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PDA Letter

Volume XLIV • Issue #2

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February 2008

In This Issue…

PDA
Parenteral Drug Association

Connecting People, Science and Regulation®

Change Control Tests Contract Manufacturing Relationships

Walter Morris and Emily Hough, PDA

Of the many challenges facing contract manufacturers and their clients, change control can be one of the toughest to handle and require the most effort.

Strong change management is a fundamental principle of a robust quality system, and while the concepts behind change management are relatively simple, the globalization of the pharmaceutical industry and the borderless supply chain supporting it create complexity. The program committee for the *2007 PDA/FDA Joint Regulatory Conference* dedicated two breakout sessions to the topic, with speakers representing regulatory authorities in the United States, Canada and Japan and the industry.

The added challenges of co-managing change control when working in a contract manufacturing arrangement was also addressed. **Luisa Paulo,** GMP Compliance, Hovione, discussed the matter from the contract manufacturer perspective, and **Randall Tlachac**, Program Director, Molecular and Cellular Therapeutics, spoke from the perspective of a "virtual" firm.

Both speakers indicated that the parties involved in a contract manufacturing relationship need to focus resources and personnel on ensuring that the partnership works. These resources must work together to manage hurdles such as different corporate cultures, barriers to communication, divergent views and perspectives on issues such as deciding what is important and regulatory interprestions. Failure to do so can jeopardize the effectiveness of the relationship and its long-term viability.

Changes to the manufacturing process, equipment and supplies, whether initiated by the drug product licensee or the contract manufacturing organization (CMO), greatly test how effectively both parties work together.

Changes required by the licensee seem to occur in the early phases of the partnership, according to Hovione's Paulo. "Usually…when [the clients] propose changes it is always at the beginning of the campaign. It is two weeks or one week before the campaign starts, and we need to rush in order to have everything in order for the campaign."

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2008 PDA Annual Meeting

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Exhibition	|	April 14-15, 2008
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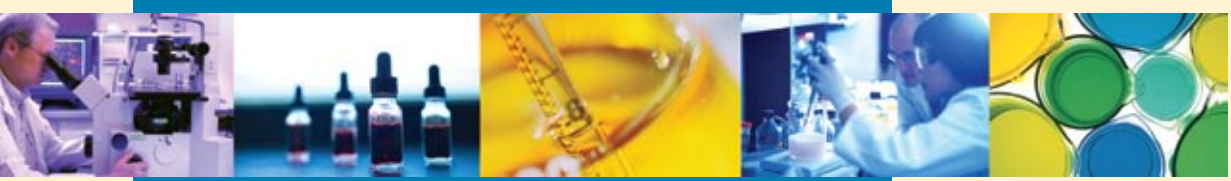
The PDA Annual Meeting is dedicated to advancing the careers of pharmaceutical and biopharmaceutical professionals by focusing program content on science and technology innovation, offering extensive formal and informal networking opportunities and providing a forum to contribute to and influence the advancement of science and regulation in the industry.

Highlights of this year's conference program include:

- Concurrent sessions organized by three tracks: Manufacturing Sciences, Biotechnology Sciences, Quality Sciences
- Keynote presentations by Linda Armstrong Kelly, the mother of Lance Armstrong, who credits her as the unsung hero who assisted him in his triumph over cancer; and Shelley Morrison who plays Rosario on the hit NBC series *Will and Grace* and who has survived two bouts of cancer.
- Novel manufacturing technologies that enhance patient safety
- New contaminants: Implications, detection and exclusion

Complementing the conference are PDA Training and Research Institute (PDA TRI) courses, an exhibition and PDA's 4th Annual Career Fair.



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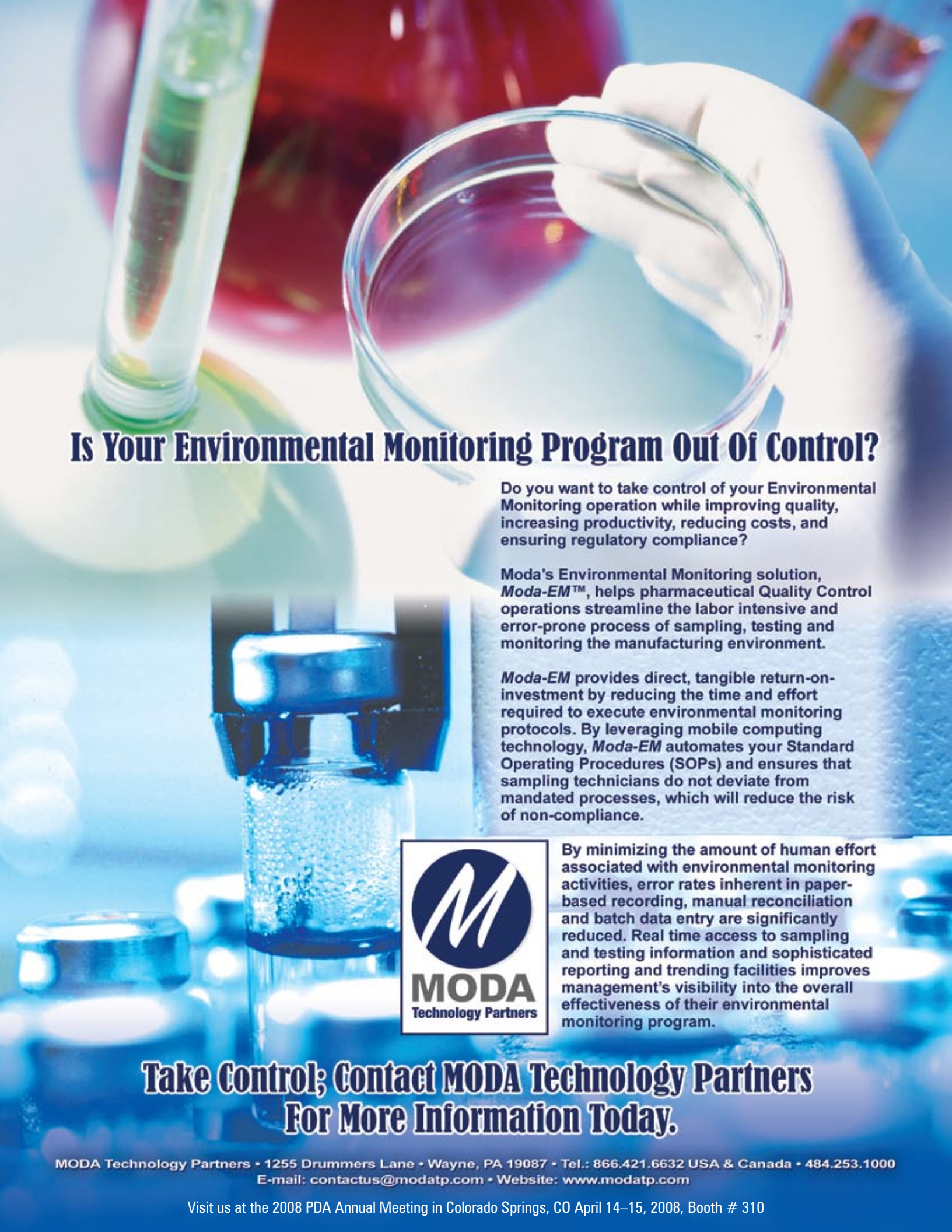

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Cover art:
Quality Agreements governing contract manufacturing arrangements should include a detailed change control procedure.
Artwork © John Berry

January Top 10 Bestsellers

1. **Environmental Monitoring: A Comprehensive Handbook, Volume I, Volume II and Protocol CD**
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17239, PDA Member $530, Nonmember $659
2. **Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple**
   By James L. Vesper
   Item No. 17219, PDA Member $235, Nonmember $289
3. **Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics**
   By Scott Sutton, PhD
   Item No. 17242, PDA Member $210, Nonmember $260
4. **PDA Technical Report 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment**
   Item No. 01039, PDA Member $100, Nonmember $225
5. **Ethylene Oxide Sterilization: Validation and Routine Operations Handbook**
   By Anne F. Booth
   Item No. 17276, PDA Member $200, Nonmember $249
6. **Bioprocess Validation: The Present and Future**
   By Trevor Deeks, PhD
   Item No. 17248, PDA Member $225, Nonmember $279
7. **Encyclopedia of Rapid Microbiological Methods, Volume I, II and III**
   Edited by Michael J. Miller, PhD
   Item No. 17252, PDA Member $730, Nonmember $899
8. **PDA Technical Report 1, Revised 2007, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control**
   Item No. 01001, PDA Member $150, Nonmember $250
9. **Systems-Based Inspection for Pharmaceutical Manufacturers**
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17243, PDA Member $255, Nonmember $319
10. **PDA Archive on CD-ROM – PDA Archive Retrieval Index** - 30% Off
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Pharmaceutical Water System Microbiology

APRIL 23-25
Practical Aspects of Aseptic Processing
Basel, Switzerland

MAY 19-21
Cleaning Validation

JUNE 4-6
Developing a Moist Heat Sterilization Program within FDA Requirements

JUNE 9-13
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Editor's Message

Editorial Committee Openings

Before I tell you about this month's issue, I want to announce that we have two openings on the PDA Letter Editorial Committee. This committee helps PDA set the editorial agenda for the Letter each year, reviews member submissions and helps us find authors and occasionally contributes articles. The time commitment for this committee includes a bimonthly teleconference. If interested, please send an email to **morris@pda.org.**

The highly informative 2007 PDA/FDA Joint Regulatory Conference continues to be a source of articles for the PDA Letter. As we discussed how to narrow down the theme Contract Manufacturing, we took note of talks at the Joint Conference by **Louisa Paulo** and **Randall Tlachac** on how contractors and licensee holders can manage change via the quality agreement. Their excellent presentations were just two among many included in a two-part session dedicated to Change Control Management at PDA/FDA.

Elsewhere in the issue, **Bob Myers** provides an overview of what members can expect from PDA this year (p. 8), PDA consultant **Henry Kwan** previews the PDA Graduate Student Symposium (see "Science & Technology Snapshot," pp. 10–11), and PDA's **Emily Hough** writes about a recently published FDA subcommittee report about the health of the Agency's science and technology (see "Health Authority Special Report in the "Quality & Regulatory Snapshot," pp. 24–25). A number of PDA chapters helped us this month to populate the Membership Resources section. We highlight several upcoming meetings and provide photos of recently passed events in Programs & Meetings, and new staff in "TRI Talk" and in the Europe section.

Hope you enjoy this issue!

Visit www.pda.org/pdaletter

At the Letter's new website, you can read selected articles and link to the members-only archive *before* your hard copy arrives in the mail! Also, you can easily submit your comments and have them published as "Letters to the Editor." Click on the "Authors Wanted" link to learn about upcoming topics and how to submit articles!

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- Implement best training practices in a highly regulated environment
- Improve the performance of your employees
- Apply the latest training trends and techniques
- Inform your team of the most current regulatory requirements

Complementing the conference are PDA Training and Research Institute (PDA TRI) training courses and an exhibition featuring vendors who provide excellent services in support of training efforts.

CONFERENCE

MAY 19–21

EXHIBITION

MAY 19–20

TRAINING COURSES

MAY 22–23

PDA Poised for Further Success in 2008

PRESIDENT'S MESSAGE

Bob Myers

The New Year is well underway and promises to be one with many highlights and increased opportunity for PDA and its members. The last three years have been very good for PDA, and I am confident we are up for the challenge of further success, particularly continued growth in Europe and in new technical arenas.

Before telling you about all the exciting things you can expect from PDA in 2008, let me reflect on our many accomplishments last year. In reviewing the various areas of accomplishment, it is hard to decide which to begin with because many of the accomplishments of 2007 will be considered milestones to our organization's history.

That being said, let me start by mentioning the consolidation of the Training and Research Institute into our Bethesda location, because that is the most tangible accomplishment of 2007. Not only did we unify our North American operations and vastly upgrade our training capabilities, we constructed the new facility on time and we received many more donations for the facility than originally expected. The outpouring of support for TRI by the various donors significantly raises the value of the new facility to our membership and endorses our view of how important the Institute is to us and our supporters.

Speaking of increasing the value of PDA membership, I am proud to remind you of the creation of the newsletter, *International Pharmaceutical Quality* (IPQ). By working with former Gold Sheet editor Bill Paulson, PDA has launched IPQ, an exciting new source of regulatory information. Each issue is a comprehensive reference document on a global regulatory or harmonization topic. It is unique in the industry. We also published *Technical Report No. 1 (Revised 2007), Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control,* a guide to manufacturers that harmonizes best practices from Europe and North America. With the publication of IPQ, TR-1 and other technical reports, PDA significantly enhanced the value of our membership.

Our programming continues to reach new levels year after year. In 2007, both the Annual Meeting and the PDA/FDA Joint Regulatory Conference drew record numbers. Total attendance at the Annual Meeting reached 1,000 and for PDA/FDA, nearly 1,200.

We also successfully improved our ability to respond to member needs. For the global membership, we significantly increased the resources dedicated to membership services in our Bethesda headquarters and established a fully staffed office in Berlin, Germany to service our rapidly expanding European operation. The staff at both locations ensures more timely service to members all over the world. Going into 2007, we placed particular emphasis on increasing our offerings to members in Europe. As a result we nearly doubled the overall value of our European operation. Overall, the Association grew to approximately 11,000 members in 2007, a 12% increase from the previous year.

Looking to 2008, PDA has many goals that, if met, will continue to enhance and grow the benefits of membership.

For one, we continue to work diligently to improve our support to our Chapters. Much was accomplished on this front in 2007, but we are ready to make further commitments in 2008.

We anticipate publishing at least six PDA technical reports, doubling last year's effort. And with the development of each tech reports, we want to provide training and support to help members exploit the value of technical reports to the fullest. Our training workshops for TR-1 have received high marks and great attendance, and we plan at least one more in 2008 in Toronto. In the future, training on TR-1 will be expanded to include three supporting technical reports covering steam in place, parametric release and moist heat sterilization as well as other related documents.

As for programming, we have many strong programs on the agenda to help our members do their jobs. In February, we will hold our second joint conference with the EMEA in Budapest. The goal is to co-sponsor a regularly scheduled event with the EMEA to bring even greater value to our membership. The 2008 Annual Meeting in April in Colorado Springs, Colo., is officially branded as PDA's top science and technology meeting. In May, our Biennial Training Conference will be held in New Orleans. For the 18th consecutive year, PDA and FDA will hold the Joint Regulatory Conference, once again in Washington, D.C., in September. PDA's conferences on prefilled syringes have been so popular that we are committed to holding one a year, alternating locations between Europe and North America; this year's event will be in October in San Diego, Calif.

