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PDA Letter

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PDA Parenteral Drug Association

Connecting People, Science and Regulation℠

EMEA's Cooke on the Future of GMPs

Robert Dana, PDA, and Gail Sherman, PDA

At the recent ISPE/PDA cosponsored Workshop on the Challenges of Implementing ICH Q8 and Q9, held in Brussels, Belgium, EMEA Inspection Sector Head **Emer Cooke** discussed the future of pharmaceutical manufacturing, focusing on inspection challenges from the EU perspective.

To set the stage for her remarks, she noted that a new vision for pharmaceutical quality began to emerge at the Brussels ICH meeting in 2003. Central to a realization of this vision was the need to develop a harmonized pharmaceutical quality system applicable across the life cycle of a product emphasizing an integrated approach to quality risk management and science. Arising from that meeting, we now have ICH guidances on Development (Q8) and Risk Management (Q9). The Quality Systems Guidance (Q10) is coming along soon. All of these recognize that:

- Product specifications should be based on a mechanistic understanding of how formulation and process factors impact quality.
- Quality cannot be tested into the product; it must be built in.

Important parts of the new vision are the concepts of quality risk management and maintenance of quality across the product life cycle. The life-cycle approach recognizes that pharmaceutical development and risk management are dynamic, not static processes. Quality risk management, properly applied, allows for a more proactive approach to areas such as pharmaceutical development, product manufacture and complaint handling, and facilitates a systematic identification of critical component and process parameters. When finalized, Cooke noted that ICH Q10, Pharmaceutical Quality Systems, would integrate these concepts and describe a modern quality system, which facilitates continual improvement over the entire product life cycle, encouraging focus on discrete GMP compliance systems at different stages of the life cycle.

Cooke identified several issues which have held back state of the art pharmaceutical manufacturing, making realization of the vision difficult. These include high costs and low efficiency of manufacture, scale up problems, and limited understanding of true root causes of problems. She maintained that industry drivers appear to have been time to market, rather than product and process

continued on page 15

2007

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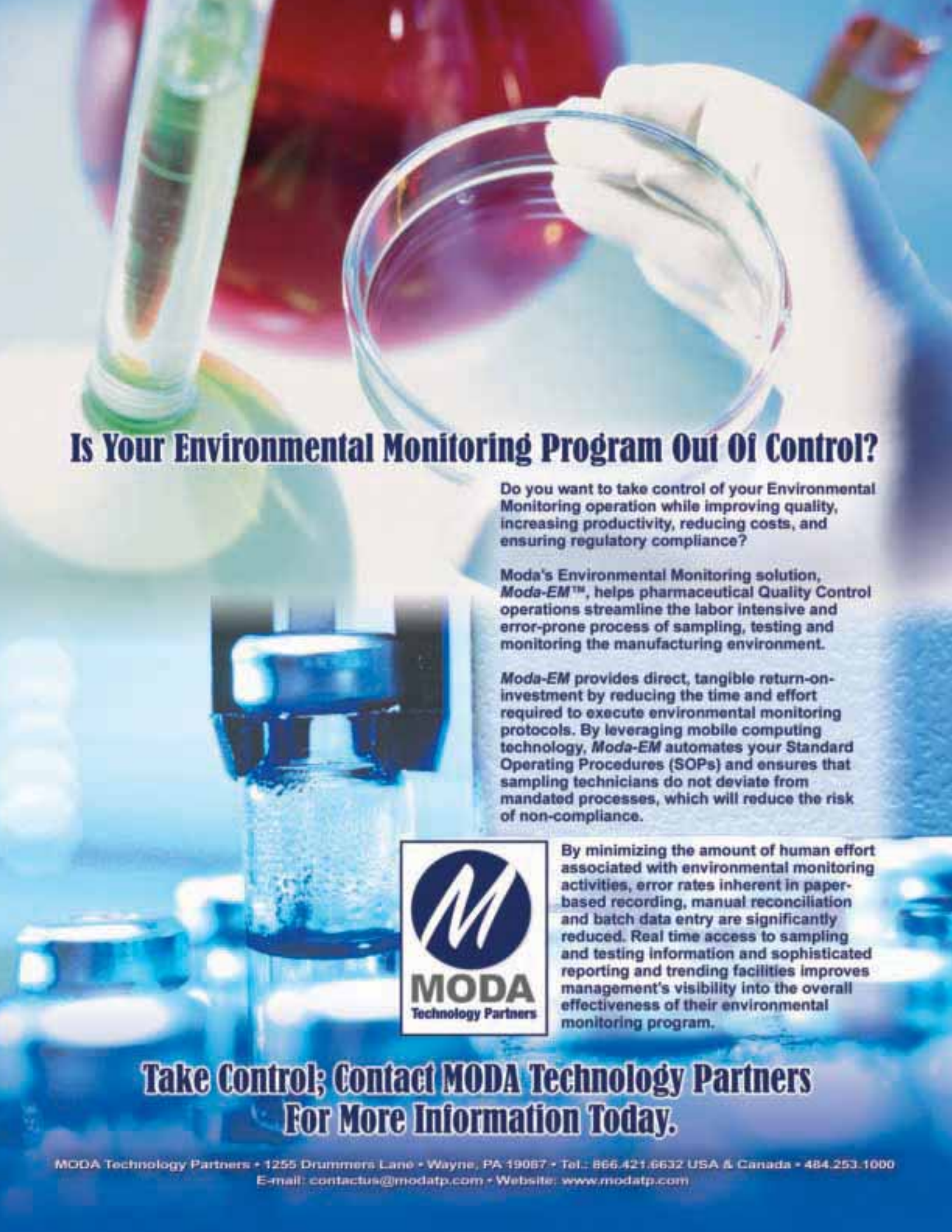
The adoption of new global regulatory initiatives like the ICH Global Quality System Guidelines, FDA's GMPs for the 21st Century and Critical Path initiative, has sparked the need for the pharmaceutical industry and regulatory authorities to determine the next steps for implementation and to continue the development of practical approaches to:

- Apply these concepts in the new paradigm of Design Space, Quality by Design, and risk-based approaches to Quality Systems
- Implement new strategies with minimal impact on manufacturing, quality and regulatory functions
- Comply with new regulations without disrupting the normal flow of processes

Hear directly from FDA, EMEA, MHLW and PIC/S representatives regarding emerging risk-based approaches, including first cycle approval, harmonization and critical path initiatives, as well as from industry experts who will relay case studies about adopting these concepts without delaying or disrupting product approvals and supplemental filings.

Take home practical approaches to compliance that you can implement as best practices at your organization!



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Cover art: When final, Q10 will complete the trio of guidances that will usher in the GMPs for the 21st century. Artwork by ImageZoo/www.images.com.

Coming Next Month
TRI 10th Anniversary Issue

PDA Parenteral Drug Association

Connecting People, Science and Regulation℠

2007 PDA Visual Inspection Forum

October 15-16, 2007 | Bethesda, Maryland

Call for Papers / Call for Exhibitors

Dear Friends and Colleagues,

The 2007 Visual Inspection Program Planning Committee invites you to submit a scientific abstract for presentation at **PDA's 2007 Visual Inspection Forum**. Abstracts are being sought for a special forum on all aspects of visual inspection processes as applied to injectable pharmaceutical products and production. Suggested topics for papers include, but are not limited to:

- Fundamental investigations into inspection processes
- Development and control of manual inspection processes
- Selection and training of human inspectors
- Statistical considerations for sampling
- New developments in automated inspection technology
- Validation of automated inspection systems
- Particulate identification
- Sources in manufacturing environment and their control

All submitted abstracts will be reviewed by the Program Planning Committee for inclusion in the meeting or for poster presentation.

Visit www.pda.org.visinspect to submit your abstract.

Abstracts must be received by June 30, 2007 for consideration.

Case studies are particularly desired. Commercial abstracts featuring promotion of products and services will not be considered. After June 30, 2007, you will be advised in writing of the status of your abstract. PDA will provide one complimentary registration per presentation. Additional presenters are required to pay appropriate conference registration fees. All presenters are responsible for their own travel and lodging, with the exception of health authority speakers.

Please include the following information and follow the steps identified in the All Academic abstract manager. Submissions received without full information will not be considered.

- Title
- Full mailing address
- Email address
- Phone number
- 2-3 paragraph abstract, summarizing your topic and the appropriate forum (case study, discussion, traditional, panel, etc.)
- Audience take-home benefits
- Rationale

For more information, please contact:

Lu Castro, Senior Coordinator
Programs and Registration Services
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Space is limited and is available on a first come, first served basis.
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Editor's Message

The world is changed. Those are the opening words of Peter Jackson's cinematic adaptation of J.R.R. Tolkien's *Lord of the Rings: Fellowship of the Ring.* While those words were apt for describing the events about to unfold in that story, they are even more fitting to the events unfolding in our industry. The world—the regulatory world at least—is changed.

Requiring companies to lockdown the manufacturing process at the time of marketing authorization is now viewed as causing stagnation in the manufacturing realm, particularly with respect to control technologies. This stagnation has resulted in inefficient processes, waste and high costs. Now, regulatory authorities want to loosen their grip on actual processes and place their focus on management and quality systems. In turn, they want companies to learn more about their processes and tighten internal controls.

While the U.S. FDA is not alone in driving this change, the Agency's cGMPs for the 21st century initiative is a good milestone for the events that have unfolded. By pushing for the use of process analytical technologies, risk-management principles and strong quality systems, FDA helped inspire an international effort to redraw the regulatory environment such that companies take more responsibility in policing their own activities and the regulators allow more manufacturing flexibility. The overarching goal is to help the pharmaceutical industry leap forward into the 21st century in terms of manufacturing efficiency and control.

Three key guidance documents are critical to achieving this goal: ICH Q8, Q9 and Q10. In this issue, PDA's **Bob Dana** and **Gail Sherman** recap the EMEA's perspective on the three documents (cover story). They cite EMEA's **Emer Cooke**, who spoke on the topic at the February PDA/ISPE conference on the ICH documents in Brussels. Our second feature is an excerpt of remarks made by FDA's **Rick Friedman** at an FDA meeting on 314.70 in February (page 16). Friedman helps define the paradigm shift we are witnessing, explaining that we are moving from an era of "technology-based" regulations to one of "management-based" regulations.

To hear the consistency in message from these two regulators several years after FDA issued its final report on cGMPs for the 21st century demonstrates that, indeed, *the world is changed.*

We hope you enjoy these and all the articles in this month's 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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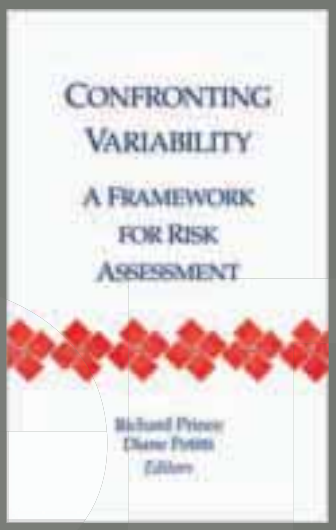
March Top 10 Bestsellers

From the PDA Bookstore:



Confronting Variability:
A Framework for Risk Assessment

Edited by Richard Prince and Diane Petitti
Provides a new perspective on the meaning and relationship of variability in relation to work performed, as well as an insightful framework for the quality assessment of risk in the pharmaceutical industry.
Published 2007. ISBN: 1-933722-04-5.

