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PDA Letter

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February 2007

In This Issue…

PDA Parenteral Drug Association

Connecting People, Science and Regulation℠

Review of USP Microbiology Chapters

A Report from the PDA Global Conference on Pharmaceutical Microbiology

David Porter, PhD, Vectech Pharmaceutical Consultants

There has been a lot of activity pertinent to general chapters relevant to microbiology in the US Pharmacopeia (USP) recently. A number of new general chapters and major revisions to existing chapters have appeared in *USP 29 2nd Supplement.* Significant revisions to additional chapters have appeared in recent issues of *Pharmacopeial Forum*. Several of these revisions were discussed in two "USP Focused" sessions at PDA's Global Conference on Pharmaceutical Microbiology, held Oct. 30 – Nov. 1, 2006, in Bethesda, Md. The purpose of this article is to report on the discussions of these chapters.

Before delving into the USP chapters that *were* discussed at the micro meeting, it is worth mentioning the one chapter that was noticeably absent from all discussion, <1222> "Terminally Sterilized Pharmaceutical Products—Parametric Release," published in *USP 27.* The lack of reference to <1222> is troubling because of the number of times parametric release of terminally sterilized products was discussed, particularly during discourse about quality by design and sterility assurance. The failure of participants to acknowledge this highly relevant USP chapter on the subject suggests that more effort needs to be extended in educating the pharmaceutical industry as to its existence and utility.

Chapter <1072> "Disinfectants and Antiseptics," published in *USP 29 2nd Supplement*, has apparently made more of an impression. It was brought up during the presentation "Disinfectant Qualification—An Overview." Presenter **Robert Guardino,** Director of Microbiology, AAI Pharma, mentioned that the chapter provided a good overview and referred to the chapter's section on disinfectant rotation. This new chapter was the focus of **J. Kirby Farrington's** presentation during the USP Focused Session. His presentation began with the importance of first cleaning the surface to be sanitized, as sanitization of a dirty surface can be problematic. Dr. Farrington, a research advisor in microbiology with Eli Lilly, then discussed the contents of the chapter in general and concluded with a statement that the chapter is a guidance document containing basic information on the effective use of disinfectants and antiseptics. This author would caution readers to remember that the USP does not enforce USP standards. Rather, it is the regulatory agencies (e.g., the US FDA) that carry out enforcement. Thus, it is possible for a regulatory agency to enforce portions of chapters numbered 1,000 or greater should they so choose.

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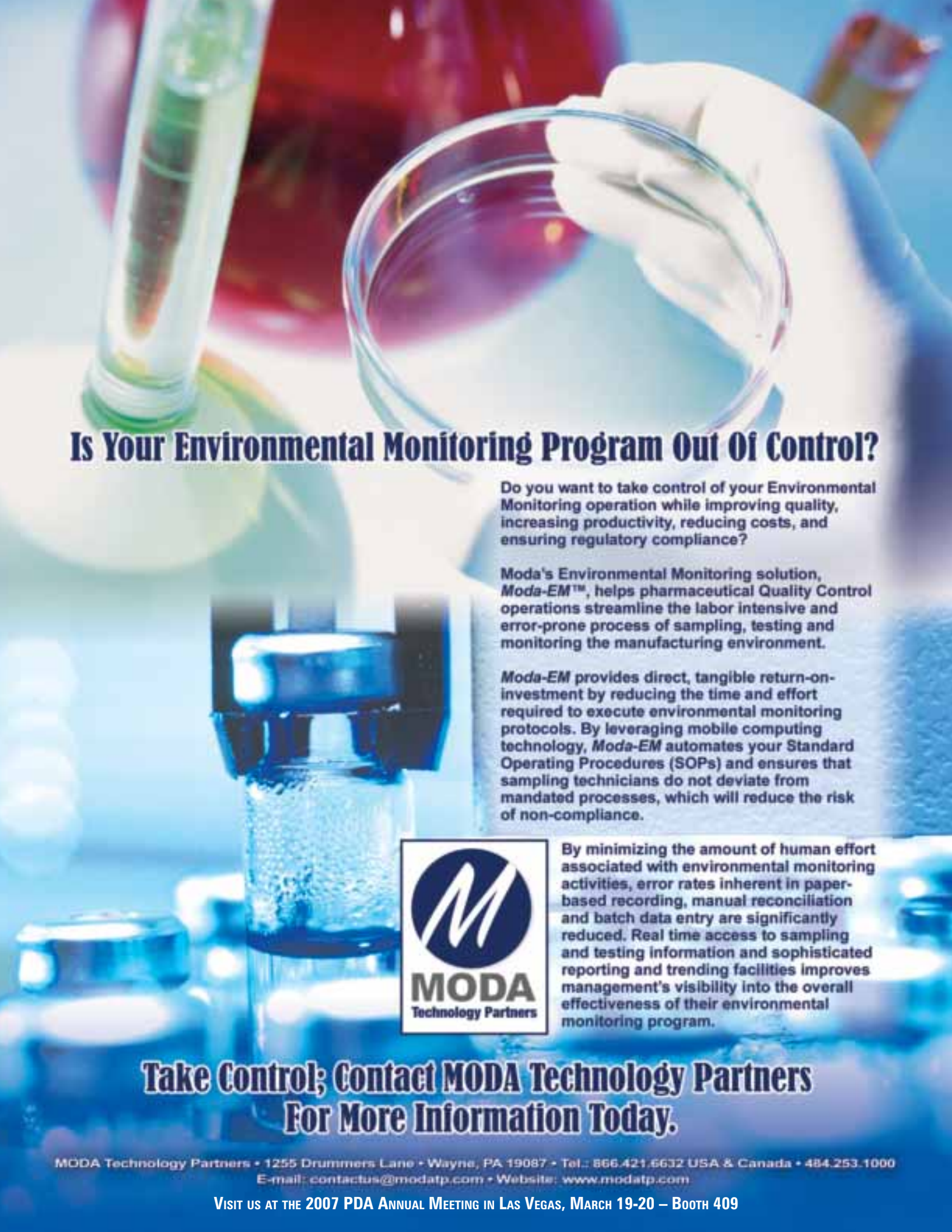

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Cover art: In late 2006, PDA sponsored a successful meeting on microbiology, a key science for many PDA members. (Image – Lactobacillus bacteria)

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Editor's Message

With sterile product manufacturing the core area of strength for PDA, microbiology is a key science for many of our members. On Oct. 30 – Nov. 1, 2006, PDA sponsored a successful meeting on pharmaceutical microbiology, which inspired the theme for this month's feature article. *PDA Letter* Editorial Committee member **Scott Sutton** helped us identify topics of interest discussed at that meeting and then followed up with speakers to request submissions. "Review of USP Microbiology Chapters: A report from the PDA Global Conference on Pharmaceutical Microbiology" by **David Porter** is one we hope will be valuable to the membership.

In the Science & Technology section of this issue, Scott also contributes a review of articles related to microbiology, which appeared in the *PDA Journal of Pharmaceutical Science and Technology* in 2006. We appreciate Scott's efforts to take his microscope, so to speak, to the Journal and identify all of the terrific microbiology-related work presented within it last year.

This month's Quality & Regulatory Affairs section contains articles originating from two other large PDA meetings during the latter half of 2006. German health authority official **Susanne Keitel** contributes "Quality Requirements for Clinical Trial Applications in the European Union" based on her talk at the 2006 PDA/EMEA Joint Conference; **Bob Dana** contributes "ICH Q10 Previewed at PDA Asia-Pacific Congress" based on a talk from the PDA Asia-Pacific Congress. In addition, the section includes reports from Europe based on two non-PDA conferences of interest: the first PIC/S stakeholders forum and an EMEA conference on Annex 1. We thank the PDA staff and members in Europe who provided these articles.

Yoshiaki Hara (far right), Sartorius KK, and colleagues take a break to perform

The newly expanded membership team is hard at work, and the fruits of some of their labor can be seen in the Letter this month. The Membership Resources section contains articles from the Puerto Rico and New England Chapters and a listing of new members. I want to highlight, in particular, the article on the Capital Area Chapter, written by the Letter's new Assistant Editor **Lindsay Donofrio**. This is Lindsay's first full article and we anticipate there will be many more in the coming months!

Finally, the February issue is the PDA Annual Meeting "Show Issue," so please be sure to check out all of the articles in the Programs & Meetings section on the conference and all of the ads from our sponsors participating in the Exhibition.

Editor's Note: The above photo from the 2006 PDA Asia-Pacific Congress was misprinted in the January 2007 issue of the *PDA Letter*. We apologize for this error.

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Articles of Interest to the Microbiologist

A Review of Microbiology-Related Research Published in Volume 60 (2006) of the *PDA Journal of Pharmaceutical Science and Technology*

Scott Sutton, PhD, Vectech Pharmaceutical Consultants

In keeping with this issue's theme of microbiology, I thought it might be interesting to go back over the past year of PDA Journals and review articles of specific interest to the field of microbiology that were published in volume 60 (2006). The scope of this review is limited to those articles on topics of immediate interest to the microbiology lab. For example, Part 11 issues are important, but not of immediate relevance, so not included. Issues of contamination in aseptic processing, on the other hand, although not specifically lab-related, are of microbiological concern and so appear below.

With that caveat, let me remind us all that the PDA Journal is a useful resource to the pharmaceutical QC microbiologist. In 2006 (volume 60) there were 12 articles and one technical report of direct relevance. These articles range from regulatory opinion, scientific review through to original research, and each are included in this review.

The summation below is arranged by issue number. Each individual citation includes the article title, author(s) and page number, followed by an uncritical description of the contents of each article (drawn heavily from the abstracts of each article). While specific passages from the abstracts are not enclosed with quotation marks, the author of this summation acknowledges the original authors and the fact that most of what appears below is, in fact, a reuse of their words.

Issue 1

Disinfection Using Ultraviolet Radiation as an Antimicrobial Agent: A Review and Synthesis of Mechanisms and Concerns. Piluso, LG *et al.* 1-16.

Piluso *et al* review the use of ultraviolet-based disinfection practices, the biological basis for them and some potential desensitization issues that may develop as well as suggesting some approaches to study and practically address these effects in this thorough review.

Issue 2

Viability-Based Rapid Microbiological Methods for Sterility Testing and the Need for Identification of Contamination. Moldenhauer, J. 81-88.

Dr. Moldenhauer reviews the science and regulatory issues surrounding the use of rapid microbiological methods (RMM) in sterility testing. She comprehensively reviewed currently available technologies against expectations. Particular weight was given to the need to have a preestablished strategy for evaluation of Sterility Test positives, as many of the rapid methods are destructive in nature. The current test, of course, allows identification of the contaminant as one of the first steps in this investigation. Dr. Moldenhauer also discussed the advantages and disadvantages of choosing a viability-based method of a non-growth-based method for this application.

Microbial Identification Strategies in the Pharmaceutical Industry. Cundell, AM. 111-123.

Dr. Cundell discusses the overall strategies that may be successfully applied to microbial identification in support of microbial monitoring of utilities, pharmaceutical ingredients, the manufacturing environment and finished products. Emphasis is given to the justification of the microbial identification program, selection of identification methods and use of speciation in successful product failure investigations.

The Expanded Application of Most Probable Number to the Quantitative Evaluation of Extremely Low Microbial Count. Sun, X *et al.* 124-134.

This paper is about the evaluation of the extremely low microbial counts from lab benches and cleanrooms by expanding the most probable number (MPN) methodology when the data follow Poisson distribution in order to achieve more accurate estimation with limited number of data. The MPN methodology was found to have a potential application for quality control in the extremely low level microbial counting environment in the cleanrooms levels ISO class 7 or above, and that further studies on the precision of this method and development of a sampling plan based on careful mathematical analysis will help to refine the approach.

Issue 3

Risk Assessment Paradigm: An Opportunity for Rationalizing the Choice of Biological Indicator During the Validation of Isolator Biodecontamination Cycles. Sansoe-Bourget, E. 156-163.

In this article the manufacture and control of biological indicators are analyzed using the hazard analysis and critical control point (HACCP) approach. The HACCP risk analysis, which must take into account the application of the isolator being qualified or requalified, is an efficient simplification tool for performing a decontamination cycle using either hydrogen peroxide gas or peracetic acid in a reliable, economical, and reproducible way. ➤

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Bacterial Adhesion to Surfaces: The Influence of Surface Roughness. Riedewald, F. 164-171.

Riedwald reviews literature on bacterial adhesion to surfaces with an eye to reduction of biofilm in pipes and other smooth surfaces. This article discusses the current practice of using highly polished stainless steel surfaces, which is thought to minimize initial bacterial attachment and at the same time to maximize cleanability. It is suggested that this industrial practice is a misconception in that it provides no real benefit, and that far rougher surfaces could be used without increasing the rate of bacterial attachment or compromising cleanability.

Issue 4

Impact of Tubing Material on the Failure of Product-Specific Bubble Points of Sterilizing-Grade Filters. Meyer, BK and D. Vargas. 248-253.

Meyer and Vargas investigated the effect of different preservatives commonly used in the biopharmaceutical industry on the product-specific bubble point of sterilizing-grade filters when used to filter product processed with different types of tubing. The preservatives tested were 0.25% phenol, m-cresol, and benzyl alcohol. The tubing tested was Sani-Pure® (platinum-cured silicone tubing), Versilic™ (peroxide-cured silicone tubing), C-Flex®, Pharmed®, and Cole-Parmer® (BioPharm silicone tubing). The results of their studies indicated that product-specific bubble point of a filter determined with only product may not reflect the true bubble point for preservative-containing products that are recirculated or contacted with certain tubing for 15 hours or greater. In addition, tubing material placed in contact with products containing preservatives should be evaluated for impact to the product-specific bubble point when being utilized with sterilizing-grade filters.

Current Practice in the Operation and Validation of Aseptic Blow-Fill-Seal Processes. Ljungqvist, B, *et al.* 254-258.