Finally, I'm very excited to announce PDA's very first meeting in China—*The PDA/FDA Co-Sponsored Workshop on Quality Systems.* PDA and FDA teamed up two times in 2007 for this two-day discussion of quality systems. In 2008, with the endorsement of China's State FDA, we will hold the workshop in Beijing (Apr. 21–22) and in Shanghai (Apr. 24–25), both important focal points of the industry in China.

As you can see, we are firmly committed to following a great 2007 with an even greater 2008. Keep an eye on the *PDA Letter*, the PDA Connector and our website for additional information on these and other membership benefits and PDA programs.

Science & Technology *Snapshot*

Investing in the Industry's Future: PDA Graduate Student Symposium

Henry Kwan, PhD, Kwan Consulting, LLC

In the last several years, PDA has put together a Graduate Student Symposium at the PDA Annual Meeting. The topics presented at these symposia tend to offer the meeting attendees insight into what the future may hold in terms of cutting-edge thinking in science and technologies pertinent to the pharmaceutical and biopharmaceutical industry.

The Graduate Student Symposium at the PDA 2008 Annual Meeting will feature five presentations from senior graduate students who are close to completing their doctoral dissertations and are aspiring to join the industry in the near future. Their presentations will cover the following topics:

- D-penicillamine: A reactive oxygen species (ROS) generating copper chelator – I. proof of concept as an anti-cancer agent, and II. synthesis, in vitro and in vivo characterization of a novel gelatin-D-pen conjugate
- Determination of end point of primary drying in freeze-drying process control
- Effect of ethanol as a co-solvent on the physicochemical properties of dexamethasone loaded poly(lactic-co-glycolic) acid (PLGA) microspheres
- Development and lyophilization of RGD-peptide conjugated fluorescent liposomes
- Development of gas-filled targeted long circulating liposomes (GFTLCL) for ultrasound mediated delivery

The future of the pharmaceutical and biopharmaceutical industry is in the hands of the next generation of members and colleagues at PDA events. I encourage the 2008 Annual Meeting attendees to show their support and enthusiasm for the future of our industry by attending the Graduate Student Symposium. Furthermore, for those attendees looking to recruit fresh talent into their companies, this offers the perfect opportunity of learning first-hand about some of the latest research at several universities as well as scouting out the next wave of doctoral students entering our industry.

Technical Report *Watch*

In Global Review: *Drafts of the following TRs are under review by the global PDA membership. To learn how to comment on any one of the drafts, contact Genevieve Lovitt-Wood at glovitt@mindspring.com.*

- **Steam In Place**
- **Moist Heat Sterilization**
- **TR-22 (Revised), Process Simulation Testing for Aseptically Filled Products**

In Edit: *After global review, task forces responsible for the TRs consider the feedback received. TRs then undergo final technical editing.*

- **TR-15 (Revised),** ***Validation of Tangential Flow Filtration in a Biopharmaceutical Application***
- ***Microbial Data Deviations***

In Board Review: *Following technical editing, TRs are reviewed by PDA's advisory boards (SAB, BioAB). If/when approved, the PDA Board of Directors (BoD) makes the final decision to publish or not publish the document as an official PDA TR. Balloting at each level can take several weeks or longer, depending on the questions posed or revisions required.*

- ***Biological Indicators for Sporicidal Gassing Processes: Specification, Manufacture, Control and Use (SAB)***
- **TR-14 (Revised),** ***Validation of Column-Based Separation Processes (BioAB)***
- **TR-26 (Revised),** ***Sterilizing Filtration of Liquids (BoD)***
- ***Quality Risk Management for Aseptic Processes (BoD)***
- **TR-44,** ***Filtration of Liquids Using Cellulose-Based Depth Filters (BoD)***

Journal *Preview*

Risk Management Survey Supports PDA Technical Report

The first article in the first issue of the Journal for 2008 presents the results of a survey conducted by PDA's Risk Management for Aseptic Processes Task Force and served as impetus for the development of the upcoming technical report on the same subject. Participation in the survey was wide with 129 respondents. Six major findings were identified by the Task Force:

1. The "Aseptic Processing/Filling" operation is the functional area identified as having the greatest need for risk.
2. The most widely used methodology in industry to identify risk is Failure Mode and Effects Analysis (FMEA). This tool was most widely applied in assessing change control and for adverse event, complaint, or failure investigations.
3. Despite the fact that personnel training was identified as the strategy most used for controlling/minimizing risk, the largest contributors to sterility failure in operations are still "Personnel."
4. Most companies still rely on "Manufacturing Controls" to mitigate risk and deemed the utilization of Process Analytical Technology (PAT) least important in this aspect.
5. A majority of correspondents verified that they did not periodically assess their risk management programs.

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Leadership *Opportunities*

Call For Technical Report Reviewers

Currently available for review:

- TR-22 (Revised), *Process Simulation for Aseptically Filled Products,* https://store.pda.org/review/login.aspx

Review pending:

- TR-3 (Revision), *Dry Heat Sterilization and Depyrogenation* – contact Genevieve Lovitt-Wood, gilovitt@mindspring.com
- TR-30 (Revised), *Parametric Release* – contact Genevieve Lovitt-Wood, gilovitt@mindspring.com
- *Moist Heat Sterilizer Systems* – contact Genevieve Lovitt-Wood, gilovitt@mindspring.com
- *Steam in Place* – contact Genevieve Lovitt-Wood, gilovitt@mindspring.com
- *Microbial Data Deviations* – contact Sue Schniepp, sue.schniepp@mac.com

In *Print*

Contract Sterilization

From Ethylene Oxide Sterilization: Validation and Routine Operations Handbook *by Anne Booth, Consultant*

The medical device industry is using contract sterilization at an increasing rate. An effective contractual relationship must exist between the manufacturer and the sterilization contractor to guarantee a well-controlled sterilization process that is capable of producing a sterile, safe and effective product. A direct impact of this trend is the downsizing of sterilization support and a reduction in technical knowledge within the medical device manufacturer's personnel. Therefore, proper communication and understanding of the activities of the sterilization contractor is essential. It is critical that the responsibility for sterility is shared and that the division of responsibilities is clearly defined and understood by both parties.

Validation of the cycle is the responsibility of the device manufacturer, but responsibility for the validation tasks may be delegated to personnel at the contract sterilization facility. Even if the sterilization contractor assumes responsibility for the validation, the device manufacturer is still ultimately responsible for the safety and efficacy of its products. Contract sterilizers are considered an extension of the device manufacturer's operation and are responsible for the manufacturing operations that they perform.

An Association for the Advancement of Medical Inspection (AAMI) Technical Information Report (TIR) entitled, AAMI TIR No. 14 – 1997: *Contract Sterilization for Ethylene Oxide,* provides additional guidance for the medical device manufacturer to augment ANSI/AAMI/ISO 11135, *Medical devices – Validation and routine control of ethylene oxide sterilization,* and uses contract sterilization facilities and contract sterilization operations.

Before the sterilization facility is chosen, a decision must be made regarding the most appropriate sterilization method. Even though some sterilization contractors perform both EO and radiation sterilization, the choice of the most appropriate method for each product and package must be considered first. Table 1 contains some significant considerations, but certainly not all, that will help with this decision.

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Selection of the Sterilization Facility

In order to determine the most appropriate sterilization contractor and to satisfy the QSR requirement 21 CFR Sec. 820.50 (a), the manufacturer should perform an audit conducted by a person who is knowledgeable about the sterilization method being considered. The audit should be performed according to a predetermined audit procedure. Once completed, the auditor should prepare a written report stating the contractor's acceptability and any corrective actions deemed necessary. The audit should cover:

- Maintenance and calibration
- Installation/commissioning of the preconditioning/sterilization/aeration chambers
- Operational qualifications
- Personnel training
- Change control and documentation procedures
- Quality systems
- Software validation
- Compliance with local regulators and safety procedures.

Obtaining a Written Contract

For interstate shipping, the requirements for a written contract can be found in 21 CFR 801.150(e), for intrastate services a contract is recommended to ensure compliance with QSR 21 CFR 820.181. The written agreement should outline the services to be supplied and the procedures to be followed by both parties. For EO sterilization, the written agreement should contain at least the following factors:

1. Information transfer: specify the individuals responsible for coordinating the flow of information
2. Records: specify the required documentation to be used and maintained
3. Process validation: specify all parameters with tolerances to be qualified and the criteria for requalification
4. Loading configuration: specify the minimum and maximum number of pallets, loading patterns, vessel loading, packaging, load wrapping, qualified chambers and location of test samples
5. Biological indicators (BIs): specify responsibility for storage, placement, retrieval, handling, processing and maximum time intervals prior to shipment of BIs and other test samples; include instructions for packaging and shipment to go to the test lab
6. Cycle parameters and process control: specify the process parameters and acceptable tolerances that should be reached once validation is complete
7. Post-sterilization handling: specify the procedures for product quarantine prior to release for shipment
8. Batch record and review: specify the procedures and responsibility for approving sterilization batch records prior to release
9. Finished product release: specify the procedures and identify individuals responsible for approving release
10. Audits: specify the scope of audits, corrective actions, type of documentation and control for confidentiality
11. Change control, process deviations and product damage: identify the individuals to be notified of any changes or deviations or product damage
12. Reprocessing of loads: specify how reprocessing procedures are established, implemented and controlled to ensure that the steps meet the validation and routine processing specifications
13. Material handling and documentation: specify how adherence to label control is conducted
14. Contract agreement criteria: specify all shipping requirements, including labeling for shipping, and identify laboratories to be used for sample testing

Table 1. Considerations in the selection of an appropriate sterilization method.

Consideration	Ethylene Oxide	Radiation
Device materials	Compatible with most materials; maximum temperature tolerance of 120–1300° F; can use 100–1200° F, but less effective	Selection of suitable grades of plastics to prevent degradation over time after exposure to maximum dose ranges
Device design	Must allow penetration of gas and humidity into interior spaces	No restrictions
Device package	Must be permeable to gas and humidity and allow aeration after cycle completion	No restrictions
Post sterile time	3–7 day quarantine for BI release and EO gas dissipation, parametric release is possible but requires additional validation and routine testing	Dosimetric release; No hold time

Verification of Validation

The validation documentation from the contract sterilizer is the same as the documentation required if the studies are performed in-house; this documentation should include the following:

1. *Sterilization process information*
   - Preconditioning chamber and aeration identification, facility location
   - Commissioning information
   - Maintenance information for equipment used to monitor and control the process ➤

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2. *Documents*
   - Validation protocol approved by the manufacturer and contract sterilizer
   - Final report approved by the manufacturer and contract sterilizer
   - Written agreement between the manufacturer and contractor
3. *Product and BI information*
   - List of products or product families included in the validation
   - Pallet or load configurations, including sample placement
   - Lots and quantity of products
   - Descriptions of product and BI test samples
   - Description of dunnage (if used)
   - Rationale for development of product families
   - Rationale for selection of PCD (if used)
   - Rationale for selection of most-difficult-to-sterilize location within the device
   - BI label information (manufacturer, lot number, expiration date, spore population and D-value)
   - Date of placement of the BIs in the device or PCD
   - Time and date of placement and retrieval of samples within the load
4. *Temperature, relative humidity (RH) sensors and pressure transducers*
   - List of thermocouples, humidity sensors and pressure
   - Locations within the product load
   - Product temperature profile for preconditioning, chamber, aeration and humidity profile for preconditioning and conditioning
   - Temperature of the load prior to preconditioning
   - Time in and out of preconditioning chamber, aeration and transfer times
   - Rationale for selection of sensor placement within the load
5. *Parameter information*
   - Preconditioning records
   - Sterilization cycle printouts
   - Aeration records
   - Amount and lot number of gas used
   - Gas certification
6. *Other information*
   - Bioburden information
   - EO residual data
   - Product and packaging functionality test results
   - BI laboratory test results
   - Product sterility test results
   - Statement of acceptance
   - Biocompatibility (if new material)
   - Pyrogen test results (if in contact with blood)
   - Bacteriostasis/fungistasis test results ➤

PDA Parenteral Drug Association

FDA

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- The Lifecycle Approach
- Elements of Modern Pharmaceutical Quality System: Risk Management and Knowledge Management

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- Change Management
- Corrective Action/Preventive Action
- Process and Product Quality Monitoring

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Routine Processing

Once the validation is completed successfully, routine processing can begin. The manufacturer is responsible for properly preparing the load and providing accompanying instruction, as indicated in the following criteria:

1. The product is packaged to maintain product integrity and cleanliness
2. The quantity of the product and test samples is documented
3. Each pallet, carton or designated shipper is marked to indicate its nonsterile nature, e.g., NONSTERILE: SHIPPED FOR FURTHER PROCESSING
4. The product being shipped has a validated process and sterilization chamber
5. The contract sterilizer is provided with instructions about handling products that are damaged
6. The number of pallets, the lot numbers of the products, and the quality of the product per lot are identified on each pallet; the total numbers are documented in the shipping papers
7. Instructions for sample placement, retrieval and shipping are to be sent to the designated test lab
8. Directions regarding post-sterilization quarantine hold and shipping times are included

Once the contractor receives the load, it is processed according to the validation process specifications. In addition, the contractor is responsible for:

1. Documenting the quantity of product and test samples received
2. Processing and reporting any deviations from the specifications
3. Segregating the products to avoid mixing sterile and nonsterile products
4. Documenting material damage
5. Reviewing batch records to ensure compliance with specifications
6. Shipping the product loads with identifying labels on each pallet containing the designation: STERILIZED – AWAITING TEST RESULTS

In addition, the contractor is responsible for providing the following documentation

- BI placement and retrieval information
- Test sample (if used) placement and retrieval information
- Lot number, quality received, sterilized and shipped
- Batch records for preconditioning, sterilization and aeration
- Times in and out for preconditioning, sterilization and aeration
- Gas usage
- Written release or acceptance of the sterilization processing records
- Documentation of any damage, deviations and changes that could affect the process

Upon receipt of the routine batch information from the contractor, the manufacturer should review the processing documentation to ensure that the validated specifications have been met. The device history file for each product lot is prepared by including, with the approved processing records, the BI (sample) sterility test results, other test results (if stipulated), any product or package inspection results and reconciliation of product lot quantities. If all records are in order, the sterilization load is released to finished goods. A qualified person reviews any deviations that may have occurred; the appropriate investigation or corrective action is then performed and documented.

Journal Preview, continued from page 11

6. A majority of the correspondents desired to see case studies or examples of risk analysis implementation (as applicable to aseptic processing) in future PDA technical reports on risk management.

The article includes all of the questions and answers from the survey. The technical report is expected to be available with the March/April Journal.