Item No. 17244 PDA Member $255 Nonmember $319

Top Ten Bestsellers:

1. **Confronting Variability: A Framework for Risk Assessment**
   Edited by Richard Prince and Diane Petitti
   Item No. 17244, PDA Member $255, Nonmember $319
2. **Systems-Based Inspection for Pharmaceutical Manufacturers**
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17243, PDA Member $255, Nonmember $319
3. **Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple**
   By James L. Vesper
   Item No. 17219, PDA Member $235, Nonmember $289
4. **Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing**
   By Destin A. LeBlanc
   Item No. 17253, PDA Member $240, Nonmember $299
5. **Environmental Monitoring, Volume I, Volume II and Protocol CD**
   Edited by Jeanne Moldenhauer, PhD
   Item No. 17239, PDA Member $530, Nonmember $659
6. **Encyclopedia of Rapid Microbiological Methods, Volume I, II, III**
   Edited by Michael J. Miller, PhD
   Item No. 17252, PDA Member $730, Nonmember $899
7. **PDA Archive on CD-Rom - PDA Archive Retrieval Index**
   Item No. 01101, PDA Member $395, Nonmember $590
8. **Risk-Based Software Validation: Ten Easy Steps**
   By David Nettleton and Janet Gough
   Item No. 17256, PDA Member $200, Nonmember $249
9. **Pharmaceutical Contamination Control Strategies for Compliance**
   Edited by Nigel Halls
   Item No. 17246, PDA Member $255, Nonmember $315
10. **PDA Technical Report 39, Cold Chain Guidance for Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment**
    Item No. 01039, PDA Member $75, Nonmember $309

Featured Titles:

Chinese Drug GMP: An Unofficial Translation Including Related Sections of the Taiwanese, U.S., and ICH-API GMP
Item: No.17263
PDA Member:$240
Nonmember: $299

Practical Safety Ventilation in Pharmaceutical and Biotech Cleanrooms
Item: No.17233
PDA Member:$250
Nonmember: $309

www.pda.org/bookstore
Tel:+1 (301) 656-5900 | Fax:+1 (301) 986-1093

PDA Recognizes Honor Award Winners at Annual Meeting

PDA recognized its 2006 Honor Award winners at the 2007 Annual Meeting in Las Vegas. Awards were handed out at the traditional banquet the night before the meeting commenced. PDA congratulates each winner and thanks them for their service to the Association.

2007 Honor Award Winners at the Annual Meeting

James P. Agalloco Award

The James P. Agalloco Award is presented annually to the PDA faculty member who exemplifies outstanding performance in education. The selection is based on student and faculty evaluations and is named for James P. Agalloco in honor of his work in developing the PDA education program. This year's James P. Agalloco Award recipient is:
Lynn Torbeck, Torbeck and Associates

Lynn Torbeck

Frederick J. Carleton Award

Presented as a tribute to lifetime contributor, past President, past Executive Director and Honorary Member Frederick J. Carleton, this award is designated for a past or present board member whose services on the board are determined by his/her peers as worthy of such recognition.
This year's Frederick J. Carleton Award recipient is:
Stephanie Gray, Boston Scientific

Distinguished Service Award

This award is given in recognition of special acts, contributions or services that have contributed to the success and strength of PDA. This year's Distinguished Service Award recipients are:
Harold Baseman, Valsource
Gabriele Gori, Bausch & Lomb
Jerold Martin, Pall Life Sciences

Frederick D. Simon Award

The Frederick D. Simon Award is presented annually for the best paper published in the *PDA Journal of Pharmaceutical Science and Technology.* This award is named in honor of the late Frederick D. Simon, a previous PDA Director of Scientific Affairs.
This year's Frederick D. Simon Award recipients are:
Brian K. Meyer, PhD, Merck
Diego Vargas, Merck

Vince Anicetti and Stephanie Gray

Vince Anicetti and Jerold Martin

Brian Meyer

Diego Vargas

Distinguished Editor/Author Award

This award is presented annually for the best editor/author of PDA-DHI co-published books as selected by PDA members. This year's Distinguished Editor/Author Award recipients are
Maik W. Jornitz, Sartorius
Destin A. LeBlanc, Cleaning Validation Technologies
Theodore H. Meltzer, PhD, Capitola Consulting
Susan Schniepp, Hospira

Maik Jornitz and Ted Meltzer

Jennie Allewell and Sue Schniepp

PDA Chapter Volunteer Award

The Chapter Volunteer Award recognizes the contributions of PDA members who participate at the chapter level. The award is a special way to acknowledge the extra effort put out by chapter volunteers. This year's Chapter Volunteer Award recipients are:
Mary W. Carver, Eisai
Jong-Kuk Kim, Pall Korea
Leonard Mestrandrea, PhD, Pfizer
Claudio Puglisi, S.I.F.I.
Traute Ryan, Merck
Mark Staples, PhD, MicroCHIPS
Kikoo Tejwani, B. Braun Medical
Amy Twitty, RMC Pharmaceutical Solutions

Vince Anicetti and Claudio Puglisi

President's Award

This new award recognizes a PDA staff member, other than Senior Staff, whose exemplary performance has contributed to PDA's success during the previous year.

Janny Chua, PDA
Ludy Yo, PDA

Vince Anicetti presented Jennie Allewell a token of PDA's appreciation for her long service on the Board of Directors

Mark Staples

The Honor Awards

BioAB Drives PDA's Biotech Strategy

Gail Sofer, GE Healthcare; John Geigert, PhD, BioPharmaceutical Quality Solutions and Richard Levy, PhD, PDA

Serving PDA membership and the at-large biotechnology community, PDA's BioAB drives biotech science and technology advancement by providing a focus for reaction to new regulatory and technical requirements for biopharmaceuticals. Each BioAB member, including the two co-chairs, all have two-year, one-time renewable terms. BioAB interacts with other PDA advisory boards: SAB, RAQC and PAB. The PDA Board of Directors has final approval of BioAB's technical reports (TRs), workshops, surveys, PDA-supported research projects and other activities. The BioAB also drives the strategic direction of all biotech activities for PDA by defining the association's future areas of focus.

Viral Safety

BioAB learned that filter manufacturers have no consistent standards to follow for characterizing and naming viral retentive filters. A PDA task force formed to address this recommended that a cooperative research and development agreement be established between PDA and the U.S. FDA to carry out needed research studies. Method evaluation and development was carried out in the FDA laboratory of **Kurt Brorson,** PhD, CBER, with generous contributions of time and materials by filter manufacturers. An experimental method was developed using the model bacteriophage PR772, leading to a classification of PR772-LRV6 (log reduction value). Initially, the goal was to achieve a log reduction value (LRV) of 4, but all the filters provided at least LRV6 under the defined conditions, which are described in TR-41. A light-scattering study was performed to accurately define the size of the bacteriophage PR772[1].

While that work was ongoing, the task force decided to also develop a technical report encompassing the operation of large virus filters, selection of virus filters, physical and mechanical characteristics, virus filter evaluation studies, integrity testing and sterilization. These projects took the 24-member task force over two years. Two of the challenges that arose were that filter manufacturers have established different integrity testing methodologies and that the task force needed to compromise over the choice of bacteriophage used for the virus filter classification. As you can well imagine, arriving at a consensus requires considerable, occasionally acrimonious, discussion. But in the end, everyone found it to be a rewarding experience.

The filter task force is now working on preparing a method for characterizing and defining small-virus filters. This project, as expected, is more difficult because commercially available filters are even more variable in their protein transmission and viral removal performance. At this point, the bacteriophage PP7 is the chosen model bacteriophage, and light-scattering studies have been performed to define its size. A model protein, a feasible endpoint definition, and a rating for 20-nm virus-removal filters have been agreed upon, but some problematic issues remain. For example, lot-to-lot filter variability has been observed with the model protein, BSA (bovine serum albumin), and such variability has been shown to affect filter performance.

Other Ongoing Projects

Virus Spike Preparations: Another industry issue that has been discussed for years is the lack of standardization of virus spike preparations. If you have performed the same viral clearance study at two different contract laboratories, you might have experienced this discrepancy. The virus spike preparation standardization task force is an ongoing project at this time with much debate about defining the quality of virus spikes. The task force members anticipate that a draft technical report will be completed sometime in late 2007 and made available for PDA member review.

Biopharmaceutical Reprocessing: Another task force is currently addressing biopharmaceutical reprocessing. The first issue being targeted is ultrafiltration reprocessing, with downstream processing and submissions to follow.

Standard Practices: Two "standard practices" TRs are also in the works. They are revisions of older reports published in 1992 that address chromatography and ultrafiltration (respectively, revisions of TR-14, *Industry Perspective on the Validation of Column-Based Separation Processes for the Purification of Proteins;* and TR-15, *Industry Perspective on the Validation of Tangential Flow Filtration in Biopharmaceutical Applications).*

Mycoplasma: A major task force is addressing mycoplasma issues in biotechnology. Prompted by findings of mycoplasma contamination in plant-derived products used to replace animal-derived products, the initial task force deliverable was a PDA sponsored workshop held in the fall of 2005. PDA will publish proceedings from this meeting in 2007.

The mycoplasma workshop also resulted in establishment of four different subgroups within the task force to address:

- Filtration test method and nomenclature standardization
- Mycoplasma spike preparation

continued on page 23

PDA Parenteral Drug Association

Connecting People, Science and Regulation℠

PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology

October 29-31, 2007 | Bethesda, Maryland

Call for Papers / Call for Exhibitors

Dear Friends and Colleagues,

The 2007 PDA Pharmaceutical Microbiology Program Committee invites you to submit a scientific abstract for presentation at **PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology**. The theme of this year's conference is *Microbiology Throughout the Product Life Cycle*. Suggested topics for papers include, but are not limited to:

- Method Development
  - In-Process Testing
  - Alternative Methods
- Qualification
  - Equipment and People
- Product/Process Development
  - Container Closure and Packaging
  - Preservative Effectiveness
  - Bioburden and Endotoxin Control
  - Sterilization Process Development
  - Validation
  - Excipient Selection
- Facility and Utilities – Design and Control
  - Water and Compressed Gasses
  - Cleaning and Disinfection
  - Isolators and Barrier Systems
  - Lyophilization
  - Sterility Assurance – Media Fills
  - Environmental Monitoring and Control
- Risk Assessment
  - Microbiological Data Deviations
  - Specifications
  - Product Stability
  - Microbial Hold Times
  - Water Activity
- Technology Transfer
  - Test Methods
  - Manufacturing Processes
- Product Registration
  - Test Methods
  - Release Specifications
  - Regulatory filing CMC/ELA/MAA
- Commercialization/Post-Marketing
  - Process Validation/ Consistency Lots
  - Test Revision
  - Change Control

Visit www.pda.org/microbiology2007 to submit your abstract.