The authors summarize a worldwide survey performed by the BFS International Operators Association to illustrate current practice in aseptic blow-fill-seal (BFS) technology. The results are summarized and compared to the media fill data from the Product Quality and Research Institute (PQRI) survey reported in 2003. The survey highlights the differences and shows the robustness of the BFS technology. Compared to the results from the PQRI survey, the BFS survey shows a tenfold lower frequency of contaminated media fills.

Issue 5

Quantitative Risk Modeling In Aseptic Manufacture. Tidswell, EC and B McGarvey. 267-283.

Quantitative risk modeling augmented with Monte Carlo simulations represents a novel, innovative and more efficient means of risk assessment. This technique relies upon fewer assumptions and removes subjectivity to more swiftly generate an improved, more realistic, quantitative estimate of risk. The fundamental steps and requirements for an assessment of the risk of bioburden ingress into aseptically manufactured products are described. A case study exemplifies how quantitative risk modeling and Monte Carlo simulations achieve a more rapid and improved determination of the risk of bioburden ingress during the aseptic filling of a parenteral product in a technique that has promise in cleanroom management as well as the use of real-time data from RMM.

Challenges to a Blow/Fill/Seal Process with Airborne Microorganisms having Different Resistances to Dry Heat. Poisson, P, *et al.* 323-330.

Controlled challenges with air dispersed microorganisms having widely different resistances to dry heat, carried out on 624 BFS machine processing growth medium, have shown that higher the heat resistance, the greater the extent of vial contamination. Differences in heat resistance affected also the extent of vial contamination when parison and vial formation were knowingly manipulated through changes made to each of three process variables, provision of ballooning air, mould vacuum delay and parison extrusion rate. The findings demonstrate that, in this investigational system, exposure of challenge microorganisms to heat inherent in the process has a controlling influence on vial contamination, an influence that could also control microbiological risk in production environments.

Issue 6

Active Air vs. Passive Air (Settle Plate) Monitoring in Routine Environmental Monitoring Programs. Andon, BM. 350-355.

Andon discusses the utility of active air versus passive air settle plate monitoring in a routine environmental monitoring program with an emphasis on the monitoring of the critical Grade A environments. While historical precedent and regulatory emphasis has encouraged the use of settle plates in the pharmaceutical industry, Andon argues that current active air sampling technology can be more advantageous and effective in assessing airborne viable contamination in cleanrooms than settle plate monitoring. Given that both methods are designed to assess viable airborne contamination, there may be no advantage in performing these two parallel methods, especially if doing so increases the number of interventions into critical areas, which may in turn increase the risk of contamination without providing any added benefit in terms of data collection and/or process control. Therefore, the best use of settle plate ➤

monitoring may be as an optional test method for those applications where other, more efficient sampling methods may not be possible or may have limited applicability.

Microbiological Evaluation of Reused Catheter Guides in a Brazilian Hospital. De Silva, MV *et al.* 356-365.

De Silva *et al* evaluated the controversial, but increasing, practice of reusing single-use medical devices. They analyzed 30 catheter guide units that were reused four times in patients at a public hospital. The catheter guides were sterilized after each use with a mixture of ethylene oxide/chlorofluorocarbons (12:88). Each unit cut into segments and the segments analyzed for microbial counts (pour plate), direct inoculation sterility test, bacterial endotoxin, in vitro cytotoxicity, physical evaluation by scanning electron microscopy and/or microbial identification *via* biochemical assays. The results confirmed the presence of bacteria considered pathogenic to immunologically compromised patients with a maximum limit of 10^4 cfu/unit (catheter guide). Furthermore, bacterial endotoxins and significant modifications of the catheter guides' physical structure were also detected. Thus, the common practice of reusing single-use devices may increase patients' risk of infection or pyrogenic reactions, adding to the total period of hospitalization.

Supplement S-2

PDA Technical Report # 28 (Revised) Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals. PDA.

This revision to a popular PDA technical report outlines process simulation practices for sterile bulk pharmaceutical chemicals (sterile BPCs), utilizing concepts drawn from both bulk pharmaceutical chemical operations and sterile product manufacturing and adapted to fit the unique nature of these materials. It presents options for determining the adequacy of aseptic operations performed during large scale manufacturing while allowing for the committee's opinion of realistic acceptance criteria for such operations.

Pharmaceutical Filtration Book is a Must-Read

Jeanne Moldenhauer, Vectech Pharmaceutical Consultants

Recently, I finished reading *Pharmaceutical Filtration: the Management of Organism Removal* by **Ted Meltzer**, PhD, Capitola Consulting Company, and **Maik Jornitz**, Group VP, Global Product Management, Sartorius Group. When selecting the book, I made the assumption that this was another in-depth handbook on filtration, which would sit on the shelf until I needed to find resources to back up my beliefs in a report to support a client investigation. Boy was I wrong!

Most of the books previously written address the practical aspects of filtration, the "how and when to" perform different activities. This book, by contrast, explains the "why" to do things and how changes in other areas affect the filtration process. In addition to the excellent resource on filtration, this book provides a wealth of information on other important topics.

Have you ever wondered how a biofilm forms? Perhaps you wanted to know how to prevent a biofilm in your facility. Others may want to know whether it is even possible to prevent biofilm. The chapter on biofilms presented a great deal of useful information in an organized way.

A great deal of engineering-type topics are also covered, like stainless steel and rouging, passivation and electropolishing, cartridge handling and so forth.

Some of the other topics included in the book are: Particles/Organisms, The Fluid Vehicle, The Operational Conditions, The Polymer Matrix, The Challenge Density, Organism Size Alterations, Grow-Through and Penetration, The Air Vent Filter, Multifilter Arrangements, Cartridge Type Constructions, Polymeric Constructions, Mechanism of Particle Retention, Mathematical Modeling of Filter Blockage, Adsorption Bonding, Electrical Double Layer, Hydrophobic Adsorptions and a great deal of Literature References.

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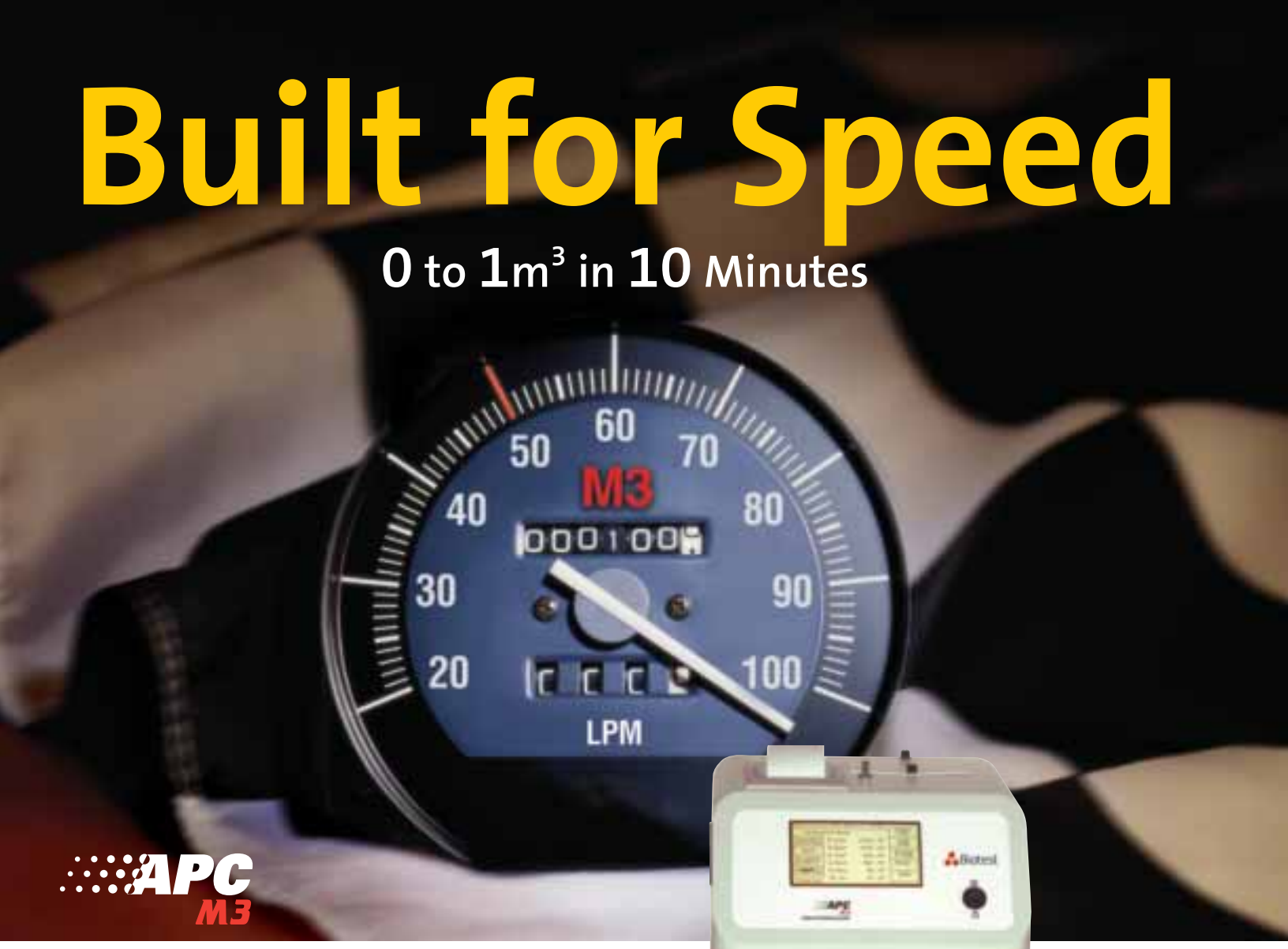

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Review of USP Microbiology Chapters, continued from cover

The newly harmonized general chapters <61> "Microbiological Examination of Nonsterile Products—Microbial Enumeration Tests," <62> "Microbiological Examination of Nonsterile Products—Tests for Specified Microorganisms," and <1111> "Microbiological Examination of Nonsterile Products—Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use," all published in *USP 29 2nd Supplement*, were considered together by FDA microbiologist **Dennis Guilfoyle,** PhD, during the first presentation of the USP Focused Session. The implementation date of Aug. 1, 2007, was the first topic discussed. It was indicated during the conference that this implementation date had caused some concern on the part of various stakeholders. Since that time, the implementation date has been shifted to May 1, 2009. This shift in the implementation date is disturbing, given that the chapters had appeared in *Pharmacopeial Forum* over two years ago. This leaves one to wonder why USP was not informed of issues of sufficient severity to require the delay in implementation prior to the chapter's publication in *USP 29 2nd Supplement*. Improvements in the new chapter versions over the current chapters were then discussed. For chapter <61>, improvements in the sections on methodologies, preparatory testing, product types, amounts used and interpretation of results were described. For chapter <62>, ➤

Topics Addressed at PDA's Micor Conference

Besides the opening and closing plenary sessions, the meeting was organized into sessions covering the following topics:

- Risk analysis in microbiology
- Microbial control in closed and open systems
- Disinfectant qualification
- Industrial practice for microbial ID—bacteria and fungi
- Microbial Data Deviation
- Isolator technologies
- USP focused session
- Environmental monitoring—data handling
- New and emerging technologies

Harmonization of Pharmacopeial General Microbiology Chapters

Kevin F. Goode and Carol M. Thomson, GlaxoSmithKline

At the Dec. 14 USP stakeholders forum held in Basel, Switzerland, an open and interactive discussion was held regarding the implementation of the general chapters for the microbiological examination of non-sterile products: <61>, <62> and <1111> (see cover story).

This was subsequent to a Oct. 2-3 European Pharmacopoeia conference in Strasbourg, France, when the positions of the three main pharmacopoeias were outlined. The status *at that time* is enumerated below:

European Pharmacopoeia

- Harmonized chapters have been incorporated in *Ph.Eur.* Supplement 5.6
- New chapters will be implemented on Jan. 1, 2007.
- Special approach has been used to facilitate transition
- EMEA Quality Working Party has endorsed the plans for transition (phased implementation) proposed by the European Pharmacopoeia Commission

Japanese Pharmacopeia

- JP's Panel on Biological Tests has completed translation to Japanese of the harmonized texts of Microbiological Quality
- Printed in *JP Forum* (15-4) in November, 2006 for official review
- JP will publish them in the *Supplement to the Japanese Pharmacopeia,* Fifteenth Edition at the end of September 2007.
- Enforcement day will be October 1, 2007
- JP's publication contents on Microbiological Quality are the same as the harmonized texts

US Pharmacopeia

- New chapters have been published *(USP 29 2nd Supplement),* scheduled to be effective August 1, 2007
- Once in effect, marketed product must comply
- Time required for revalidation/recertification
- US FDA has verbally asserted that they would not insist on immediate compliance provided there is a plan in place to become compliant
- On November 2, however, the USP Microbiology and Sterility Assurance Expert Committee voted to postpone the implementation of chapters <61>, <62> and <1111> until May 1, 2009. At its Dec. 14 stakeholders meeting, USP was asked to clarify the status of these chapters over the next two and a half years. USP explained that the new chapters are published in the USP for use by sponsors in US regulatory filings, subject to the agreement of the FDA. USP reps reinforced the new implementation date of May 1, 2009. This will bring the timing for final implementation of the general chapters for all three major pharmacopoeias into line in 2009. A revised notice to this effect was posted on the USP website on December 22, 2006 [www.usp.org/USPNF/notices/postponementHarmonMicrobiology.html].

the inclusion of additional species and the requirement to confirm the identification of screened species with appropriate identification tests were discussed. A very important extension of chapter <62> pertained to the question of whether demonstration of the absence of specified microorganisms within a monograph is sufficient to satisfy the requirement that pharmaceutical products be free of objectionable microorganisms. The answer to this question was a resounding "no." Additional species may need to be considered based upon the product type, its mode of administration, its intended users, susceptibility of the product to damage by given microbial species (exclusive of direct pathogenicity to patients), environmental flora, etc. The bottom line is that it is impossible for any standard to reflect all potentially objectionable microorganisms. It is therefore up to the manufacturer to assure that all potential objectionable microorganisms relative to their products are excluded. There was also a brief discussion pertaining to chapter <1111>, referring to the tables with acceptance criteria. These may be used when specific monographs do not exist for a specific product or the existing monograph does not list specified microorganisms. Again, remember that the manufacturer bears the ultimate responsibility for assuring the absence of objectionable microorganisms, even if the relevant monograph does not indicate such microorganisms.