Be sure to check out the survey with your January/February Journal as well as articles on:

- A push-pull based osmotic delivery system
- The preparation, characterization and pharmacokinetic evaluation of puerarin submicron emulsion
- The use of a nanoemulsion system for transdermal delivery
- The preparation and characterization of solid lipid nanoparticles
- A review of microemulsions used as potential delivery systems

PDA Interest Groups & Leaders

PDA Interest Groups are divided into five sections by subject matter. This aligns them for improved effectiveness, supports increased synergies and provides the opportunity for Interest Group members to play a more active role in Task Forces. The five sections are Quality Systems and Regulatory Affairs, Laboratory and Microbiological Sciences, Pharmaceutical Development, Biotechnological Sciences and Manufacturing Sciences. PDA's goal is for each group to have co-leaders from the three major regions in which the Association is active: Asia, Europe and North America. Any PDA member can join one or more Interest Group by updating their member profile (www.pda.org/volunteer). Please go to www.pda.org/interestgroups for more information.

SECTION TITLE

Biopharmaceutical Sciences	Laboratory and Microbiological Sciences	Manufacturing Sciences	Pharmaceutical Development	Quality Systems and Regulatory Affairs

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Change Control Tests Contract Manufacturing Relationships, continued from cover

Oftentimes, the sense of urgency is compounded by a pending marketing authorization. The licensee should understand changes "give rise to new versions of the documents always, at least batch records," Paulo said. "We have time constraints and we have a lot of iteration issues between all the areas and with the client."

CMOs Must Work with Various Cultures

Contract manufacturers need to be adept at working with various corporate cultures. According to Paulo, in some companies either no one makes a decision or decisions are delayed until the last minute. Other companies, she said, make many decisions and end up providing too much information to the manufacturer.

Sometimes companies place added stress on the CMO as a result of the "huge pressure to have products to get results." Because of this pressure, some firms place many people on the same project, she said, "but they are not very well organized in terms of hierarchy—and this is an issue we handle with customers." Hovione must work hard to manage information when the customer has multiple representatives working on the project. Although her firm might have one QA and one QC person on the project, customers have sent information from various sources, including QA, development, the validation team, etc. "So we need to have discipline and have a very well-defined organization," said Paulo.

In some situations, the customer does not fully appreciate the differences between the three phases of product development, according to Paulo. "Another point is that products under development have three distinct phases and the controls should increase from phase 1 to phase 3. "This sometimes is difficult to be accepted by the customers." Sometimes customers "ask us for everything" in phase 1 as if it were a commercial product. "This is something we also need to discuss with the client in terms of changes."

Paulo has seen situations where the licensee fails to provide enough information to the CMO to support the change. "What we also have to take into consideration is that sometimes the changes are required by the client but without rationale, and we need to take care of this." This can cause problems when the regulators visit the CMO for the preapproval inspection. "We know that at the time of the preapproval inspection, FDA will ask us, 'Okay, you have changed—why you have changed?'" Stating "'because of client requests' is not the best rationale we can have. So this is something we need to handle also when we evaluate the change control or the changes in the manufacturing."

In some situations, the customer does not fully appreciate the differences between the three phases of product development, according to Paulo.

Varying perspectives among the parties to the contract manufacturing arrangement can be ameliorated with a strong quality agreement. For instance, Paulo described how clients often take a short-term view of the process, usually in light of the urgency to receive marketing approval. "Clients always think of the present movement; they do not think of the long term view," she said. "Sometimes it happens because the timing for clients is the filing of the NDA." By contrast, the CMO has a longer time horizon which includes the marketing authorization and at least the first five years post approval, Paulo said.

When the CMO proposes changes, it should not discount the important role that the licensee should play in evaluating the proposed changes, said Paulo. Typically, the licensee is in a better position to assess the impact of change on the safety and effectiveness of the drug product and on the filling.

"When you work in contract manufacturing, the client is the most important piece. If you want to change something, you need to have the client on your side to give support for the changes." The client "can help assess the changes that you want to perform in terms of formulation, because he knows everything about the formulation in terms of the safety and effectiveness of the drug product and of the filing." However, the licensee needs to respect the manufacturer's knowledge, said Paulo. "We know the product. We know the process. We know the problems we face during the manufacturing of the product."

Discuss Change Control in Quality Agreement

A strong change control procedure built into the quality agreement along with solid lines of communication between the two parties can help the parties overcome these challenges.

Paulo noted that change control is a "formal process used to ensure that a product, service or process is modified in line with the identified necessary change." She suggests defining in quality agreements which changes need to be reviewed and approved by customers. "These are issues that we need to handle, and we need to quantify all this work."

Molecular and Cellular Therapeutics' Tlachac also advocated developing a tight change control procedure in the quality agreement. For virtual firms, the more comprehensive the procedure, the better. "When I speak of a virtual firm, of course, they take on many different forms and are many different sizes."

Tlachac's presentation addressed the needs of a virtual firm undergoing its first experience with a contract manufacturing arrangement. "It is very difficult sometimes for them to understand what they are exactly dealing with. So the meaning of change management for virtual firms, I believe, is the task of managing the change and most importantly the relationship between your firm and the CMO. It's the process of risk evaluation and assessment and includes the definition of the level and detail of information that has to be shared between the two parties—and also an understanding of procedures and mechanisms for effectively managing change. [Change management] involves an assessment of the systems that both firms use to enable change in a risk-based manner while allowing for innovation, process improvement and optimization while ensuring quality by design and all the time focusing on relationship building."

Such firms face a number of unique challenges, according to Tlachac. When it comes to change control, they must manage two quality systems and changes both within the control and outside the control of their organization. "Often times you have to use your best skills of influencing to accomplish your goals. You need to identify the interfaces and differences between your elements of the quality system and the CMO's and recognize that each firm sees risk in a different way. And often times, especially if you have a large CMO, change may primarily be viewed as a cost and may not be something they're particularly interested in at the outset."

Tlachac advises virtual firms to self-evaluate whether or not they will be anticipative or reactive when it comes to change. "By that," he said, "I mean whether they can truly act in a proactive role with the CMO. In some cases it may be better for [virtual firms] to take a reactive position to the CMO, especially if they have greater capacities than your firm has."

Tlachac notes that virtual firms must learn to understand how they and the CMO interpret the regulatory impact of various manufacturing changes and "master parallel review cycles."

First, licensees must "recognize that different firms have different processes for the regulatory interpretation of changes, and this gets to be very important in areas you may not think of, such as minor changes in processes or minor changes in equipment that were not even anticipated….Examine carefully the philosophy and the process for the CMO interpretations, ensure that you have a good agreement in how changes are interpretated and ask specifically the questions regarding process equipment, method and procedural changes and how they are processed."

Tlachac advises virtual firms to self-evaluate whether or not they will be anticipative or reactive when it comes to change.

Second, "it is very important to try and achieve efficient parallel reviews at both firms, and often that means the virtual firm must perform at a very effective pace in order to keep the process going." If possible, Tlachac added, the virtual firm should consider utilizing the CMO's process and achieve equivalent risk assessment mechanisms.

Real-Time Data Sharing Helps Relationship

To facilitate document review, Hovione's Paulo urges the use of an electronic change control management system with a World Wide Web interface. Hovione utilizes a Web interface which allows the customer "access to the information on real time."

Tlachac acknowledged that Web-based systems for document review is becoming more common. "So when I talk about the basis for regulatory approval, we are talking about what information is transferred from the virtual firm to the CMO. And this of course can occur at various levels, depending on when the process and product is actually transferred."

Data sharing can be initiated by the CMO in the form of a questionnaire or a technology transfer package. Either way, "it certainly relies on the documentation from the CMC, including specs, batch records, protocols and summaries." The licensee must understand and identify "key differences" in how the CMO prepares documents and to integrate those differences.

Tlachac used stability reports as an example: "It might be how the CMO reports stability in a summary, and the licensee might find that stability summary does not include all the information it would like to be report to FDA, so it may convert that summary to its own document."

To deal with all of these issues, like Paulo, Tlachac emphasized that the quality agreement needs to be comprehensive and items need to be spelled out such as roles and responsibilities, points of control, documentation change control, risk management, and deviation and out-of-specification procedures. In addition, "ensure that provisions are in place for evaluation of regulatory changes for both parties and agree on timelines and expectations for evaluation and risk assessment."

Tlachac continued, "A good quality agreement will maintain involvement and understanding. It will define changes a manufacturer may make using the risk management process. It will identify raw material, component, process and product controls within the design space to create requirements or a guideline against which change management, risk assessment and audits may be preformed. Periodic onsite reviews to evaluate deviations, ➤

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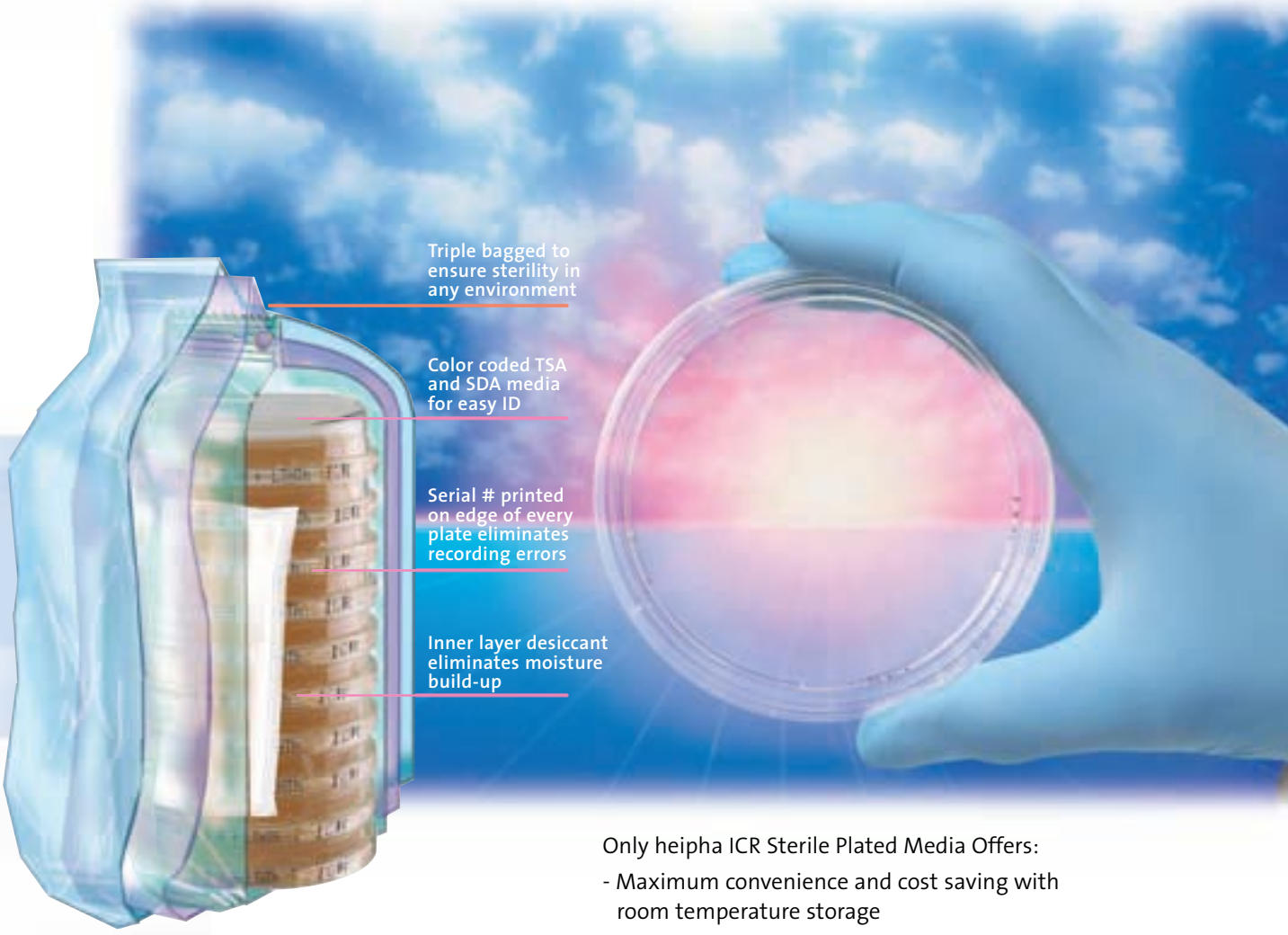

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Change Control Tests Contract Manufacturing Relationships, continued from page 20

CAPA and outcomes of joint actions are important—primarily from the standpoint of examining performance between the two groups."

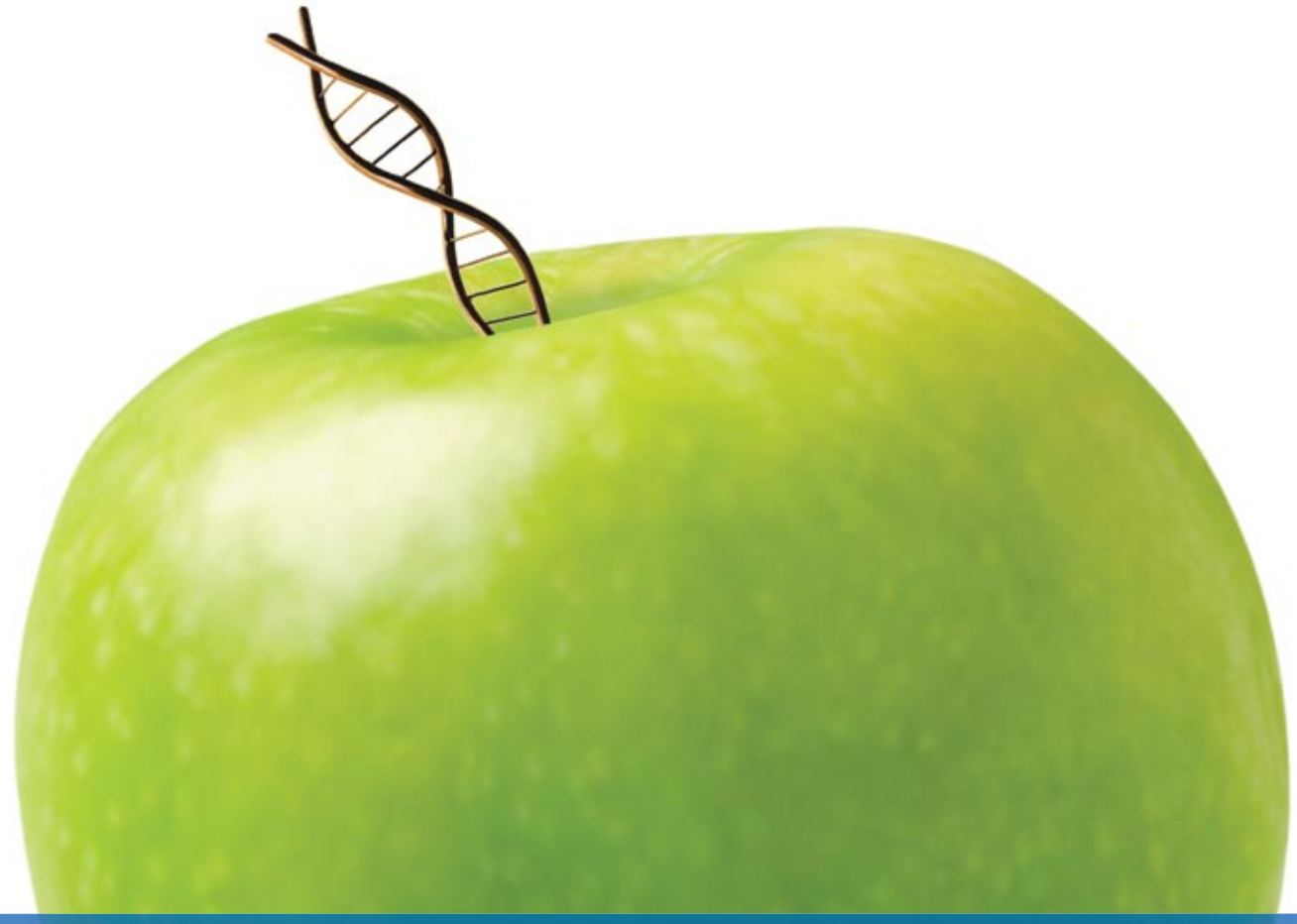
In general, Tlachac explained, "change control systems should be dynamic enablers for optimization, and I think we have all experienced cases where change control seems to be a break in the entire process transfer or process improvement." Paulo agreed noting that "change cannot be avoided." She said that whenever a contractor is working with a client to develop a process, changes "should be looked upon as opportunities to gain knowledge and further support of the design space."