Abstracts must be received by May 1, 2007 for consideration.

Case studies are particularly desired. Commercial abstracts featuring promotion of products and services will not be considered. After May 1, 2007, you will be advised in writing of the status of your abstract. PDA will provide one complimentary registration per presentation. Additional presenters are required to pay appropriate conference registration fees. All presenters are responsible for their own travel and lodging, with the exception of health authority speakers.

Please include the following information and follow the steps identified in the All Academic abstract manager. Submissions received without full information will not be considered.

- Title
- Full mailing address
- Email address
- Phone number
- 2-3 paragraph abstract, summarizing your topic and the appropriate forum (case study, discussion, traditional, panel, etc.)
- Audience take-home benefits
- Rationale

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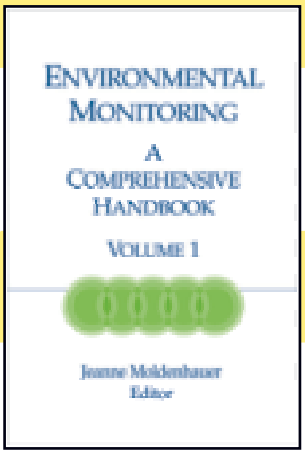
New Booklet Releases
from the PDA Bookstore

Chapters have been pulled from the following PDA-DHI Publications and are now useful booklets available for purchase.

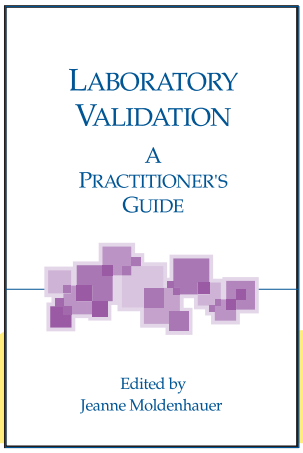


***Environmental Monitoring*, Volume I**
Edited by Jeanne Moldenhauer, PhD
Item No. 17211, PDA Member $305, Nonmember $379

Environmental Control Systems Used in Parenteral Facilities
Author: Franco De Vecchi
50 Pages. ISBN: 1-933722-14-2
Item No. 17275, PDA Member $65, Nonmember $79

***Environmental Monitoring: A Comprehensive Handbook*, Volume II**
Edited by Jeanne Moldenhauer, PhD
Item No. 17237, PDA Member $305, Nonmember $379

Identification of Environmental Isolates
Author: Klaus Haberer
28 Pages. ISBN: 1-933722-09-6
Item No. 17270, PDA Member $45, Nonmember $59

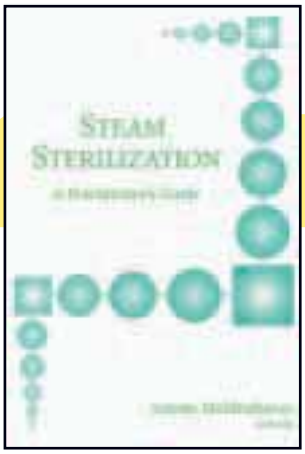


Environmental Impact on Media Fills
Author: John Lindsay
32 Pages. ISBN: 1-933722-10-X
Item No. 17271, PDA Member $45, Nonmember $59

Environmental Monitoring for Sterilization Process Development
Author: Anne Booth
26 Pages. ISBN: 1-933722-11-8
Item No. 17272, PDA Member $45, Nonmember $59

***Laboratory Validation: A Practitioner's Guide* – 20% Off**
Edited by Jeanne Moldenhauer, PhD
Item No. 17201, PDA Member $295, Nonmember $369

Analytical Method Validation in the Chemical Analysis Laboratory
Author: Robert B. Kirsch, PhD
40 Pages. ISBN: 1-933722-12-6
Item No. 17273, PDA Member $65, Nonmember $79



***Steam Sterilization: A Practitioner's Guide* – 20% Off**
Edited by Jeanne Moldenhauer, PhD
Item No. 17183, PDA Member $260, Nonmember $319

Packaging Considerations for Steam Sterilization
Author: Edward J. Smith
32 Pages. ISBN: 1-933722-13-4
Item No. 17274, PDA Member $45, Nonmember $59

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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. Any PDA member can join one or more Interest Group by updating their member profile (www.pda.org/pdf/join_IG_instruction.pdf). Please go to www.pda.org/interestgroups for more information.

North American Interest Groups

Section Leader	Frank Kohn, PhD *FSK Associates*	David Hussong, PhD *U.S. FDA*	Don Elinski *Lachman Consultants*	Sandeep Nema, PhD *Pfizer Inc.*	Robert Dana *PDA*
Section Title	**Biopharmaceutical Sciences**	**Laboratory and Microbiological Sciences**	**Manufacturing Sciences**	**Pharmaceutical Development**	**Quality Systems and Regulatory Affairs**
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European Interest Groups

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EMEA's Cooke on the Future of GMPs, continued from cover

knowledge and understanding. This approach can lead to post approval manufacturing problems. In addition, she recognized that industry continued to be uncertain about how regulators would respond as industry moved forward to embrace the future. She also noted that the vision is unlikely to be totally embraced by all parties and that there would still need to be optional elements to implementing all the concepts necessary to achieve the new vision.

Cooke noted that there is a lot underway to improve interactions between assessors and inspectors.

Cooke went on to identify several challenges associated with the implementation of risk-based approaches. These include resource requirements (more resources required initially), the need to promote common understanding and approaches and the need to achieve international consistency. She noted that the European Union has several mechanisms in place to help achieve global consistency: the European Directorate for the Quality of Medicines and healthcare products (EDQM), the International Conference on Harmonization (ICH) and its Veterinary counterpart (VICH), the Pharmaceutical Inspectorate Cooperation Scheme (PIC/S), the World Health Organization (WHO), Mutual Recognition Agreements (MRAs) as well as individual agreements with specific countries. She also emphasized that the European Union is committed to completion of those ICH and VICH activities underway and implementation of these agreements in Europe. Operational challenges she identified as needing to be overcome include appropriate introduction of the new concepts into the European GMP Guide and implementation by the various EU inspectorates and assessment agencies. She noted there are now 27 member states and 46 competent authorities in the European Union; numbers which are expected to continue to grow. Continuing European enlargement necessitates ongoing focus on consistent implementation of GMP and inspection standards, communication between authorities and coordinated training.

Implementation of ICH concepts is also a challenge. For example, there are few examples of Q8 implementation to date, and practical challenges remain with the implementation of Q9 as well. In the context of discussions on Q10, Pharmaceutical Quality systems, she reminded participants that there was already a requirement within Europe for pharmaceutical manufacturers to have an appropriate quality system in place.

Recognizing the need for better consistency, Cooke addressed opportunities for improved cooperation between all the various players involved with national and international inspection programs. One approach being explored is the development of strategic partnerships with organizations such as PIC/S (inspector training) and FDA (a cooperation arrangement is already in place). Future agreements with Canada and the Japanese Ministry of Health, Labor and Welfare are possible as well. The EudraGMP database, which will include information on all EU manufacturers and EU plans for inspections outside the European Union, will also provide an opportunity for better information sharing and cooperation. She also noted that industry cooperation will be required to achieve success.

While acknowledging more work remains to be done, Cooke noted that there is a lot underway to improve

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Recommended Resources

PDA TRI Courses

Risk Management and Design for Six Sigma: Partners in the Drug Development Lifecycle
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Indianapolis, Ind. • May 9, 2007
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Statistical Tools Supporting Quality Risk Management and Analysis
Indianapolis, Ind. • May 9, 2007
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System-Level Risk-Based Assessment for Electronic Records Regulatory Requirements
Philadelphia, Pa. • October 15-16, 2007
www.pdatraining.org/philadelphia

Elements of Risk Management
San Diego, Calif. •November 27-28, 2007
www.pdatraining.org/sandiego

PDA On-Demand Web Seminars

Please visit www.pda.org/ondemand to view the below web seminars.

2006 PDA/FDA: Impact of ICH Q8, Q9 and Q10 Implementation on Regulatory Submissions—An Industry Discussion—On Sale! Originally held on September 12, 2006

2006 PDA/FDA: Understanding the Impact and Applying the Concepts of ICH Q8, Q9, Q10—On Sale! Originally held on September 13, 2006

Management-Based Regulations New FDA Goal

Rick Friedman, FDA, Director, CDER Office of Compliance, Division of Manufacturing and Product Quality

ICH Q8, Q9 and Q10 (once completed) will facilitate the emergence of cGMPs for the 21st century. Q10, in particular, will help usher in an era of "management-based" regulations, according to FDA's ***Rick Friedman,*** *Director, CDER Office of Compliance, Division of Manufacturing and Product Quality. At an FDA open meeting on 21 CFR 314.70, "Supplements and Other Changes to an Approved Application," Friedman discussed how management-based regulation allows the most flexibility to industry compared with "technology-based" and "performance-based" regulations, the Agency's current paradigm. Below are Friedman's complete remarks from a transcript of the event, available at www.fda.gov/cder/meeting/CMC.htm. CDER OPS Director* ***Helen Winkle*** *set the table for the meeting by stating FDA's goal of reducing the number of post-market supplements. "Whether you're in industry or in FDA, I think that's the goal that everyone has."*

Good morning. I am happy to be here on behalf of CDER's Office of Compliance to endorse the initiative to create a regulatory system that is more amenable to manufacturing changes, representing a modern regulatory approach today that is rooted in the belief that the right balance of regulatory scrutiny and flexibility will promote innovations and improvements that better serve the public interest. In accord with our cGMPs for the 21st century initiative, this new model will promote continuous improvement and implementation of technological advancement. It would also focus limited FDA resources on those changes to a product that truly pose a significant risk and cannot be addressed by a firm's internal quality system alone. We also hope to more precisely identify in which cases a pharmaceutical company must continue to clear a manufacturing change with FDA prior to its implementation. The new paradigm under consideration allows for enhancements in CMC and GMP program coordination.

While the CMC review program would be expected to continue with needed oversight of changes that directly impact product safety or efficacy, many of the changes that occur over the product life cycle would be handled by the FDA cGMP program. It will be far less common for FDA to ask a firm to delay a change while awaiting FDA review of the modification to their operations. Instead the CMC review function and GMP programs will work more synergistically to create an environment conducive to continuous improvement by the manufacturer. This modern regulatory mind set emphasizes the responsibility of the firm to implement effective change control practices and of FDA in its routine surveillance inspection program to verify that changes are adequately implemented.

It will be far less common for FDA to ask a firm to delay a change while awaiting FDA review of the modification to their operations.

There are two fundamentals of cGMP to reach this desired state of change control, driven by the internal quality system; science-based change control procedures and sound quality risk management. I'll expand on these concepts a little later, but first I thought it would be useful to discuss at a higher level the public policy philosophies behind our proposed paradigm shift.