The USP chapter <1112> "Microbiological Attributes of Non-Sterile Pharmaceutical Products – Application of Water Activity Determinations," reviewed by **Tony Cundell,** PhD, Director Pharmaceutical Science, Microbiology, Schering-Plough, generated some discussion. Information in the chapter may be used to:

1) Develop product formulations
2) Set microbiological release specifications
3) Establish microbial testing programs
4) Determine potential shelf life stability from microbial growth

Typically products with water activities less than 0.75 are not susceptible to microbial growth of organisms found with compendial microbiological culture media.

A revision to <1116> "Microbiological Evaluation of Clean Rooms and Other Controlled Environments" entitled "Microbiological Control and Monitoring Environments Used for the Manufacture of Healthcare Products" was reviewed by **James Akers,** PhD, President, Akers, Kennedy & Associates. Many of the microbiological levels are suggested for amendment while the physical attributes of cleanroom monitoring are strengthened in this draft information chapter, released late in 2005. This draft chapter is based on the premise that data from viable environmental monitoring measurements should be considered a survey of environmental conditions rather than a method capable of providing evidence regarding sterility assurance.

The bottom line is that it is impossible for any standard to reflect all potentially objectionable microorganisms.

The new USP general chapter <1117> "Microbiological Best Laboratory Practices" was also considered during the USP Focused session in a talk by **Don Singer,** Global Lead Manager, GlaxoSmithKline. It was emphasized that until this chapter, there was no general overview for the industry pertaining to the design of microbiology quality intent in a microbiology laboratory. General areas considered were aseptic technique, media control, test strain control, equipment control, data and documentation control, design of the laboratory and staff training. Much attention was paid to quality control of microbiological growth media. For USP microbiological testing, this is essential because all such testing is dependent upon the capability of existing microorganisms to grow. If the media won't support growth, USP microbiological testing will not "see" the microorganisms. Essential differences in inherent variability of microbiological data versus analytical chemistry data were emphasized. It is essential that staff be appropriately trained in the significance of such variability when interpreting microbiological data. The presentation concluded with the statement that chapter <1117> should be considered as "The Quality Manual for USP Microbiological Testing."

A historical perspective of informational chapter <1211> was provided by FDA's **David Hussong**, PhD, Associate Director for New Drug Microbiology, CDER. It originated about 90 years ago as a chapter describing methods of sterilization and evolved into a discussion of several methods, their uses, validation and controls. The importance of sterility assurance rather than end-product testing is based on the weakness of testing, for statistical reasons and lack of microbiological sensitivity. The existing <1211> contains references to abandoned practices (i.e., first and second stage sterility tests), discontinued standards (i.e., FS-209) and old units of measure (i.e., MRad). The PF (2004) attempted to update <1211> and many comments were received revealing the value of reorganizing <1211> into a chapter focused on "Validation of Sterilization Processes" with sub-chapters to address specifics of individual processes (e.g., moist heat, dry heat, radiation, filtration, and gasses). This new approach allows a fresh look at the science and offers new opportunities for participation by individuals and organizations. ➤

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New USP chapter <1223> "Validation of Alternative Microbiological Methods" also was presented [by the author]. Some of the background documents of importance were considered, namely PDA Technical Report No. 33: *Evaluation, Validation and Implementation of New Microbiological Testing Methods* and FDA documents on comparability protocols, GMPs for the 21st Century and process analytical technology. The purpose of this chapter is clearly stated as describing the requirements for validating a test as an alternative to a compendial test. As was discussed in other new USP chapters, it is emphasized in this chapter that microbiological data has much more inherent variability than analytical chemistry data. Therefore, some aspects of validation as discussed in chapter <1225> "Validation of Compendial Procedures," a chapter directly applicable to validation of chemistry-based procedures, are not directly applicable to microbiological methods.

The chapter describes three basic types of compendial microbiological tests. One type asks, "Is something there?" The quintessential example of this type of qualitative test is chapter <71> "Sterility Tests." Another type asks, "How many are there?" The enumeration tests in newly harmonized chapter <61> exemplify such quantitative tests. The final type asks, "What are you?" Newly harmonized chapter <62> outlines testing for the absence of specified microorganisms. Chapter <1223> addresses the validation of alternative tests for the first two types. Validation of alternative identification tests will be the subject of a chapter yet to be developed. For qualitative tests, data elements to consider include specificity, limit of detection, ruggedness and robustness. Quantitative tests also include robustness and ruggedness, but diverge from qualitative tests in that accuracy, precision, and limit of quantitation data elements also need to be considered.

The presentation on chapter <1223> concluded with a discussion on variability, statistical usage and the importance of answering the question about what it is that one is attempting to validate. While it is well-known that microbiological data is inherently more variable than analytical chemistry data, it still behooves the microbiologist to exercise control over variability whenever possible. Statistical analysis can be very helpful, but it is essential that appropriate statistical techniques be employed. For example, many parametric techniques assume that the underlying distribution of the data is normal, and that the variance in the data between different treatment groups be homogeneous. If these assumptions are violated, the results of the statistical analysis are likely to be invalid. Appropriate statistical tests exist for different distribution, such as nonparametric procedures, and these should be used where they are better suited to the data. Finally, it is also essential to be able to clearly state what it is one is attempting to validate. After all, validation of a method means to demonstrate that the method is suited to its intended purpose. Without a clear statement of that intended purpose, how can one say that the method has been validated?

All in all, this conference was a great success in communicating issues of importance to the microbiology community. The quality of the chapters in USP is influenced by input from the field, and these sessions provided a great deal of food for thought.

About the Author

David Porter, PhD, recently joined Vectech Pharmaceutical Consultants, Inc. Previously, he worked at USP in the area of general chapters. More on David can be found at www.vectech.com

Senior Staff Members Earn Promotions at PDA

PDA is pleased to announce the promotion of three veteran PDA staff members. **Nahid Kiani** was promoted to VP, Membership Services and Sales; **Wanda Neal-Ballard** to VP, Programs and Registration; and **Dee Kaminsky** to Director, Marketing Services.

Nahid Kiani has served PDA for 11 years in the areas of marketing, membership and sales, and was most recently Director of Sales. In this role she was responsible for outstanding growth in the areas of exhibits, publications and advertising. In her new role, her responsibilities include Membership Services and support of our US chapters.

Wanda Neal-Ballard has been with PDA nine years and has steadily progressed in level of responsibility. Her most recent position was Director, Programs and Meetings. This area has enjoyed record performance in terms of increased attendance over the past two years. Added to Wanda's responsibility are the Registration and Customer Service units.

Dee Kaminsky has been with PDA since January 2005 and has served most recently as our Associate Director, Marketing Services. In her role as Associate Director, Dee increased the effectiveness of PDA's marketing efforts for both conferences and the Training and Research Institute (TRI) and supervised the development of the new website.

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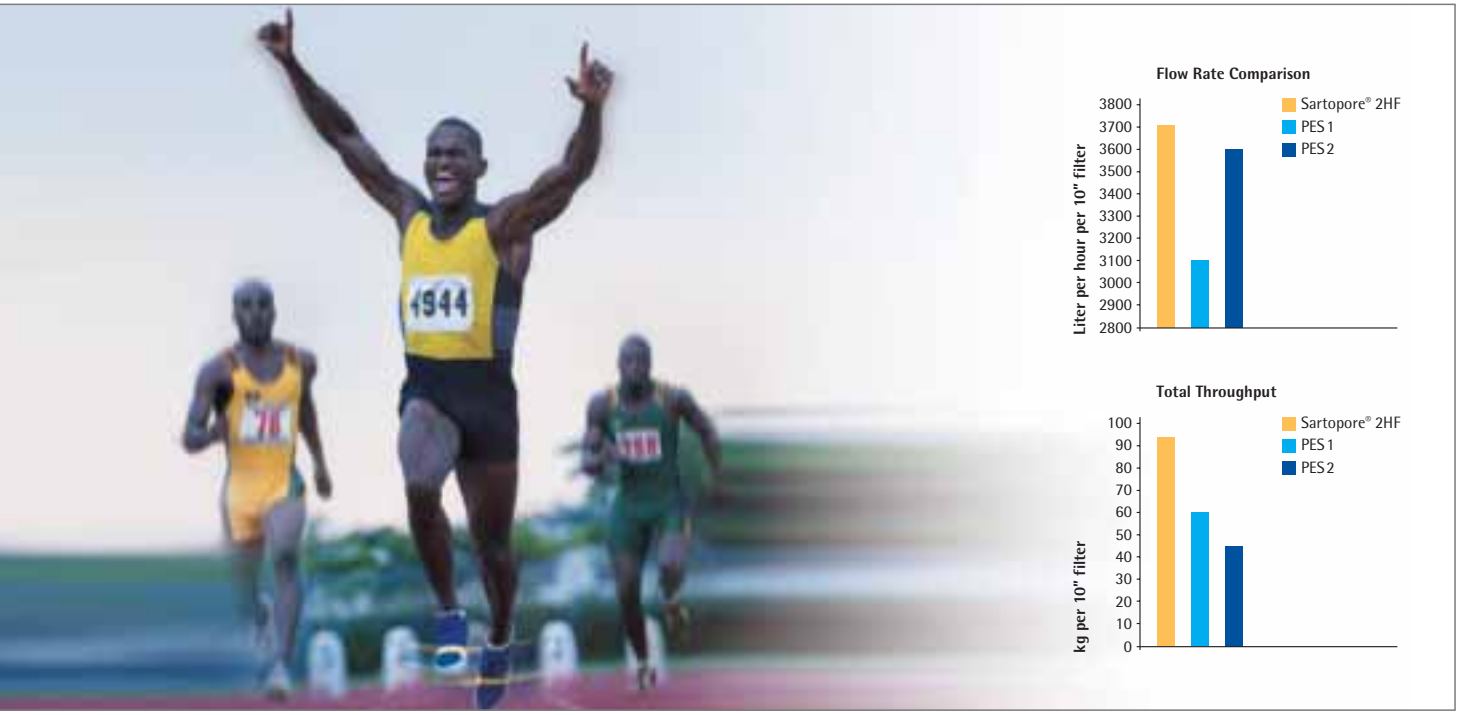

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Quality Requirements for Clinical Trial Applications in the European Union

A Report from the 2006 PDA/EMEA Joint Conference

Susanne Keitel, PhD, Federal Institute for Drugs and Medical Devices, Germany

This article is based on Dr. Keitel's presentation on the same topic at the 2006 PDA/EMEA Joint Conference in London in October.

Article at a Glance

- EU member states have harmonized clinical trials requirements as of May 1, 2004, per EU Parliament Directive 2001/20/EC (called "Clinical Trials Directive").
- An Investigational Medicinal Product Dossier must be filed to launch clinical trials in European Union.
- A CHMP guideline (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/18540104en.pdf) on the directive for chemically-defined substances, radio-pharmaceuticals and radio-labeled medicinal products as well as herbals became effective in October 2006.

EU Directive 2001/20/EC of April 4, 2001, called Clinical Trials Directive, created the background for the harmonization of requirements for conducting clinical trials. As defined by the Union's legal system, member states had to implement the directive into their respective national laws by May 1, 2004.

One of the new requirements introduced by the Clinical Trials Directive is the necessity to submit an Investigational Medicinal Product Dossier (IMPD) containing the relevant information on quality, safety and—as far as already available—on any clinical studies previously conducted. In addition, an IMPD is required for all types of products used in clinical studies, be it the investigational medicinal product (IMP) itself, any reference product or a placebo.

At the time the Clinical Trials Directive went into force, member states had different histories with respect to clinical studies. The United Kingdom, for example, had a long-standing history of requiring information on the quality of an IMP. Member states like Germany, on the other hand, had limited their requirements to information on the clinical study itself, including safety data, the Investigator's Brochure and information on the composition of the IMP.

The directive itself and its explanatory documents provide rather high-level information on the requirements of the IMPD. With respect to information required on product quality, the directive is basically limited to a listing of headings taken from the Common Technical Document with a disclaimer that not all sections need to be submitted in every case. Concerned that this paucity of specificity could damage the competitiveness of the European clinical trials environment, both regulators and industry felt the need for a guideline that clearly defined and harmonized the requirements espoused in the directive. As a consequence, a concept paper for this guideline was published in April 2004, with a draft guideline published for comments in December 2004. Based on the high number of comments received, several additional draft versions and two hearings with industry associations were necessary before the guideline was finally adopted by the Committee for Human Medicinal Products (CHMP) in March 2006.

Scope of the Guideline

The guideline, entitled *The Requirements to the Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products in Clinical Trials,* was published in Volume 10 "Clinical Trials – Notice to Applicants" as part of *The Rules Governing Medicinal Products in the European Union* in July 2006. The guideline went into force in October 2006.

EU guidelines are always intended to provide guidance; deviations from guideline requirements, however, are always possible if adequately justified. While all EU guidelines aim at striking a balance between precise guidance and over prescription, this guideline covers a very broad range of situations and is by its nature less precise in defining requirements than other guidelines. Therefore, the use of common sense is very much required by both industry and regulators.

The guideline addresses chemically-defined substances, radio-pharmaceuticals and radio-labeled medicinal products as well as herbals. It clearly does not address biologicals (see box below for more on guidance for biologicals).

The guideline helps define the risk-based aspects of the directive and differentiates the requirements for IMPDs from those for Marketing

Guideline for Biotech Clinical Work Forthcoming

The CHMP's Biologicals Working Party (BWP) has published the Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products to be used in clinical trials for comments. Furthermore, the BWP's 2007 work plan includes the development of a guideline on requirements on the quality part of biotechnological products to be used in clinical trials. This should address those biotech-specific aspects needing clarification in addition to the information already provided in the adopted document summarized in this article.

Authorisation Applications (MAAs). Points to be considered include the nature of the IMP, the state of development/clinical phase, the patient population, the nature/severity of the illness, as well as the type and duration of the planned clinical trial itself.