Virtual firms should seek to establish relationships with operators and analysts at the CMO to encourage understanding and participation in the change control process, advised Tlachac. "You can do this in a variety of ways—getting to know them as a part of your onsite reviews or by asking the CMO to include [those] personnel…on the project teams. Certainly, to identify and avoid the potential for disincentives for change, [the inclusion of] many people on this team, you will be doing exactly that."

Virtual firms should seek to establish relationships with operators and analysts at the CMO to encourage understanding and participation in the change control process, advised Tlachac.

Ultimately, the success of a contract manufacturing arrangement rests on the culture of the two organizations and the relationships that have developed. These relationships will have the greatest impact when problems arise. This is especially important, Paulo said, "when we are producing. When we are manufacturing, of course problems arise and sometimes big problems arise. Sometime we need to call the client and say, 'Oh sorry, but we have a problem—we lost some kilos or we have the product contaminated or we whatever.' Problems always happen and if we have not built a good relationship with our customer, we will have problems….And this can be the start of a good relationship or could be the end of the relationship with the client."

Both Paulo and Tlachac indicated that the benefits of an effective contract manufacturer relationship are vast for virtual firms and the CMO. To make that a reality, a vision and plan for achieving change, developing and implementing a communication plan, establishing standard meeting times for participants, awards and incentives are needed.



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Quality & Regulatory *Snapshot*

China in the News and the Place for PDA QS Training

Bob Dana, PDA

Welcome to this month's edition of the Quality and Regulatory Snapshot.

To begin with, I'd like to call your attention to the November/December 2007 issue of *International Pharmaceutical Quality* (IPQ), specifically with regard to some of the quality and regulatory initiatives underway within and impacting China. This article details some significant historical GMP issues which could impact the quality of drug substances and products manufactured in and exported from China. Historically, the stringency of Chinese GMP regulations, especially in the area of APIs, has not been of the same standard expected in Western countries, necessitating a greater level of oversight by purchasing firms, according to the IPQ article. Chinese and other global regulatory agencies and manufacturers have recognized the concerns and are taking measures to help ensure greater oversight and control, which is intended to provide higher quality products. Some of these measures include publication and implementation of new GMP standards, a greater emphasis on oversight of the manufacture of sterile drugs and a strengthening of Quality Management supervision. In addition, emphasis is being placed on education and training programs for Chinese firms and regulators. These education and training programs include things such as the recently enacted Memorandum of Understanding between the U.S. Department of Health and Human Services and the General Administration of Quality Supervision, Inspection and Quarantine of the Peoples Republic of China, to address the safety of drugs and devices and the recent opening of a USP laboratory facility in China. I would refer you to the original IPQ article for additional details.

Speakers from the 2007 Quality Systems Conference in Dublin, Ireland (Gregg Claycamp is missing from the photo)

Speaking of education and training programs in China, PDA and the U. S. FDA are co-sponsoring two Quality Systems Conferences in China this year, one in Beijing April 21–22 and another in Shanghai April 24–25. These are essentially repeats of the highly successful conferences held in Bethesda, MD and Dublin, Ireland in late 2007 (See *PDA Letter,* January 2008, cover). In addition to many of the speakers from the Bethesda and Dublin meetings, the conferences in China will also feature presentations from the local Beijing and Shanghai FDA offices. Visit www.pda.org/qualsys for details of these Conferences.

On to another topic. In 2007, the Product Quality Research Institute (PQRI) completed work on a tool designed to help assess the impact of changes to approved manufacturing processes for sterile products. The work group which developed this tool was led by PDA's **Glenn Wright,** included in this month's Snapshot. The tool can be accessed at the PQRI web site at www.pqri.org.

Finally, FDA recently published two new Guidance documents of interest. The first is a final guidance entitled *The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations* and it explains for premarket approval application (PMA) applicants the process involved with a review of a PMA manufacturing section and inspection of the manufacturing operations described in the manufacturing section. It's also involved with the review of manufacturing information in certain PMA supplements. The guidance is expected to help both applicants and FDA schedule and complete their work in a timely manner. The second is guidance entitled *The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program.* This guidance provides PMA application applicants with information about the bioresearch monitoring (BIMO) review process, including a BIMO evaluation of clinical and non-clinical information in the PMA and certain PMA supplements as well as preapproval BIMO inspections. The information in this guidance is intended to help both applicants and FDA better understand the BIMO review and inspection so it can proceed in a timely manner. For more information, go to www.pda.org/regulatorynews.

Don't forget to provide us your feedback on the Quality and Regulatory Snapshot to snapshot@pda.org.

PQRI *Update*

PQRI Working Group for Post Approval Changes for Sterile Products

Glenn E. Wright, Eli Lilly

The task of the Product Quality Research Institute (PQRI) Working Group for Post Approval Changes for Sterile Products was to assess the risk of change.

Over the course of 19 months, the 20 member working group consisting of members from the U.S. FDA and industry identified common changes that occur in the manufacture of sterile drug products, constructed a standard risk assessment model, and completed 55 risk assessments on topics from sterile filtration to increasing batch size. Based on the differences that exist in parenteral drug product manufacturing processes, only common changes were covered during this activity.

I have to commend the group on their drive and commitment to complete a rather difficult task in a relative short amount of time. As the group's chair, it was a pleasure to lead such an expert working group that not only had the deep technical knowledge needed for the task, but also a true passion for the subject matter. The 123-page report represents to my knowledge, one of the most comprehensive examples of how risk assessments can be used to better understand the risks associated with change.

An important part of the report is the identification of the types of data needed to support the various changes. In many cases this has a direct impact on the ability to detect a potential undesired event and therefore the overall risk level. As you read the report, it is important to understand its purpose. The report, as described in the approved work plan, is to provide regulatory Chemistry Manufacturing & Control information that will be of value when considering the development of a Post Approval Guidance for Sterile Drug Products. It certainly meets that goal, representing a significant step forward that will, hopefully, stimulate discussion and progress towards a guidance document.

One question that was asked repeatedly during the activity was how this effort aligned with Design Space. The development of a post approval guidance based on risk in this area is viewed as complementing the Design Space concept. Many of the changes covered, such as a change in the sterilizing filter

continued on page 31

Health Authority *Special Report*

Year-Long Study Finds U.S. FDA Science and Mission at Risk

Emily Hough, PDA

A subcommittee of the U.S. FDA's Science Board, an advisory panel for the Office of the Commissioner, cast doubt on the Agency's scientific and technological capacities to fully support FDA's core regulatory functions and decision making throughout product life cycles, today and during the next decade.

On Nov. 30, 2007, the subcommittee released a report entitled, *FDA Science and Mission at Risk.* It states that the nation's drug, device supplies and nation's food supply are at risk.

Over 30 experts formed the subcommittee, which was convened upon the request of FDA Commissioner **Andrew von Eschenbach,** MD, in December 2006. The subcommittee was chaired by **Gail Cassell,** MS, PhD DSC (hon), Eli Lilly. Other voices from industry on the committee were: **Allen Roses,** MD, FRCP (hon), GlaxoSmithKline; **Susan Desmond-Hellmann,** MD, MPH, Genentech; and **Eve Slater,** MD, Vertex Pharmaceuticals.

Following nearly a year of research, the subcommittee argues that "the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." According to the report, the deficiencies exist because the "demands on the FDA have soared" and "the resources have not increased in proportion to the demands."

The subcommittee further asserts: "FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak; it has a fire-fighting regulatory posture instead of pursuing a culture of proactive regulatory science, especially related to food safety; it cannot adequately monitor development of food and medical products because it is unable to keep up with scientific advances (systems biology, wireless healthcare devices, nanotechnology, medical imaging, robotics, cell and tissue based products, regenerative medicine and combination products); it cannot fulfill its surveillance mission because of inadequate staff and IT resources to implement cutting-edge approaches to modeling, risk assessment and data analysis and the FDA lacks a coherent scientific structure and vision as a result of weak organizational infrastructure and a lack of consistent and rigorous external peer review."

continued on page 28

North America Events

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

Conferences

March 11-14, 2008
2008 PDA Pharmaceutical Cold Chain Conference and Training Course
(Conference, Course and Exhibition)
Bethesda, Maryland

April 14-18, 2008
PDA 2008 Annual Meeting
(Conference, Courses, Exhibition and Exhibition)
Colorado Springs, Colorado

April 16-17, 2008
Quality Requirements for Phase 0/1 Pharmaceutical Development Studies - A PDA Workshop
(Immediately follows PDA 2008 Annual Meeting)
Colorado Springs, Colorado

May 19-23, 2008
2008 PDA Biennial Training Conference
(Conference, Courses and Exhibition)
New Orleans, Louisiana

September 8-12, 2008
2008 PDA/FDA Joint Regulatory Conference
(Conference, Courses and Exhibition)
Washington, D.C.

Training

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

Lab Courses

February 21-22, 2008
Environmental Mycology Identification Workshop

March 3-5, 2008
Development of Pre-filled Syringes

March 6-7, 2008
An Introduction to Visual Inspection

March 17-20, 2008
Downstream Processing: Separation, Purification and Virus Removal

March 26-28, 2008
Pharmaceutical Water System Microbiology

May 19-21, 2008
Cleaning Validation

June 4-6, 2008
Developing a Moist Heat Sterilization Program within FDA Requirements

Lecture Courses

February 21-22, 2008
Computer Products Supplier Auditing Process Model: Auditor Training

June 11-13, 2008
Environmental Monitoring Database and Trending Technologies

Course Series

March 10-12, 2008
San Francisco Training Course Series
San Francisco, California

June 2-4, 2008
Raleigh Training Course Series
Raleigh, North Carolina

Web Seminars

March 6, 2008
Pharmacy Compounding - Potential Impact on Pharmaceutical Manufacturers
Online

Chapters

February 18, 2008
Canada Chapter
2008 Montreal Annual Conference

February 20, 2008
Puerto Rico Chapter
Cleaning Validation Update

March 13, 2008
Southeast Chapter
2008 Spring Meeting

Europe/Asia-Pacific Events

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

Europe

February 18-21, 2008
2008 PDA/EMEA Joint Conference
(Conference, Exhibition, Courses and Workshop)
Budapest, Hungary

February 18-19, 2008
Cleaning and Disinfection - An Advanced PDA Workshop
(Immediately precedes the 2008 PDA/EMEA Joint Conference)
Budapest, Hungary

February 19, 2008
EU GMP Annex 2 - Open Meeting
Budapest, Hungary

April 1-2, 2008
2008 PDA Compendial Forum
(Conference and Exhibition)
Frankfurt, Germany

April 23-25, 2008
Practical Aspects of Aseptic Processing
Basel, Switzerland

June 3-5, 2008
2008 PDA Virus and TSE Safety Forum
(Conference and Exhibition)
Berlin, Germany

June 24, 2008
The Universe of Pre-filled Syringes and Injection Devices
Dublin, Ireland

Asia-Pacific

February 1, 2008
Japan Chapter
Toyama Area GMP Syposium

February 28, 2008
Japan Chapter
Sterile Product GMP Committee Symposium

April 21-22, 2008
PDA/FDA Co-sponsored Conference Series on Quality Systems
Beijing, China

April 24-25, 2008
PDA/FDA Co-sponsored Conference Series on Quality Systems
Shanghai, China

November 11-12, 2008
Japan Chapter
PDA Japan Annual Meeting

Health Authority Special Report, continued from page 25

The report concludes by saying that FDA's scientific and regulatory programs could not be separated from the lack of resources available to support the Agency's scientific base, hire and train a broadly-capable scientific workforce, and build a sophisticated and modern information technology infrastructure and that the Office of the Commissioner should develop and report to the Science Board a comprehensive plan for timely and effective implementation of these recommendations.

On Dec. 3, 2007, the Subcommittee submitted their findings to the Science Board. According to **Sandy Walsh,** Public Affairs Specialist, FDA Office of Public Affairs, the Science Board voted 10-0 to accept the findings and requested further information to add to the report, but there is no specific timeline yet for that gathering of information or for the further discussions the Science Board will have.

The Science Board agreed to provide further review of high priority scientific programs needed by the agency. They will review the role of the National Center for Toxicological Research and the scientific capacity and processes of the FDA's Office of Regulatory Affairs, according to Walsh. Additionally, the Science Board has sought input on the report from FDA leaders and the public. By way of a *Federal Register* notice, the FDA opened a public comment period on Jan. 4 requesting comment on the science and technology report. Links to more information on the report can be found at www.pda.org/regbriefs.

The Consolidated Appropriations Action Act for Fiscal Year 2008 provided FDA an overall program level increase from FY 2007 of 13%. The Act provided budget authority for the FDA in the amount of $1.72 billion. For the FY 2008, FDA asked for a total budget of $2.1 billion.