Three Types of Regulation Defined

A paper[1] in *Law & Society Review* in 2003 defined the three basic types of government regulation. Let's take a moment to look at each of them: a technology-based, performance-based, and management-based regulation.

The first is the most onerous. The review and approval of manufacturing process steps or the associated equipment used for such processes is a technology-based regulatory strategy. As stated in the paper, technology-based approaches intervene in the acting or production stage, specifying technologies to be used, or the steps to be followed, to achieve a social goal. This type of approach includes regulatory approval of the details of the firm's manufacturing approach and regulatory permission when a firm would like to change one or more steps in a process or introduce a new technology.

A somewhat lower level of regulatory scrutiny is the review and approval of product specifications. This is akin to a performance-based regulatory strategy as defined by the authors, and allows a firm to identify the approaches used to meet these specifications, and then holds the firm accountable to do so consistently. The authors state that performance-based approaches intervene at the output or testing stage, specifying social outputs that must or must not be attained. In other words, the regulator establishes requirements for measuring the product and the product output, or the production output is tested to ensure it conforms to those criteria. So that is acceptance criteria or specifications. ➤

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The third system provides the most latitude to the manufacturer to innovate and improve, and that's the management-based regulation or regulatory approach. It's defined as one which requires firms to produce plans that comply with general criteria designed to promote the targeted social goal and places responsibility on the manufacturer to routinely evaluate and refine their management of issues to reach the stated social objective on a daily basis. The authors clearly encourage management-based approaches for industries such as the pharmaceutical industry, where there is diversity amongst the regulated industry and rapid change in technology.

They note that management-based approaches hold a number of potential advantages over traditional regulation. They place responsibility for decision-making with those who possess the most information about risks and potential control methods. Thus the actions that firms take under a management-based approach may prove to be not only less costly, but more effective. By giving firms flexibility to create there own regulatory approaches, management-based regulation enables firms to experiment and seek out better and more innovative solutions. In contrast, the authors caution that technology-based regulatory regimes can be problematic for such industries. They state that regulation that imposes requirements for specific technologies can eliminate incentives for firms to seek out new technologies that would achieve public goals at a lower cost too. They add that even if a required technology seems effective at the time of initial approval by the regulator, it may prove significantly less cost effective than the technologies that would have been selected if firms had flexibility and the opportunity to innovate.

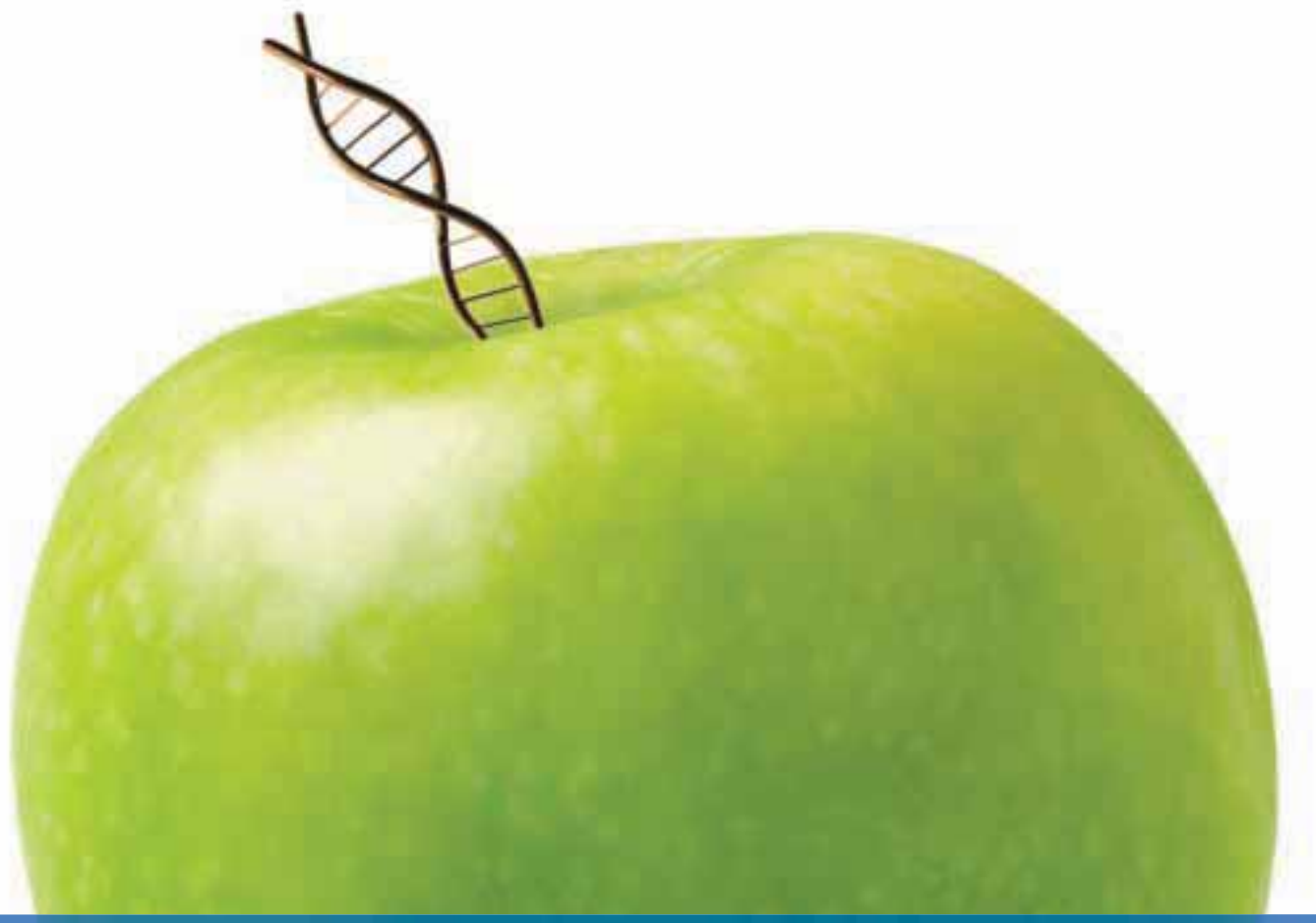
By giving firms flexibility to create there own regulatory approaches, management-based regulation enables firms to experiment and seek out better and more innovative solutions.

314.70 Should Align with cGMPs for 21st Century

So this brings us back to our initiative to revise 314.70. Our *Federal Register* announcement for this meeting notes that the current 314.70 categorizes post-approval CMC changes and their associated reporting requirements without consideration of the applicant's risk management activities or internal quality systems and practices. It indicates an excessively rules-based or prescriptive approach to regulating post-approval manufacturing changes is not desirable. This rules-based approach is an example of a technology-based regulatory scheme, and the appropriate application of management-based regulations in this arena of post-approval CMC change would greatly serve to achieve the desired state we have outlined over the last few years and as reinforced again today by my colleague's excellent presentations.

Our 314.70 work group has recognized that the Agency's cGMP program and its quality systems approach afford an existing platform to institute continual improvement. The cGMP regulations are rather broad and primarily management-based regulations. They do not prohibit or require specific equipment or process steps. In the cGMP regulatory framework, regulatory hurdles are lowered to facilitate the use of advances in manufacturing technology; continual improvement is integrated into the manufacturer's process-control strategies. Firms are still held ultimately responsible for ensuring the quality of their products, and inspections will of course continue to monitor the effectiveness of the firm's operations, and in fact might spend more time on the change control aspects, with the change control program, which is a crucial cog of the pharmaceutical quality system at a firm.

So these continual improvement concepts are found throughout our recently finalized quality systems guidance, and are the basis for their ongoing work of ICH Q10. Scott Tarpley, a statistician whose insights into process control have contributed significantly to our 21st century initiative, likes to say that process experience tells us whether things really work. And here is a relevant quote from the quality systems guidance that underscores that a well-functioning quality system uses a holistic approach throughout the life cycle of a process to provide insight into state of control. By measuring points of process variability and using good systems for data acquisition and analysis, a firm will continue to accumulate process understanding and learning throughout the product life cycle to the last day of the product life cycle. Yet this in-process or analytical lab data does not tell the whole story. It doesn't provide the full picture of whether the process is under control. There is other relevant information in the quality system that is important in evaluating whether there is a need for change and improvement. Examples of important sources of this information that are discussed in our quality systems guidance are: nonconformance reports, batch rejections, returns and complaints; information on the state of maintenance, control, and calibration of equipment, facilities and utility systems; and information from internal and external audits. ➤



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– FDA Guidance For Pharmaceutical cGMPs, September 2004

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These metrics and others provide the firm with the means to gauge whether and how equipment, facilities or processes the need to be improved or adjusted. An effective quality system will reveal significant problems before there is a product quality consequence. This would seem to be not only good quality, but also good business according to a team of researchers from Wharton School who published a study in the *Journal of Risk Analysis*. The Wharton School of Business researchers found that early warning systems that turn lessons learned into prompt process improvements avert later production errors and failures that could have caused a serious public health impact. They call it crises or catastrophes for us—and I think in the pharmaceutical industry you would then say, a recall would be that—a crisis like that. So you are averting those kinds of problems and using sound early warning system approaches. They say that the failure of a system to identify and then remedy manufacturing flaws is highly problematic. FDA today is talking about removing hurdles to such process improvements.

FDA today is talking about removing hurdles to such process improvements.

Finally, when a responsive quality system identifies the need for a change—the change control program manages the change. A GMP compliance change control procedure will do four basic things. First thing it will do is reliably estimate the risk posed by the proposed change. And just to note that as we move to this paradigm, there is a responsibility of manufactures to handle changes in a way that the right questions are being asked before the change is implemented. [There should be] a vigorous, open discussion of what issues might be associated with the change, and that means the right scientific disciplines from your company need to be at the table to estimate the risk accurately.

The second thing in this change-control procedure is the determination of how much scrutiny should be applied to the change; how much scrutiny is needed. For example: What type of data needs to be generated? Is validation or revalidation necessary?

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Management-Based Regulations New FDA Goal, continued from page 20

FDA's quality systems guidance and the ICH Q10 initiative provide the needed framework to accomplish this goal.

Who needs to be involved with the internal sign off of the change? etc. The third is documenting the change and any relevant data or information that is generated. And of course, the fourth, do science and quality risk management call for analysis of the data, subsequent to the change in order to ensure its effectiveness? So the final major feature of change control would be to evaluate the actual impact of the change.

So that last slide is just a quick look at what I think is the key procedure that will enable the modern paradigm of post-approval change management. If we are going to make sure that this is realized, your change control program needs to be a robust one. In summary, if FDA can create a regulatory system that focuses even more acutely on limiting consumer exposure to unsafe products, while also facilitating technological advancement, both the FDA and industry will be well served.

The management-based regulatory paradigm of the cGMP's provides a foundation to allow for many post-approval manufacturing changes to be properly implemented by firms without prior regulatory oversight. FDA's quality systems guidance and the ICH Q10 initiative provide the needed framework to accomplish this goal.