Phase-Dependant Requirements

Unlike for MAAs, EU regulators jointly decided to allow for more flexibility in the selection of pharmacopeial references for IMPs, agreeing to leave that choice to the applicant. This decision was made to facilitate provision of clinical supplies for use in different countries/regions. However, a note of caution has been added in the general chapter of the guideline that EP requirements must be met for any subsequent MAA due to their legally binding nature. This may be of special importance to sponsors of generic bioequivalence studies intending to file a subsequent MAA in the European Union.

The general requirements on the active substance and IMP clearly follow the structure of the Common Technical Document, with the amount of detail expected largely dependant on the respective clinical phase. For example, phase I specifications will have to be reevaluated and possibly adjusted to the state of development for phases II and III. The same goes for validation of analytical procedures and stability studies/expiry dating (see graphic below). For methods validation, it is important to stress, however, that at a full validation report, covering ICH-conforming validation, will never be requested during the clinical phases. Regarding expiry dating, extension of the expiry date for a running study is possible and does not require a substantial amendment if the sponsor has defined the principles on which they will extend the expiry date in the initial IMPD.

Authorized Test, Comparator Products, Substantial Amendments

In order to facilitate clinical studies in the European Union, regulators decided to accept medicinal products authorized in the ICH regions and Mutual Recognition Partner (MRP) countries based on proof of the existence of a marketing authorization in the respective home country. In addition, minimum information for an identity test must be submitted in order to fulfill the requirements of Article 13 (3) of directive 2001/20/EC. For products from non-ICH and non-MRP countries, however, a complete IMPD must be submitted.

Modifications by an IMPD sponsor to an authorized medicinal product require additional work by the sponsor. Typical information required for an authorized modified IMP includes description and composition and a summary of all changes performed. The level of detail required depends on the nature of the modifications performed. The guideline covers how much data is required.

If amendments to the IMPD are performed during an ongoing clinical study, a notification to the competent authorities may be required, depending on the nature and significance of the changes themselves. The guideline attempts to explain the general principles of classifying such changes as significant or insignificant. While the onus is on the sponsor to make a risk-based decision, the guideline provides a list of examples of what could be classified as significant or insignificant. For those cases requiring a substantial amendment, it may be worthwhile to consider the possibility of postponing the change until the start of the next study (which in itself will require an updated IMPD) to avoid an unnecessary hold in a running clinical trial.

Specification Requirements Per Clinical Stage

Validation of Analytical Methods

Phase I

- Confirm method of suitability for intended use
- Submit tabulated summary of acceptance criteria and parameters to be verified in a subsequent validation study

Phase II and III

- Prove suitability of test methods
- Provide a tabulated summary of results

Stability

Phase I

- Commit to the conduct of stability studies (covering both accelerated and long-term storage conditions) in conjunction with clinical trial and commence study prior to start of clinical trial (minimum requirement)
- Submit available stability data
- Base expiry date on extrapolation (not limited to extrapolation rules described in ICH Q1E, Evaluation of Stability Data)

Phase II and III

- Summarize and submit the available results of the studies conducted

About the Author

Susanne Keitel, PhD, is the Head of the Pharmaceutical Quality Division at the Federal Institute for Drugs and Medical Devices in Germany. She serves as the rapporteur for the recently published EU guideline, entitled *The Requirements to the Chemical and Pharmaceutical Quality Documentation Concerning Investigational Medicinal Products in Clinical Trials*. She appeared at the 2006 PDA/EMEA Joint Conference in London to present background information on the development and philosophy of the document.

First PIC/S Industry Forum: New Opportunity to Discuss Global GMP Issues

Tim Marten, AstraZeneca and PDA Board of Directors; Stephan Roenninger, F. Hoffmann La-Roche Ltd and PDA RAQC member; and James Lyda, PDA

The first meeting of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Industry Forum took place in Geneva on Nov. 23, 2006. PIC/S is a forum where the inspectorates of member countries (many from Europe but also from countries such as Australia, Singapore and Canada) discuss GMP topics resulting in training, publications and guidance for inspectorates around the world. In 2006 the US FDA applied for PIC/S membership and their application is currently under review.

PIC/S hosted this forum to establish a more effective and open relationship with the industry associations affected by inspections and to determine areas of mutual interest for collaboration. The PIC/S delegation was led by the PIC/S Chairman, **Jacques Morénas,** PhD, Assistant Director, AFSSAPS France, as well as the PIC/S committee members.

Industry and professional organizations were invited and represented at the meeting: Parenteral Drug Association (PDA), International Society for Pharmaceutical Engineering (ISPE), International Pharmaceutical Federation (FIP), European Federation of Pharmaceutical Industries and Associations (EFPIA) and International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

[**Note:** The three authors comprised the PDA delegation to the forum. This report is based on notes from the PDA delegation and should be considered an informal and unofficial record of the forum. Action items are not covered in detail pending final adoption of the official record of the meeting.]

PIC/S Plan for the Future

The "PIC/S Blueprint" was issued in 2005 and provides an overview of PIC/S today and its goals for the next decade.

[**Editor's Note:** The PIC/S Blueprint is available at the "Basic & Misc. Publications" section of the PIC/S website, www.picscheme.org.]

Training for GMP inspectors

Training of inspectors of the member inspectorates is one of the main activities of PIC/S and is conducted three different ways: the Annual Seminar, Expert Circles Meetings and the Joint Visits Programme. A project to coach inspectors during inspections is currently being considered.

Although PIC/S Seminars are not open to industry participants, experts from industry are often invited to speak on various topics, e.g., new developments, technologies and interpretations of requirements. During the Annual Seminars inspectors consider implementation problems associated with new guidelines, technology and equipment in order to enforce harmonized interpretations. The 2007 PIC/S Annual Seminar will be in Singapore in November and will focus on the inspection of solid dosage forms. PIC/S is seeking video clips and photos on particular aspects of the production of solid dosage forms (e.g., granulation) for inspector training purposes.

PIC/S will start a new Expert Circle on Quality Risk Management (QRM) open to EU, US and Japanese inspectorates. PIC/S is looking for concrete examples from industry on the implementation of QRM. One model could be based on the review of a similar QRM scenario separately by inspectors and industry experts (e.g., see what was done in a particular case and discuss what should or could have been done). The outcome of this process could then be presented at a joint session in order to compare the conclusions reached by inspectors and the industry.

Visits to companies for training purposes can be arranged by the industry. These visits should be more than just a "walk-around," and should achieve a better understanding of the manufacturing process and new technology or equipment.

PIC/S delegates articulated an important message regarding inspectors who attend third-party training: There is a need for inspectors to be able to attend training courses of associations like PDA, ISPE and FIP *as trainees.* Frequently, once identified in the class, the inspectors spend more time answering questions than being trained. It was suggested that the organizations who provide training should consider ways to avoid that inspectors are pinned down with questions while they are receiving training.

Exchange of GMP information

PIC/S provides for the voluntary exchange of information with no obligation for participating authorities to accept or recognize inspection results. The exchange of information is limited; nevertheless PIC/S believes it is a useful tool.

The inspectorates generally believe that the principles of QRM define manufacturing sites located in "third countries," and not participating in PIC/S, to be a higher compliance risk. Often there is an inadequate regulatory system, inspection results are limited in scope and some companies have reduced QA/QC functions to reduce costs.

The WHO Certificate for Pharmaceutical Product (CPP) is usually used for submitting applications only. This ➤

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form may represent a major improvement if used to reflect inspections status. For now, however, the CPP is relevant to pharmacovigilance purposes only. In addition, the WHO GMP guide is different from the PIC/S GMP guide; although both are designed to protect the same patients.

Biennial Inspections

Can QRM affect the current inspection frequency of two years? In the European Union the two-year inspection frequency is only a recommendation, not a requirement. But sometimes the frequency is fixed in legal binding agreements between states. Companies are always free to share the last inspection report from another competent authority during the most recent inspection or when they are contacted to set-up an inspection. But in some cases companies do not inform inspectors of such inspections. This can have a bearing on the frequency or scope of an inspection.

It seems that for sterile products, it is difficult to extend the two-year inspection period. A possible way of reducing the number of inspections by PIC/S participating inspectorates is "team inspections" (e.g., the inspection of one manufacturing site by inspectors of different PIC/S authorities). PIC/S indicated companies should be more pro-active by (i) fixing problems across the board (e.g., entire site and in other sites), and (ii) ensuring the commitment of the company's top management to GMP.

Over Inspection

The EFPIA 2005 inspection survey with responses from 25 EFPIA member companies shows the number of foreign inspections increasing as GMP inspections become mandatory in more and more countries. The three most active agencies/organizations are the US FDA, those representing the European Union (the sum of all member states) and Brazil's agency. In terms of "inspector days," 2005 inspections by the US FDA were highest (569) followed by Brazil (385) and the European Union (283). Other active authorities represent: Argentina, Belarus, Canada, Colombia, Japan, Korea, Libya, Mexico, Nigeria, Pakistan, Saudi Arabia, Tunisia, Uganda and Zimbabwe. This survey will be continued.

Possible ways to reduce foreign inspections are:

1) Allow access to the new EUDRA GMP database.
2) Encourage the accession to PIC/S of other authorities.

The influence of industry associations in getting authorities to apply to PIC/S could be helpful. For example, the Japanese Pharmaceutical Manufacturing Association (JPMA) is encouraging Japanese authorities to join PIC/S.

[**Note:** "Over inspection" was addressed in the article "Solving the Over-Inspection Problem" (*PDA Letter,* October 2006, p. 24), which provides more details on this issue and suggests that many members of PDA share the same concerns as EFPIA.]

PIC/S GMP Guidance Documents

PIC/S described its commitment to the preparation of guides and guidance documents for the member inspectorates. This is necessary in order to ensure consistency and uniform interpretation of different GMPs and support harmonisation. PIC/S has issued a number of GMP guides, recommendations and aides-memoires as support for the inspection process. Industry can and should use these nonbinding documents for self-audit.

According to PIC/S policy, industry and professional organizations are invited to comment only on the GMP guide. Other guidance documents are rarely submitted for external consultation, but PIC/S might review this policy in the near future. Consultation on EU GMP Annex 1, "Sterile Medicinal Products," was done in parallel between the EU and PIC/S. The revised Annex 1 will soon be subject of additional consultation.

[**Editor's Note:** PDA recently participated in a consultation session with EMEA on Annex 1. See article on p. 23.]

FDA is expected to recognize some of the PIC/S guidance documents. Many comparisons have been made in the past between the various GMP guides and regulations. While the structure can be different, the inspectorates believe that there are no critical differences regarding requirements in focus to protect the patients.

There was comment that FDA's application to join PIC/S represents a major change in its attitude towards PIC/S and approach to international cooperation in the GMP area in general. There was an industry comment that FDA's accession to PIC/S will affect both organizations significantly. The maximum period for a decision on an application to be processed is six years, but the application for FDA will likely be processed much more rapidly.

Future Cooperation

Possible areas of cooperation were discussed during the meeting. Participants were free to offer concrete proposals. Regarding the possibility of another industry forum, professional and industry associations as well as the PIC/S Committee would have to evaluate the results of the present meeting. The consensus was that the forum was very useful and constructive and might be repeated in 2007.

PDA Participates in Annex 1 Consultation

Jim Lyda, PDA

On Dec. 6, 2006, the EMEA Inspections Sector hosted a special meeting for interested parties to gain reaction to further refinements of the in-process revision of GMP Annex 1, "Manufacture of Sterile Medicinal Products." **Gabriele Gori,** Bausch & Lomb; **Joerg Zimmermann,** Vetter Pharma; and **Jim Lyda**, PDA, represented PDA.

[**Note:** Readers are cautioned that the final version of Annex 1 has not been released at press time. It is not known if the terms described in the discussion draft will remain or be changed.]

In preparation for the meeting, EMEA issued a discussion draft which outlined their current thinking on the key issues associated with aseptic processing and the expectations of the inspectorates. On the subject of cleanroom and clean air device classification, the latest proposal states that such devices "should be classified in accordance with EN ISO 14644-1" and that "classification should be clearly differentiated from operational process environmental monitoring." It *is* further stated that cleanroom and clean air devices should be routinely monitored in operation and the monitoring locations based on formal risk analysis study and results obtained during the classification of rooms and/or clean air devices.

[**Editor's Note:** Further discussion of the "discussion draft" is included in the full version of this article available at the "Current Issue" section of www.pda.org/pdaletter.]

Following the meeting PDA captured its comments in a letter to the EMEA inspections sector (see below). The contents of this letter are consistent with the official PDA comments on Annex 1 (www.pda.org/regulatorycomments), prepared by a task force chaired by **Steve Bellis**, CMC Biopharmaceuticals.

Following the Dec. 6, 2006, EMEA GMP Inspection Service meeting, PDA's European office sent a letter to David Cockburn, EMEA Inspections Sector, restating PDA's official comments on Annex 1. Below is the content from the body of that letter. The complete letter can be viewed at www.pda.org/regualtorycomments.

On behalf of PDA and its members please accept our sincere thanks for hosting the Interested Parties Meeting relative to Annex 1, on 6 December 2006. The discussions were open and constructive, helping all parties more fully understand each other's positions. To be most helpful to the drafting group, this letter serves as a restatement of PDA's views on the topics discussed at the meeting.

Clause 4: Cleanroom and clean air device classification:
PDA has no issue with most of this clause in the draft discussion text. The harmonisation with ISO 14664 is a big step forward.

Clause 47: Validation of aseptic processing
The alignment of this clause with the current FDA Guidance is very positive. As far as PDA is concerned, the only open issue here is the requirement of performing media fills on a "per shift" basis, where the definition of "shift" is unclear. With modern operating practices the definition of "shift" could be merely a time interval with no effective relationship to the operations actually being performed in this period. In addition, environmental data from years of operation show that there is little deterioration of the cleanroom conditions over time. PDA therefore suggests (a) to state the requirement to qualify and requalify all people involved in routine operations via participation in media fills, and (b) to replace the word shift with *"covering all routine operations over the time of a normal fill"*.

