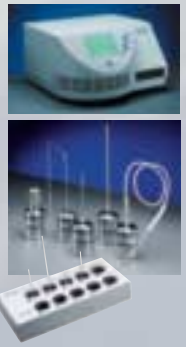

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Calendar of Events

2003

December

December 4–5, 2003
PQRI Blend Uniformity Workshop
Hyatt Regency, Bethesda, MD

December 4–5, 2003
PDA Training & Research Institute Laboratory Course
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

◆ December 8–9, 2003
PDA Presents
Basel Pharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

2004

January

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

February

February 4–6, 2004
PDA Training & Research Institute
Lake Tahoe Course Series
Hyatt Regency Lake Tahoe, Incline Village, NV

February 12–13, 2004
PDA Training & Research Institute Laboratory Course
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

◆ February 16–20, 2004
2004 PDA International Congress—Basel
Science, Technology and Regulations in the Global Pharmaceutical Industry
Congress: February 16–18
Courses: February 19–20
Tabletop Exhibits: February 16–18
Messe Basel Convention Center
Basel, SWITZERLAND
PDA Training & Research Institute Lecture Courses:
February 19
Clinical Trials Directive & MP for Investigational Medicinal Products
Risk Estimation in Aseptic Processing
February 19–20
CGMPs for Bioprocesses
Ventilation & Airborne Contamination in Cleanrooms
Pragmatic Cleaning Validation

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

March

◆ March 1, 2004
PDA Presents
European Rotational Forums
Location TBA
Barcelona, SPAIN

March 4–5, 2004
PDA Training & Research Institute Laboratory Course
Ensuring Measurement Integrity in the Validation of Thermal Processes
PDA-TRI Baltimore, MD

March 8–12, 2004
PDA SciTech Summit™
Conference: March 8–12
Courses: March 10–12
Exhibition: March 9–11
Orlando County Convention Center, Orlando, FL

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

◆ March 29, 2004
PDA Presents
Basel Pharmaceutical and Biopharmaceutical Forums
UBS Ausbildungs-und Konferenzzentrum
Basel, SWITZERLAND

April

April 19–21, 2004
PDA Training & Research Institute Laboratory Course
Cleaning Validation
PDA-TRI Baltimore, MD

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

May

May 13–14, 2004
PDA Training & Research Institute Laboratory Course
Environmental Mycology Identification Workshop
PDA-TRI Baltimore, MD

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, 2004
PDA Presents
European Rotational Forums
Location TBA, Amsterdam, THE NETHERLANDS

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

June

◆ June 7–8, 2004
PDA/R3 Nordic
Scientific, Industrial, and Regulatory Aspects of Clean Products and Devices
Stockholm, SWEDEN

continues on page 36

◆ Denotes European program/meeting

■ Denotes Pacific Rim program/meeting

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