At the end of the day, if the Agency can provide a regulatory environment that will not impede needed changes, but instead encourage and facilitate manufacturing refinements over the life cycle, we will truly seize this opportunity for a great synergy between the regulator and the regulated. Thank you very much.

Reference

1. Cary Coglianese and David Lazer. "Management-Based Regulation: Prescribing Private Management to Achieve Public Goals." *Law & Society Review, vol. 37, is. 4, p. 691, Dec. 2003.*

BioAB Update, continued from page 10

- Mycoplasma test methods
- Emerging mycoplasma issues in plants and insects

Bioburden Control: Finally, another BioAB endeavor is to address industry concerns related to in-process bioburden testing and control. A survey is completed and will be sent out for comments this year. Results will be collated and described in PDA publications and at conferences.

Looking To The Future

In 2007, BioAB plans to establish task forces to address validation of analytical methods used to support clinical studies; cell substrate characterization for toxicology through licensure; GMP requirements for phases 1, 2 and 3; and cell culture process validation. PDA will sponsor a meeting on Quality by Design for Biopharmaceuticals in May 2007.

If you've never worked in a consensus organization, think about the challenges volunteer task forces face. Participating members come into a task force with different perspectives and opinions formed by a variety of work experiences. They must negotiate based on scientific discussions. Sometimes task-force members decide to include multiple points of view to provide readers of a technical report with logical, science-based best practices that take into account current global regulatory positions on various issues. And they need to do this without being prescriptive, because PDA is not a standards setting organization. If this type of a challenge makes you interested in joining a PDA task force, please contact BioAB through the PDA web site at www.pda.org.

Reference:

1. Lute S, et al. Characterization of Coliphage PR772 and Evaluation of Its Use for Virus Filter Performance Testing. Appl. Environ. Microbiol. 70(8) 2004: 4864–4871; http://aem.asm.org/cgi/reprint/70/8/4864.pdf.

[**Editor's Note:** This article is excerpted from the original version, published in the March 2007 edition of *BioProcess International*.]

PDA Calendar of Events for North America

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

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May 21-22, 2007
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Bethesda, Maryland

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

June 13-14, 2007
2007 PDA Pharmaceutical Cold Chain Management Conference
Bethesda, Maryland

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

October 15, 2007
PDA Visual Inspections Workshop
Bethesda, Maryland

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

November 1-2, 2007
PDA/FDA Co-Sponsored Conference Series on Quality Systems
Bethesda, Maryland

Training

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

Laboratory Courses

May 1-4, 2007
Pharmaceutical and Biopharmaceutical Microbiology 101

May 8-11, 2007
Downstream Processing: Separation, Purification and Virus Removal

May 16-18, 2007
Developing a Moist Heat Sterilization Program within FDA Requirements

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

May 21-23, 2007
Operator Qualification

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

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

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

October 17-19, 2007
Visual Inspection Training Course
Bethesda, Maryland

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

Lecture Courses

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

Course Series

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

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

Chapters

April 11, 2007
PDA New England Chapter
Cold Chain Management
Burlington, Massachusetts

April 17, 2007
PDA Metro Chapter
Pharmaceutical GMP Compliance
Somerset, New Jersey

April 18, 2007
Delaware Valley Chapter
Quality by Design
Malvern, Pennsylvania

April 18 and 19, 2007
PDA Southern California Chapter
Computer Validation and Evolution "Then and Now" and Requirements and Specifications of Computer Systems
Irvine, West Lake Village and La Jolla, California

Europe/Asia-Pacific

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May 2, 2007
Quality System Strategies for Investigational Drugs - Getting It Right the First Time
Lyon, France

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

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

June 11, 2007
Supplier Quality
Bologna, Italy

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

June 20-21, 2007
Biopharmaceutical Development and Manufacturing "Challenges in the European Environment"
Berlin, Germany

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

September 13, 2007
Technology Transfer
Basel, Switzerland

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

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

November 13-15, 2007
European Training Course Series
Berlin, Germany

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The Closed Vial Technology: A New Concept in Aseptic Filling to Increase Patient Safety

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To reserve your space, please contact Cindy Tabb at tabb@pda.org or +1 (301) 656-5900, ext. 222.

EMEA's Cooke on the Future of GMPs, continued from page 15

interactions between assessors and inspectors. These include ongoing interactions at the EU level, the activities of the EMEA Process Analytical Technology team, joint training, participation on product-focused inspections and the worksharing pilot on variations. These interactions are also leading to more effective ways to mutually embrace new technologies. In the area of new technologies, other specific examples of work underway included the revision of Annex 2 (biological medicinal products) to the EU GMP Guide (a draft should be available by late spring/early summer 2007) and a new draft regulation on Advanced Therapies (2008/2009). Another area being given attention by the European Commission is how best to handle post approval changes and variations.

Cooke concluded her presentation by describing her view of the ideal world—one with enhanced integrated drug substance and drug product development processes with an integrated quality risk management program, all operating under the umbrella of a modern pharmaceutical quality system. In her view, this would lead to lower risk operations, innovation, continual improvement, an optimized change management process and, hopefully, a more flexible regulatory approach. She summarized her points by noting that manufacturers must embrace new technologies and efficiencies, regulators must be open to change, and risk-based approaches must be supported by knowledge and science. The challenges faced are global, not regional, thereby calling for more international sharing of resources to achieve success.

Quality by Design for Biopharmaceuticals

Rebecca A. Devine, PhD, Regulatory Consultant, and Anurag Rathure, PhD, Amgen

In August 2002, the U.S. FDA launched the *Risk Based Approach to Pharmaceutical cGMPs for the 21st Century*, which contained some innovative concepts that FDA felt would modernize the regulation of pharmaceutical manufacturing and product quality. Several of the key concepts enveloped by the initiative included encouraging the early adoption of new technological advances, facilitating industry application of modern quality management techniques and encouraging implementation of risk-based approaches. An outgrowth of using the newest technological advances was the PAT initiative. FDA outlined the expectations for PAT in its guidance *PAT—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance*.

In addition to the new concepts being considered by FDA in its cGMP initiative, two important guidance documents were also published as part of the ICH process: ICH Q8, *Pharmaceutical Development*, and ICH Q9, *Quality Risk Management*. ICH Q8 described the expectations for the Pharmaceutical Development section of the common technical document and ICH Q9 outlined approaches to producing quality pharmaceutical products using the most current scientific and risk-based approaches. Much work and progress has been made in defining the application of these expectations in the pharmaceutical industry. The biopharmaceutical industry has also been actively working on applying these expectations to the development and manufacture of biopharmaceutical products.

All of these initiatives recognize the importance of Quality by Design (QbD). In a QbD approach a biopharmaceutical product is designed so that it will meet its desired clinical performance, and the process is designed to consistently deliver a product that meets the quality attributes necessary for this clinical performance. This requires that one understand the impact of starting materials and process parameters on product quality, and that the process be continually monitored and updated to assure consistent quality over time. The use of design space as a tool for assuring that a biopharmaceutical product will continually meet the quality attributes necessary for clinical performance is now being considered within the biotechnology industry. Defining the design space for a biopharmaceutical product, however, will not be a simple task.

ICH Q8 defines design space as: *The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. Working within the design space is not considered as a change. Movement out of the design space is considered to be a change and would normally initiate a regulatory post approval change process. Design space is proposed by the applicant and is subject to regulatory assessment and approval.*

In the traditional approach to biopharmaceutical process validation, companies use process understanding from process characterization studies to define critical, key and noncritical process parameters. The critical process parameters are then controlled within a narrow range, and the process is validated to assure it operates within the defined ranges for these process parameters. Identifying critical process parameters will still be an important part of defining the design space for a biopharmaceutical process. Now, however, companies will need to go further in their understanding of both product quality attributes and how they relate to clinical performance, as well as understanding how the process will assure these identified properties are maintained. Since the factors affecting the quality attributes of a biopharmaceutical product are complicated and multivariate, complex statistical tools will be needed to characterize the design space.

Design of experiment (DOE) studies are one tool the biopharmaceutical industry is looking at for defining design space. DOE studies can look at the impact of varying multiple process parameters on the quality attributes of the product. Coupled with an understanding of which quality attributes are critical for clinical performance, the company can then begin to define the design space for the biopharmaceutical product. Once the process parameters critical to the design space have been identified, the process is expected to operate within the design space, and continual monitoring tools will ensure the process results in acceptable quality product.

The use of PAT for the continual monitoring of the process is being examined by the biopharmaceutical industry and is an important aspect of QbD. Advances in technology will most likely be necessary for new PAT tools to be available in the biopharmaceutical sector. Use of on-line monitoring has been successful in some aspects of biopharmaceutical processes such as fermentation processes, and possibilities for future applications in the raw materials and downstream process are currently being studied. Once the design space has been defined it will be continually reassessed and changed as appropriate. This is part of continuous improvement within the quality systems approach.

continued on page 30

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ONDQA, FDA

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The Quality by Design for Biopharmaceutical workshop will be held in conjunction with the PDA Global PAT Conference.

Two FDA Speakers Confirmed!

Barry Cherney, PhD
CDER, FDA

Chris Joneckis
CBER, FDA

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.

North America

U.S. FDA Releases Draft Alt. Med. Guide, *Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration*

FDA has announced the availability of a draft guidance for industry entitled *Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration*. In recent years, the practice of complementary and alternative medicine (CAM) has increased in the United States, and FDA has seen increased confusion as to whether certain products used in CAM are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act) or Public Health Service Act (PHS Act). FDA has also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act. Comments are invited by April 30, 2007.

U.S. FDA Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology Announces April 30 Meeting

The Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (formerly Advisory Committee for Pharmaceutical Science) will meet on April 30, 2007, from 8:30 a.m. to 5 p.m. in at the Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, Md.

Agenda:

1. As an awareness topic, discuss issues pertaining to the stability of tablets split for patient use.
2. Receive a general update and discuss current strategies on quality by design and the Office of Generic Drugs' question-based review.
3. Receive an update on and discuss the status of the Office of New Drug Quality Assessment Chemistry, Manufacturing, and Controls Pilot Program.

U.S. FDA Pharmaceutical Science Advisory Committee Renamed/ Repurposed

Effective March 5, the FDA renamed the "Advisory Committee for Pharmaceutical Science," established in 1990, to the "Advisory Committee for Pharmaceutical Science and Clinical Pharmacology."

According to the Agency, the new name more accurately describes the subject areas for which the committee is responsible. The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the commissioner of food and drugs. The committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

U.S. FDA Announces Seminars on Medical Device Regulations

FDA has announced a series of three two-day seminars entitled The Essentials of Food and Drug Administration Medical Device Regulations: A Primer for Manufacturers and Suppliers. The seminars will be held in Irvine, Calif. (March 15 – 16); Lakewood, Colo. (May 22 – 23) and Pittsburgh, Pa (June 6 – 7). The seminars are being sponsored in cooperation with AdvaMed's Medical Technology Learning Institute. The seminars are designed to address the training needs of start-up and small device manufacturers, as well as their suppliers.