Clause 57: Bioburden testing
Consistent with our original comments of 24 April 2006, PDA suggests the requirement to perform a bioburden assay on each batch is, under certain circumstances, unnecessary, e.g., double-filtration. We suggest rewriting the fourth sentence to read "Where duplicate sterilising grade filters are used for aseptic processing, or where overkill sterilisation parameters are set for terminally sterilised products, the bioburden might be monitored only at suitable scheduled intervals."

Clause 93: Capping of vials
The requirement for capping in a Grade A environment or under Grade A air supply in case it is done as a clean operation outside the aseptic core area, still has some open issues. It is suggested, as in our original comments, that the requirements be aligned with those of the FDA and other regulatory agencies. The EFPIA / IFAH paper presented at the meeting documents well the current expectations for this operation based on the written guidance in Japan, Canada and the USA. We believe that GMP requirements should be harmonized unless there is a well documented and scientific justification for a more demanding requirement in one region.

continued on page 26

PDA Calendar of Events for North America

Please visit www.pda.org for the most up-to-date event, lodging and registration information.

Conferences

March 19-23, 2007
PDA 2007 Annual Meeting
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Las Vegas, Nevada

March 22, 2007
Workshop on the Universe of Pre-Filled Syringes
Las Vegas, Nevada

May 21-22, 2007
Quality by Design for Biopharmaceuticals: Concepts and Implementation - A PDA Workshop
Bethesda, Maryland

May 22-23, 2007
PDA Global PAT Conference
Bethesda, Maryland

September 24-28, 2007
2007 PDA/FDA Joint Regulatory Conference
(Conference, Courses and Exhibition)
Washington, D.C.

October 15, 2007
PDA Visual Inspections Workshop
Bethesda, Maryland

October 29, 2007
PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology
Bethesda, Maryland

Training

Lab and Lecture events are held at PDA TRI Baltimore, Maryland unless otherwise indicated.

Laboratory Courses

February 27-28, 2007
Computer Products Supplier Auditing Process Model - Auditor Training

March 1-2, 2007
Environmental Mycology Identification Workshop

March 28-30
Cleaning Validation

May 1-4, 2007
Pharmaceutical and Biopharmaceutical Microbiology 101

May 8-11, 2007
Downstream Processing: Separations, Purifications and Virus Removal

May 16-17, 2007
Developing a Moist Heat Sterilization Program within FDA Requirements

May 21-22, 2007
Developing and Validating a Cleaning and Disinfection Program for Controlled Environments

May 21-23, 2007
Operator Qualification

August 2-3, 2007
Environmental Mycology Identification Workshop (Session 2)
Bethesda, Maryland

August 20-24 and September 17-21, 2007
Aseptic Processing Training Program (Session 3)
Bethesda, Maryland

October 1-5, 2007
Rapid Microbiological Methods
Bethesda, Maryland

October 15-19 and November 5-9, 2007
Aseptic Processing Training Program (Session 4)
Bethesda, Maryland

October 31-November 2, 2007
Advanced Environmental Mycology Identification Workshop
Bethesda, Maryland

Lecture Courses

March 5-7, 2007
Fundamentals of Pharmaceutical Filtrations and Filters

March 22-23, 2007
PDA 2007 Annual Meeting Training Courses
Las Vegas, Nevada

October 8-10, 2007
Advanced Pharmaceutical Filtrations and Filters
Bethesda, Maryland

Course Series

May 7-9, 2007
Indianapolis Training Course Series
Indianapolis, Indiana

June 11-13, 2007
Baltimore Maryland Training Course Series
Baltimore, Maryland

Europe/Asia-Pacific

Please visit www.pda.org for the most up-to-date event, lodging and registration information.

Europe

March 26-27, 2007
Continuous Improvement in Pharma Industry and its Impact on cGMPs Conference and Exhibition
Verona, Italy

May 3-4, 2007
Good Practices for Investigational Medicinal Products
Lyon, France

May 8-9, 2007
Best Practices in Aseptic Manufacturing
Milan, Italy

June 11, 2007
Supplier Quality
Balogna, Italy

June 19-20, 2007
Current Facility Issues in Pharma Manufacturing
Monitoring of Non-Sterile Facilities (June 19)
Dedicated Facilities (June 20)
Langen (Frankfurt), Germany

June 20-21, 2007
From Biopharmaceutical Development to Manufacturing — Challenges in the European Environment
Berlin, Germany

September 11-12, 2007
Industrial Freeze Drying and Spray Drying
Cologne, Germany

September 13, 2007
Technology Transfer
Basel, Switzerland

October 9-10, 2007
Cleanrooms/Isolators/RABS
Co-sponsored by PDA and R3 Nordic
Berlin, Germany

October 17-18, 2007
Pharmaceutical Cold Chain
Berlin, Germany

Online Learning

Please visit www.pda.org for the most up-to-date registration information.

Web Seminars

February 15, 2007
Online Liquid Chromatography as a PAT in Biotech Process Development and Manufacturing

ICH Q10 Previewed at PDA Asia-Pacific Congress

Bob Dana, PDA

At the 2006 PDA Asia-Pacific Congress in Tokyo, Japan, **Gerry Migliaccio**, VP, Global Quality Operations, Pfizer, spoke to the attendees on the scope and status of the ICH guidance on pharmaceutical quality systems (Q10). Migliaccio noted that Q10 will not introduce any new regulatory expectations, stating that the guidance will represent a blend of good business practice and common sense.

Migliaccio began his presentation with a discussion of how GMPs and pharmaceutical quality systems interrelate. While GMPs are a key element of a quality system, they do not drive a life-cycle approach and are instead focused on manufacturing. Furthermore, they don't address how to bring a product to market nor do they address continual improvement. Critical elements such as technology transfer, product and process design and management responsibility are addressed only briefly, if at all, under GMP. Migliaccio made the point ➤

PDA Participates in Annex 1 Consultation, continued from page 23

Some clarification should be made to the "Grade A air supply". PDA suggests replacing this with "ISO 5 air supply". Also, it is suggested to allow alternative methods of local protection, like plastic shields, e.g., Perspex or Plexiglas covers, for stoppered vials transferring to the capping machine. As outlined in the paper presented by EFPIA, it is the stopper which provides effective sealing of the vials. There are methods available for reliable detection of unsealed vials prior to the capping station.

In summary, and consistent with our original comments, we encourage wording in the Annex similar to that in the FDA guideline *"…stoppered vials exit an aseptic processing zone or room prior to capping, appropriate assurances should be in place to safeguard the product such as local protection until completion of the crimping step. Use of devices for on-line detection of improperly seated stoppers can provide additional assurance."*

Other clauses and comments
While the most pressing issues were discussed at the meeting, there are other issues for which time did not permit further exchange. PDA would like to take the opportunity to note these once more.

Clause 5:
The opening paragraph, 3rd sentence, includes the statement "The Grade A zone should be monitored at such frequency and with suitable sample size that all interventions, transient events and any system deterioration would be captured…" (underlining added.) The absolute requirement to capture "all" interventions and transient events is unrealistic and may not be possible. Consistent with our original comments, we recommend the word "all" be deleted and the text rewritten as, *"The Grade A zone should be monitored for non-viable particles at such a frequency that interventions and other transient events would be captured and trigger an alarm if excursions from normal operating values occurred."*

Clause 7:
Clause 7 does provide some detail on clean-up times for cleanrooms and recognizes that there might be some low levels of 5 µm particles at the point of fill. However, particles from product are not restricted to a particular size range. Therefore the second sentence should be revised to deleted the reference to ≥ 5.0 µm particles and read as follows: *"It is accepted that it may not always be possible to demonstrate low levels of particles at the point of fill when filling is in progress due to the generation of particles or droplets from the product itself."* The revised sentence is consistent with other international guidance documents, e.g., the FDA Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing, Current Good Manufacturing Practice, Section IV. A.

Suggested timing for implementation
Industry was asked to provide recommendations on possible timing to be allowed for implementation of the revised Annex after it is published final. This question is difficult to answer as it depends very much on the content and requirements in the final version.

Capping in Grade A
It is our belief that changes to the requirements for capping will have the biggest impact and will take the most time to implement. If this requirement is adopted, an implementation period of approximately 24 months must be given as major reconstruction will be necessary in a significant number of plants. This allows time for equipment design, delivery, installation and qualification and validation studies.

Again, we value the opportunity to give input into the revision of Annex 1.

that it is critical to establish a harmonized global guideline which addresses all elements of an effective quality system, noting that both technical innovation and regulatory flexibility depend on it.

Discussing how Q10 fits with other ICH guidances, he noted that Q8 is more heavily focused on the earlier stages of the product lifecycle, Q9 introduces risk management concepts across the entire product life cycle and Q10's role grows as the product moves through its life cycle. Applied individually, Q8 helps ensure enhanced product and process understanding, while Q10 will ensure the development of robust quality systems. Q9 grounds the entire process on risk management principles. Combining the concepts embodied in the three guidance documents provides benefits like ensuing quality by design, having lower risk operations, ensuring innovation and integrating continual improvement. All benefits lead to anticipated application of regulatory flexibility such as risk-based regulatory decisions by reviewers and inspectors, a higher degree of self-management of change, reduced intensity of inspections and real-time assurance of quality, including real-time release. Properly implemented, these guidances should collectively help ensure that science and risk management will drive the regulatory process.

Migliaccio moved to a discussion of the draft document. Q10 describes a model for an effective quality management system for the pharmaceutical industry that ensures the realization of a quality drug product, establishes and maintains a state of control and facilitates continual improvement over the product life cycle. Q10 is intended to complement and serve as a bridge between regional GMP regulations and facilitate the implementation of Q8 and Q9.

The current draft document discusses the objectives and design considerations of a pharmaceutical quality system and contains an extensive section on management responsibility. This section outlines various must-have elements of a sound quality system:

- Strong management commitment
- A quality policy
- Advanced quality planning
- Predetermined quality objectives
- Appropriate resource management
- Controlled outsourced operations
- Proper oversight of the quality system (including the need for management review)

Q10 is intended to complement and serve as a bridge between regional GMP regulations and facilitate the implementation of Q8 and Q9.

Migliaccio emphasized the need for management review to provide for a periodic review of quality performance, including the use of appropriate product quality and quality system performance indicators, and the need for a system to allow for escalation of issues.

In discussing the section on management and continual improvement of quality over the product life cycle, he noted that it addresses development, technology transfer, manufacturing and product discontinuance. The guidance discusses essential principles and tools, such as knowledge management and quality risk management. This section also addresses such key elements of a pharmaceutical quality system as the process and product quality monitoring system, the CAPA system, the change management system and the system for management review of product quality.

Chapter 5 of the guidance discusses management and continual improvement of the pharmaceutical quality system itself. This will include monitoring of the quality system using process indicators, e.g., recalls, complaints and product returns; knowledge of those factors that impact the quality system (new and emerging regulations and changes to a firm's business and portfolios, etc.); and ensuring the periodic review of the quality system by management.

To help ensure all parties have a common understanding of terms, Migliaccio also noted that a glossary will be included.

Migliaccio continued his presentation by providing his perspective on the applicability of and benefits associated with adoption of the principles contained therein. He reported that the concepts would be applied in an incremental manner, recognizing the differences among and the different goals of the product life-cycle phases (development, technology transfer and manufacturing). He also noted that, since many companies utilize outsourcing for some stages of the lifecycle, quality agreements are a useful means to describe the quality system activities conducted by various firms over the product life cycle.

Migliaccio concluded his presentation with some views of how Q10 might be used. He suggested it might be a useful assessment tool for existing quality systems and would enhance management responsibility and review. He also suggested it would be used to demonstrate an effective quality system to regulatory authorities. Properly implemented, the three newest ICH quality guidances (8, 9 and 10) should demonstrate that a firm or site has systems in place to identify what is critical to quality, establish appropriate controls, assess and mitigate the risk of quality failures and implement continual improvement changes. This should then result in the firm or site being considered lower risk, and the intensity of regulatory oversight should be commensurate with the level of risk.

PDA Comments on FDA and EMEA Guides

For the complete comments, including the comments grids, go to www.pda.org/regulatorycomments.

December 28, 2006

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REF: Doc. Ref. EMEA/CHMP/BWP/398498/2005-corr

Dear Alexis:

The Parenteral Drug Association (PDA) is pleased to provide these comments on the draft Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products. PDA is an international professional association consisting of almost 10,000 individual members having an interest in the fields of pharmaceutical manufacturing and quality. Our comments were prepared by an international working group consisting of industry professionals from pharmaceutical companies and service providers.