FDA's program level for FY 2008 will be at $2.27 billion, including user fees, according to **Crystal Rice** from the CDER Division of Public Affairs. According to the summary of the FDA's FY 2008 budget, $11.2 million would be put towards modernizing drug safety, $7.2 million would improve medical device safety and device application review, and $21.3 million would be used for "conducting more and more timely generic drug reviews" and $10.6 million would go towards strengthening food safety. The other budget initiatives would be used for relocating FDA operations, establishing reinspection and export certificate user fees and funding pay inflation for FDA's workforce. More information on the budget summary and the Consolidate Appropriations Act can be found at www.fda.gov/oc/oms/ofm/budget/documentation.htm.

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Regulatory Briefs

Regulatory briefs are compiled by PDA member volunteers and staff directly from official government/compendial releases. Links to additional information and documentation are available at http://www.pda.org/regulatorynews.

Harmonization

ICH Publishes Annex to Q8

An annex to ICH Q8 Pharmaceutical Development has been published. The annex provides clarification of key concepts outlined in the parent ICH Q8 Guidance. In addition, it describes the principles of Quality by Design and shows how the concepts and tools described in the original document, such as design space, can be put into practice for various dosage forms.

Europe

Revised Regulation: Advanced Therapy Medicinal Products

The European Commission has announced that the revised regulation on Advanced Therapy Medicinal Products will be in effect on Dec. 30, 2008.

The regulation will bridge the regulatory gap between divergent national approaches of legal classifications and authorizations which currently impair the free movement of tissue engineered products within the Community and hinders patients' access to innovative therapies.

The framework of the regulation addresses all advanced therapies, including tissue engineering, and fully takes into account their scientific and technological characteristics as well as the specificities of the economic operators concerned.

EMEA discusses ENCePP

EMEA is moving forward as part of an effort to enhance the safety-monitoring of medicines marketed in Europe by creating the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

ENCePP will be responsible for identifying, characterizing and assessing risks related to marketed medicines in Europe. A wide range of interested parties met several months ago in 2007 to discuss the proposed concept and working model for ENCePP.

North America

U.S. FDA Publishes Step 2 ICH Guidances for Comment

A Jan. 10 *Federal Register* notice announced the availability of the draft ICH Guidance Q8(R1) *Pharmaceutical Development Revision 1.* This draft guidance, which is currently at step 2, is an annex to the original ICH guidance entitled Q8 *Pharmaceutical Development.* FDA is requesting comments be submitted by April 9, 2008.

In addition, FDA released for comment two annexes to ICH Q4B, *Evaluation of Pharmacopoeial Texts for Use in the ICH Regions*: *Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter* and *Annex 3: Evaluation and Recommendation of on Test for Particulate Contamination: Sub-Visible Particles.* Each ICH region will publish the annexes for comment through their respective regulatory processes. Comments on both annexes may be submitted until Feb. 15, 2008.

U.S. FDA Takes Look at Science and Technology Capabilities

In the Jan. 4 *Federal Register,* the U.S. FDA asked for the public to comment on a year-long report issued by a subcommittee of FDA's Science Board.

The report, *FDA Science and Mission at Risk,* casts doubt on the ability of the Agency's scientific and technological capacities to fully support FDA's core regulatory functions and decision making throughout product life cycles, today and during the next decade. See "Health Authority Special Report," p. 25.

PQRI Update, continued from page 25

used, would not be included in the Design Space model but would most likely still require some type of filing or notification. As you review the final report I hope that you will find it useful as a model for assessing the risk of change and as a focal point to continue the discussion.

The final report can be found at the PQRI website at www.pqri.org.

PQRI Post-Approval Changes for Sterile Products Working Group Members

Chair: Glenn E. Wright, *Eli Lilly*
Kristen Anderson, PhD, *FDA*
Thomas Dolan, *Centocor*
Patricia Hughes, PhD, *FDA*
David Hussong, PhD, *FDA*
Louise Johnson, *Vertex*
Stephen Liebowitz, PhD, *Bristol Myers Squibb*
Russell Madsen, *The Williamsburg Group*
John Metcalfe, PhD, *FDA*
William Miele, PhD, *Pfizer*
John Pavlik, *Astra Zeneca Pharmaceuticals*
Jean Poulos, *Luitpold Pharmaceuticals*
Frederic Pratt, *Luitpold Pharmaceuticals*
Joe Rinella, PhD, *Pfizer*
Ian Symonds, *GSK*
Lisa Skeens, PhD, *Baxter Healthcare*
Brenda Uratani, PhD, *FDA*
Martin VanTrieste, *Amgen*
Robyn Wong, *Watson Laboratories*
Susan Zordan, *Eli Lilly*

Volunteer Spotlight

Looking back, being part of the team that started up the New England PDA chapter in the late 1980's is the most memorable.

Louis T. Zaczkiewicz

Company: Hyaluron Contract Manufacturing

Title: Sr. Validation Engineer

Education: BA Biology/Microbiology, Boston University

PDA Join Date: 1984

Areas of PDA Volunteerism:
Chair NEPDA Activities Committee: 1988
NEPDA Activities Committee: 1987–1990, 2002–2008
President-Elect NEPDA: 2005–2006
President NEPDA: 2007–2008
PDA North America Chapter Council Co-Chair: 2006–2008

Professional Awards Won:
Certified Quality Engineer through the American Society for Quality

Interesting Fact about Yourself:
I was a househusband; I took care of 2 children, cooked, cleaned (yes, even vacuumed) and dealt with finances for seven years. My first job back into the workforce was as a facilities validation contractor which involved 100% travel.

Of your PDA experiences, which stand out the most?
Looking back, being part of the team that started up the New England PDA chapter in the late 1980's is the most memorable. Tim Leahy and Bob Pazzano sent out letters to the PDA members in New England inviting us to come to a meeting at Millipore. Bob became the first NEPDA President, Mark Staples became chair of the Constitution and Bylaws committee, and I served as chair of the activities committee. Since we were on a shoestring budget, our first dinner-meetings were held at Millipore and then later at other company facilities. It is rewarding to see how this chapter has grown and how it has been able to help influence the growth of the pharmaceutical and biotechnology industries in New England.

Which member benefit do you most look forward to?
The *PDA Journal of Pharmaceutical Science and Technology* with the included Technical Reports is my favorite PDA member benefit. I learned about PDA by attending a training program in Montreal on TR-1 (steam sterilization) and TR-3 (dry heat sterilization and depyrogenation). PDA has become known for the quality of these and the other industry-standard technical reports.

Which PDA event/training course is your favorite?
I look forward to the PDA Annual Meeting. The meeting is a great way to learn about pharmaceutical advances and technologies, participate in committees that expand the PDA's influence, and network with friends and colleagues. This event also helps the chapters to develop future programs and align them with those of global PDA. Finally, the meeting locations are outstanding.

How has PDA benefited you professionally?
The chapter and PDA global activities allow development of a professional network. I correspond with eight people from this network weekly and another 20 or so monthly. I've been able to direct programs at work to comply with current industry standards by reading the PDA scientific literature, participating in the SciTech discussion forum (listserv), attending the chapter meetings and discussing topics with my network.

Volunteer Spotlight

Markus Lankers

Company: rap.ID Particle Systems GmbH

Title: Sr. Managing Director

Education: PhD Physical Chemistry, University Wuerzburg

PDA Join Date: 2001

Areas of PDA Volunteerism:

Visual Inspection Interest Group Leader in Europe

Visual Inspection Forum Program Committee Co-Chair

Speaker and moderator at numerous PDA meetings.

Professional Awards Won:

Pfizer Colleague Recognition Award for developing and delivering training in microbiology, aseptic processing and sterilization technology

Pharmacia & Upjohn Special Recognition Award for Visual Defect Definition and Classification Team

Upjohn Quality Control Academy

Carroll College President's Society

Jane Tichy Award, presented to outstanding graduate in chemistry from Carroll College

Interesting Fact about Yourself:

I am interested in both cooking and old books. I managed to combine both hobbies into historical cooking. I try to cook recipes out of very old cooking books as authentic as possible, using special herbs and spices.

Of your PDA experiences, which stand out the most?

I enjoy the networking opportunities available through PDA that allow me to meet and interact with fellow industry colleagues. The collaboration of people from all over the world working on the same topic is one of the most positive aspects of globalization and PDA gives a platform for this. To connect these experiences with my profession makes PDA an outstanding experience.

Which member benefit do you most look forward to?

I benefit most from the networking I establish at the various conferences I attend. But also the *PDA Journal of Pharmaceutical Science and Technology* and PDA Technical Reports are very useful. They contain specialized information which is hard to find in other sources. The use of these documents electronically via the PDA Technical Archive on CD-ROM makes it much easier to find the needed information.

Which PDA event/training course is your favorite?

The visual inspection forum is my favorite event; I have to say this as a co-chair of the conference, but from a scientific point of view I am interested because my company is mainly involved in particle identification technologies. I was actively involved in the creation of the second meeting in 2001 and have continued to help organize it each year since. I also attended the *Universe of Prefilled Syringe and Injection Devices* meetings with great pleasure. It was extremely interesting to see the different challenges connected with prefilled syringes

How has PDA benefited you professionally?

My company strongly supports PDA activities, which benefits both parties. The organization of conferences gives me cutting edge information about new technologies and offers a professional network. This is important for PDA and my company's interests. Furthermore, PDA provides a professional forum for the presentation of research results of our company.

I am interested in both cooking and old books. I managed to combine both hobbies into historical cooking.

Technical Report No. 22 Revision Discussed at Metro Chapter Meeting

Naomi Baer, Vice President, PDA Metro Chapter

On December 6 the PDA Metro Chapter held its 2007 Vendor Show and Panel Discussion on proposed revisions to PDA *Technical Report No. 22, Process Simulation for Aseptically Filled Products.* The expert panel was led by **James Agalloco,** PhD, Agalloco & Associates, and included **Robert Tomaselli,** Johnson & Johnson, **Phil De Santis,** Schering-Plough, and **Leonard Mestrandrea,** PhD, Mestrandrea Consulting. The event attracted 70 attendees and was held at the Ramada Inn in Somerset, N.J.

The technical report was made available to our attendees prior to the meeting for their review. The discussion between the panel and attendees was highly engaged. Our panel showed their expertise! Each person on the panel went over different sections of the guideline and posed questions and challenges to engage the audience. This encouraged the audience to ask questions freely and provide good feedback for the revision. Everyone on the panel agreed that it is vital to get the scientific community's input to ensure the final version of the report properly reflects current industry practice.

PDA'S Who's Who?

James Agalloco, PhD, President, Agalloco & Associates

Naomi Baer, Sr. Application Specialist, Millipore Corp.

Phil DeSantis, Sr. Director, Engineering Systems and Compliance, Schering-Plough

Leonard Mestrandrea, PhD, Principal Consultant, Mestrandrea Consulting LLC

Robert Tomaselli, Director, Quality and Process Technology, Johnson & Johnson

Attendees focused much of their feedback on four specific areas of the document:

- **Risk Assessment**
- **Hold Times**
- **Failures**
- **Interventions**

Attendees discuss the 2007 PDA Metro Chapter event that was held earlier in the evening on Technical Report No. 22

Regarding risk assessment, conference participants suggested that the content should help clarify how risk assessment shapes the design of the aseptic process simulation, applies in the evaluation of intervention procedures and corrective actions, and applies in the response to failures.

The topic of hold times was discussed at length with respect to product, room, components and sterilized equipment. The recommendation was that TR-22 defines which of these can be supported by simulation and which could be done in a different manner.

Meeting attendees wanted to see an expanded discussion in the document specific to bad simulation results (failures), particularly with respect to previously released and in-process materials and their disposition.

Regarding interventions, participants openly questioned if there was a way to "qualify" or "validate" them that does not require an aseptic process simulation.

The TR-22 Revision Task Force encourages each of you to get the document, review it and provide your comments!

The exhibit was very successful with the following vendors in attendance:

Biotest
Cardinal Health
Carltex, Inc.
Celsis, Inc.
ITW Texwipe/ALMA
Micronova Mfg.
Millipore Corp.
PPD, Inc.
Remel
Sparta Systems
Steris Corp.
Veltek Associates.

Attendees were given a bingo card for vendors to mark as they visited the vendor booths. This qualified them for various door prizes and gave the vendors maximum exposure. There were excellent vendor prizes ranging from movie and restaurant gift certificates, Giant Microbe stuffed animals (which were a big hit!) to a free year subscription to global PDA for a new member!

The Ramada hotel did a great job providing excellent food and food service with their walk around buffet. Roberta Ekstedt, the Director of Catering at the Ramada went above and beyond to make sure everything was perfect. I must say, the appetizers, multiple carving stations and chef staffed pasta station was a big hit!

Although December is a challenging month to schedule a meeting with holidays and work demands, the attendees and the vendors thought they received a good value for their money. Our feedback surveys indicated that

continued on page 39

Landmark Court Ruling Discussed at Delaware Valley Chapter Seminar

Sue Vogt Speth, PDADV Operating Committee Member

The final 2007 educational series hosted by the PDA Delaware Valley Chapter (PDADV), held on November 28, covered a unique topic and was titled, "The History and Status of the Utah Medical Case: Deciding to 'Push Back' at the FDA and Succeeding." Over sixty participants from local area pharmaceutical and biopharmaceutical companies attended the meeting at the Desmond Hotel and Conference Center in Malvern, Pa.

Daniel G. Jarcho, a partner and head of the Federal Regulatory Litigation practice in the Washington, D.C. office of McKenna Long & Aldridge LLP, presented first-hand information on the case, including preliminary deposition testimony. Jarcho was lead counsel in the litigation team that successfully represented Utah Medical in this case. He described the complaint put forth by the U.S. FDA, Utah Medical's response, the legal theory used in Utah Medical's defense and the reasoning in U.S. Federal Judge Bruce S. Jenkins' ruling.

In the suit, FDA alleged that Utah Medical, a small manufacturer of prenatal and neonatal medical devices, failed to comply with the Quality System Regulation primarily because Utah Medical did not use an Installation Qualification, Operating Qualification or Performance Qualification validation model and Utah Medical did not adhere to various guidance documents and current industry practices. In the ruling, Judge Jenkins found that FDA may not require a specific methodology, except by explicit specific regulation. Judge Jenkins also found that, since the regulations do not explicitly incorporate any industry standards or FDA Guidance, FDA may not insist that companies adhere to either of these. In effect, Judge Jenkins prohibited the practices of "regulation by Guidance," or "regulation by current industry practice."

On Oct. 21, 2005, Judge Jenkins, Senior Judge of the U.S. District Court for the District of Utah filed a memorandum opinion and order that may have far-reaching effect on the way process validation and computer validation are performed. The order dismissed the suit that FDA had brought against Utah Medical.

At the close of his presentation, Jarcho entertained dozens of questions. As always, copies of the presentation were forwarded to all attendees by the PDADV Chapter president.