Quality by Design for Biopharmaceuticals,* *continued from page 28

Of course the use of QbD and design space will have regulatory implications. Both FDA and industry recognize that if the design space can be appropriately defined, changes that stay within the design space could benefit from regulatory relief from submitting the change for approval by FDA before it is implemented. It remains to be seen if and when the biopharmaceutical industry will begin to benefit from these opportunities. Much work has been done, but much also remains to be done. The regulatory agencies are working hard to define how these new tools can be applied to biotechnology and biological products.

PDA will be hosting a one and a half day conference May 21-22, 2007, in Bethesda, Md., which will bring together both regulators and the biotechnology industry to discuss the advances that have been made in QbD within the biopharmaceutical industry, as well as where the field is going. This workshop will provide a useful forum for discussing what has been done in the biotechnology industry and for learning how to approach QbD for biopharmaceutical products.

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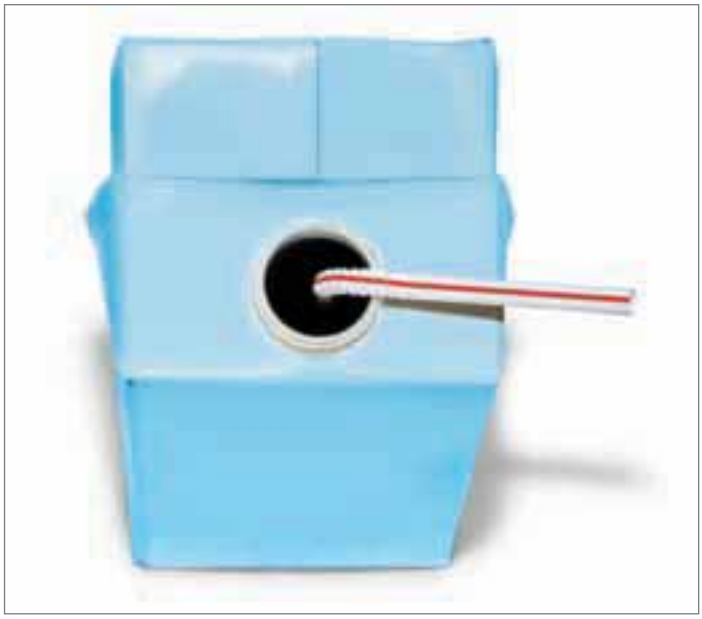

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Dedicated Local Leaders Help Grow PDA Chapters

Lindsay Donofrio, PDA

Myron Dittmer, New England Chapter (NEPDA) board member, and **Peter Rauenbuehler,** PhD, West Coast Chapter (WCPDA) board member, are continually searching for ways to help develop and improve PDA chapters.

Dittmer, a 20-year veteran of PDA, became involved with the chapter upon the request of a few friends in 2003. At this time, interest in the chapter had been declining. The challenge of rejuvenating the chapter intrigued Dittmer, so he decided to join and become active in helping with the planning of the chapter's events. Shortly thereafter, **Mark Staples,** PhD, then NEPDA president, asked Dittmer to serve as vice president with the expectation of taking over as president. "No problem. I love doing this," said Dittmer.

Rauenbuehler became involved with WCPDA about 15 years ago. Working for Genentech, he was exposed to many colleagues with tight ties to PDA, including **Vince Anicetti,** PDA Board of Directors Chair. "This area was the genesis of biotechnology, and there wasn't a lot going on. So the chapter got organized fairly quickly back in the early 1990s, focusing on biotech," noted Rauenbuehler. He assumed a leadership position about nine years ago and served as treasurer for six years. Next, he served as WCPDA president in 2005 and 2006.

Because chapter members live in the same communities, they often face similar challenges. Thus, PDA chapters offer a unique forum for these members to share solutions. "It's local and it's easy to get to. People spend a couple of hours at our meetings and get a lot of information," reported Dittmer. "But basically it's about meeting people who have similar likes as you, so that you can call them up and say, 'What do you think about this?' That's done all the time."

Myron Dittmer, PDA New England Chapter

Peter Rauenbuehler, PhD, PDA West Coast Chapter

PDA chapter meetings not only offer members the chance to network with their colleagues and discuss solutions to common problems and issues, but these meetings allow for career development. "I can't overemphasize the networking aspect of chapter meetings," said Rauenbuehler. "Whether it's people with challenges or people looking for new jobs and opportunities, it's a good way for people to have professional development opportunities in addition to their own careers."

Both NEPDA and WCPDA have been successful because of the consistency with which they offer events. Rather than wondering when activities might take place, chapter members have come to expect quality events held on a regular basis. "It's kind of like when the gas bill comes every month. People aren't searching us out because they know what's been planned," observed Rauenbuehler. In addition to consistently providing interesting topics and engaging speakers, these chapters have become distinct resources for their communities. "People now know us and recognize us. We have a strong identity in the pharmaceutical and biotechnology industries in this area," said Dittmer.

Chapter leaders dedicate a great deal of time and effort to maintaining the high quality of their events and speakers. When Dittmer became president, he knew "the chapter wanted to do big things and needed a lot of help." Since the board was a small group, he started a planning committee of about 10 colleagues. "The 10 people on the planning committee plus four or five more from the board make a pretty good group you can disseminate and distribute work to," he noted. The planning committee meets about once a month to coordinate the organization of upcoming meetings. Each person takes a different meeting and develops a program for that event, while the other committee members assist as necessary. Depending on the size of the chapter and involvement of volunteers, different structures may be better suited for other chapters. For example, once a chapter reaches a certain size, it may make sense to have additional committees and subcommittees.

The NEPDA planning committee also serves as a natural conduit for the chapter board. New members who think they might want to get more ➤

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involved usually start by helping out at chapter meetings. As they learn more about the chapter and its organization, they may decide to join the planning committee. "They'll come on board and see how things are done, and, if their interest and commitment is there, then they'll want to go further," observed Dittmer. "It does take commitment. You really have to want to help your fellow PDA person."

Individuals such as **Melissa Smith,** NEPDA Secretary, and **Kristina Nordhoff,** WCPDA Secretary, serve as examples of creative individuals who have been recognized by their chapters. Smith "took it upon herself to motivate people and get an electronic newsletter started," reported Dittmer. The newsletter features science and regulatory/quality affairs articles, messages from the board and upcoming chapter activities. Nordhoff develops a brochure for WCPDA events, which includes speakers, topics, vendors, news and upcoming chapter events. "She puts in a lot of personal touch and personal commitment," said Rauenbuehler. "She's been a big help to us, so we highlighted her in January as our own Chapter Volunteer of the Year."

While there is a plethora of positive activity surrounding the chapters, Dittmer and Rauenbuehler are constantly searching for ways to improve their chapters and increase the dissemination of knowledge within the industry. Having been in the industry over 35 years, Dittmer "sometimes wonders if we're preparing our students to fill in behind those of us who will be retiring soon." As NEPDA continues to grow, he hopes to expand the chapter to local university students. "I really think our future is in getting students involved in the biotechnology and pharmaceutical fields and showing them the advantages of careers in these sciences," he explained. "If somebody knows or hears that their classmate is in this organization, a student chapter of PDA, and they start finding good jobs, that's going to spread faster than any public relations work."

Rauenbuehler, a member of the PDA Chapter Council, dedicates his efforts to creating a more fluid flow of communication between chapters. "We really need to rally the chapters and get them excited about what's good and positive," he said. "We all need to share our ideas about what's working and what's not working for our chapters. Then instead of dwelling on the negatives, we can start talking about some of the solutions." In 2006, **Henry Kwan,** PhD, started consulting with the PDA as senior chapter liaison. For a little over a year now, Kwan has worked to bring more continuity between chapters and has served as a link between PDA headquarters and the chapters. "Henry is one of those amazing guys. He links people up and gets them to talk to each other," said Rauenbuehler. "I would bet 50% of the issues chapters have are pretty common, so Henry can work with the chapters to share common solutions."

Since Rauenbuehler became involved with WCPDA, he has been devoted to learning more about the industry and sharing that knowledge throughout the region. "With a lot of start-up companies, it's really valuable for them to hear some of the experiences others have had and how they relate back to their current situations," he reported. For Rauenbuehler, his time with PDA has been about building a network of trusted colleagues. He elaborated, "It has never been about finding another job. I've been at Genentech for 19 years and, if I'm here another 19, it'd be terrific. It's really been more of a professional development process for myself."

Dittmer agrees that one of the greatest benefits of working with PDA chapters has been meeting industry colleagues and sharing in the wealth of scientific information. "All of us who are involved in this area continue to learn. There is so much new development going on all over the industry," he noted. "It's really hard to keep track of it, and the only way you can really do that is by listening and participating in these meetings. It's such a joy to see there are so many creative and innovative people out there."

Dittmer and Rauenbuehler's commitment to PDA and its chapters is apparent in the success of both NEPDA and WCPDA. Both chapters average around 70 members per event, and, in some cases, may draw over 100 attendees depending on the topics and speakers. Their focus on quality has made these individuals local leaders among PDA.

PDA's Who's Who?

Vince Anicetti, PDA Board of Directors Chair; VP, Commercial Quality, Genentech

Myron Dittmer, New England Chapter Member-at-Large; MFD & Associates

Henry Kwan, PhD, PDA Senior Chapter Liaison; Kwan Consulting, LLC

Kristina Nordhoff, West Coast Chapter Secretary; PDA Letter Editorial Committee Member; Partnership Manager, External Collaborations, Genentech

Peter Rauenbuehler, PhD, West Coast Chapter Member-at-Large; Senior Director, Global QC, Genentech

Melissa Smith, New England Chapter Secretary; MJ Quality Solutions

Mark Staples, PhD, VP, Research and Development, MicroCHIPS

Comparability Protocols Discussed at First Midwest Chapter Dinner of 2007

PDA Midwest Chapter Board

The PDA Midwest Chapter had its first dinner meeting of the year on Thursday, Feb. 22, at the Hilton Northbrook hotel, just north of Chicago, Ill. The meeting's presentation, entitled "Implementing Changes to Manufacturing and Laboratory Areas by Using Comparability Protocols," was presented by **Jeanne Moldenhauer**, PhD, Vectech Pharmaceutical Consultants. In addition to her expertise as a senior quality assurance/regulatory affairs professional with extensive background in the development and management of a variety of sterilization and validation processes in the healthcare industry, she is also a PDA Microbiology/Environmental Monitoring Interest Group leader and Task Force member for two upcoming technical reports.

The Midwest Chapter will soon be conducting board elections, including the positions of president-elect, secretary, treasurer and three member-at-large positions. Ballots will be available electronically at the Midwest Chapter website, www.pdamidwest.org, beginning in April 2007. For more information regarding the process or if you are interested in submitting your name for inclusion on the ballot, please contact Chapter VP **Peter Noverini**, Baxter, at peter_noverini@baxter.com.

In addition, the Midwest Chapter plans to have monthly meetings starting in April. Various industry experts are expected to speak on a variety of topics this year, so continue to look for more details and scheduling information on the Midwest Chapter website. In addition to the informative dinner meetings, the chapter will also host its annual social golf outing in August 2007—details and sponsorship opportunities will also be posted on the website.