PDA welcomes guidance in the area of virus safety evaluation for Investigational Medicinal Products (IMPs) and we support efforts for a harmonized approach. Attached, please find specific detailed suggestions regarding the draft guideline. Our general suggestions are summarized below

- Regarding design of virus clearance studies, the worst-case parameters for virus removal are not always understood and should not be assumed to be the worst-case parameters for other performance attributes like step yield or peak resolution.
- It should be made clearer that column lifetime studies are tied to MAA, not Phase III trials.
- In our opinion, provision of raw data should be limited to special situations only, e.g., when a novel technique is used. We would like clarification about when raw data for virus testing and virus validation will be requested for submission (Sections 4.3/4.5).
- Viral safety testing at the end of production should follow a risk-based approach. For example, we are concerned that the document has an implied expectation that (1) cell culture manufacturing processes are set early in development and do not evolve as the products proceed in development or (2) that extensive testing should be required between each production run, if even minor changes are made. Neither of these two scenarios is in alignment with the current practice of clinical product development. In reality, clinical runs of the same product in development can have varying cell culture lengths and concomitant varying cell age (measured as cell doublings). Changes are common because of increasing demand as products traverse phase 1 though 3, because of improvements in the cell cultures strategy that increase productivity, product uniformity and other quality attributes, and because of scale changes. The draft guideline states each time there is an extension of the cell age the limit of in vitro cell age studies must be repeated; in effect multiple studies would need to be performed for each new product. Successful products can have many production runs during clinical development in order to meet the demands of large clinical trials; each one may have an incrementally increased cell age. These studies can require 4-6 months of testing because the assay panel includes in vivo studies and co-cultivation studies for retroviruses. We feel that this requirement would have the impact of discouraging cell culture process optimization, possibly even negatively impacting product consistency optimized during this development process.
- Application of ICH Q5A, unless justified due to unusual risk, is a burden to industry that could delay Phase III trials. For example, we are concerned about the stated requirement in this draft guideline that viral clearance validation studies conforming to ICH Q5A should be performed prior to the use of investigational products in Phase III clinical studies. In general, full conformance with ICH guidance documents is an expectation for marketed, not investigational, products. We fully agree that viral safety is a very serious concern; this principle should not be compromised. However, the current industry practice for phase III trials does not include full conformance with each aspect outlined in ICH Q5A for virus clearance studies. Instead, industry takes a holistic approach for each investigational product by evaluating all the components of the viral safety program in place (e.g. careful raw material selection and testing, well characterized and tested cell lines, demonstration of robust clearance by the process of enveloped and non-enveloped model viruses, etc). Given the excellent safety record of industry as a whole in assuring the viral safety of investigational biopharmaceutical products, we feel that it is warranted to allow flexibility to conduct the Q5A viral validation studies during phase III clinical development instead, with the requirement to submit full reports later in the marketing authorization application.
- Regarding the testing and validation requirements for phase III products, different sections of the document word EMEA's expectations differently. We provide examples of the different wording in our detailed in the accompanying comments. Please consider unifying the language describing testing and validation expectations in the different sections of the draft. ➤

December 21, 2006

Office of Communication Training & Manufacturers' Assistance
Center for Biologics Evaluation & Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
HFM-40
Rockville, MD 20852-1448

Ref.: Draft Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases – FR Notice September 29, 2006; Vol. 71, No. 189; Docket No. 2006D-0383

Dear Sir or Madam:

PDA is pleased to provide comments on the *Draft Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases* as published in the Federal Register on September 29, 2006. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological and device manufacturing and quality. PDA assembled a task force of representatives from the vaccine industry to review and provide specific comment on the Draft Guidance. PDA wishes to thank the FDA for the opportunity to comment on this important document.

PDA is optimistic the publication of this document will provide industry with valuable information and insights into FDA's expectations and requirements for the development and manufacture of prophylactic viral vaccines. Detailed comments are provided in the enclosed table. Comments are identified by topic and section number of the Draft Guidance. The following is a brief overview of two major points the PDA review team believes are important to highlight to the FDA.

Consistency with International Consensus Based Documents

The first point for consideration is related to the harmonization of terminology and requirements. In reviewing the document, the PDA task force identified numerous instances in which the authors have used terminology or made statements contradictory to those found in internationally accepted documents developed and issued under the auspices of the International Conference on Harmonization (ICH). These apparent conflicts with the ICH documents can create serious difficulties for companies seeking to market products in multiple regions. PDA requests that FDA reconcile the current draft guidance document with the other relevant guidance documents wherever possible. Where not possible, PDA requests that FDA provide scientific rationale for the decision. Specific examples may be found in the accompanying table.

Requirements for Stage Specific Testing

The second point for consideration is related to the lack of clarity in the requirements for stage specific testing. While the same test is often performed at multiple stages of manufacturing, the specific study design and the nature of the test article (sample) are different at different stages. This distinction is not entirely clear in the discussion of the test methods. The lack of clarity can lead to unnecessary or inappropriate testing, resulting in data packages that are incomplete and/or difficult to interpret. PDA requests that additional clarity regarding the specific testing required at each stage of manufacture, using a specified test article be articulated in the document.

PDA believes it is of critical importance to ensure there is a clear and shared understanding between FDA and the industry of the concepts outlined in this Draft Guidance and their practical application. PDA believes that all parties will benefit from continued dialogue in this regard and PDA looks forward to continuing to contribute to this discussion.

PDA Task Force

Amy-Scott Billman, GlaxoSmithKline (Chair)
Rebecca Devine, regulatory consultant
John Geigert, BioPharmaceutical Quality Solutions
Denise Rieker, sanofi-aventis
Taryn Rogalski-Salter, Merck
Michael Vanderwerf, GlaxoSmithKline
Ruth Wolf, Biologics Consulting Group

- Acceptability of in-house data on virus removal by chromatography should be clarified. PDA welcomes the concept of in-house experience in the draft document. We feel that acceptance of in-house virus validation experience will streamline product development and improve product safety. Our one concern is that we feel that in-house data for chromatography steps is probably more robust and reliable than the draft document allows. We feel that manufacturers with extensive experience with virus removal by chromatography can provide examples of this robustness and reliability; we would welcome a more extensive discussion of this issue.

PDA would be pleased to meet with the BWP to discuss our comments, and PDA would also be willing to attend and/or co-sponsor a public meeting to hear and understand the concerns of BWP and to jointly work with BWP on proposed alternative wording. Any questions regarding these suggestions should be addressed to Dr. Richard Levy, Senior Vice President, Scientific and Regulatory Affairs at levy@pda.org.

Capital Area Chapter Tailors Events to Members' Needs

Lindsay Donofrio, PDA

PDA's chapters are thriving and are integral to helping the Association deliver high-quality professional advancement opportunities that are both cost-effective and tailored to the local needs of the membership.

In October, the *PDA Letter* had an opportunity to sit down with Capital Area Chapter President **Allen Burgenson,** Regulatory Affairs Manager, Lonza, to take a closer look at how one chapter fulfills this mission. The Capital Area Chapter serves Maryland, the District of Columbia, Virginia and West Virginia and holds quarterly meetings, featuring networking opportunities, dinner and well-known speakers.

In 1994, the Capital Area Chapter was chartered under the leadership of **Rande Leibowitz**, then of UniVax Biologics, and **Bill Stoedter**, then of Chesapeake Biological Laboratories and former PDA Director of Regulatory Affairs. About two years later, Burgenson joined Leibowitz and Stoedter as chapter Secretary. Early on, the number of people participating in the chapter was limited. "Honestly," said Burgenson, "when we first started the chapter, it was four guys sitting around the table over pizza and beer."

Through the hard work of these early leaders, the chapter continued to grow, and, eventually, its members could no longer fit around the kitchen table. Finding a new home for meetings, however, was not easy, particularly because of the large territory represented—a challenge for all PDA chapters. At first, the chapter tried hosting its meetings in different cities throughout its region, including Baltimore, Md., and Frederick, Md., with variable success. Finally, the chapter concluded that events located close to Washington, D.C., best suited the needs of chapter members. Since those days of trial and error, the Gaithersburg Holiday Inn in Maryland has served as the chapter's home, drawing the highest attendance and offering the best value. If attendees register a week in advance, the fee is only $35 (US) per attendee. "Where else can you get that kind of value?" says Burgenson.

The Capital Area Chapter serves as a perfect example of how chapters can tailor their offerings to the specific communities they serve. For example, Burgenson notes that they have considered other meeting formats, including full day programs and vendor shows. However, the chapter has learned that the local community, which might not ordinarily attend a national PDA event, responds best to more focused, single-session meetings held after work. "We serve everyone from presidents to vice presidents of organizations to bench analysts, who are actually doing the QC tests, to the QA auditor, who doesn't have a lot of experience," says Burgenson. "That's our audience." In many cases, chapter members have spent the majority of their careers with one organization. Burgenson aims to broaden the members' knowledge by providing people with an industry-wide experience.

The Capital Area Chapter meetings—like most PDA chapter meetings—are priced to encourage broad participation of the local community. "One thing you'll find in the I-270 biotech corridor[1] is a lot of start-ups without a lot of money," said Burgenson. "We don't want to exclude those people." In this way, the chapter serves as a conduit for PDA. "I hope that after coming to our meetings at the local level, people will get involved at the national level," said Burgenson.

In order to gather attendees' feedback, questionnaires are distributed during most dinner meetings. The chapter values this feedback so much that they hold a raffle to encourage participation. Often, they award not one, but two prizes—gift certificates to local retail stores or sometimes PDA technical books. "By investing around $50 we get a lot of feedback on how our meeting really went," said Burgenson. Unique and creative ideas like this enable chapters to collect the feedback needed to raise member input and involvement. Through increased chapter participation, the association can better bring PDA to its members.

Burgenson has been a PDA member since 1991. Besides serving as Capital Area Chapter President, he sat on the PDA/FDA Joint Regulatory Conference program committee in 2002 and 2003, and then served as Chair of that committee in 2004.

"It is important to me to make time for PDA and the chapter because I enjoy it and believe in what we're doing," said Burgenson.

Note
1. Maryland's biotech center located along interstate 270

PDA Puerto Rico Chapter is Reborn

Manuel Meléndez, Senior Director, Quality, Amgen Manufacturing Limited and Puerto Rico Chapter Acting President

With great enthusiasm and a full agenda, the Puerto Rico Chapter is getting ready for 2007. This is the story of our chapter's renewal. Last summer, **Martin Van Trieste,** VP, Commercial Quality, Amgen, (newly elected to the PDA Board of Directors) approached me with the idea of reactivating the chapter in Puerto Rico. With 25% of the world's manufacturing capacity located in Puerto Rico, the presence of an organization such as PDA and the benefits it can bring to the pharmaceutical and biotechnology industries is a natural fit. I was immediately attracted to the project.

Following Martin's visit, PDA President **Bob Myers** visited our island and also encouraged me to reorganize the local chapter. I accepted the challenge, and within a few months we were on our way. Bob and I invited a group of local industry representatives to get involved with the chapter, and they embraced the idea with enthusiasm. By October 2006, we were meeting twice a month and now our chapter is active and growing.

I want to thank the following founding team for their support and eagerness to actively participate in the development of the Puerto Rico chapter:

- **Evelyn Marchany**, Schering-Plough
- **Miguel Montalvo**, Expert Validation Consulting
- **Gloria Martinez**, Amgen Manufacturing Limited
- **Adalberto Ramirez**, Amgen Manufacturing Limited
- **Miguel Pereira**, Amgen Manufacturing Limited
- **Thomas Kelleher**, Amgen Manufacturing Limited
- **Maribel Rivera**, Bristol Myers Squibb
- **Carmen Ortiz**, Wyeth

We will be celebrating our first educational event in March. As acting president, I am committed to helping PDA members access professional development tools and to promote networking with the pharmaceutical and biopharmaceutical industries. The key to success is having the correct resources to develop our industry. As we work toward our goals, we look forward to increased technical and scientific development in Puerto Rico.

I am proud to lead this organization, aspiring to effectively promote our values and vision and above all to put the organization's resources to work for our members.

For more information on joining the Puerto Rico Chapter, please contact Manuel Meléndez at manuelm@amgen.com.

New England Chapter Tours Applied Biosystems' Facility

Myron Dittmer, MFD & Associates and New England Chapter President

Approximately 40 people attended the New England Chapter dinner meeting on "Networking for Career Development" on December 13, 2006. The dinner meeting was sponsored by ValSource, LLC.

The event included a walk-through tour of Applied Biosystems' large-scale manufacturing facility for POROS® chromatography media located in Bedford, Mass. The facility includes production areas (chemical reactors, mixing and drying vessels and washing systems), testing labs, as well as receiving and shipping areas.

Attendees dined at the Hilton Garden Inn in Burlington, Mass., and were treated to a talk by guest speaker **David Hennessy**, Vice President, Keystone Partners, Boston, Mass. His presentation included a discussion of

continued on page 34

Upcoming New England Chapter Events

Event Topic/Title:	Chromatography Validation
Date:	Thursday, February 15, 2007
Location:	Wilmington, Mass.
Event Type:	Facility Tour & Dinner Meeting
Event Topic/Title:	Shipping Qualification
Date:	Wednesday, April 11, 2007
Location:	Burlington, Mass
Event Type:	Facility Tour, Networking & Dinner Meeting

One of Applied Biosystem's manufacturing suites, located in a 30,000 sq/ft manufacturing facility located in Bedford, Massachusetts.

Chapter Contacts

The following is a list of the PDA Chapters, organized by the regions of the world in which they are located. Included are the Chapter name, the area(s) served, the Chapter contact person and his or her e-mail address. Where applicable, the Chapter's Web site is listed. More information on PDA Chapters is available at www.pda.org/chapters/index.html.

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Enhance Your Membership at the 2007 Annual Meeting

Be sure to visit the following events at the 2007 Annual Meeting to learn how to take full advantage of your PDA Membership. In addition to these membership-specific events, PDA's Annual Meeting is a great place for members to network and socialize with their fellow industry leaders—see related article, p. 41.

Learn More About PDA at the New Member Breakfast

PDA continues the tradition of hosting its annual New Member Breakfast at the 2007 Annual Meeting. The breakfast will take place on site at the Red Rock Casino, Resort and Spa in Las Vegas, Nev., on **March 19 at 7:30 a.m.** All individuals who became PDA members subsequent to April 1, 2006, are invited and encouraged to attend.

The New Member Breakfast will be hosted by the PDA Board of Directors and staff. Presentations by board members will educate and prepare attendees to fully use the resources available to them as new members. PDA staff will also be available to answer any questions and concerns and prepare attendees for an exciting week. This is a wonderful opportunity to learn more about the quality services offered by PDA and to meet fellow members.

If you are a new member, please RSVP to info@pda.org or call (301) 656-5900. For more information on the 2007 Annual Meeting, please visit www.pda.org/annual2007. We look forward to seeing you there.

Advance Your Career: Attend the Career Fair at the 2007 PDA Annual Meeting!

The PDA Career Center, established in 2004, is a valuable benefit that allows members to search for pharmaceutical and biopharmaceutical positions in the privacy of their own homes. Members can post their resumes anonymously, set up personalized job alerts to notify themselves when a specific job is posted and browse the current job listings.

Career Fairs were introduced as an additional career-advancement tool. The Career Fair held at the PDA Annual Meeting is by far the most popular. This year's Career Fair will be held on **March 19-20** in Las Vegas, Nev.