Grand Ceremony and Pharmaceutical Seminar Mark PDA Korea Chapter's 10th Anniversary

Woo-Hyun Paik, PhD, Korea Pharmaceutical Technology Education Center

On December 12, the PDA Korea Chapter celebrated its 10th anniversary with a grand ceremony and pharmaceutical seminar at the Seoul Education & Culture Center in Seoul. About 120 members and guests including **Richard Levy,** PhD**, Nahid Kiani** and **Kunio Kawamura**, PhD, Japan PDA attended.

Congratulatory addresses followed the seminar by **Chang-Koo Shim**, **In-Koo Chun**, **Kawamura**, and **Levy**.

PDA's Who's Who?

In-Koo Chun, Chairman, the Pharmaceutical Society of Korea; Professor of Dongduk Womens' University

Chang-Koo Shim, PhD, Professor of Seoul National University; Former Commissioner of the Korean FDA

Woo-Hyun Paik, PhD, President, Korea Pharm. Tech. Education Center and Korea Chapter President

Kunio Kawamura, PhD, Executive Advisor, Taiho Pharm.Co

Nahid Kiani, VP, Membership, Services & Sales, PDA

Richard Levy, PhD, Senior VP, Scientific & Regulatory Affairs, PDA

Levy presented an overview of the PDA organization, current PDA Task Force activities and a technical review of the newly revised Technical Report No. 1 on the validation of moist heat sterilization. He stated PDA's mission to "develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of global membership." He also said that "through our Chapter activities and Task Force deliverables, such as Technical Reports, we have built scientific knowledge, provided education and training, encouraged regulatory participation and enhanced membership experiences."

On behalf of PDA, Levy presented the Chapter with a plaque from the PDA Board of Directors commemorating the 10th anniversary of the foundation of KPDA.

Kawamura said "since the day of establishment, the Korea Chapter has played a role as a GMP education organization or the national promoter of GMP, technical training center in Korea, and even has shown a direction where the Korean pharmaceutical industries should go. [The Korea Chapter] has not limited [itself] to the area of GMP, but also to all activities in science and technology in Korean pharmaceutical industries."

Before the anniversary ceremony, the chapter held its 29th seminar on pharmaceutical technology and GMP; the one-day seminar was titled, *Recent Enactment and Revision of Global GMP Validation Guidelines.*

During its 10 years, the Korea Chapter has held seminars 29 times serving over 4,000 professionals, and published a periodical called *News and Technology Information* and various GMP books. Paik announced the Chapter's intent to publish a translation of ICH Q7A, Q&A and a medicinal terminology dictionary sometime in 2008.

Rich Levy and Nahid Kiani stand with members of the Korea Chapter after a seminar, the Chapter's 29th in 10 years

Korea Chapter Seminar Timeline

December 12–13, 1997:	Validation Concept and Validation of Aseptic Processing for Injections
September 11, 1998:	GMP Validation and Regulations on Filtration and Optimization Techniques for Economic Filtration
December 3–4, 1998:	The Manufacture and Validation of Bulk Pharmaceutical Chemicals
July 8–9, 1999:	Practices of Validation
December 12–13, 1999:	Preparing for and Passing an FDA or MCA/EMEA Inspection and CGMP in Ready-to-Sterilize Closures
May 25–26, 2000:	Case Studies on Validation by Dosage Forms in Advanced Pharmaceutical Companies (I)
August 17–18, 2000:	Case Studies on Validation by Dosage Forms in Advanced Pharmaceutical Companies (II)
November 30–December 1, 2000:	Fundamentals and Essentials of Pharmaceutical Water Systems
May 17, 2001:	FDA and International Inspection Program
August 31, 2001:	FDA Perspective to 21 CFR Part 11 Compliance
December 12–13, 2001:	Design, Validation & Monitoring of Pharmaceutical Manufacturing Ventilation System
May 2–3, 2002:	Case Studies on Validation in Advanced Pharmaceutical Companies (III) and Points for FDA Approval
August 27–28, 2002:	Case Studies on Validation in Advanced Pharmaceutical Companies (IV) and Case Study on Approval of Chinese GMP Factory
December 11–12, 2002:	Explanation on ICH GMP (Q7A) and Case Studies on FDA Approval by Q7A
April 10–11, 2003:	FDA System Inspection Program and Case Studies on Process Validation in Advanced Pharmaceutical Companies (V)
August 28–29, 2003:	Case Studies on Validation in Pharmaceutical Companies (VI)
December 11, 2003:	Achievement of WHO/FDA GMP and Validation of Part 11 & Computer System
June 15, 2004:	Points of Rational and Economic Conceptual Design for GMP Plants
September 9, 2004:	Fundamentals for Successful API Equipment Qualification and Process Validation Programs
December 8, 2004:	Models on Process Validation of Injections and Tablets
May 23, 2005:	Industrial Measures to GMP Inspection and DMF
September 8, 2005:	Measures to Marketing Approval of Drugs in Europe and Recent Case Studies
December 12, 2005:	Discussion on Draft KGMP & Facilities Regulations and PAT
June 8, 2006:	Rapid Microbial Detection Method, Quality Risk Management and PAT
September 11, 2006:	CGMP Compliance, FDA Inspection and Case Study of Recent FDA Approval
June 12, 2007:	Theory and Practices of Validation (1)
June 26, 2007:	Theory and Practices of Validation (2)
July 10, 2007:	Theory and Practices of Validation (3)
December 12, 2007:	Recent Enactment and Revision of International GMP & Validation Guidance

Rich Levy and leaders of the Korea Chapter cut a celebratory cake

Professor Chang-Koo Shim congratulates the Korea Chapter for 10 successful years

Professor In-Koo Chun gives a congratulatory speech at the Korea Chapter celebration


Rich Levy presents the Korea Chapter President Woo Hyun Paik, Korea Pharm. Tech. Education Center, a plaque for 10 years of distinguished service

Taking a Chance: New England Chapter Forms First PDA Student Chapter

Louis Zaczkiewicz, NEPDA President

We deal with risk throughout our lives. The pharmaceutical industry is full of "Risk-Based Approach" guidance documents that direct us to control our processes based upon risk. Running a PDA chapter requires us to steward the finances, programs, membership and heritage entrusted to the current leadership.

When we first started the New England Chapter of the PDA (NEPDA), the PDA gave us seed money to get us going, and we proceeded cautiously with our finances. We kept meeting prices low to encourage more people to attend. To do this, we offered programs in host company facilities instead of in hotel banquet rooms. Over time, our finances grew as membership and sponsorship increased. We moved our meetings to area hotels, thus taking a larger risk that an event could loose money if we didn't get enough attendees or meeting sponsors. After 20 years of programs, our finances are healthy enough to survive a program cancellation—a real risk during New England winters. Moreover, we are now comfortable enough to develop new programs that will further benefit our members and the industry.

On November 14, we held our fifth meeting of 2007 to highlight PDA's Technical Report No. 1. Industry interest on this topic was high following the summer re-publication of this landmark report, initially issued in 1978. Our featured speakers were **Mike Finger** and **Donald Drew,** the faculty for PDA's Training and Research Institute course on autoclave validation. The meeting site, Café Escadrille, drew high praise from those who attended. They enjoyed the food, accommodations and location. The higher meeting costs were offset by the participation of eight industry sponsors and 100 attendees.

In the weeks prior to this meeting, we contacted people at Middlesex Community College (MCC) to see about starting a student chapter there. Located in the Boston suburbs of Lowell and Bedford, their thriving Biotechnology certificate program is designed to train people from other industries such as electronics or communications to work in the pharmaceutical, medical device and biotechnology industries. We invited three of their faculty and one of their students to attend our November meeting and networking event. During this time we discussed the possibility of starting a student chapter. Both organizations realized that the strengths of the PDA and MCC programs were complimentary and officially committed to start PDA's first student chapter. When this was announced during the meeting, five volunteers came forward to serve on the new NEPDA committee run by **Jerry Boudreau.** Over the next year, this committee will help the faculty and 85 students enrolled in the MCC program develop the new chapter's constitution and bylaws.

Featured speakers Mike Finger and Donald Drew on Nov. 14, 2007 highlighted PDA's Technical Report 1

Another risk we've taken is to reach out to the Massachusetts science education program. Many Massachusetts high school students conduct independent research and present the results at local and regional science fairs. The winners at the local and regional levels present their research at the state science fair. We've developed a new NEPDA Science Fair committee chaired by **Mark Staples.** This spring the NEPDA Science Fair committee will judge the student entries and select the best three that align with the PDA mission of promoting advances in pharmaceutical and biopharmaceutical science. The winners will receive monetary awards and will be invited to display their presentations at a NEPDA meeting.

What about the risk of having a NEPDA dinner meeting outside the Boston, Mass. area? It sounds strange that a New England chapter would be concerned about meeting in Maine, but most of our members are in Eastern Massachusetts. In May we will tour Baker Laboratories, the makers of biological safety cabinets and isolate systems in Sanford, Maine. The meeting topic is PDA *Technical Report No. 13, Fundamentals of an Environmental Monitoring Program* and *Technical Report No. 34, Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products.* This meeting will bring NEPDA closer to people in northern New England while giving

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PDA Introduces a New Way to Share the Benefits of Membership

Trevor Swan, PDA

A new feature now available online will allow you to quickly and easily educate a colleague about the value of PDA member resources. Simply visit the PDA website and click on "refer a colleague" under the membership section or enter www.pda.org/refer. Once you enter a colleague's information, an email from you will be automatically generated informing them of the PDA resources structured to support their work and advance their professional career.

When you use this new feature to refer a colleague and they join PDA, your name will be entered in a quarterly drawing to win valuable prizes like a $50 American Express Gift Card (see website for details and eligibility).

Once your colleague has joined, they will immediately have access to the tools needed to contribute to the advancement of the industry, influence regulation and propel their career. Participation on PDA Committees, Task Forces, Advisory Boards and chapters will all be open to them. Additionally they will begin receiving membership publications including the *PDA Journal of Pharmaceutical Science and Technology,* PDA Technical Reports, *International Pharmaceutical Quality,* and the *PDA Letter.* Membership discounts will also be immediately available to them.

Joining PDA is not only a reliable way to gain access to first tier scientific and regulatory resources and unparalleled networking opportunities, but it also means joining and contributing to a distinguished community of industry leaders. Share the value of a PDA membership experience—refer a colleague!

To learn more about PDA's refer a colleague process or to discover more about volunteering with PDA, please contact **Hassana Howe** directly at +1 (301) 656-5900 ext. 119 or online at **howe@pda.org.**

Technical Report No. 22 Revision Discussed at Metro Chapter Meeting, ***continued from page 34***

the attendees and vendors liked the room, the food and the topic presented by our panel. We are also using their suggestions for the planning of our 2008 vendor show and upcoming chapter events. We want to thank our distinguished panel for attending and providing their expertise to make the discussion both interesting and valuable to the revision process. Global PDA was also very supportive of the event. The Ramada Inn provided excellent services and food. Best of all, it turned out to be a very enjoyable evening for all!

PDASE Student Awards 2007

The PDA South East Chapter is contributing towards the future of drug development through the establishment of the PDASE Student Awards. The following universities/programs now have an endowed PDASE Student Award:

- Campbell University School of Pharmacy, Pharmaceutical Sciences Program
- North Carolina State University, BTECH (Biomanufacturing Training and Education Center) Program
- North Carolina Central University, BRITE (Biomanufacturing Research Institute and Technology Enterprise) Program
- University of North Carolina, Chapel Hill

Below you will find a list of the inaugural student award recipients:

1. **Lam Nguyen**, Campbell University
2. **Ogechi Ihenatu**, North Carolina Central University
3. **Ikechukwu Ihenatu**, North Carolina Central University
4. **Nicole Seabrook**, North Carolina State University
5. **Stacey Foti**, Graduate Winner, University of North Carolina, Chapel Hill
6. **Jessica Steve**, Undergraduate Winner, University of North Carolina, Chapel Hill

(l-r) Linda Love, Marketing/Recruiter for BRITE; Ogechi Ihenatu, student winner; Ikechukwu ("Ike") Ihenatu, student winner; Dr. Li-An Yeh, Head of BRITE at North Carolina Central University; Dr. Wendy Haines, PDASE Philanthropy Committee Member; Dr. Weifan Zheng, Professor at BRITE

Additional information about these and other PDA sponsored Student awards can be found at www.pda.org/ssp.

(l-r) Dr. Wendy Haines, PDASE Philanthropy Committee Member; Jessica Steve, undergraduate winner; Bruce Craven, PDASE Treasurer; Stacey Foti, graduate winner

Stacey Beth Foti is in her final year at the University of North Carolina, Chapel Hill pursuing her PhD in Neurobiology in the labs of Jude Samulski and Thomas McCown. Stacey's thesis work revolves around generating novel Adeno-Associated virus (AAV) vectors to deliver therapeutic neuropeptides that will reduce the occurrence and severity of seizures. While in graduate school, Stacey generated and then used viral vectors for gene therapy, and as a tool to elucidate brain function. She would like to work in a challenging and team-oriented job, perhaps for a small biotechnology company. In this environment, Stacey would be able to explore what types of work she will enjoy and determine how she can best contribute to the drug industry.

Ogechi Ihenatu is a senior and in the charter class of the Biomanufacturing Research Institute and Technology Enterprise, BRITE, Program at North Carolina Central University. Ogechi is number one in her class and will graduate in May 2008 with a BS degree in Biology with a concentration in Biotechnology. She would like to attend Pharmacy School upon her graduation. Ogechi envisions herself working for a biotechnology company in the future.

Ikechukwu ("Ike") Inhenatu is a senior and in the charter class of the Biomanufacturing Research Institute and Technology Enterprise, BRITE, Program at North Carolina Central University. Ike is number two in his class and will graduate in May 2008 with a BS degree in Biology with a concentration in Biotechnology. He would like to pursue an MD/PhD combined degree upon his graduation this May. Ike is very interested in staying in the lab and performing research for either the U.S. FDA or National Institutes of Health.

(l-r) Bruce Craven, PDASE Treasurer; Nicole Seabrook, winner

Lam Nguyen is a senior in the Pharmaceutical Science Program, at Campbell University, School of Pharmacy. She attended Georgia Perimeter College in Lawrenceville, Ga. her freshman year of college, and then transferred to Campbell University. Lam is very interested in careers in molecular biology. After obtaining her BS in Pharmaceutical Sciences in August of 2008, she plans to get a MS in Pharmaceutical Sciences, with a concentration in Biotechnology. In the future, Lam would like to work in cancer therapeutics research.

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 email address. Where applicable, the Chapter's website is listed. More information on PDA Chapters is available at www.pda.org/chapters.