The Midwest Chapter serves pharmaceutical professionals and education organizations from the Midwestern United States. Our events draw individuals primarily from Illinois and Indiana, with a focus in the Chicago area. Our dinner meetings, featuring guest speakers and diverse topics, are informative and engaging. We collaborate with businesses to allow them to promote their products in an effort to match the best products and services for our membership. We work to create dialogue that illustrates the industry standards and best practices that are most successful based on empirical uses. Our chapter initiates discussions regarding regulatory trends and expectations. The Midwest Chapter looks forward to increasing membership involvement and serving your needs. Please contact us through our website with any questions, concerns or feedback.

Volunteer with PDA

Among the many potential volunteer opportunities within PDA, chapters serve as an ideal forum for members who would like to make a difference in their own communities. Depending on the interests of the region, chapters tailor their events to suit the needs of local members. Chapter events offer relevant and interesting information along with convenience and a reasonable price. Whether you'd like to simply attend a chapter event or become more involved as a chapter leader, PDA chapters offer several levels of involvement. To contact your local chapter, please visit www.pda.org/chapters. If you'd like to reach your PDA chapters representative, call **Ta-Méla Jeffries** at 301-656-5900, ext. 272 or email her at jeffries@pda.org.

PDA Welcomes New Members

Marisel Acosta, Cordis
Prafulla Agrawala, sanofi-aventis
Purna Airan, Amgen
Sergio Alcala, Laboratorios Cryopharma
Theresa Allyn, Bayer HealthCare
Limaris Alvarado, ECHO Consulting Group
James Ambrosini, Protiviti
Ranael Amundson, PDL BioPharma
Carrie Anderson, Hollister-Stier Laboratories
Keiji Anzai, Astellas
Dieter Bachmann, Johnson & Johnson
Susan Bantz, Novartis
Corinna Barber, Genentech
Robert Barrett, FRS Instrumentation & Controls
Felix Barron, Clemson University
Shelli Baxter, Protherics
Richard Becker, Northern Illinois University
Jean Bender, Genentech
Tami Benjamin, Synthes
Christoph Benzinger, Cilag
Juan Bernard, Amgen
Ed Bernasky, Lifecell Corporation
Ramon Antonio Berrios, Eli Lilly
Anthony Binsol, sanofi-aventis
Taryn Boivin, Cardiome Pharma
Tom Breum Jensen, Novo Nordisk
Michael Broderick, Prenax
John Brown, Alkermes
Arleen Candari, C&A Consulting
Alaine Carrier, Sandoz
Robert Caunce, Hospira
Bikash Chatterjee, Pharmatech Associates
Suhe Chen, Amgen
Andrew Chen, Amgen
Leonard Chernow, Protiviti
Vinay Chhatre, Northern Lipids
Hi-Shi Chiang, Durect Corperation
Kamei Chiharu, N.V. Ashi Vasel Planova Europa
Nameeta Chimanji, Wyeth
Danny Chou, Amgen
Evelyn Choy, Solstice NeuroSciences
Piet Christiaens, Toxikon Europe
Maxine Close, Schering-Plough
Martin Coronel, Tanox
John Coundouris, Tercica
David Coyle, C&A Consulting
Michel Crevoisier, Lamprecht Pharma Logistics
Luz Cuevas, Turabo University
Gill Dando, Domnick Hunter
Andrea De Lisle, Bayer HealthCare
Chathra De Silva, Mayne Pharma
Ariel Decastro, Perrigo
Lily Deng, Allergan
Piyush Desai, Sovereign Pharmaceuticals
Rahul Dev, Kaisha Manufacturers
Colette Dolan, Wyeth
Meredith Dow, Kforce Scientific
Darryl Drake, Abbott
Candice Duhon, Wellstat Biologics
Neil Dunstan, F. Hoffmann La Roche
Martain Eicholtz, sanofi pasteur
Anne Eickhoff, GlaxoSmithKline
Katherine Eley, KAE Validation Services
Ashley Evans, Science Applications International
Richard Fahrner, Acambis
Suzanne Farr, Extronex
Mojtaba Fatemi, Novartis
Majed Fawaz, Abraxis BioScience
Igor Ferlan, Probiomed
Geoff FitzGerald, SlaxoSmithKline
Deborah Fizz, Validation Services
Katherine Flagg, Rapid Micro Biosystems
Ingrid Freeland, Cardinal Health
Larry French, Genentech
Kelly Frye, Wyeth
G. Michael Funk, Pfizer
Guylen Galarneau, Invensys Validation Technologies
Eileen Garry, Advanced Instruments
Labranque Gilles, Sofrigam
Carolyn Gilligan, Ipsen Biopharm
John Glavas, Draxis
Steve Gorczany, Perrigo
Sonia Gourary, Amgen
Benjamin Greenbowe, Vertex Pharmaceuticals
Marc Grinwis, Crucell
Michael Grogan, Actavis
Cheryl Gurecki, Bayer HealthCare
Emily Ha, CovX Research
Sari Hakli, Stora Enso
Kevin Hall, Pfizer
Robert Hanes, W.L. Gore and Associates
Colleen Hansen, Bayhill Therapeutics
Leonard Hayflick, University of California
David Hemmerlin, Novartis
Joyce Henry, Dow Corning
Christopher Hepler, Talecris Biotherapeutics
Lizauri Hernandez, Johnson & Johnson
Steven Herring, Grifols Biologicals Inc.
Kenneth Hinds, Centocor
Bernhard Hinsch, Baxter
Alec Hir, Amgen
Michael Hitchingham, Cardinal Health
Chin Siong Ho, Amgen
Tamara Hodge, Pfizer
William Holden, BSH
Ning Hu, Gilead Sciences
Anthony Hurley, Genentech
Wesley Hutchison, Chemimage
Dina Iezzi, Draxis Health
Takuji Ikeda, Sonac
Ian Jester, Charles River Laboratories
Jienping Jiang, BioVigilant
Joyce Jin, Allergan
Catherine Jones, Berkshire
Suma Kallurkar, Microbial ID
John Kandl, Tercica
Kevin Kannady, Genentech
Stanley Kidd, Pall
Wendy Klem, Sykehusapotekene
Ivar Kljavin, Genentech
Tracy Klutch, GlaxoSmithKline
Paul Kolosick, Merck
Arne Koops, tesa

Karen Korroch, Organon do Brasil
Son Kuan, Solstice Neurosciences
Sylvester Kugblenu, Chapel agte
Alok Kulshreshtha, Alcon Research
Ronja LaBrecque, AstraZeneca
Ellen Landmark, Landmark
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Shawn Latham, Baxter
Serge-Staophane Laveault, Celltrion
Steve Laven, Pharmaceutical Services
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Kyunghee Lee, YuYu Industrial
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Manoj Sahu, Promed
Cori Sandy, Biogen Idec
Camilla Sarensen, Novo Nordic
David Schwarzenbek, Kforce Scientific
Raj Selvaraj, Abraxis BioScience
il Chang Seo, Jeil Pharmaceutical
Sundeep Shankwalkar, Global Leadership Solutions
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Charles Smith, Seattle Genetics
Stephen Smith, sanofi pasteur
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Kimberly Vaughn, DavenportMajor Executive Search
Curtiss Vavra, Tissue Banks International
Benoit Verjans, Aseptics Technlogies
Shahneela Versey-Usman, sanofi pasteur
Eric Vincent, Sandoz Canada
Josefina Vocos, Gador
Alice Wei, Favrille
Phoebe Weingast, Human Genome Sciences
Andrew White, Acambis
Adam Widera, Grifols Biologicals
John Wiggins, Abraxis BioScience
Clark Williams, Alkermes
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Carsten Witt, Lytzen
Heinz Wolf, Packaging Technologies & Inspection
David Wolozyn, Eli Lilly
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David Woodland, GlaxoSmithKline
Amy Wu, Shire
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If your information appears inaccurate in this list, please visit www.pda.org to update your profile or email changes to info@pda.org.

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 Web site is listed. More information on PDA Chapters is available at www.pda.org/chapters/index.html.

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Connecting People, Science and Regulation℠

2007 PDA/FDA Meeting to Address Emerging Regulations

Washington, D.C. • September 24–27, 2007

Susan Schniepp, 2007 PDA/FDA Joint Regulatory Conference Chair

With the adoption of ICH Q8 and Q9 and the emergence of Q10, industry and regulatory authorities need to review the regulations and come to a consensus on their application in light of the new paradigm of Quality by Design, risk-based approaches to quality systems and design space. In addition, industry needs to consider the impact of these regulations on manufacturing, quality and regulatory functions during the product life cycle.

Please join us September 24–28, 2007 in Washington, D.C., for the 2007 PDA/FDA Joint Regulatory Conference. The aim of the meeting is to address these new and emerging regulations and to challenge attendees to rethink, reinterpret, redesign and reapply industry processes and practices using a scientific and risk-based approach in the global market. This year's conference will focus on the *Evolution of the Global Regulatory Environment: A Practical Approach to Change* and, once again, will provide the knowledge and input of industry and U.S. FDA experts combined with the invaluable face-to-face learning experience.

Concurrent sessions will focus on pharmaceutical industry case studies covering current areas of interest, including laboratory operations, global change control processes, PAT implementation, six sigma, quality systems and risk-based initiatives that do not compromise regulatory approval. During these sessions, attendees will learn key strategies for implementation and compliance with regulatory expectations from the individuals who have already tested and tried them at their own organizations. To complement these sessions, panel discussions with industry and FDA representatives from all sectors of the agency will immediately follow.

In addition, plenary sessions will set the stage for each day's agenda content. On Monday, the Opening Plenary Session will explore the concept of "near misses" in the chemical industry. On Tuesday, Plenary Session 2 will address the new Good Review Management Practices (GRMPs) and their impact on the first cycle approval objective. The last day of the conference will be a one-of-a-kind experience, featuring two plenary sessions. The first session will bring together U.S. and non-U.S. regulators to discuss the future of the global industry, followed by the closing plenary session in which all present FDA representatives will discuss the agency's direction for the future of pharmaceutical regulation.

For more information on the 2007 PDA/FDA Joint Regulatory Conference, please visit www.pda.org/pdafda2007.

PDA's Upcoming Cold Chain Management Meeting

Bethesda, Maryland • June 13–14, 2007

Rafik Bishara, PhD, PDA PCCDG Chair and Program Committee Chair

Global members of the pharmaceutical and biopharmaceutical industries continue to be faced with new regulations and pharmacopeial standards for handling, storing and distributing temperature-controlled products, including those that require controlled room temperature, refrigeration and freezing conditions. Risk management of these challenges and the overwhelming array of new technologies offering possible cold chain solutions are in constant development to ensure the quality and integrity of temperature-sensitive medicines are not compromised in the distribution channels.

The 2007 PDA Pharmaceutical Cold Chain Management Conference will bring together industry and regulatory representatives to provide guidance on patient safety and product integrity as it relates to the distribution of temperature-sensitive pharmaceuticals. Global experts will also address the current risk-based regulatory environment and how it is affecting Cold Chain Management processes.