Members from all over the globe will have the opportunity to network with the world's leading pharmaceutical and biopharmaceutical companies right on site. Private interview rooms create a confidential and open environment to discuss career opportunities. Companies such as Amylin and Boston Scientific are already eagerly awaiting the fair and hope to make meaningful connections with potential employees.

If you are interested in attending this year's Career Fair please visit www.pda.org/careerfair to register and submit your resume. Companies are already scheduling private interview times, so don't wait. While you are there, visit the current job postings on the Career Center site and post your resume. The Career Center is a free service and we hope you take advantage of it.

Employers interested in exhibiting at the 3rd Annual Career Fair should contact Ta-Méla Jeffries at jeffries@pda.org.

Publish with PDA: Submit to the *PDA Letter* and PDA Journal!

Do you have a hankering for writing? Is your inner author yearning to break out? If so, PDA wants you! Both the *PDA Journal of Pharmaceutical Science and Technology* and the *PDA Letter* are seeking authors. Attend this lunch-time session on the Letter and Journal, **Tuesday, March 20, 12:15–1:30 p.m.,** to learn about PDA's two membership publications.

Both publications are provided to all PDA members as part of their regular membership fees. The Journal is the perfect medium to communicate your scientific research and the Letter is the place to publish articles on science, technology, quality, regulatory affairs and more!

At this session, you'll learn all you need to know in order to get your ideas published!

New England Chapter Tours Applied Biosystems' Facility, continued from page 31

networking techniques and strategies for both career development/advancement as well as for career changes. The presentation included information on such topics as:

- What is networking?
- Why should you network?
- How to network?

Hennessy also provided real-life examples to demonstrate how to develop skills for effective networking. He effectively generated audience participation as attendees spent time discussing networking questions at their tables.

For additional information on registering for the above events please contact **Rusty Morrison**, Commissioning Agents, Inc., at rusty.morrison@cagents.com; **Melissa Smith**, MJ Quality Solutions, at melsm@hotmail.com; or **Louis Zaczkiewicz**, Hyaluron Contract Manufacturing, lzaczkiewicz@hyaluron.com.

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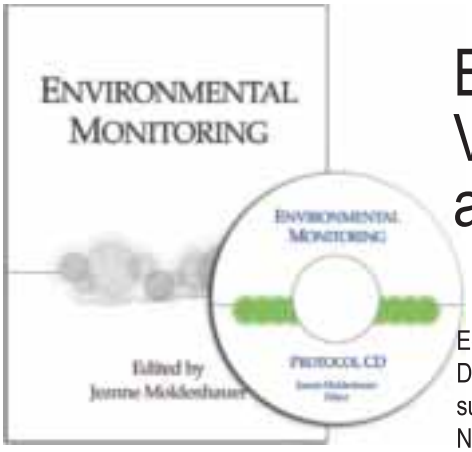
From the PDA Bookstore



Environmental Monitoring, Volume I, Volume II and Protocol CD

Edited by Jeanne Moldenhauer, PhD
Describes methods for developing and operating an appropriate, sustainable microbiological program both in the lab and during production. Numerous useful protocols are included on the CD. Published 2005.

Item No. 17239 PDA Member $530 Nonmember $659

Check out these titles and more from the PDA Bookstore.

Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
By James L. Vesper
Item No. 17219, PDA Member $235, Nonmember $289

Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing
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Item No. 17253, PDA Member $240, Nonmember $299

Encyclopedia of Rapid Microbiological Methods, Volume I, II, III
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Understanding the United States Pharmacopeia and National Formulary: Demystifying the Standard Setting Process
By Susan Schniepp
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Computer Infrastructure Qualification: For FDA Regulated Industries
By Orlando Lopez
Item No. 17251, PDA Member $255, Nonmember $319

Pharmaceutical Quality
Edited by Richard Prince
Item No. 17207, PDA Member $285, Nonmember $359

Risk-Based Software Validation: Ten Easy Steps
By David Nettleton and Janet Gough
Item No. 17256, PDA Member $200, Nonmember $249

The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance
By Siegfried Schmitt, PhD
Item No. 17234, PDA Member $225, Nonmember $279

Successfully Validating ERP Systems (and other large, configurable applications)
By David Stokes
Item No. 17245, PDA Member $250, Nonmember $309

Practical Safety Ventilation in Pharmaceutical and Biotech Cleanrooms
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Maria Fernandez, Iname
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PDA Parenteral Drug Association

2007 ANNUAL MEETING

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Recommended Reading

Encyclopedia of Rapid Microbiological Methods, Volume I, II and III
Edited by Michael J. Miller, PhD (Item no. 17252)

Environmental Monitoring, Volume I, Volume II and Protocol CD
Edited by Jeanne Moldenhauer, PhD (Item no. 17239)

Pharmaceutical Filtration: The Management of Organism Removal
By Theodore H. Meltzer, PhD and Maik W. Jornitz (Item no. 17235)

Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
By James L. Vesper (Item no. 17219)

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By Siegfried Schmitt, PhD (Item no. 17234)

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Understanding the United States Pharmacopeia and National Formulary: Demystifying The Standard Setting Process
By Susan Schniepp (Item no. 17250)

Using Statistics to Measure and Improve Quality
By Lynn D. Torbeck (Item no. 17258)

PDA Technical Report 28 Revised, Process Simulation Testing for Sterile Bulk Pharmaceutical Chemical
(Item no. 01028)

PDA Technical Mongraph 1, Validation of Steam Sterilization Cycles
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Faces and Places

ISPE and PDA Joint Conference on ICH Q8 and Q9
Washington, D.C. • Dec. 6-7, 2006

Keynote Presentation and Session P1: (l-r) Joseph Phillips, ISPE; Janet Woodcock, MD, FDA; Stephan Roenninger, PhD, F. Hoffmann-La Roche; Jean-Louis Robert, PhD, Laboratoire National de Sante Service du Controle des Medicaments

Session P2: (l-r) Charles Hoiberg, PhD, Pfizer; Susanne Keitel, PhD, Federal Institute for Drugs and Medical Devices; Moheb Nasr, PhD, FDA

Session P6: (l-r) Yukio Hiyama, PhD, National Institute of Health Sciences; Gail Sherman, PDA; Shigeki Tamura, PhD, Astella Pharma Inc.

Session P4: (l-r) Betsy Fritschel, Johnson & Johnson; Zena Kaufman, Abbott Laboratories; Malcolm Holmes, GlaxoSmithKline; Joseph Famulare, FDA

2007 PDA/FDA Program Planning Committee Meeting
Bethesda, Md. • Nov. 28, 2006

(From back right, clockwise) Vince Matthews, Eli Lilly & Company; Amy J. Giertych, Baxter; Rick Friedman, FDA; Kathleen Wessberg, Abbott Laboratories; Judy Bausch, PDA; John Finkbohner, PhD, MedImmune, Inc.; Wanda Neal-Ballard, PDA; Gail Sherman, PDA; Cynthia Garris, FDA; Paul Allen, Clarkston Consulting

Keynote and Closing Day Speakers Set for Annual Meeting

Keynote Speaker

PDA is pleased to announce the keynote talk will be delivered by **Dan W. Denney, Jr.**, PhD, Founder, Chairman of the Board of Directors and Chief Executive Officer, Genitope Corporation, on personalized medicine.

Dan W. Denney, Jr., PhD, Genitope Corporation

Denney is the founder of Genitope Corporation and has served as Chief Executive Officer since November 1999 and Chairman of the Board since August 1996. Denney did his postdoctoral research in the Chemistry Department at Stanford University, where he was a Merck Fellow. He then served as a Visiting Scholar at the University of Alberta in Canada prior to founding Genitope. Denney holds a BA from Vanderbilt and a PhD in Microbiology and Immunology from Stanford University School of Medicine.

Closing Speaker

The meeting will conclude with a talk by Washington food and drug lawyer **Peter Barton Hutt**.

Peter Barton Hutt, Covington & Burling LLP, Washington, D.C.

Hutt is a senior counsel in the Washington, D.C., law firm of Covington & Burling LLP specializing in food and drug law. Hutt served as Chief Counsel for the US FDA from 1971–1975. He has been a member of the Institute of Medicine since it was founded in 1971. Hutt was named as one of the 40 best healthcare lawyers in the United States by the *National Law Journal* and as the best FDA regulatory specialist in Washington, D.C., by *European Counsel*. In 2005, Hutt received the FDA distinguished Alumni Award for research advocacy.

Attend the Prefilled Syringes Workshop at the 2007 PDA Annual Meeting

Las Vegas, Nev. · March 22, 2007

Michael N. Eakins, PhD, Eakins and Associates and Workshop Co-Chair

The growing interest in prefilled syringes for the delivery of a wide range of pharmaceuticals and biopharmaceuticals was demonstrated by the high attendance at PDA's The Universe of Prefilled Syringes and Injection Devices forum held in Bethesda in 2006. PDA is bringing this topic to the west coast in 2007 and will present a one-day workshop on The Universe of Prefilled Syringes at the Annual Meeting on March 22 to provide up-to-date information on both the scientific and regulatory aspects of prefilled syringes.

Topics to be covered include materials of construction, new developments in design and coating materials, as well as case studies on potential product interactions with syringe components, especially biopharmaceuticals. Product development case studies will discuss extractables and leachables and the issue of plunge movement during air shipment. Manufacturing case studies will highlight the development of two-chambered syringes and new vacuum filling technologies and the workshop will close with two presentations on the regulatory aspects of developing prefilled syringes as combination products.

So take this opportunity to extend your stay in Las Vegas by one day and take home the latest information on the development of prefilled syringes.

Expanded Networking Activities You Can't Afford to Miss!

With PDA's enhanced focus on networking, this year's Annual Meeting in Las Vegas offers a wide variety of formal and informal networking opportunities that capitalize on the local surroundings and attractions. Guests are welcomed to attend many of these events. Go to www.pda.org/annual2007 for information on how to register and any additional fees for the following events.

Sunday, March 18

1st Annual PDA Golf Tournament at Arroyo Golf Club
8:00 a.m. Shotgun Start

The tournament will be set up in teams of four, maximum of 12 teams, using a "best ball" format. The Arroyo Golf Club offers a four star course and is the newest Arnold Palmer Signature course. It ventures through the rugged terrain nestled between the spectacular landscapes of Red Rock Canyon, and stunning views of the Las Vegas Strip. Bold bunkering, dramatic water hazards and the stark contrast of emerald greens against the tanned desert mountain, make the Arroyo course as visually striking as it is challenging.

Lake Mead Riverboat Cruise and Hoover Dam
11:00 a.m. – 4:00 p.m.

Bring a guest and spend a leisurely day aboard the Desert Princess, an enclosed Mississippi-style paddle wheeler, on the largest man-made lake in the United States, Lake Mead. While cruising, view the beautiful scenery, the rugged rock formations and possibly see Bighorn sheep. Lunch will be served during the cruise. Next, board your coach for a short ride to one of the seven man-made wonders of the world, Hoover Dam. Experience for yourself the grandeur of this tremendous architectural achievement.

Meet-and-Greet Reception
3:00 p.m. – 7:00 p.m.

Whether you're new to PDA, a long-time member or a first time Annual Meeting attendee, you're sure to benefit from this unique networking opportunity. Join chapter representatives, PDA members, other conference attendees and the PDA 2007 Annual Meeting Program Planning Committee for an informal reception to learn what's in store for you at this year's meeting and how you can make the most out of your experience in Las Vegas. Don't miss your chance to exchange ideas with your peers, learn more about the current activities at PDA and make valuable contacts to take home with you.

Monday, March 19

Cirque du Soleil's LOVE
Showtime: 7:00 p.m.

LOVE will bring the magic of Cirque du Soleil together with the spirit and passion of The Beatles to create an intimate and powerful entertainment experience. The custom-built theatre at The Mirage features 360-degree seating, panoramic video projections and surround sound which will envelop the audience, who will experience The Beatles music like never before.

Monday, March 19 & Tuesday, March 20

PDA's 3rd Annual Career Fair

Come face-to-face with industry-leading employers from all over the world at PDA's 3rd Annual Career Fair. Be sure to bring multiple copies of your resume as there will be opportunities for confidential, on-site interviews (see related article, p. 34).

Networking with Exhibitors

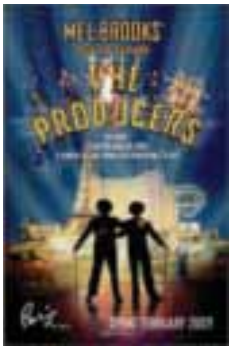
Get an up-close look at the latest pharmaceutical and biopharmaceutical technologies available when you join the exhibitors for a networking lunch and cocktail reception. Relax with friends, learn about exciting new technology and win great prizes!

Tuesday, March 20

Gala Reception
5:15 p.m. – 7:15 p.m.

Bring a guest to a Las Vegas night at the Red Rock Resort! Join your friends and colleagues to start the night with Vegas-style festivities. One ticket is included with registration. Your spouse or guest is welcome to attend this event. Additional tickets may be purchased for $50 (US).

The Producers
Showtime: 8:00 p.m.



Following the Gala Reception, spend an evening on Broadway…in Vegas! Based on the Academy Award-winning 1968 film of the same name, The Producers is the story of down-on-his-luck theatrical producer Max Bialystock and Leo Bloom, a mousy accountant. Together, they hatch the ultimate scam: Raise more money than you need for a sure-fire Broadway fiasco…and pocket the difference. The Producers has become a Broadway phenomenon, turning the tradition of a Broadway musical on its head and earning more Tony Awards than any other show in the history of the Great White Way.

PDA Parenteral Drug Association

2007 ANNUAL MEETING

Putting Science and Technology into Practice

LAS VEGAS, NEVADA | MARCH 19-23

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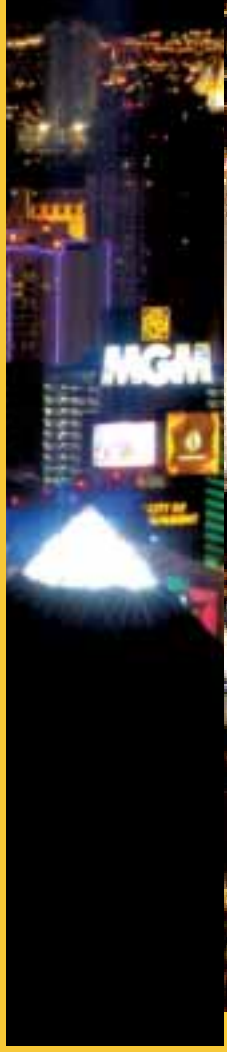

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Putting Science and Technology into Practice

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Let it Ride on Two More Days in Vegas!