Asia-Pacific

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Please Welcome the Following Industry

Edel Alcairo, Engineering Support Team

Ethar Al-Sageer, FDA

Najib Babul, TheraQuest Biosciences

Surendra Balekai, Sartorius

Cecile Begat, Health Protection Agency

Samarjit Bhowmik, Sartorius

Michael Bogan, Integrated Commissioning & Qualification

Mike Broughton, Eli Lilly

Jason Burdette, Shire

Ryan Burnside, Wyeth

Mathius Bwemba, BM Infotech Trading

Brigitte Caluwaerts, GlaxoSmithKline

Chinhwa Cheng

Warren Cheung, K.C. Pharmaceuticals

Jade Chin, BMS

Darlene Chiu, Watson Pharmaceuticals

Seong Pil Cho, Celltrion

Glenn Courtney, Aventis

Chris Cullen, IMB

Don Cummings, Covex

Joseph De Paul, Cypress Systems

Dirk De Preter, Pfizer

Michael DeFelippis, Eli Lilly

Damaris DeGraft-Johnson, DJA Global Pharma

Ishwin Dembla, Campbell University

Nicolas DeMinico, GlaxoSmithKline

Nils DePui Martinsen, The Nema Group

Aisling Desmond, Wyeth

Agnes Devlin, RCM Technologies

Enrique Dilone, NovaDel Pharma

Eva Donnelly, Wyeth

Veronica Donner, MedPointe

Miriam Doyle, Helsinn Chemicals Ireland

Mary Beth Ebert, GlaxoSmithKline

Bill Ellington, DSM Pharmaceutuicals

Gilbert Eustice, BioMimetic Therapeutics

Josep Ferres, Laboratorios Hipra

David Fetterolf, BioTechLogic

Dian Feuerhelm, Genentech

Maria Funelas, Proteolix

Luciano Gambini, Consultant

Tony Gardner, DSM Pharmaceuticals

Mody Gerges, Micro-Clean

Bernard Giletta, Pharmasystems

Maribel Gonzalez, Watson Pharmaceuticals

Lance Goodreau, Lonza

Daniel Gralak, Main Pharmaceutical Inspectorate

Chiara Granozzi, Sanofi-Aventis

Patricia Griffiths, Abbott

Blanka Gstettner, Steris Deutschland

Karen Held, Shire

Gertjan Horsthuis, Solvay Biologicals

Angela Hoskins, Health Protection Agency

Brent Huberty, St. Jude Medical

Jeong Duk Jang, SK Chemicals Life Science Divisional Group

Marek Janku, Pliva-Lachema

Stewart Jason, Biotest Diagnostics

Haksong Jin, NIH

Brian Joseph, Pall

Beth Kirschenheiter, Hospira

Julia Klink, Merck

Michael Kraus, Baxter

James Kronauge, Molecular Insight Pharmaceuticals

Puneet Kulshrestha, Cipla

Rajesh Kumar, Alkermes

Ganesh Kumraj, Panacea Biotec

Bon Lam, BMS

Steven Lancello, Auxilium Pharmaceuticals

Robert Langevin, Microtest Laboratories Manufacturing

Sang Woo Lee, Korea Otsuka Pharm.

Sebastien Lefebvre, GlaxoSmithKline

Stein Lokstad, Brenntag Biosector

Jennifer Longstaff, Bausch and Lomb

Maria Leticia Lospice, STM Books

Charles Lu, Watson Pharmaceuticals

Cecelia Luna, Wyeth

Maryanne Maines, Sartorius

Leaders to the PDA Community

Charlene Martinez, Microtest Laboratories Manufacturing

Elisabetta Matarrese, Industria Farmaceutica Serono

Takehiro Matsumura

Dwyane May, DSM Pharmaceuticals

Peter Mayne, OSI Pharmaceuticals

Justin McCain, BioMimetic Therapeutics

Tracey McKennon, Seattle Genetics

Andrew Meek, WHO

Bruce Meiklejohn, Eli Lilly

Fayyaz Memon, Fisher BioServices

Daniel Meshnick, Acambis

Deborah Meshulam, ImmunoGen

Francis Mohapi, BM Infotech Trading

Rana Mohd. Masud, Popular Pharmaceuticals

Evan Moniuszko, Pharmaceutical Calibrations & Instruments

Thomas Montague, Becton Dickinson

Lorenzo Montrasio, AIFA Agenzia Italiana del Farmaco

Ria H.A.M. Nibbelling, RIVM National Institute of Public Health and the Environment

Jeanne O'Connell, Astellas

Ryan O'Keefe, sanofi pasteur

David Olson, Allergan

William Orciuch, Microtest Laboratories Manufacturing

Russell Owen, Pacira Pharmaceuticals

Efrain Pagan, Wyeth

James Page, Amylin Pharmaceuticals

Hiren Patel, Dr. Reddy's Laboratories

Sajal Patel, University of Connecticut

Thomas Pende, PALL

Stefanie Pfleging, Boehringer Ingelheim

Annika Plsson, AstraZeneca

William Rash, Blue Stream Laboratories

Mohammad Rawashdeh, FDA

Amanda Reeser, Array Biopharma

Michael Rinck, MT Promedt Consulting

Jose Rodriguez-Perez, Business Excellence Consulting

Shundon Roy, Commissioning Agents

Giuseppe Ruggirello, CTP Tecnologie di Processo

Manuel Saavedra, Kimberly Clark

Rico Schulze, Regierungspräesidium Dresden

Nicole Seabrook, North Carolina State University

Karen Seiberlich, Amgen

Shrenik Shah, Sun Pharma Advanced Research Company

Jun Shao, Procter & Gamble

Kamana Singh, North Carolina State University

Debbie Smith, Eli Lilly

Maria Soler Nunez, Eli Lilly

Kylie Sproston, Protherics Australasia

Yvonne Stewart, GlaxoSmithKline

Clark Stika, Watson Pharmaceuticals

Lori Stinehelfer, PDL BioPharma

Julia Stoll, Emergent

Aeby Thomas, NNE Pharmaplan

William Tilton, Shire

Sharon Trelford, Alkermes

Zofia Ulz, Main Pharmaceutical Inspectorate

Christopher Urban, Amgen

Amarilis Vellon, Wyeth

Dana Vickey, EMC

Timothy Wagner, Hollister-Stier Laboratories

Yeong Wang, Baxter

Robert Weisser, BioMimetic

Erwin Wenning, Bayer

Keith Weseli, Commissioning Agents

Larry West, Nereus Consulting

Shin Wha-Ja, Bayer

Kathy White, Amgen

Graham Wrigley, Pfizer

King Yau, Oragnon

Kozhanova Zhanar, National Center of Medicines Expertise

If your information appears inaccurate in this list, please visit www.pda.org to update your profile or email changes to info@pda.org.

PDA and the U.S. FDA Promote Quality Systems in China

Beijing, China • Apr. 21–22 • Shanghai, China • Apr. 24–25 • www.pda.org/qualsys

Program Co-Chairs Zena G. Kaufman, Abbott Laboratories and Steven Mendivil, Amgen, Inc.

One unique characteristic of our industry, and the people that are part of it is the wealth of discussions we have on quality-related matters. These discussions are unique because they often combine quality concepts and technical matters encased within regulatory expectations. Having the opportunity to discuss, share and benchmark, links us back to our collective goal of providing quality medicines to patients around the world.

The evolution of our industry during the past 25 years has facilitated the need for integrated Pharmaceutical Quality Systems across the product lifecycle. We've moved from Quality Control to Quality Assurance to Quality Management, and now we are moving towards a harmonized Quality Systems approach. In addition, the industry has expanded to include not only companies with plants that supply local markets, but multi-national companies with plants that supply the world.

While implementing tools such as Quality Risk Management and Knowledge Management, we must augment our Quality Systems with these tools to improve how we correct and prevent deviations from reoccurring, monitor our processes and develop process knowledge to effectively manage change at our manufacturing sites and to keep our management information and engaged.

On behalf of the Program Planning Committee, we would like to invite you to join industry and regulatory representatives at one of the *PDA/FDA Co-Sponsored Conference Series on Quality Systems* in China to share your knowledge, benchmark new ideas and engage in valuable discussions regarding the integration of Pharmaceutical Quality Systems throughout the lifecycle of our products.

The meetings in China follow two very successful ones in the United States and Ireland and are endorsed by the Shanghai Food and Drug Administration.

Our industry is becoming global in nature; forcing each quality and manufacturing professional to be conversant in understanding national and regional expectations and developing global quality systems. The previous meetings provided background key opinion leaders in the topic, both from industry and regulatory agencies. Highlights of the talks include:

- Keynotes from **Barbara Allen,** Eli Lilly and **Neil Wilkinson,** AztraZeneca; both industry representatives on the ICH Expert Working Group for current ICH draft Guidance on Pharmaceutical Quality Systems.
- Case Studies from **Gerry Lohan,** Merck on Change Management Systems, **Martin Van Trieste,** Amgen on Corrective Action/ Preventive Action with practical examples of good quality systems.
- Management Review at a Corporate Level by **Rick Bowles,** Schering-Plough and at a Site Level by **Teri Hoen,** Abbott Laboratories.
- Closing Plenary Remarks by **Gerry Migliaccio,** Pfizer and **Monica Caphart,** FDA. Both are leaders in their field of Quality.

Please join us at the *PDA/FDA Co-Sponsored Conference Series on Quality Systems* to learn more about Pharmaceutical Quality Systems and the benefits of implementation.

New England Chapter Forms First PDA Student Chapter,* *continued from page 38

our more southerly members the chance to tour this marvelous facility. We will move this meeting to a Friday to allow people to take this opportunity to stay in Maine for an early spring weekend.

To offset the financial risk of these programs, we will have three upcoming meetings in the Boston area; a March meeting on aseptic process simulation with a tour of the new Massachusetts Biologics Laboratory; a September meeting on glass defects; and a November meeting on cleaning validation. We held a meeting in January on process validation with a tour of Shire HGT. Also, our bimonthly newsletter helps control our finances through vendor sponsorships and brings in added exposure to parenteral science, PDA, the Chapter and our programs.

We hope that you will consider attending one of our upcoming meetings described here. Details are available in the newsletters and on the PDA website at www.pdachapters.org/newengland.

2008 Annual Meeting: Questions Welcomed

Colorado Springs, Colorado • April 14–18 • www.pda.org/annual2008

Harold Baseman, Valsource, LLP

Our industry is entering a time of change. There are proposed modifications to the U.S. GMPs and to the European GMP Guidance. There are new ICH Quality guidances, new standards, and an emphasis on Quality by Design, Process Analytical technology and risk management. We are moving away from traditional check list approaches to product development, manufacturing and testing, and towards sound science and process understanding-based decisions. Market and patient demands for more affordable and effective products are driving our industry to much needed technical, scientific and regulatory improvement. Today, we recognize the need to innovate; innovation is the practical application of understanding and knowledge.

Industry meetings and conferences play an important role in facilitating understanding and the transfer of knowledge. Meetings and conferences provide us with an opportunity to network. They provide information and education. They also provide an escape from the workplace, a place to exchange ideas and catch up with colleagues.

The Parenteral Drug Association is the industry organization which focuses on the science of manufacturing healthcare products. To that end, PDA's 2008 Annual Meeting has a carefully crafted theme: *Science Driven Manufacturing: The Application of Emerging Technologies.* This conference is designed to provide an exchange of ideas related to the scientific and technical state of the industry. Sessions have been selected to present new topics and to promote discussion, discourse and exchange of opinions.

This conference boasts a number of important features. For one, there will be more than 30 papers and presentations given by some of the most prominent and experienced people in our industry. These papers are designed to provide information and knowledge to the attendees, but also to stimulate discussion and the exchange of ideas on topics related to manufacturing, biotechnology and quality science. Though the subject matter is diverse, their common focus will be practical and suggest a more effective application of technology. There will be ample opportunity to ask questions, pose problems and present ideas.

continued on next page

Must-Attend Mycoplasma Four-Part Special Focus Session at PDA 2008 Annual Meeting

Barbara Potts, Director, Genentech

Complementing a strong conference program at the PDA 2008 Annual Meeting in Colorado Springs, Colo., April 14–18, 2008, is a four-part special focus session on mycoplasma within the biotechnology track. This session is a must-attend for anyone working in the Biological and Biopharmaceutical industry. It begins on Tuesday, April 15 in sessions S and V and continues into Wednesday, April 16 with sessions X and Z.

Mycoplasma contamination, while not given as much public discussion as virus contamination, is no stranger to the biologics industry. There have been many reported cases of mycoplasma contaminations in cell banks and cell culture processes. What is somewhat surprising is that it was FDA in 2004 in its Q&A section on the cGMP website that first indicated to our industry that mycoplasma contamination could also occur in the downstream manufacturing process, and even during a media fill of a drug product filling line.

Going "vegetarian" for biological manufacturing is considered a safe pathway to minimize the risk of introducing adventitious agents such as Bovine Spongiform Encephalopathy (BSE) also known as Mad Cow Disease. But are we safer using plant-derived raw materials rather than animal-derived raw materials? We have reduced the risk of BSE transmission but, in our complacency, has a new adventitious agent issue surfaced?

The special focus session on mycoplasma will provide the information Biological and Biopharmaceutical professionals need to understand the full significance of this adventitious agent contaminate. Speakers will examine case studies that outline how plant peptones and complex plant-derived materials can be a source of mycoplasma contamination. In addition, Leonard Hayflick from the University of California, San Francisco, a global expert on mycoplasma, will discuss emerging mycoplasma issues. Speakers will also discuss how the Biologics industry is working with regulatory authorities to adopt rapid methods for mycoplasma detection, as well as the many challenges in the standardization of mycoplasmic removal from 0.1 micron filters.

Achieving Fundamental Process Understanding: the Goal of 2008 QbD Conference

Frankfurt, Germany • October 7–8 • www.pda.org/calendar

Program Co-Chairs Mohammed Barkat, Draxis and Michiel Rook, Millipore

The evolution of our industry during the past 25 years has justified us unlocking the knowledge of our current process and practices. By being transparent, we are meeting our goal to provide safe, effective and quality medicines to patients around the world.

PDA recognizes the challenges that growing companies face with respect to fully understanding the logical steps of the Quality by Design (QbD) process and its successful execution. As such we are holding a PDA Global QbD conference and exhibition on Oct. 7–8 in Frankfurt.

This conference will include sessions addressing the concepts of modern QbD approaches as well as novel technologies to gain fundamental process understanding from a practical point of view. This conference will also follow the natural flow in development and focus on the following applications:

- Risk assessment
- Determination of critical parameters
- Design of experiment
- Multivariant statistical analysis/ Chemometrics
- Definition of design space
- Control strategy

Finally, it will be illustrated what registration strategies could be successful through presentations by regulatory agencies and industry leaders.