Eight plenary sessions will focus on the following areas as they pertain to those who are involved with cold chain and temperature-controlled management practices:

- PCCDG and Technical Report No. 39
- Global Regulatory Requirements
- Global Cold Chain Risk Management—Case Studies
- Validation and Risk Management
- Application of Cold Chain Standards for Risk Management
- Interaction of Packaging Components for Risk Management of Temperature-Controlled Pharmaceuticals
- Handling and Transportation of Cold Chain Bulk and Intermediate Pharmaceuticals
- Support of Service Providers to TR-39

2007 PDA Pharmaceutical Cold Chain Management Conference

June 13-14, 2007 | Bethesda, Maryland

CONFERENCE | EXHIBITION

Transportation and Storage of Temperature-Sensitive Pharmaceuticals in a Risk-Based Regulatory Environment: A 21st Century Initiative

www.pda.org/coldchain

PDA Parenteral Drug Association

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Faces and Places

ISPE/PDA Joint Conference: Challenges of Implementing ICH Q8 and Q9—Practical Applications
Brussels, Belgium, February 12–13, 2007

(l-r) Hal Baseman, Valsource; John Lepore, PhD, Merck; and Gail Sherman, PDA, enjoy the networking reception

Conference Co-Chair Joseph Phillips, ISPE, (left) poses with Keynote Speaker Emer Cooke, EMEA (right)

(l-r) Susanne Keitel, PhD, Federal Institute for Drugs and Medical Devices; Jacques Morenas, French Health Products Safety Agency; Stephan Roenninger, PhD, F. Hoffmann-La Roche; and colleague share ideas between sessions.

Meeting attendees attentively listen to presentations.

PDA Headquarters Looks Forward to Spring

The PDA headquarters welcomes spring after a brutal few months of freezing temperatures and snow. In February, PDA VP Bob Dana stood outside his Syracuse, New York, home in 29 inches of snow!

PDA
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Web Seminars

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PDA Web Seminars are a cost-effective, high-quality training option for professionals wanting to gain the latest information about pharmaceutical/biopharmaceutical sciences and technology—with minimal impact on your time and budget. Accessible via your home, office or anywhere else you can access a computer, these live seminars provide detailed training right at-your-fingertips! All you need is a touch-tone telephone, computer and an Internet connection to participate in a session.

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PDA has a vast selection of *On-Demand Web Seminars*—a perfect professional resource for you and your staff. These recordings of previous Web Seminars and select Conference sessions feature live sessions with synched audio and presentation, including Q&A.

www.pda.org/ondemand

2008 PDA Biennial Training Conference

Focus on Performance: Partnering for Business Success

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

Announcement and Call for Papers

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

SUBMISSION DEADLINE: MAY 1, 2007

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

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

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

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

Submissions must include the following information:

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

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

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

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

PDA

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Mark your calendar!

Five laboratory training courses, including two-new programs, will be held this May by the PDA Training and Research Institute. That means five hands-on opportunities to learn from the expert faculty only PDA TRI can deliver!

Pharmaceutical and Biopharmaceutical Microbiology 101
PDA #142 | May 1-4, 2007
www.pdatraining.org/pbm101
Instructor: **David Matsuhiro**, President, *Cleanroom Compliance, Inc.*

Downstream Processing: Separations, Purifications and Virus Removal
PDA #176 | May 8-11, 2007
www.pdatraining.org/downstream
Instructors: **Michael Dosmar, Jeff Mora, and Mark Trotter**, *Sartorius Corporation*
Jennifer Campbell and Paul Genest, *Millipore Corporation*

NEW COURSE!

Developing a Moist Heat Sterilization Program within FDA Requirements
PDA #506 | May 16-18, 2007
www.pdatraining.org/dmhs
Instructors: **Jeanne Moldenhauer, PhD**, Pharma Consultant, *Vectech Pharmaceutical Consultants, Inc.*,
Margarita Gomez, Manager of Technical Services, *VPCI*

Developing and Validating a Cleaning and Disinfection Program for Controlled Environments
PDA #324 | May 21-22, 2007
www.pdatraining.org/DVCD
Instructor: **Art Vellutato, Jr.**, Vice President of Technical Support Operations, *Veltek Associates, Inc.*

Operator Qualification
PDA #337 | May 21-23, 2007
www.pdatraining.org/operator
Instructor: **Anne Marie Dixon**, Principal, *Cleanroom Management Associates, Inc.*

NEW COURSE!

Location:
PDA Training and Research Institute
UMBC Technology Center
1450 South Rolling Road
Baltimore, Maryland 21227 USA

For more information, please contact:
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Visit: *www.pdatraining.org*

TRI TALK

Demolition for New TRI Facility Begins

Gail Sherman, PDA

Remember when the local newsboy cried, "Extra, Extra, Read All about It," or lately, when it's been "Breaking News" that interrupts your favorite television show? Well, here's our PDA breaking news—in March, we began the demolition for our new TRI facility in Bethesda, Md. See below for a photograph of me with the sledge hammer putting the first hole in the wall (even if I did try to hammer through a stud)! Fortunately, **James Wamsley,** PDA's Manager of Laboratory Education, did a bit better actually making a hole in the wall.

With our permits already into the county, we are hopeful construction will be well underway by the time you read this—it truly is March Madness[1] after all! Stay tuned for more pictures next month.

I also want to take this opportunity to thank Aramark for donating navy blue lab coats to TRI. We are excited to be able to provide our students with these coats. They even have the PDA logo on them. We are very grateful! See below for a picture of our TRI team in the new coats.

On a more serious note, we are still providing training and will do so almost up to moving day. So please come out and visit with your favorite instructors in our soon to be old stomping grounds at the University of Maryland Baltimore County. Also, we will be in Berlin, Germany, on November 13–25, 2007, and in Dublin, Ireland, on December 5-7, 2007. We are also planning some courses associated with other conferences in Europe, so look for registration forms and announcements on these soon.

We still need equipment and lab furniture donations and support for the Bethesda, Md., facility, so if you have anything tucked away in the back room that is perfectly functional, let us know.

I am looking forward to our TRI anniversary issue in May, but we need your help. Please send your anecdotes about TRI over the years, photos and anything else you would like to share to me at sherman@pda.org or to the PDA Letter Assistant Editor **Lindsay Donofrio** at donofrio@pda.org.

Note
1. March Madness describes the popular U.S. collegiate basketball tournament, which lasts three weeks in March. It is viewed by many Americans as the World Cup of college basketball.

(l-r) PDA's James Wamsley, Megan Lahti, Jessica Petree and Gail Sherman examine the contents of a petri dish in their brand new lab coats, which were donated by Aramark.

Gail Sherman, PDA, commences the demolition of the space which will soon be the new TRI facility.

James Wamsley, PDA, takes a closer look before taking another swing at the soon-to-be collapsed wall.

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June 11-13, 2007

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- Analytical Problem Solving for CAPA Systems
- Beyond the GMP/ISO Basics – Practical Strategies for Everyday Compliance
- Designing, Monitoring and Validation of HVAC Systems
- Quality Programs – The Road to Continuous Improvement

www.pdatraining.org/baltimore

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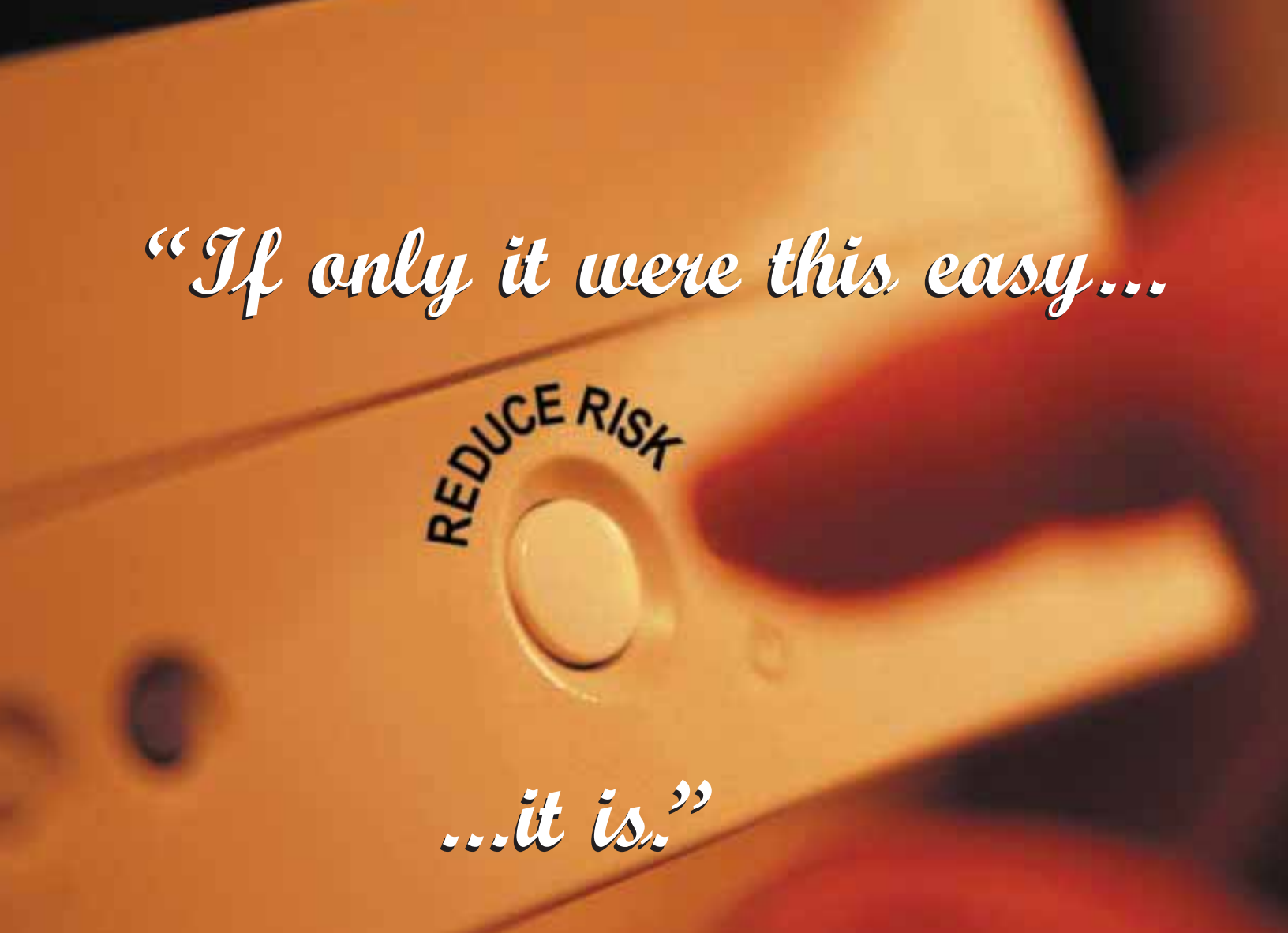

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