PDA Training and Research Institute presents two full days of Training Courses

March 22, 2007

A Comprehensive Guide to OOS Regulations
Faculty: Lynn Torbeck, *Torbeck and Associates, Inc.*

Development of Qualification and Validation Protocols - A Risk Management Approach
Faculty: Hal Baseman, *ValSource, LLC*

Essentials of U.S. and EU CMPs for Manufacturers of Active Pharmaceutical Ingredients (APIs) – **New Course!**
Faculty: Michael H. Anisfeld, *Globepharm Consulting*

Process Validation for Biopharmaceuticals – **New Course!**
Faculty: Anurag S. Rathore, PhD, *Amgen, Inc.*; Gail Sofer, *GE Healthcare*

March 22-23, 2007

Preparing for and Managing FDA Inspections
Faculty: David L. Chesney, *PAREXEL Consulting*
Paul McKim, *PAREXEL Consulting*

Courses will be held at:
Red Rock Casino and Resort
11011 West Charleston Blvd.
Las Vegas, NV 89135

March 23, 2007

Assay Validation Basics
Faculty: Lynn Torbeck, *Torbeck and Associates, Inc.*

Methods of Reducing Costs for Cleanroom Operations – **New Course!**
Faculty: Anne Marie Dixon, *Cleanroom Management Associates, Inc.*

Pharmaceutical Cold Chain Distribution Best Practices – **New Course!**
Faculty: Tom Pringle, *SCA Packaging North America*

Risk Estimation of Aseptic Processing
Faculty: Klaus Haberer, PhD, *Compliance Advice and Services in Microbiology, GmBH, Köln*

All courses will be held from 8:30 a.m. – 4:00 p.m. on their respective dates.

For full course details, including faculty listings, accreditation, and learning objectives, please visit:

www.pda.org/annual2007

or contact Jessica Petree, Manager, Lecture Education
Tel: +1 (410) 455-5800, Email: petree@pda.org

PDA

Connecting People, Science and Regulation℠

Successful Quality Control Requires a Keen Eye for Identifying Contamination

PDA Training and Research Institute is offering several **Microbiology**-focused courses in 2007—helping you develop the skills required to ensure a quality product

Up Next:

Environmental Mycology Identification Workshop
PDA #230
Session I: March 1-2, 2007
Baltimore, Maryland, USA
www.pdatraining.org/mycology

Identification of fungal contamination is a must for any successful quality control program. This course is designed to offer hands-on experience with both traditional and new fungal identification techniques for QA/QC and Microbiology personnel. Various methods, including fungal detection, identification flow charts and use of camera for documentation will be introduced. By providing participants with the proper tools to perform accurate and reliable fungal identifications in-house, outsourcing costs for fungal identification can be reduced/eliminated.

Upcoming in 2007:

Pharmaceutical and Biopharmaceutical Microbiology 101
PDA #142
May 1-4, 2007
Baltimore, Maryland, USA
www.pdatraining.org/pbm101
One Time Only in 2007!

Environmental Mycology Identification Workshop
PDA #230
Session II: August 2-3, 2007
Bethesda, Maryland, USA
www.pdatraining.org/mycology

Rapid Microbiological Methods / PDA #326
October 1-5, 2007
Bethesda, Maryland, USA
www.pdatraining.org/rapidmicro
One Time Only in 2007!

Fundamentals of D, F and z Value Analysis
PDA #301
October 23-24, 2007
Bethesda, Maryland, USA
www.pdatraining.org/DFZ
One Time Only in 2007!

Advanced Environmental Mycology Identification Workshop
PDA #396
October 31-November 2, 2007
Bethesda, Maryland, USA
www.pdatraining.org/advmycology
One Time Only in 2007!

For a complete listing of training courses from PDA TRI, please visit *www.pdatraining.org.*

TUAA7

Gaining Comfort in a Strange Land…or Classroom

Gail Sherman, PDA

TRI TALK

When I sat down to write this month's article, I was stumped—what might be an interesting topic and how does it relate to education and training? I was having a bit of a brain drain. I wrote about 2006 last month, and there isn't quite anything to say about 2007, yet. However, by the time you're reading this, I will have had the sledge hammer in my hand for at least a few minutes of knocking down walls at our new Bethesda facility!

So where was I? Talking to the PDA editorial folks, they inquired about my recent travels and thought that there might be a message there. Through some brainstorming, we came up with an idea. Many of us travel to countries with different cultures. I'm sure you can recall the unfamiliarity you felt the first time you walked through the airport of a country you have never been to. If you think back to a time when you were a student, you must remember how strange it felt to walk into a classroom for the first time—not knowing what to expect from the instructor, your classmates or even the course content. You probably wondered: "Why am I here?" "Why did I decide to go on this trip?" or "Why did I choose to take this course?"

In the last three months of 2006, I had the opportunity to attend the PDA/EMEA Joint Conference in London, the PDA Asia-Pacific Congress in Tokyo and a personal visit in Israel. I have been to both London and Israel several times, so I should have had the same sense of comfort as when I travel through a US airport. It all seems so familiar—same concessions, signs in English and the US dollar. However, when I walked through customs at the London Heathrow Airport, I realized I still had to get to my hotel in the city. Being the penny pincher that I sometimes am, I decided that an expensive taxi ride from the airport was out of the question. So, I had to find the train. I thought I knew London, but still managed to end up at the wrong hotel—long story. Then I had to figure out the currency and try to understand the English I thought I knew. (I now have a pocket full of Euros, pounds, Swiss Francs, yen and shekels, none of which I can tell apart.) So, how different is this from the student who looks up MapQuest® [www.mapquest.com] directions to TRI in Baltimore, and then ends up on the other side of town? And yes, this happens often!

Next there was Tokyo. I arrived at a very unfamiliar airport alone, and I knew I had to find the bus into the city. Again, the taxi would have been outrageously expensive, as some of my colleagues learned. However, there were no signs that said "bus." They said something like "taxi." Eventually, I managed to find the right line, got on the bus and tried to figure out where to get off once in Tokyo. Unfortunately, the scrolling sign said one thing. And when I looked at where I was and where the hotel was, I knew this wasn't correct—but who to ask? So I asked "anyone," and finally an English voice told me to wait until the next stop. I did, though I felt unsure as I watched the hotel get farther and farther away. Nevertheless, I made it. Then I had to find out where to register with maps drawn by hotel staff. I imagine some of my aseptic students feel the same way when we toss a gown at them and tell them to put it on without touching anything. For the first time student, some of what we do at TRI must seem like a foreign language!

And so how does this all tie together? Well, it shows that we must demonstrate patience. Everyone doesn't know what we do in the classroom or in that airport or city in Japan, or in the United Kingdom or in the Middle East. We are learning all the time. Through this learning, we will be better able to help others and show them the way. And most importantly, we learn the importance of developing our skills and our abilities and broadening our knowledge so that we have greater comfort when arriving at that very strange destination—called TRI!

2008 PDA Biennial Training Conference

Focus on Performance: Partnering for Business Success

May 19–23, 2008 | Ritz Carlton Hotel | New Orleans, Louisiana

Announcement and Call for Papers

PDA is seeking abstracts for the 2008 PDA Biennial Training Conference. The attendees will include regulatory training professionals training managers, quality professionals, human resource professionals, supervisors, technical trainers, and others who train within the international pharmaceutical, biopharmaceutical and related industries. PDA will consider abstracts of a noncommercial nature that significantly contribute to enhancing the knowledge and skills of regulatory and technical trainers in these industries.

SUBMISSION DEADLINE: MAY 1, 2007

This conference will focus on building successful partnerships between pharmaceutical trainers and their customer groups to develop, sustain and continually improve value-added training programs for their sites. Abstracts outlining problems/solutions, best practices, and the latest trends in training, including but not limited to the following topics are being sought:

- **Technical Training:** Trainer qualification, OJT, effective procedures/SOPs, partnering with e-learning, cross training, measuring training impact, training in aseptic areas
- **Training Theory and Design:** Developing learning objectives, evaluation methods and methodologies; developing e-learning; measuring the impact of training; facilitation techniques; participant-centered training; developing games
- **Training Program for Senior Managers:** How to engage senior management to influence workplace learning, training as a business goal, non-training solutions, from trainer to problem-solver, successful performance consulting, training top management, training vs. performance improvement, learning initiatives
- **Training Professional:** Effective needs assessments, from trainer to problem-solver, influencing workplace learning, business goals and training, diversity on the training floor, training outside North America, internal consultant and performance improvement professional
- **Regulatory Training:** Ways to effectively communicate existing and changing regulations, guidance documents and other compliance related information
- **Technology-based Training:** Using various computer/web-based delivery mechanisms, electronic LMSs and simulators

Visit www.pda.org/Training2008 to submit your abstract today.
Commercial Abstracts Promoting Products and/or Services Will Not Be Considered.

PDA will provide one complimentary meeting registration per presentation.
Additional presenters will be required to pay appropriate conference registration fees.

Submissions must include the following information:

- Presenter
- Title
- Company
- Full address
- Phone, fax and email address of presenter
- Presenter's biography (<100 words)
- Co-presenter(s)
- Title(s)
- Company
- Full address(es)
- Phone, fax and email address of co-presenter
- Co-presenter's biography (<100 words)
- Proposal title
- Target audience (by job titles, department and specialty areas)
- Session description - Describe format and include methods to ensure participants' involvement (estimate facilitator speaking time and participant interaction time) (Examples - presentation with small group discussions, case studies, demonstration, panel discussion)
- Presentation Duration (including content and interactive portions) select one: 45 or 75 minutes
- Learning objectives for the session
- Rationale: Explanation of specific take-home benefits your audience can use immediately on the job

Upon review by the program committee, submitters will be advised in writing of the status of their abstracts after October 1, 2007.

If you have any questions, please contact Jason E. Brown, Senior Coordinator, Program & Meetings, PDA at 301-656-5900 ext. 131, or via email at brown@pda.org.

PDA also reaches a broad market with their signature audio conferences. If you are interested in submitting your abstract as a possible audio conference or web seminar 1-2 months after the conference, please contact Jiwan Giri, PDA at 301-656-5900 ext. 132 or giri@pda.org.

2008 "Trainers' Choice" Awards

2008 PDA Biennial Training Conference

New Orleans, Louisiana | May 19-23, 2008

Trainers' Choice Awards are presented to trainers, by their peers, for outstanding achievement, creativity and originality in design, development, and delivery of cGMP and technical training programs or materials. The awards will be presented during the final day of the 2008 PDA Biennial Training Conference (May 21), at the Ritz Carlton, New Orleans.

Categories May Include:

- **Multimedia Presentation** (Videos, slide shows and PowerPoint presentations)
- **Classroom Training Manual** (Course design and materials from classroom training – participant handouts and trainer guides)
- **E-Learning program/web-page design** (Interactive computer-based programs, Web pages, Web programs)
- **Experiential/Interactive Training** (Games, simulations, exercises, magic tricks)
- **Other Creative Approaches**

Eligibility

Consideration for this award will be given to all trainers currently employed in the pharmaceutical, biotechnology, medical device, biologics, or related health-science industries. Consultants or vendors to such industries are not eligible. **Internal training staff must have designed and own the training programs and materials.**

All entries must be received by January 31, 2008

Please visit www.pda.orgTraining2008 for submission information and to complete the application outlining your entry. Submissions without full information will not be considered.

Preliminary Judging

The PDA Training Conference Committee will conduct preliminary judging. (Entries will be judged on how well they meet the stated objective, serve the target audience and incorporate principles of adult learning theory. Finalists will be notified by March 15, 2008. Finalists should be prepared to display their materials and be available to answer questions at the 2008 PDA Biennial Training Conference. Displays should be designed for tabletop demonstration. Exhibits larger than a tabletop will not be permitted, nor will the distribution of premiums promoting the company or the exhibit. A standardized fact sheet with information on the design of the material will be the only item which may be distributed to conference attendees.

Final Selection

All finalists' programs will be displayed at the conference site, The Ritz Carlton, New Orleans, on May 19-21, 2008. Winners will be chosen by vote of the trainers attending the 2008 PDA Biennial Training Conference. Finalists selected to display at the conference are required to pay the full registration fee.

Recognition Ceremony

Finalists will be recognized and the winners announced on the final day of the Conference, May 21, 2008.

Questions about the Award

Please address all questions to: Jason Brown, Coordinator, Programs and Meetings, PDA
+1 (301) 656-5900, ext. 131 or brown@pda.org.

Not *Everything* that happens in Vegas...

Stays in Vegas

Register early and save **www.pda.org/annual2007**

PDA 2007 ANNUAL MEETING – MARCH 19-23

Putting Science and Technology into Practice

CONFERENCE | EXHIBITION | TRAINING COURSES

Take home the Knowledge, Connections and Experience that will make a difference all year.

What's new this year? The exciting setting of Las Vegas and an expanded schedule of networking activities make it easier than ever to meet colleagues, exchange ideas and have fun!

What has not changed? Our commitment to providing valuable bio/pharmaceutical knowledge, insights and training

Join PDA at the spectacular Red Rock Resort, Casino and Spa

- Develop your practical knowledge of science and technology
- Connect with decision makers and thought leaders
- Strengthen your role in advancing sound science and regulation

Expanded networking activities you can't afford to miss!

- PDA's 1st Annual Golf Tournament at Arroyo Golf Club
- Las Vegas signature shows and live entertainment
- Spouse/guest/child day programs
- Local sightseeing tours

PLUS: New member orientation, receptions, an expanded career fair and a gala event you won't forget!

PDA℠
Parenteral Drug Association