On behalf of the Program Planning Committee, we would like to invite you to join industry and regulatory representatives from EMEA/FDA at the PDA Quality by Design Conference to share knowledge, benchmark new ideas and engage in valuable discussions regarding the integration of QbD and PAT's recent success across our industry. We look forward to seeing you in Frankfurt.

2008 Annual Meeting: Questions Welcomed, continued from previous page

PDA will present ten recently released technical reports on topics requested by members through interest group and conference discussions. These important reports present approaches and guidance on several important areas of product development, manufacture, testing, and transport. They were prepared by PDA members and are a reflection of the collective experience of those teams. The presentations will provide attendees with knowledge of the reports, and also provide an opportunity to suggest and participate in future technical report projects.

Eleven of PDA's interest groups will provide interactive forums for discussion on the most recent developments and trends in their respective industry areas. The Interest Groups are the place to work directly with colleagues to explore new ideas and develop initiatives, which will be the basis of future efforts to educate, guide, and improve our industry. As such it is a unique opportunity to be a part of the solution, rather than just a recipient of its benefit.

There will be 11 courses given by the PDA's incomparable Training and Research Institute and faculty. These courses compliment the theme of the conference and provide a very practical, hands-on, interactive medium for presenting knowledge and promoting understanding.

Finally and perhaps most importantly, this conference will provide us with the opportunity to meet and network directly with industry professionals who share our interests and challenges. This is the time to talk, agree, and disagree on questions, approaches and answers.

There are times to quietly present standard approaches and practices and then there are times to discuss change. The former you can read about. The latter you need to be an active participant. This is not the time to sit back as you would at other conferences and politely listen. This is a time to weigh in on issues, to openly discuss, argue, and refine approaches, and to be part of the change and not merely an observer. Observers can wait for the other conferences. People who want to be part of the change should to come to this event.

Faces and Places

PDA/FDA Co-Sponsored Conference Series on Quality Systems-Dublin

(l-r) Steven Mendivil, Amgen; Emer Cooke, EMEA: Jean-Louis Robert, National Health Laboratory; William Burton, Russell Square Quality Associates

(l-r) Neil Wilkinson, AstraZeneca; Gerald Lohan, Merck & Co.; Martin Van Trieste, Amgen; John O' Sullivan, Pfizer

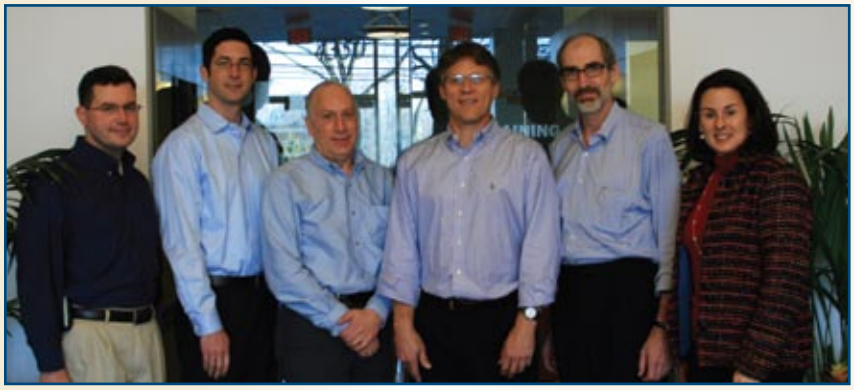
(l-r) Barbara Allen, Eli Lilly; Tim Marten, AstraZeneca; Zena Kaufman, Abbott Laboratories; Neil Wilkinson, AstraZeneca

(l-r) Swroop Sahota, Schering-Plough; Gregg Claycamp, FDA; Anders Vinther, Genentech; Diane Beno, Abbott Laboratories

Board of Directors December Meeting in Bethesda

The 2007 Board of Directors meeting in December at PDA headquarters: (l-r) Yoshihito Hashimoto, Chiyoda; Martin Van Trieste, Amgen; Steven Mendivil, Amgen; Rebecca Devine, Regulatory Consultant; Kathleen Greene, Novartis; Anders Vinther, Genentech; Louise Johnson, Aptuit; Maik Jornitz, Sartorius Stedim Biotech; John Shabushnig, Pfizer; Amy Scott-Billman, GlaxoSmithKline; Vincent Anicetti, Genentech; General Counsel Stephen Schaefer, Esq., O'Brien, Butler, McConihe & Schaefer

TR-15 Revision Task Force



(l-r) Michael Mulcare, Biogen Idec; Glen Bolton, Wyeth; Peter Levy (Chair) PL Consulting; Chris Bussineau, BioVascular; Michael Dosmar, Sartorius Stedim Biotech; Genevieve Lovitt-Wood, G.I. Lovitt & Associates

Steam In Place Task Force

(l-r front row) Genevieve Lovitt-Wood, G.I. Lovitt & Associates; Jose Goin, Genentech; Leesa McBurnie, Meissner Filtration; Keith Bader, JM Hyde Consulting; Garth Corkhill, Pall Life Sciences; Anton Ponomarenko, Bayer; Randy Wilkins, Millipore; (l-r back row) Tim Cirbo, Lilly; Dave Adams, Baxter; Tony Van Hoose, Sanofi Pasteur; Kevin Trupp, Hospira (Task Force Chair)

TRI TALK

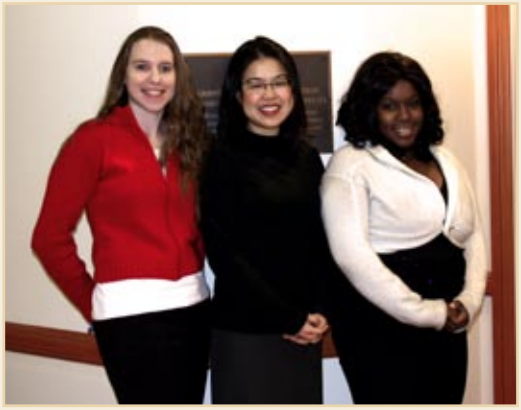
The Faces of TRI

Gail Sherman, PDA

As we "train" into the New Year, I thought it would be nice to introduce you to the faces of TRI—and they even agreed to have their pictures taken for this article!

We brought two of our staff from Baltimore to Bethesda, and many of you have worked with both of them. **James Wamsley,** Senior Manager, Laboratory Education, has been with TRI for four years in January and was our key staffer in the building of the new TRI facility. Additionally, he manages all of the laboratory training for PDA, both at TRI in Bethesda and for the Aseptic Processing training held in Basel, Switzerland. **Megan Lahti Knode,** Senior Education Coordinator, has been with PDA for four years and with TRI for nearly two. She keeps me on my toes, makes sure our instructors and students are happy, and pretty much handles the administration of the office. She also provides support at our course series on the road and at major PDA meetings.

We gained two new staffers in November and December: **Stephanie Ko** and **Alexis Robertson.** Stephanie is our Manager for Lecture Education and has a broad background both in the sciences and academics having worked for the Embassy of Kuwait in Washington, D.C. managing their student exchange programs. Note Stephanie's smile in the photo—it is not just for the picture. Those of you who are TRI instructors will soon see it and feel it; she even smiles on the phone!



(l-r) Megan Knode, Stephanie Ko, and Alexis Robertson stand in the TRI Lobby.

Alexis joined our staff in December as a Coordinator, Laboratory Education, working with James to assure that our laboratory training programs run smoothly. She previously worked for a contract research organization before coming to PDA, has a BS in Biology and experience working with an autoclave.

On another note, we completed training in November for the Kazakhstan Ministry of Health—three weeks for 40 delegates from the Expert Committee and Pharmacy Committee. This training was well received, and some of the delegates were at PDA for the fourth time in three years. We hope to welcome many of them back yet again next year (see next page for more on the training).

As a reminder, visit our website for our courses listing for 2008. If you would like a print catalogue and haven't received one yet, please let me know. While most of our training series are full for this year, there is opportunity to provide suggestions to add courses to our 2008 schedule or for 2009. We hope to hear from you!

PDA Offers Fourth Training for Kazakh Health Authority Officials

TRI offered a fourth session of training to the Kazakh health authorities in November 2007. Representatives from the Kazakhstan Pharmacy Committee and National Expert Committee attended the three-week course. PDA's **Bob Myers, Jim Lyda**, **Gail Sherman**, **Rich Levy**, and **Bob Dana** were the instructors for courses covering the United States Pharmacopeia (USP), anti-counterfeiting, regulatory compliance/inspection trends issues and the International Conference on Harmonisation.

The government of Kazakhstan has been pleased with the training offered by PDA, and additional sessions are being planned for 2008.

Bob Myers shows off gifts from the Kazakh health officials. He wears a Kazakh cap and sits next to a model Yurt, a traditional Kazakh nomad tent.

Rich Levy, PDA, teaches health officials from Kazakhstan about policies, practices and ICH governance

Rich Levy, PDA poses with officials from Kazakhstan

PDA Welcomes New European Staff Members

PDA is pleased to welcome new key employees to the European Headquarters office in Berlin, Germany. **Antje Petzholdt, Astrid Günther** and **Frederike Gräper** are working with **Georg Roessling,** PDA Sr. Vice President for Europe, to improve customer service, marketing efforts and event planning.

Antje serves as the liaison between PDA and European Members and Chapter Leaders. Her roles include responding to membership inquiries, processing registrations, recruiting volunteers and providing support for European Chapters. Antje comes to PDA with professional training from the University of Berlin and extensive customer service experience from several companies including Multipharm and Von Roll Isola. Antje is proficient in German, English, French, Spanish and Russian.

Astrid is the Berlin office's Marketing Manager. She has valuable marketing and event planning experience from various trade fairs and has served previously as both an event manager and project director. Her new roles include marketing for all European events, supporting the exhibitors and sponsors, and booking venues.

Frederike is the Berlin office's new Event Manger. Before joining PDA, she worked as an Intern at the Public Affairs Department at the U.S. Embassy in Berlin, where she organized events for the American Ambassador. Frederike will work as the liaison between PDA, program committees and speakers.

In an effort to improve PDA's customer service and events in Europe, the team encourages you to send your comments and suggestions to either Antje, Astrid or Frederike.

For General Membership/Chapters Questions or Volunteer Opportunities in Europe, contact:
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For Questions for any PDA Europe Events:
Frederike Graeper (Event Manager)
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graeper@pda.org


Antje Petzholdt


Frederike Gräper


Astrid Günther

Upcoming European Events

2008 PDA Compendial Forum
April 1–2: Frankfurt
Future Directions of the Pharmacopoeias (in cooperation with PH. Eur., JP and USP)

2008 PDA Virus & TSE Safety Forum
June 3–5: Berlin

TSE Symposium
June 5–6, Berlin

PDA/EBE Biopharmaceutical Development and Manufacturing
June 24–25, Berlin

2008 Pharmaceutical Freeze Drying Technology
September 23–25, Brussels

Quality by Design
October 7–8, Frankfurt

2008 PDA Visual Inspection Forum
October 14–17, Berlin

Pharmaceutical Cold Chain Management
November 4–7, Berlin

Microbiology: Inspection of RMM
November 11–13, Berlin

For a full list of PDA Events, please visit www.pda.org/calendar. For any questions on European events, please email info-europe@pda.org.

2008 PDA Annual Meeting

EXHIBITORS

Last updated 1/7/08

April 14-18, 2008

Colorado Springs, Colorado

AAI Pharma
ABM Janitorial Services
Accugenix, Inc.
AES - Chemunex, Inc.
Agilent Technologies
Allergan, Inc.
Althea Technologies, Inc.
American Pharmaceutical Review (Russell Publishing)
American Stelmi Corporation
Anhydro A/S
Applied Biosystems
ARAMARK Cleanroom Services
Asahi Kasei Medical America, Inc.
Aseptic Technologies
Associates of Cape Cod, Inc.
ATCC
BD Medical - Pharmaceutical Systems
BEPC, Inc.
Berkshire
Bio-Concept Laboratories, Inc.
Biocorp
Biologics Consulting Group, Inc.
bioMerieux Industry, Inc.
BioPharm International
BioProcess International/ BioExecutive International
Bioscience International
Biotest
BioVigilant Systems Inc.
BOC Edwards Pharmaceutical Systems
Brightwell Technologies, Inc.
Celsis, Inc.
Charles River Laboratories
Commissioning Agents, Inc.
Compliance Software Solutions, Corp.
Contec, Inc.
Contract Pharma Magazine
DPT
Draxis Pharma
Drumbeat Dimensions, Inc.
Duoject Medical Systems, Inc.
DuPont Qualicon
Eisai Machinery U.S.A., Inc.
Ellab, Inc
EMD Chemicals, Inc.
FDA.com
Fluid Imaging Technologies
FP Developments
Garvey Corporation
Gavin Pharma
General Physics Corporation
Genesis Packaging Technologies
Gerresheimer AG
HECHT Anlagenbau GmbH
Helvoet Pharma, Inc.
HiMedia Laboratories Pvt. Limited
HRA Research
Hyaluron Contract Manufacturing
IMA North America, Inc.
Invensys Validation Technologies
ISPE
JM Hyde Consulting, Inc.
Lancaster Laboratories
Lighthouse Instruments, LLC
Linac Technologies
Lonza, Inc.
Maas & Peither AG Gmp-Publishing
Masy Systems, Inc.
Metall + Plastic
Microbiology International
MIDI, Inc.
Millipore Corporation
Mission3
Moda Technology Partners
Molecular Epidemiology, Inc. (MEI)
Nicomac, Inc.
Novatek International
OMPI of America
Optima Group Pharma
Overlook Industries, Inc.
Pace Analytical Life Sciences
Pall Life Sciences
Parenteral Drug Association (PDA)
Particle Measuring Systems
Pharmaceutical Formulation & Quality (PFQ)
Pharmaceutical Technology
Pharmaceutics International, Inc. (PII)
PharmaSys, Inc.
Pharmasystems Inc.
PML Microbiologicals
Precision Pharma Services
ProPharma Group
Rap-ID
Rapid Micro Biosystems
Raven Labs
Remel, Inc.
Rommelag USA, Inc.
Saint Gobain Desjonqueres
Sancilio & Company, Inc
Sartorius Stedim Biotech
Sharp Corporation
Skan US, Inc.
SL Pharma Labs, Inc.
Sparta Systems, Inc.
Sterigenics
STERIS Corporation
SynTegra LLC
ThermoScientific
TriboGlide
Uhlmann Packaging Systems/Visiotec
Vectech Pharmaceutical Consultants, Inc.
Veltek Associates, Inc.
Vetter Pharma-Fertigung GmbH & Co. KG
West Pharmaceutical Services

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